

# VALUE CHAIN ANALYSIS FOR THE PHARMACEUTICAL SECTOR IN JORDAN

Industry Overview in Jordan

Trade for Employment (T4E) Project

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## Abstract

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The Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH ('GIZ') is looking to invest in Jordan in key sectors in order to increase job creation as part of their focus on Employment and Education. GIZ hence commissioned Euromonitor to assess the pharmaceutical and chemical sectors in Jordan to identify and understand what needs to change in order to increase exports and make Jordanian products more competitive. This is part of the Trade for Employment (T4E) project that focuses on building capacities and strengthening structures in a sustainable manner to enhance the conditions of Jordanian companies to increase their trade performance for employment. GIZ need to know what fields of intervention the T4E team can focus on over the course of the coming 3 years to help Jordanian companies increase export.

The present study provides an in-depth analysis of the current pharmaceutical industry in Jordan and its outlook. The focus of the study is to reach a comprehensive assessment of Jordan's regulatory framework, possible innovation-facilitating instruments, and key innovation assets – research and human capital. It proposes a stronger monitoring and evaluation (M&E) framework and provides a sectoral analysis with respective recommendations in key areas.

The methodology used in order to reach this objective consisted of a combination of extensive primary and secondary research to gather data that was subsequently cleaned, processed and analysed in order to obtain insights on the situation of the value chain and on potential steps for improvement. Data gathered from secondary sources has been blended with in-depth interviews with stakeholders of the industry such as manufacturers, exporters and industry specialists. These results were complemented with knowledge on international best practices and research on case studies of other developing countries (e.g. Bulgaria), which has been successful in developing their pharmaceutical industry. The international benchmarking studies have emphasised on the importance of increasing the efficiency in the production processes, start substantial R&D practices, combat cost pressures and explore new export opportunities.

## Executive Summary

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This report presents a review of current issues in the pharmaceutical sector in Jordan. It examines the government's role (drug policy, regulations, pricing), the value chain (sourcing, R&D, production, packaging, storage, distribution) and the export process (which represents estimated 70% of profit generation)<sup>1</sup>. Its recommendations are intended to serve as practical options for reform, by articulating short- and medium-term low-cost strategies for managing pharmaceutical expenditure and increasing business opportunities in both local and foreign markets.

Jordan is considered a pioneer among countries in the Arab world in terms of the pharmaceutical industry, being recognised as a cost-efficient manufacturer of high-quality generic drugs, with the industry being worth estimated USD 1.2 billion in 2018<sup>2</sup>. Despite this positive positioning, the country's industry has not managed to evolve into a manufacturing originator stage (developing original molecules for medicines), due to the limited allocation of resources for R&D by both private and public sectors. Moreover, the country faces a significant dependence on foreign active pharmaceutical ingredients (APIs) for the sourcing stage, and is increasingly focusing on highly lucrative re-export activity, which trades pharmaceutical products from Western nations (Germany, USA, France, Switzerland) into neighbouring Arab countries. Private and public stakeholders must recognise these market trends/threats and implement moderate reforms in order to secure competitiveness, profitability and higher levels of employment for the sector (currently estimated at 26,000 workers).

Local manufacturers indicate that their operations could benefit greatly from extended support of the Jordan Food and Drug Administration (JFDA)<sup>3</sup> during the drug registration process. Sources state their operations are greatly affected by slow registration periods for new drugs, intended for both local and export markets.

Other issues include JFDA unified pricing regulations, by which the vast majority of generics are set on a fixed price for local sale, with this price also acting as a benchmark for export negotiations with foreign importers. This report addresses the need for a registration process that streamlines manufacturers' local/foreign drug sales, in order to secure a healthy cash flow. Moreover, it is imperative that local manufacturers (supported, if possible, by foreign cooperation agencies) invest in the development of more lucrative drug alternatives, such as super-generics and biosimilars.

Other significant actions required are a higher investment in local workforce capabilities, as the vast majority of the industry relies on poorly-qualified blue-collar workers, which are trained in-house to reduce human resource costs. Local manufacturers must understand that the pharmaceutical industry cannot evolve if they insist on conservative low-cost production models, based on the employment of uneducated staff that earns salaries as low as USD352 a month.

In conclusion, both private and public stakeholders have to recognise the need for modernisation of the pharmaceutical industry in order to open up further business opportunities. Export trends benefitted from growth in Middle Eastern economies (mainly GCC countries) in recent years, which resulted in increased government spending on the healthcare sector and the implementation of mandatory health insurance schemes. Jordanian manufacturers/exporters must focus on capitalising on these trends, as increasing life expectancy and literacy rates regionally are expected to lead to a greater awareness of health-related issues and a consequent increase in demand for high-quality, cost-efficient pharmaceutical products.

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<sup>1</sup> | Euromonitor International trade analysis, 2019

<sup>2</sup> | Euromonitor International trade analysis, 2019

<sup>3</sup> | Euromonitor International trade analysis, 2019



## Macroeconomy

Jordan has one of the smallest economies in the Middle East (USD42.3 billion in 2018), and its lack of natural resources and water scarcity put constraints on economic development. Following the global financial crisis of 2008 growth slowed significantly; the deteriorating regional situation since 2011 and subsequent mass influx of Syrian refugees has made recovery difficult, though marginal increases in growth are predicted in the coming years. In 2015, the government launched “Jordan 2025”, a national vision for economic and social development which analyses the challenges faced by the country and reviews the goals and aspirations to be achieved by 2025. Through this model, the economy is expected to increase between 4.8% to 7.5% in a 10-year period<sup>4</sup>.

Annual GDP growth dropped from 8.2% in 2007 (prior to the global financial crisis) to 2.0% in 2017<sup>5</sup>. Jordan's trade deficit reached USD11.4 billion in 2018<sup>6</sup> – largely

due to its reliance on energy and food imports – the country reported a fiscal deficit of USD459.9 million in 2017<sup>7</sup>. The debt to GDP ratio rose to 95.9% in 2017, reaching USD38.4 billion<sup>8</sup>. While foreign currency reserves are high, and inflation is stable, the informal sector is significant, accounting for an estimated 17% of GDP in 2017. The economy is expected to improve in 2019. The re-opening of the border with Iraq and associated trade and investment agreements; the extension and broadening of the trade agreement with the European Union; as well as other efforts to lower the cost of generating energy, all bode well for a steady recovery in investment, exports, competitiveness, and economic growth. Real GDP growth is expected to average about 2.5% in 2020, before climbing to around 3.0% per year over 2022-2026<sup>9</sup>. Jordan's unemployment rate reached 18.6% in 2018, an unprecedented level unseen in the last 25 years.

**Table 01:** Jordan's macroeconomic indicators, 2014-2023

INDICATOR	UNIT	2014	2018	2023
Population	000	8,809.3	9,903.8	10,473.9
GDP	US\$ mn	35,877.8	42,290.9	56,511.0
Inflation	%	2.9	4.5	2.5
Unemployment rate	%	11.9	18.4	17.1

Source: Euromonitor International

<sup>4</sup> <http://www.jordantimes.com/news/local/gov%E2%80%99t-launches-jordan-2025%E2%80%99-development-blueprint>

<sup>5</sup> <https://data.worldbank.org/country/jordan>

<sup>6</sup> <http://dosweb.dos.gov.jo/>

<sup>7</sup> <http://www.jordantimes.com/news/local/public-debt-drops-958-gdp-budget-deficit-rises-jd4351-million>

<sup>8</sup> <http://www.jordantimes.com/news/local/public-debt-drops-958-gdp-budget-deficit-rises-jd4351-million>

<sup>9</sup> Euromonitor International

<sup>10</sup> <http://dosweb.dos.gov.jo/>

## Economic Strengths

### Strategic Location

Jordan is well situated as a regional entry point, being well connected to neighbouring countries and global markets through modern transportation and communication networks. Jordan's location allows for diversification and expansion into increasingly affluent markets. Trade agreements give Jordan access to a market of more than one billion consumers.

### Stable Macroeconomy

Jordan's macro-economic fundamentals are sound and leading indicators point to continuing slow growth and development over the next several years. Careful planning and policy reforms, a strong economy, and the creation of ideal conditions ripe for business investment have led to a surge in foreign investment in Jordan.

### Favourable Business Policy Framework

Jordan is a free market-oriented economy (an economic system in which prices are determined by unrestricted competition between privately owned businesses), with outward-oriented economic policies and a private sector-led approach to business development. Jordan experienced ongoing privatisation in recent years of major state-owned enterprises and implemented significant advances in structural and legal reform.

### Qualified and Talented Workforce

Jordan's human capital includes training investments in the high-tech, manufacturing and service sectors, while labour costs remain the most competitive in the Middle East.

### Foreign Relations

Decades of political stability and security ranked Jordan as one of the top 10 countries in terms of security worldwide in 2017<sup>11</sup>. Jordan has good relations with all its neighbours and has maintained continuous stability, moderation and security in a region prone to potential volatility. Jordan is an active member of the UN and several of its specialised agencies, including the Food and Agriculture Organisation (FAO), International Atomic Energy Agency (IAEA), and World Health Organisation (WHO). Jordan is a member of the World Bank, International Monetary Fund (IMF), Organisation of Islamic Cooperation (OIC), Non-Aligned Movement and Arab League.

<sup>11</sup> | <http://www.jordantimes.com/news/local/jordan-9th-safest-country-worldwide-2nd-among-arab-states>

<sup>12</sup> | <http://www.doingbusiness.org/en/reforms/overview/economy/jordan>

**Table 02:** Jordan's Foreign Investment Policy Enhancements (2017-2019)**POLITICAL WILL TO EASE DOING BUSINESS AND IMPROVE GLOBAL COMPETITIVENESS**

Jordan is largely open to foreign investment, and there is strong government support for this. Foreign and local investors are treated equally under the law. Jordan recognises the importance of enhancing its doing business environment, cutting red-tape and bureaucracy, upgrading its economic legislation framework, and streamlining its economic judicial transactions. Jordan's foreign investment policy enhancements (2017-2019).

**TAXATION**

Jordan made paying taxes less costly by increasing the depreciation rates for some fixed assets.

**CROSS-BORDER TRADE**

Jordan made exporting and importing easier by streamlining customs clearance processes, advancing the use of a single window and improving infrastructure at the Aqaba customs and port.

**ACCESS TO CREDIT**

Jordan improved access to credit information by establishing a new credit bureau.

**ACCESS TO CREDIT**

Jordan improved access to credit information by reporting data on credit payments from retailers.

**PROTECTING MINORITY INVESTORS**

Jordan strengthened minority investor protections by extending access to evidence before trial, increasing the rights and role of shareholders in major corporate decisions, clarifying ownership and control structures, and requiring greater corporate transparency.

**TAXATION**

Jordan made paying taxes easier by implementing an online system for filing and payment of general sales tax.

**CONTRACT ENFORCEMENT**

Jordan made enforcing contracts easier by introducing a system that allows users to pay court fees electronically.

**2017****2018****2019**

Source: Euromonitor International from The World Bank



## Contribution to Economy

Jordan's top contributing sectors to GDP are government services, finance, manufacturing, tourism & hospitality, transport and construction respectively<sup>13</sup>.

**Table 03:** Jordan's top contributing sectors to GDP (2018)

SECTOR	GROWTH FACTOR	% CONTRIBUTION TO GDP (2018)
<b>GOVERNMENT SERVICES</b>	Government Services (public services such as fire brigade, police, air force and paramedics) are not expected to boast significant growth as the government remains under pressure of further fiscal tightening.	15%
<b>FINANCE, INSURANCE, REAL ESTATE AND BUSINESS SERVICES</b>	The Central Bank of Jordan is the country's monetary authority. Other financial institutions include approximately 15 local and foreign commercial banks and specialised credit institutions, such as the Industrial Development Bank. Specialised credit institutions focus on offering equity capital. Banks, both foreign and Jordanian, may be established in trade free zones, however, they must deal exclusively in foreign currency, and must operate independently of other banking activities in the country.	25%
<b>MANUFACTURING</b>	The manufacturing sector (clothing, fertilisers, potash and phosphate mining, pharmaceuticals, petroleum refining, cement) has been strengthened by the rules of origin in the EU. However, Jordan must invest in preparing its manufacturing sector for compliance with EU quality requirements, identifying and establishing private sector trade linkages and partnerships, credit facilities, and feasible transport solutions.	21%
<b>TRADE, RESTAURANTS AND HOTELS</b>	Growth in hospitality and trade requires investments in marketing Jordan to targeted countries and new regions, maintaining and upgrading tourist sites and infrastructure, and improved security in the region.	11%
<b>TRANSPORT AND COMMUNICATIONS</b>	Potential investment in the Aqaba port, which acts as a gateway for Iraq and to a lesser extent for Syria. The sector could also benefit from upgrades to public transport.	10%
<b>OTHERS</b>	Others are majorly represented by agriculture, social and personal services, electricity and water, and construction. Investment in both power (electricity) and water are critically needed given the increase in population and the rise in demand for these basic services. Population growth also increased demand for food. As Jordan currently imports the vast majority of its basic food crops, including almost 100% of cereals, this will place an increasing burden on the current account unless Jordan can increase its agricultural productivity. The country needs to substantially increase its infrastructure to accommodate the surge in its population. School infrastructure, hospital facilities, and increased housing are all required.	25%

Source: Central Bank of Jordan

<sup>13</sup> | <http://www.ssif.gov.jo/UploadFiles/JEGProgramEnglish.pdf?lang=ar>

<sup>14</sup> | <https://www.pkf.com/media/608484/doing%20business%20in%20jordan.pdf>

## Exports

Jordan's top 10 exports accounted for over two-thirds (68.8%) of the overall value of its global shipments. Inorganic chemicals were the fastest-growing among the top 10 export categories, up by 21% from 2016 to 2017.

**Table 04:** Jordan's export distribution (2018)

EXPORT	EXPORT VALUE (JOD '000)	SHARE OF EXPORT VALUE (%)
Miscellaneous Manufactured Articles	1,415,717	30.3%
Chemicals	1,162,419	24.9%
Crude Materials, Inedible, except fuels	742,053	15.9%
Food and Live Animals	649,577	13.9%
Manufactured Goods	364,376	7.8%
Machinery and Transport Equipments	183,443	3.9%
Mineral Fuels, Lubricants and Materials Related	1,415,717	30.3%
Beverages and Tobacco	58,888	1.3%
Commodities and Transactions not Classified Elsewhere	9,412	0.2%
Animal and Vegetable Oils, Fats and Waxes	2,429	0.1%
TOTAL	4,668, 425	100.0%

Source: Central Bank of Jordan

## Trade Partners

Neighbouring countries in Africa and Middle East accounted for almost half of Jordan's exports and almost a third of all imports sources in 2018, making them the country's largest trade partners.

**Table 05:** Jordan's largest trade partners (2018)

MAJOR EXPORT DESTINATIONS	2018 SHARE (%)	MAJOR IMPORT SOURCES	2018 SHARE (%)
Africa and Middle East	44.7	Africa and Middle East	29.6
North America	28.5	Europe	28.6
Asia Pacific	17.6	Asia Pacific	26.3
Europe	4.8	North America	8.9
Other Countries	4.0	Latin America	5.0
Latin America	0.3	Australasia	1.0

Source: Euromonitor International

# Global and Regional Trends in Pharmaceutical Industry

## Global Trends

The global pharmaceutical sector is experiencing cutting pricing pressure from multiple governments, which are interested in curbing healthcare costs by setting pricing regulations. This affects overall profit margins for pharmaceutical operations<sup>15</sup>. Operational/development trends in 2018-2019 are focused on overcoming this profitability issue, either by exploring more lucrative business opportunities (such as biosimilars) or by implementing cost-efficient measures to reduce overall costs. The most significant trends can be summarised below.

### Industry 4.0 in manufacturing

Industry leaders recognise the sector must become more streamlined and cost efficient at manufacturing its products. Adoption of disruptive Industry 4.0 technologies offers a potential solution, such as setting up intelligent factories with highly integrated, flexible IT and manufacturing systems. This type of investment allows companies to increase productivity, by implementing a higher level of automation and control on human intervention, while scaling-up production through data driven program management<sup>16</sup>.

### Biosimilars to gain further ground

Production of biosimilars (medicines that are made from living microorganisms found in plant or animal cells) is expected to be spurred by the loss of patent protection for bestselling biologics. Industry reports indicate 66 innovator biologics are due to come off-patent in the market between 2020 and 2025. Consequently, it is expected there will be an increasing number of biosimilar review applications to FDAs in the incoming years. This is especially attractive to the pharmaceutical sector, as the sector offers more lucrative opportunities, as this type of product is mostly destined to premium, high-value-added drugs<sup>17</sup>.

### Pharmaceutical companies to restructure in search of cost efficiency

Pharmaceutical companies are continuing to reduce overall costs, by reducing staff, refocusing R&D, closing manufacturing plants and divesting poorly-performing or sub-scale businesses. These savings are expected to be used to re-stock pipelines with promising new drug candidates<sup>18</sup>.

### Artificial Intelligence (AI) to be implemented in R&D

AI will increase drug development efficiency by streamlining research efforts. The predictive and analytical powers of AI are expected to enable companies to make smarter, faster, and more strategic decisions, by collecting and aggregating disparate data sets and identifying patterns, which in turn will generate more insights<sup>19</sup>.

### Mergers and Acquisitions (M&A) expected in 2019

M&A will be driven by a need to consolidate a highly fragmented business sector. Large pharmaceutical companies continue to outsource more of their manufacturing activity and want to simplify the outsourced manufacturing supply chain by having larger integrated suppliers. Investors, fuelled by the continued availability of relatively low-cost finance, will see this as an opportunity to be the consolidator in an evolving, long-term successful business sector<sup>20</sup>.

## Conclusion

A combination of these strategies is used to overcome a deteriorating trade environment in the light of pending Brexit and the US-China trade disputes, as well as the mentioned regulatory pricing measures from governments. Company revenues, especially in North America, are also expected to be negatively affected by pending patent expirations for some high-revenue drugs.

<sup>15</sup> | Euromonitor International

<sup>16</sup> | <https://www.rdmag.com/article/2018/10/pharma-40-industry-40-applied-pharmaceutical-manufacturing/>

<sup>17</sup> | <http://www.pharmexec.com/three-trends-point-biosimilars-market-boom-ahead-bpcia-10th-anniversary/>

<sup>18</sup> | <https://www.cphi.com/europe/visit/news-and-updates/pharma-outlook-12-trends-watch-2019/>

<sup>19</sup> | <https://emerj.com/ai-sector-overviews/ai-in-pharma-and-biomedicine/>

<sup>20</sup> | <https://www.genengnews.com/a-lists/10-takeover-targets-to-watch-in-2019/>

## Regional Trends

The MENA pharmaceutical industry currently benefits from multiple demographic factors, such as changing population dynamics, where population is increasing but also ageing rapidly. The population of the region is increasing at 2% per year (7 million per year), the second highest rate in the world after sub-Saharan Africa. The MENA's population is expected to nearly double in the next 50 years<sup>21</sup>. Life expectancy of the average MENA inhabitant is now 73 years of age, close to that of many developed nations<sup>22</sup>. Additionally, lifestyle changes have led to higher incidences of non-contagious chronic diseases and conditions such as cardiovascular disease, obesity and type-2 diabetes<sup>23</sup>.

The current landscape of the pharmaceutical markets in the MENA region varies greatly between different nations. A high spending power and a cultural preference for expensive foreign brands in Saudi Arabia has resulted in 85% of pharmaceuticals in the country being imported<sup>24</sup>, whereas in Egypt, 90% of consumption is locally produced with a much greater market share for generics<sup>25</sup>. Jordan is currently the only country in the Middle East with a positive pharmaceutical manufacturing trade balance, as it has a well-established industry and many years of experience, exporting reported 70% of its pharmaceutical produce, with a generic penetration of over 50% in its market<sup>26</sup>.

In general, MENA governments and private sectors are interested in increasing their pharmaceutical manufactur-

ing installed capacity. Morocco for example has become an emerging player in the global pharmaceutical market, thanks to its stable political framework and key geographic position in the Mediterranean area. Both domestic and multinational pharmaceutical companies are present in the country with manufacturing facilities<sup>27</sup>. In 2015, the industry in Morocco was able to cater for 65% of their local demand (compared to 49% in Tunisia and 30% in Algeria)<sup>28</sup>. Saudi Arabia is actively trying to increase generic consumption through regulating imported branded drugs and promoting local generic production, by presenting opportunities for local generics manufacturers and for foreign firms who are willing to move into the country. Sanofi opened a new production facility in King Abdullah Economic City in Saudi Arabia in December 2014, producing antibiotic drugs, diabetic treatments and cardiovascular drugs<sup>29</sup>. Countries such as Algeria and Sudan are enforcing protective trade mechanisms to ensure priority to locally produced drugs by banning imports of those drugs from other countries.

Further growth of the pharmaceutical market in the MENA region is likely to manifest in the forms of more individuals getting private health insurance, the development of medical tourism, increases in local manufacturing, better access to innovative drugs and the possible drug price harmonization strategy among GCC countries as part of a potential pharmaceutical free trade agreement<sup>30</sup>.

21 | <https://www.prb.org/populationtrendsandchallengesinthemiddleeastandnorthafrica/>

22 | [https://ubmemeaensoprod.s3.amazonaws.com/CPHI\\_mea/cphi\\_pharma\\_insights\\_mea\\_-\\_final.pdf](https://ubmemeaensoprod.s3.amazonaws.com/CPHI_mea/cphi_pharma_insights_mea_-_final.pdf)

23 | <https://www.lifescienceleader.com/doc/the-mena-pharma-market-an-untapped-opportunity-0001>

24 | <https://books.google.com.ni/books?isbn=1910068071>

25 | <https://www.pharma-iq.com/market-access/articles/middle-east-north-africa-pharmaceutical-market-in>

26 | <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1031.2223&rep=rep1&type=pdf>

27 | <https://www.pharmaworldmagazine.com/from-morocco-the-opportunities-for-the-pharmaceutical-industry/>

28 | <https://www.chemanager-online.com/en/topics/economy-business/mena-pharmaceutical-market>

29 | <https://www.bioprocessonline.com/doc/sanofi-opens-new-production-facility-in-kaec-saudi-arabia-0001>

30 | <https://www.epmmagazine.com/analysis/changes-forecasted-for-mena-pharma-market/>

# Industry Overview: Jordan

## Background

The Jordanian pharmaceutical sector is an advanced sector in the region. The country's first pharmaceutical company, Arab Pharmaceutical Manufacturing Company (APM), was established in 1962. During the 1990s, the sector witnessed remarkable development with the establishment of nine companies. This development was a direct result of the flow of capital from Gulf states, such as Iraq, due to the Gulf War and because the Jordanian government enacted several laws and procedures regarding investment to encourage and facilitate investment in Jordan. Furthermore, the healthcare system in Jordan has a strong reputation across the region given its international quality standards, local experts and world-class hospitals<sup>31</sup>.

By 2018, the pharmaceutical sector comprised 23 companies, registered at the Jordanian Association of Pharmaceutical Manufacturers (JAPM), which manufacture mostly branded generics (formulated drugs that have lost patent protection). Both public and private healthcare systems are supplied by these manufacturers. Physicians, hospitals and pharmacies generally buy pharmaceuticals directly from the manufacturer or through a distributor. Prices are fixed by the Jordanian Food and Drug Administration (JFDA) and hence companies compete on brand building. The first company to introduce a generic version of a drug will most likely gain the largest market share. Manufacturers devote around 5% of their installed capacity to contract manufacturing for global pharmaceutical companies<sup>32</sup>.

The industry caters to two main markets: Prescription and Over-the-Counter (OTC) medication. It is estimated that 70% of pharmaceutical drugs produced in Jordan are prescribed, while 30% are over-the-counter (OTC) drugs. Local pharmaceutical companies are primarily engaged in producing several dosage forms such as solids, semi-solids, liquids and injectable. Specialties include antibiotics, anti-ulcer cures, hormones and anti-cancer treatments. Jordanian pharmaceutical firms such as MS Pharma are also venturing into bio-technology via partnerships and rather not directly into actual manufacturing in Jordan.

The Jordanian pharmaceutical industry grew in terms of investment volume, having invested around USD263.7 million over 2005-2015 in their manufacturing infrastructure, including their laboratory facilities. In 2017, pharmaceuticals ranked second in Jordanian exports despite the fact that 40% of its production depends on concession

rights to foreign companies and 60% depends on licenses. These factors tend to affect medium-term planning as concessions and licenses can be revoked. At the same time, the industry's products accounted for nearly 8.9% of total Jordanian exports in 2017, with the products being exported to more than 60 countries due to their high quality, excellent reputation and competitive pricing<sup>33</sup>.

The industry contributed to the development of the Jordanian economy as it provided jobs to 26,000 people and hard currency from exporting over 75% of its production<sup>34</sup>. It is reported that females make up 40% of the sector's workforce.

The sector is one step ahead of its regional counterparts as it imposed a law on performing bio-equivalency studies through Contract Research Organisations (CRO) in 1999, with seven CROs currently in Jordan. CROs in Jordan provide clinical and bioanalytical services for the pharmaceutical industry.

## Production

Industry sources report that local production of pharmaceuticals was estimated at USD1.2 billion in 2017<sup>35</sup>. Given the small size of the local market, exports represent nearly 75% of local production.<sup>36</sup>

The sector reports an average value Compound Annual Growth Rate (CAGR) of 4.5% over 2013-2018, supported by consistent foreign demand from Saudi Arabia, Algeria and Iraq. However, in recent years, demand from these countries downsized as governments in these markets are limiting imports to strengthen their local industries.

Demographic trends in the region, such as increasing life expectancy and literacy rates, are expected to lead to a greater awareness of health-related issues and a consequent increase in demand for pharmaceutical products. Global innovation has become more complex and despite continuing R&D spend, new drug approvals are lagging. Jordanian pharmaceutical companies are expected to continue focusing on generic manufacturing and as such, industry sources expect a similar performance over 2019-2023, with value CAGR of 4-6%<sup>37</sup>.

<sup>31</sup> | <http://www.jordanecb.org/library/634448627045122500.pdf>

<sup>32</sup> | Euromonitor International trade analysis, 2019

<sup>33</sup> | [www.JAPM.com](http://www.JAPM.com)

<sup>34</sup> | Taifour, M., 2011. The relationship between the capital expenditure and financial operational performance in Jordanian pharmaceutical manufacturing corporations. MSc Thesis, Middle East University, Amman, Jordan.

<sup>35</sup> | Euromonitor International trade analysis, 2019

<sup>36</sup> | Euromonitor International trade analysis, 2019

<sup>37</sup> | Euromonitor International trade analysis, 2019

## Key Stakeholders

STAKEHOLDERS	TYPE	MAIN ROLE
Ministry of Health (MoH)	GOVERNMENT	Responsible for the administration and supervision of health services offered by the public and private sectors. The objective of the Ministry of Health is to maintain public health by offering preventative treatment and health control services, providing insurance to over 40% of the population.
Jordanian Food and Drug	GOVERNMENT	The JFDA Drug Department is the directorate that deals with drugs from early stages as a raw material through to the finished product. It is responsible for registering and pricing of drugs, following up on clinical studies and monitoring them through all stages, monitoring and inspection of all pharmaceutical institutions, issuance of licenses for concerned parties and exporting and importing of drugs. JFDA approves and licenses the production location and the factory's production line.
Jordanian Association of Manufacturers of Pharmaceuticals and Medical Appliances (JAPM)	PUBLIC- PRIVATE	The manufacturing sector (clothing, fertilisers, potash and phosphate mining, pharmaceuticals, petroleum refining, cement) has been strengthened by the rules of origin in the EU. However, Jordan must invest in preparing its manufacturing sector for compliance with EU quality requirements, identifying and establishing private sector trade linkages and partnerships, credit facilities, and feasible transport solutions.
Joint Procurement Department (JPD)	GOVERNMENT	The JPD was created in 2005 with the objective of improving the efficiency of the procurement process in the public sector through demand aggregation, process standardisation, and duplicity elimination. It is responsible for organizing drugs procurement procedures, participation terms, bids study method, and decision making in the tendering process. JPD maintains and stores drugs supplies in the central warehouses for further distribution to the public healthcare system.
Jordan Pharmacists Association (JPA)	PUBLIC - PRIVATE	Representing body of pharmacists in Jordan. JPA participates in committees to negotiate and regulate laws concerning distribution and supply of pharmaceutical products in Jordan.

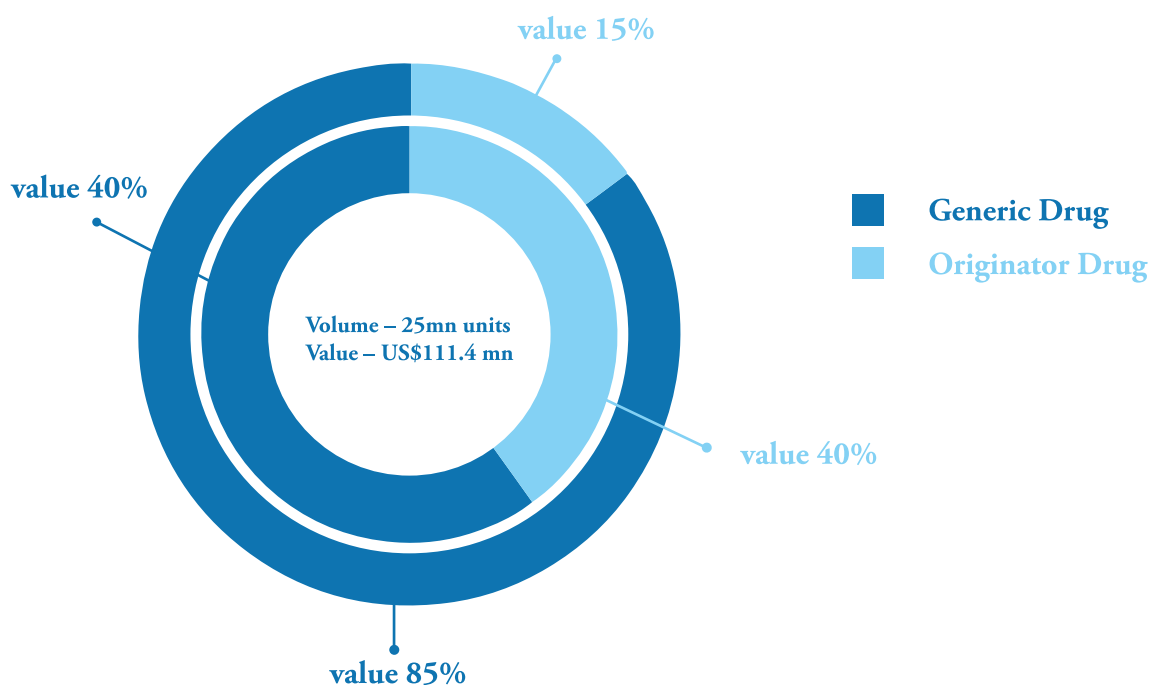


## Competitive Landscape

### Overview

Generics (mostly supplied by local companies) dominate the market in volume terms, however, given their much lower prices compared to originators, they account for a lower share in value terms.

**Chart 01:** Value and volume share of generic vs. originator drugs, 2018



Source: Euromonitor International Trade Analysis, 2019

## Local Players

The key local pharmaceutical companies in Jordan are publicly-listed, and include<sup>38</sup>:

### Hikma Pharmaceuticals (HIKMA)

A multinational company established in 1978, listed on the London Stock Exchange since 2005. Hikma was the first Arab drug manufacturing company to successfully pass FDA inspection and obtain FDA approval for some of its products and the first Arab company to obtain British MHRA (Medicines and Healthcare products Regulatory Agency) approval to register and export one of its products to the UK. They serve through the development, manufacture and marketing of a broad range of solid, liquid and injectable generic and licensed pharmaceutical products based principally in the Middle East and North Africa region.

### Dar Al Dawa Development and Investment Company (DADI)

The company was established in Amman in 1975. It was one of the first pharmaceutical companies to enter the Jordanian market; the company complies with World Trade Organisation's regulations and specialises in the development and manufacture of pharmaceutical products, both own-brand products and licensed products through partnerships and alliances.

### Arab Pharmaceutical Manufacturing Company (APM)

A pharmaceutical and healthcare company based in Amman, APM was founded in 1962 and operates two main production facilities, in Al Salalem and Buhayra. APM produces dozens of products. The company is listed on the Amman Stock Exchange's (ASE) Weighted Index and is now listed under AL-Hikma Group.

### The Jordanian Pharmaceutical Manufacturing (JPHM)

This Jordan-based company is listed on the Amman Stock Exchange. The Company's principal activity is the manufacture and production of medicine, medical appliances and cosmetics and it was established in 1978.

### Middle East Pharma and Chemical Industries and Medical Appliances Company (MPHA)

The company was founded in 1993 and is engaged in the distribution and manufacture of pharmaceuticals.

### Hayat Pharmaceutical Industries Company (HPIC)

This Jordan-based company specialises in the manufacture, import, export and marketing of general medicinal products and was established in 2007.

### Arab Center for Pharmaceuticals and Chemical Industries (APHC)

This company was established in 1983 and is a leading manufacturer of empty hard gelatin capsules. It is currently owned by Middle East Pharma and Chemical Industries and Medical Appliances Company.

### Philadelphia Pharmaceuticals (PHIL)

The company, established in 1993, started commercial production in 1997 and was listed on the ASE in May 2010. The company produces 69 pharmaceutical products, specialising in generic drugs used for human medications.

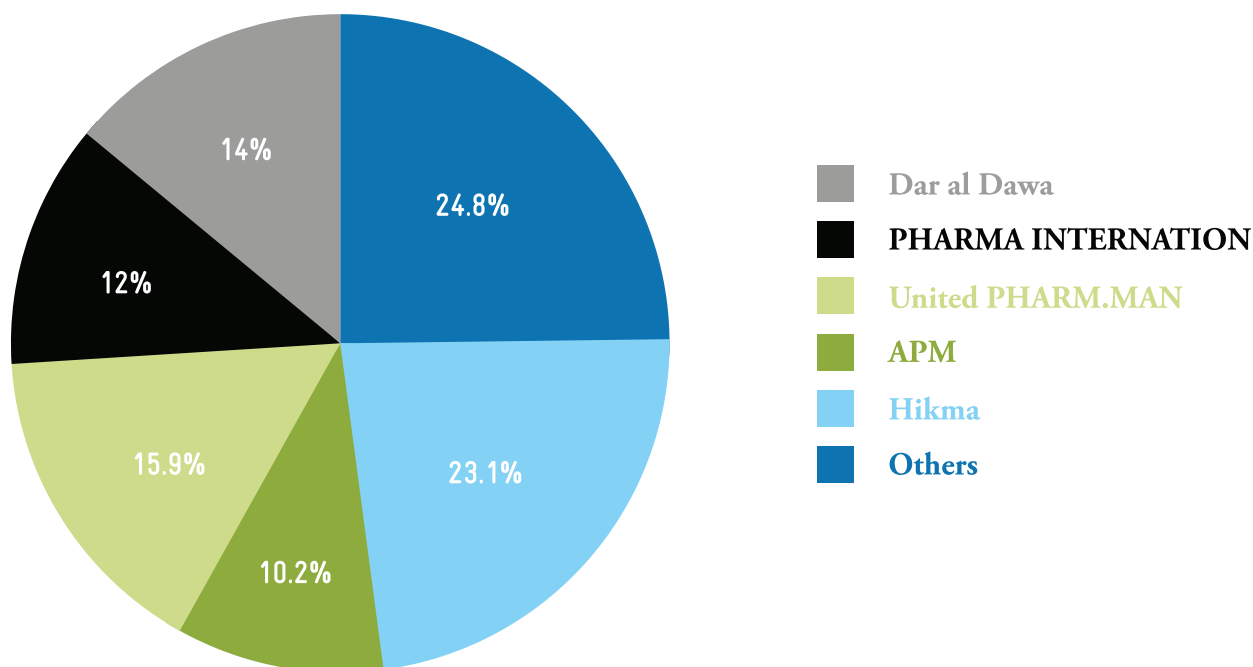
### MS Pharma

The company manufactures and markets, branded-generic medicines via strategic markets across the Middle East, Turkey, and Africa (META) region. MS Pharma unifies EL KENDI in Algeria, UPM in Jordan, MS Pharma Injectables and other MS Pharma affiliates in META.

### Pharma Internation

Pharma International Company (PIC) is a leading biopharmaceutical corporation established in 1994, in Jordan. The company's product portfolio addresses therapeutic classes that includes Anti-infectives, Nervous System, Respiratory System, Cardio Vascular and Lifestyle conditions.

<sup>38</sup> | <http://inform.gov.jo/Portals/0/Report%20PDFs/3.%20Strategic%20Sector%20Development/ii.%20Healthcare&Pharmaceuticals/2010%20Zawya-Pharmaceutical%20Sector.pdf>

**Chart 02:** Market share by value of key Jordanian companies, 2018

Source: Euromonitor International Trade Analysis, 2019

### International players

In 2018, multinational companies hold a significant portion of local market share, estimated at around 70% in Jordan<sup>40</sup> in value terms. They are present in the market either directly or through licensed/contract manufacturing. Many multinational companies have also entered into co-marketing arrangements with local companies. Most pharmaceutical imports are from European countries and are largely comprised of therapeutic products not covered by local production<sup>41</sup>.

<sup>39</sup> | Euromonitor International trade analysis, 2019

<sup>40</sup> | <http://www.jordanecb.org/library/634448627045122500.pdf>

<sup>41</sup> | <http://www.jordanecb.org/library/634448627045122500.pdf>

## Role of Government

Besides the key role played by the JFDA and MOH, the Jordanian government considers the sector as a key pillar to the economy. Jordan imposes 0% tariff on import of drugs as a result of WTO regulation and existing trade agreements. This limits protection of the sector for domestic companies. Also, the government may need to negotiate trade agreements with target countries for 0% tariff on exports of drugs from Jordan.

### Tax Incentives

15% price incentive is provided to local manufacturers in the tendering process as compared to foreign manufacturers.

### Trade Agreements

Jordan holds multiple bilateral trade agreements with advanced economies such as the US and the EU; despite this, their pharmaceutical exports are largely focused on neighbor countries such as Saudi Arabia, Iraq and UAE, countries with which Jordan does not hold active trade agreements.

#### US-Jordan

The United States-Jordan Free Trade Agreement (FTA) entered into force on December 17, 2001 and was implemented fully on January 1, 2010. The Qualifying Industrial Zones (QIZs) program, established by the U.S. Congress in 1996, allows products to enter the United States duty free if manufactured in Jordan, Egypt, or the West Bank and Gaza, with a specified amount of Israeli content<sup>42</sup>.

#### EU-Jordan

Trade relations between the EU and Jordan are governed by the Association Agreement which entered into force in May 2002. This agreement established a Free Trade Area opening up two-way trade in goods between the EU and Jordan. The EU and Jordan have developed their FTA further through additional agreements on agricultural, agri-food and fisheries products, and on a bilateral Dispute Settlement Mechanism which entered into force in 2007 and 2011 respectively<sup>43</sup>.

#### GAFTA-Jordan

Jordan has actively sought greater integration into the regional economy as well. Greater Arab Free Trade Area is part of an effort to boost economic cooperation among the 22 Arab League member states. The agreement came into full effect in 2005 and has resulted in multiple exemptions from Customs duties and charges. GAFTA has significantly increased Jordan's trade relations with neighboring countries. Particularly vital to Jordanian exporters is the Iraqi market. Jordan is a natural gateway for goods destined for Iraq, and the kingdom's port city of Aqaba has historically played an important role in transporting goods to the country. However, recent turmoil in the region has taken a toll on bilateral trade, increasing security risks and transportation costs for truck drivers crossing Iraq's Anbar Province and disrupting traffic<sup>44</sup>.

#### Turkey-Jordan

Jordan on November 2018, began imposing custom duties on Turkish imports as the free trade agreement (FTA) between the two nations was terminated, according to a government official. Custom duties ranging from 20%-30% are being imposed on Turkish imports<sup>45</sup>.

Other significant bilateral FTAs signed and ratified by Jordan include Canada-Jordan FTA<sup>46</sup>, Jordan-Singapore SJFTA<sup>47</sup>, Jordan-Lybia FTA<sup>48</sup> and free trade zone treaties signed with Syria and Tunisia.

#### International Donors

<sup>42</sup> | <https://ustr.gov/trade-agreements/free-trade-agreements/jordan-fta>

<sup>43</sup> | <http://ec.europa.eu/trade/policy/countries-and-regions/countries/jordan/>

<sup>44</sup> | <https://oxfordbusinessgroup.com/analysis/focus-free-trade-raft-trade-agreements-have-strengthened-global-ties-0>

<sup>45</sup> | <http://www.jordantimes.com/news/local/cancellation-trade-agreement-turkey-goes-effect>

<sup>46</sup> | <https://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/jordan-jordanie/fta-ale/background-contexte.aspx?lang=eng>

<sup>47</sup> | <https://www.enterprisesg.gov.sg/non-financial-assistance/for-singapore-companies/free-trade-agreements/ftas/singapore-ftas/sjfta>

<sup>48</sup> | <http://www.intracen.org/country/libya/>

## Labour Needs

The International Finance Corporation's (IFC) investment program in Jordan has ramped up in recent years, with the portfolio growing from USD50 million in 2005 to around USD650 million as of end-March 2013. As of January 2018, IIFC have invested over USD300 million collectively across 13 projects facilitating private sector investments over USD1 billion in Jordan's power distribution and generation sectors. The investments has been to support the infrastructure (power and transportation) and manufacturing (pharmaceuticals and chemicals) sectors . Furthermore, in May 2017, IFC supported MS Pharma with an equity investment of USD45 million for the company's expansion into new export markets and produce affordable generic medicines and healthcare products across the Middle East, Turkey, and Africa (META) region.

USAID's Jordan Competitiveness Program (JCP) 2019 supported the JFDA in streamlining and automating the drug registration process in Jordan. The aim is to reduce pharmaceutical products' time-to-market from over two years to just over one year, thus increasing the competitiveness of companies exporting to regional markets.

The pharmaceutical sector is essential in resolving the high unemployment rates in the country. In 2016, the sector created around 26,000 direct and indirect jobs. In local pharmaceutical companies, pharmacists work in all departments, including research and development, quality control, regulatory affairs and sales and marketing. They generally manage inventory and the preparation and dispensing of medicines. One of the strengths enjoyed by the sector is the low cost of wages paid to unskilled workers who are recruited in the packaging and distribution departments (minimum estimated at JOD280 per month)<sup>50</sup>.

The supply of pharmaceutical graduates exceeds domestic demand, on average 400 pharmaceutical students graduate a year. Furthermore, according to industry sources, the education system in Jordan faces many challenges and hence graduates lack the required skills. This causes issues for companies who, in some instances, have to send their staff abroad to get the required training. Existing scientists also require training which means that positions are often filled by external instructors from abroad. According to industry sources, the lack of a competent workforce is one of the key bottlenecks in the value chain. It is a cornerstone to the industry, specifically in the research and development stage, which is vital to innovation in the industry. The majority of the pharmaceutical degree holders work in pharmacies, with only a few working at the manufacturing sites.

<sup>49</sup> | [https://unctad.org/Sections/un\\_ceb/docs/ceb2015\\_unido\\_vol2\\_2015ed\\_en.pdf](https://unctad.org/Sections/un_ceb/docs/ceb2015_unido_vol2_2015ed_en.pdf)  
<sup>50</sup> | [www.jordantimes.com.news](http://www.jordantimes.com.news)

## Market Demand and Supply – Production and Consumption

**Table 06:** Production volume and value from 2015-2018

	2015	2016	2017	2018 (est)	CAGR% (2015-2018)
Volume (million units)	24.4	24.3	24.1	25.0	0.8
Value (US\$ million)	100.5	107.1	109.7	111.4	3.5

Source: Euromonitor International Trade Analysis, 2019

### End Consumers

OTC consumption is estimated to have reached USD77.8 million in 2018, increasing by a CAGR of 7.8% from USD53.5 million in 2013. This significant increase is due to the influx of Syrian refugees, who demand OTC to attend to basic health needs, especially at point of arrival. Jordan's prescribed consumption is estimated at USD181.5 million in 2018, representing 70% of overall consumption<sup>51</sup>. This high percentage is due to 87% of the Jordanian population

holding health insurance<sup>52</sup> and a significant proportion of those have multiple insurances. The largest provider of health care in Jordan is the public sector, via the MoH, providing insurance to 40% of the population, followed by the Royal Medical Services (RMS), covering 27.5% of the population. The remaining 19.5% are covered by insurance companies associated with banks, professional syndicates, universities or private companies. 70% of local consumption is considered to be covered by imports.

**Table 07:** Consumption volume and value from 2013-2018

	2015	2016	2017	2018 (est)	CAGR% (2015-2018)
Volume (million units)	63.9	65.1	65.5	65.3	0.7
Value (US\$ million)	335.4	355.8	372.1	374.0	3.7

Source: Euromonitor International Trade Analysis, 2019

<sup>51</sup> | <https://pdfs.semanticscholar.org/d7cc/3b3fd906dfac2347deb764b5a6526a7c7805.pdf>

<sup>52</sup> | HAI/WHO Medicine prices, availability, affordability & price components in Jordan (2007)



## Market Demand and Supply – Imports and Exports

### Imports

Industry sources indicate imports will prevail due to the following reasons<sup>53</sup>:

- There is a significant market of consumers and doctors who prefer to consume/prescribe imported drugs, as they are perceived to be of higher quality.
- Imported brands have very competitive pricing compared to local brands
- The lack of R&D investment among local manufacturers secures import's share, as they are not likely to be developed by local players in the short-to-medium term.
- Imported brands carry out strong marketing campaigns such as promotions to doctors and pharmacies via local medical representatives. Imports do not require local testing (by the JFDA); this improves their stock management capacity as they simply have to estimate forecast demand and request adequate volumes to be imported according to their needs.

**Table 08:** Jordan, declared imports trade value

	2013	2014	2015	2016	2017	2018
Total Imports in US\$ million	418.1	441.7	449.1	418.1	462.4	473.3

Source: Trademap (HS codes: 3003 – unpackaged medicaments and 3004 – packaged medicaments)

**Table 09:** Jordan, declared imports trade value (USD million), including main markets

	2013	2014	2015	2016	2017	2018	2018 (% share)
Total Imports	420.1	443.7	451.1	466.0	464.4	475.3	100%
Germany	51.1	59.1	57.0	58.9	68.4	64.6	13.6%
France	49.0	56.1	54.7	48.4	49.6	53.0	11.1%
United States of America	29.3	30.3	33.4	42.6	51.0	51.7	10.9%
Italy	29.5	31.9	41.3	42.1	32.5	38.0	8.0%
Switzerland	43.5	45.7	37.9	36.9	34.0	26.9	5.6%
Denmark	22.2	18.3	23.1	24.7	19.3	26.5	5.6%
Others	195.5	202.4	203.7	212.3	209.5	214.7	45.2%

Source: Trademap (HS codes: 3003 – unpackaged medicaments and 3004 – packaged medicaments)

<sup>53</sup> | Euromonitor International trade analysis, 2019

## Exports

Jordan exports benefitted from a dual trend, acting as a cost-efficient exporter and re-exporter of OTCs and branded generics to Saudi Arabia and UAE. On one hand Jordan's exports benefitted from its lower operational costs, based on lower-cost labour and strategic geographic location between Western Europe and GCC countries (for re-exports). On the other hand, the country benefitted from steady demand for generics from Algeria, Sudan and Libya; however, recently, these countries started to implement protective mechanisms to support their local pharmaceutical industries and limit imports. Furthermore, political turmoil and financial pressures in Sudan resulted in sharp decline of the country's currency reserves hence

created challenges in currency exchange and payment of exporters. Due to sanctions from USA, Sudanese banks are prevented to deal with correspondent banks in other countries. Pharmaceutical export divisions could benefit greatly from trading/research trainings, to explore new markets, especially in Sub-Saharan Africa, non-EU Eastern Europe and the Caucasus<sup>54</sup>.

Depending on the complexity of the target market, the size of the company and product to be exported, some pharmaceutical companies might arrange export clearance and logistics with companies such as Aramex, DHL and AL Naseer Company<sup>55</sup>.

**Table 10:** Jordan, declared exports trade value (USD million), including main markets

	2013	2014	2015	2016	2017	2018	2018 (% share)
<b>Total Imports</b>	<b>708.6</b>	<b>643.1</b>	<b>621.2</b>	<b>703.4</b>	<b>650.6</b>	<b>647.3</b>	<b>100%</b>
<b>Iraq</b>	77.1	77.4	49.4	80.3	84.8	119.4	18.4%
<b>KSA</b>	140.2	150.3	132.2	154.2	157.9	119.4	18.4%
<b>Algeria</b>	114.3	80.8	66.1	91.3	63.7	70.5	10.9%
<b>UAE</b>	37.6	33.4	43.7	49.0	53.2	51.6	8.0%
<b>Sudan</b>	55.8	52.3	60.4	46.6	61.7	34.8	5.4%
<b>Lebanon</b>	36.5	36.0	38.8	43.1	34.1	29.2	4.5%
<b>Others</b>	247.2	212.8	230.6	238.9	195.2	222.3	34.3%

Source: Trademap (HS codes: 3003 – unpackaged medicaments and 3004 – packaged medicaments)

The government has shown efforts to reduce export costs by streamlining customs clearance processes, advancing the use of a single window and improving infrastructure at Aqaba customs and port<sup>56</sup>. Price ceiling of generics has been set at 80% of the price of the originator brand in

Jordan. Thus, prices of generics in Jordan are high as compared to free market prices for generics in other countries, but this serves as an incentive for achieving higher revenue in exports markets, as most countries consider the price in the country of origin price as a reference<sup>57</sup>.

<sup>54</sup> | Euromonitor International trade analysis, 2019

<sup>55</sup> | Euromonitor International trade analysis, 2019

<sup>56</sup> | <http://www.doingbusiness.org/en/reforms/overview/economy/jordan>

<sup>57</sup> | <https://pdfs.semanticscholar.org/d7cc/3b3fd906dfac2347deb764b5a6526a7c7805.pdf>

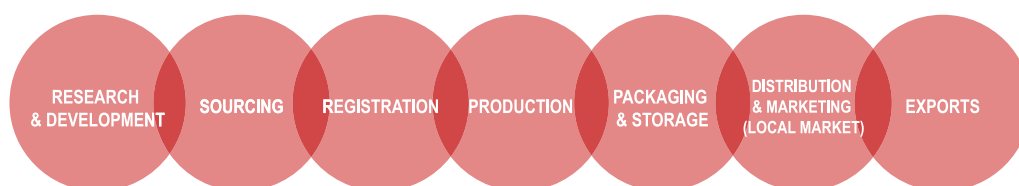
**Table 11:** HS Codes for Pharmaceuticals

<b>300320</b>	Medicaments containing antibiotics, not in measured doses or put up for retail sale
<b>300331</b>	Medicaments containing insulin, not in measured doses or put up for retail sale.
<b>300339</b>	Medicaments containing hormones or steroids used as hormones, not containing antibiotics, not in measured doses or put up for retail sale.
<b>300390</b>	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale.
<b>300410</b>	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, or streptomycins or derivatives thereof, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale.
<b>300420</b>	Medicaments containing antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale.
<b>300431</b>	Medicaments containing insulin but not antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale.
<b>300432</b>	Medicaments containing corticosteroid hormones, their derivatives or structural analogues but not antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale.
<b>300439</b>	Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale.
<b>300440</b>	Medicaments containing alkaloids or derivatives thereof, not containing hormones, steroids used as hormones or antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale
<b>300450</b>	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof used primarily as vitamins, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale
<b>300490</b>	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale

Source: TradeMap

# Value Chain Analysis

The pharmaceutical sector value-chain in Jordan constitutes the following activities:



## Research and Development (R&D)

As the industry is skewed towards production of generic drugs, there is limited investment in R&D. Manufacturers in Jordan invest in formulating and producing drugs that are out of patent<sup>58</sup>. However, investment in innovation or brand differentiation is not common among most manufacturers, hence most produce branded drugs. Sources indicate that local manufacturers currently spend 1% or less of their revenue on R&D<sup>59</sup> due to a lack of funds and total focus on a cost-efficient operation<sup>60</sup>. Jordan's pharmaceutical lab teams mainly invest in product development through formulation and stability. Drugs which require bioequivalence studies are done by CROs. Manufacturers can produce any drug that has been registered in the country, after 5 years from registration date (Data Exclusivity) even if it still under patent, unless the patent was registered in Jordan.

### Challenges in R&D

- No direct funding from government towards product-oriented research
- Financial limitations among manufacturers to develop new products that require clinical studies and to invest in new products with high cost of APIs.
- Shortage specialised training in new techniques and technologies such as in biotechnology products, anti-neoplastic, injectables, aerosols who possess the required knowledge and expertise in R&D and patent applications and analysis.

## Sourcing

The vast majority of APIs are imported (mainly from China and India). As per the JFDA, manufacturers can have a maximum of three suppliers. The companies can choose one from the three to deliver the APIs depending on the lead time and can register the corresponding API. Other criteria that manufacturers consider when selecting API suppliers are quality, effectiveness and price. Companies do not face any problem with sourcing of excipients as they are available and sourced from Europe at low prices, and less lead times as compared to APIs sourced from India and China. Hence, Jordanian

companies prefer import of APIs from India and China and excipients from Europe due to low cost of procurement as per the raw material.

There are many product conditions listed by the JFDA in approving APIs including specifications on stability data, impurity data, method of analysis, validation of method of analysis and schematic synthetic route. The API manufacturer should also have a Good Manufacturing Practices certificate from an accredited health authority in the country of origin. Starting in 2019, all APIs are required to be registered in JFDA, otherwise manufacturer will be required to pay an additional 35% of API cost.

A recent regulation for API sourcing by JFDA, which is yet to be implemented, requires the auditing of API manufacturer facilities by the pharma companies or third-party auditors. This regulation arose following identification of impurities in some APIs. However, if the regulation is implemented will likely increase the cost of APIs as not all API suppliers will be able to provide additional certificates and accommodate audit of manufacturing facilities. API suppliers' compliance to specific certificates and site audits will result in price increase in APIs from India and China.

Absence of local sourcing of APIs is due to the small size of the Jordanian market which does not allow for economies of scale, hence importing APIs will always be cheaper. Hikma is the only manufacturer that owns an API plant in Jordan specialising in oncology medicine. It is worth noting that technical know-how in API manufacturing is available in Jordan.

### Challenges in the sourcing stage

- Shortfall in planning at the manufacturers end delays sourcing and procuring APIs.
- Recent additions to regulations such as audit of API manufacturing facilities will impact costs and possibly the registration period.
- Setting local API manufacturing facility is a challenge due to the small size of the market and limited possibility of exports.

<sup>58</sup> | Euromonitor International trade analysis, 2019

<sup>59</sup> | Euromonitor International trade analysis, 2019

<sup>60</sup> | Euromonitor International trade analysis, 2019

## Registration

The drug registration process is identified as the most critical challenge and hindrance faced by pharmaceutical manufacturers, who claim that the process is very long and complex. According to manufacturers, the entire drug registration process takes no less than two years given the stringent nature of the process. However, this varies from one company to another.

According to the JFDA, the duration of the registration process was officially 6 months in 2018. Comparing the JFDA's registration process with that of other markets such as Saudi Arabia, Algeria, Tunisia, it is within the same range. The common steps that take place in the registration process are:

- 1) Submit the CTD for registration of the product
- 2) Approval of manufacturer site for the product
- 3) Evaluation of CTD by technical committee
- 4) Evaluation and Approval of bio-equivalence study if CTD contains such study
- 5) Pricing of the product by pricing committee post approval by technical and bio-equivalence committee

Manufacturers find the validation data in the quality part of the CTD to be challenging because in the quality part of the CTD the manufacturer should include the qualification of the manufacturing process and validation of drug analysis. The CTD when submitted with deficiencies in validation data is rejected by the JFDA from approval and request for more information which delays the registration process.

Until December 2016, companies had to present hard copies of the registration documents known as Common Technical Document to register their drugs at the JFDA. With the introduction of electronic submission of the Common Technical Document (eCTD) in the registration process, the timeframe for registration of drugs is expected to decrease. The eCTD system is expected to be mandated by the JFDA in the near future and will result in a more streamlined and faster registration process for manufacturers.

### Challenges faced by the JFDA at registration stage

- **Lack of full-time staff of assessors:** The assessors of drugs for the registration process are academics who only work for the JFDA for very limited time (less than eight hours a week). This is mainly due to the cost involved in hiring a full-time team, the cost of providing the necessary experience for full-time assessors and a change in regulations. This makes the evaluation process non-consistent and hence results in higher number of deficiency letters
- **Deficiencies in submission of the registration file:** Most CTDs submitted for registration do not clear the process the first time. This is because CTD files are sometimes missing results from tests and do not always have all the documentation required to achieve drug registration within 6 months. This is primarily due to the lack of adherence to best practices by manufacturers and submission of CTD and related files with less deficiencies to the JFDA.

### Challenges faced by manufacturers at registration stage

- Manufacturers face high compliance costs as the industry is highly regulated and regulators frequently impose new changes.
- Tightened control over laboratory tests slows the process. In some cases, additional tests are required, or tests have to be repeated, which consumes additional time, money and effort.
- Shortage of qualified R&D and regulatory personnel on the manufacturers' side: regulatory affairs personnel responsible for filing the CTDs for registration lack the technical know-how to prepare the necessary documentation without deficiencies for the registration process and are not updated with most recent changes in pharmacopeia.

## Production

### Manufacturing facilities

Manufacturing facilities are inspected and accredited by JFDA. All manufacturers meet the GMP certification, which is required by the JFDA for accreditation of a manufacturing facility to commence production. Every two years, all facilities are inspected by JFDA on a periodic basis and are under supervision by JFDA

### Labour

Given the high unemployment rate in the country, there is wide availability of low-cost skilled workers who are high school graduates and B.Sc. degree holders. The minimum monthly salary for an unskilled factory worker who works 45-55 hours per week, is around JOD280 and that of an operator in the production line is JOD600.

### Costs

Utility costs constitute up to 2% of the revenue of pharmaceutical manufacturers depending on the demand and usage of production lines. This however varies especially for companies using alternative power systems to save on electricity bills. Manufacturer must pay out of every employee's salary, a part of social security tax (14.25%).

Registration costs vary, but on average are broken down as follows: JOD200 for each sample, JOD400 for bioequivalence study (if needed), JOD200 for registration fees, JOD25 for sample analysis.

The table below lists the estimated share of costs out of total revenue:

**Table 12:** Share of costs in the production of pharmaceuticals in Jordan in 2018

METRIC	SHARE OF REVENUE (%)	METRIC	SHARE OF REVENUE (%)	METRIC	SHARE OF REVENUE (%)
EXPORT & AGENT FEES	20%	PACKAGING	6%	REGISTRATION	1%
MARKETING	20%	UTILITY COSTS	4%	PROFIT MARGIN	15%
LABOUR & FIXED COSTS	15%	TRANSPORTATION & LOGISTICS	3%		
RAW MATERIALS (APIS AND EXCIPIENTS)	5%-15%	R & D	1%		

Source: Euromonitor International trade analysis, 2019

### Pricing

Pricing, for both branded and generic drugs, is governed by JFDA and controlled by a syndicate of pharmacists. A generic drugs' price can only be up to 80% of the price of the originator drug. The price of a drug in export markets is linked to the drug's price in the country of origin. Government regulation limiting prices impacts pricing in local market and consequently in the export markets.

### Challenges in production

- The JFDA conducts periodic inspections to the manufacturer production facilities to ensure they adhere to production standards. This can range from few days to a month (depending on number of production lines) which sometimes causes delays in manufacturers being able to complete their orders
- Increasing utility costs such as costs of electricity and water has turned into a bottleneck for manufacturers to address in the production stage as it impacts the cost of production and hence the profit margin.



## Packaging and Storage

The majority of packaging is sourced from China due to its low-cost<sup>62</sup>. The JFDA does not specify special packaging requirement to differentiate OTC and prescription drugs<sup>63</sup>. Most companies only produce ordered volumes plus an additional 10-15% as stock, to avoid overstocks, reduce storage costs and waste levels<sup>64</sup>. Packaging varies according to the type of API used in the drug and according to the country of sale. Drug stores are visited by the JFDA to check for cleanliness, expired materials, or other irregularities<sup>65</sup>.

### Challenges in packaging

Labelling requirements in export markets demands packaging accordingly. For example, Algeria demands labelling in French and English. This increases the cost of the packaging.

## Distribution and Marketing: Local Market

Supplies, mainly procured annually by JPD tenders, are first received in the main warehouse in Amman.<sup>66</sup> Distribution to the private sector is managed by importers/manufacturers, using representative cars or delivery companies such as Aramex.<sup>67</sup>

### Challenges in marketing

Since prices are regulated in the market, companies adopt conventional marketing using medical representatives for branding among pharmacists and doctors. Companies fall short of specialized pharmaceutical marketing skills in workforce as well as exposure to address in medical conferences both in domestic and international markets. This needs to be addressed both for the domestic and export markets<sup>68</sup>.

## Exports

Exports form the core business of pharmaceutical manufacturers. Drugs that are exported are required to undergo the same registration process at the JFDA like the drugs sold in Jordan's domestic market. In addition to this, the drugs meant for exports need to comply with local health authorities' regulations of the destination countries. Exports from Jordan are facing challenges in the North African region due to protective mechanism of countries with developed pharmaceutical industries (i.e. Morocco, Tunisia), which result on limitations of imported drugs that are locally produced.



<sup>62</sup> | Euromonitor International trade analysis, 2019

<sup>63</sup> | Euromonitor International trade analysis, 2019

<sup>64</sup> | Euromonitor International trade analysis, 2019

<sup>65</sup> | Euromonitor International trade analysis, 2019

<sup>66</sup> | <https://pdfs.semanticscholar.org/d7cc/3b3fd906dfac2347deb764b5a6526a7c7805.pdf>

<sup>67</sup> | Euromonitor International trade analysis, 2019

<sup>68</sup> | Euromonitor International trade analysis, 2019

## Export Process

### Overview

Jordanian pharmaceutical companies have established a strong rapport with FDAs in Arab countries, providing those markets with quality OTC branded and generic drugs at competitive prices. Jordanian pharmaceutical companies are avid in supplying drugs with reasonable timing and efficient logistic management within the GCC, Levant and North Africa area<sup>69</sup>. Industry sources indicate the key criteria influencing foreign buyers' decisions include<sup>70</sup>:

#### Compliance with regulations of their local FDA

Jordanian pharmaceutical companies have strengthened communications and understanding of local FDA requirements of the main markets they target, mainly in the Arab League (KSA, Iraq, Algeria, Sudan, UAE). Few manufacturers export to other regions such as, Hikma Pharmaceuticals has been granted FDA approval to USA, and MS Pharma exports to Europe. JFDA is in the process of joining the members of Pharmaceutical Inspection Co-operation Scheme (PIC/S). Once JFDA's membership is approved, it will ease the export of pharmaceutical products to other member countries of PIC/S.

#### Quality

The quality of Jordan's pharmaceutical products is well-recognised in GCC, Levant and North African countries; high demand is especially evident for antibiotics and pain killers, followed by drugs for respiratory systems, vitamins and drugs to treat diabetes and cancer.

Availability: Availability and fast delivery (2-4 weeks) are substantial requirements from buyers; small pharmaceutical companies mentioned having issues with cash flow to purchase sufficient APIs for the further production of

orders for the export market.

#### Pricing

Pricing is key in export negotiations; the fact that the JFDA provides unified/fixed prices for most pharmaceutical products in the local market facilitates negotiations, as these prices act as the benchmark when setting FOB prices for the export market.

#### Packaging

Jordan's pharmaceutical companies have vast experience in dealing with all sort of packaging, such as blister packs, bottles and pouches. Moreover, companies have advanced

<sup>69</sup> | Euromonitor International trade analysis, 2019

<sup>70</sup> | Euromonitor International trade analysis, 2019

## Export Procedures and Supply Chain

In the key export markets such as Algeria, Saudi Arabia, Sudan, and UAE the ad valorem equivalent import tariffs are nil for both unpackaged medicaments (HS 3003) and packaged medicaments (HS 3004) from Jordan. Lebanon imposes an ad valorem equivalent tariff of 0.67% on unpackaged medicaments and 0.08% on packaged medicaments. The major barrier/difficulty is delays in JFDA registration and approval of drugs meant for export and meeting the regulatory standards set by destination countries. There are other requirements to be met for customs clearance, which include a certificate of origin, original invoice, airway bill, and packing list. The shipment must be certified from the embassy of the country of destination to be official. All information such as quantity, drug type, or serial number must be written clearly on the shipment for it to be cleared by the customs department<sup>71</sup>.

Major local stakeholders in the exports supply chain include:

- The exporting company or local manufacturer in Jordan.
- Export agents (Aramex, DHL, AL Naseer Company) who handle export clearance in Jordan.
- Jordanian customs officials located at physical borders, ports and airports who clear transport of pharmaceutical products.
- Importers in the destination country who handle clearance procedures.

### Challenges Faced by Exporters

The main challenges encountered in the export process include<sup>72</sup>:

#### Pricing

While pre-established (by JFDA) local prices act as facilitator benchmark when setting export FOB prices, multiple players indicate this restricts the level of profit they can achieve for their products, blocking in many cases their capacity to re-invest in R&D to develop more advanced, profitable items.

#### Registration Timeframe in Jordan

While the JFDA continues to make efforts to streamline the local registration process, the fact is that new drugs still take over a year to be fully-registered. In the case of re-exports multiple pharmaceutical companies simply prefer to pay for land allowance at the airport, without an official import process, and simply re-fly products once they arrive from their origin.

### Destination Countries' Registration Conditions

Registration of new products in foreign FDAs can also be lengthy and challenging. This is especially the case when exporting to African countries, where rules tend to change depending on current government and customs/FDA officials.

### Tax Increase and Export Costs

Sources indicate that during export clearance they pay high fees to government customs agencies for their services to test and issue certificates of origin.

### Traditional Export Markets

Saudi Arabia and GCC, Iraq, Algeria, Sudan and Yemen that were once key export markets for Jordan have, in recent years, developed their local industries and in turn adopted policies to protect them by limiting imported pharmaceuticals.

### External Challenges

Export managers must monitor external situations in countries under political turmoil, such as Iraq and Syria; political/economical paralysis can result in foreign buyers not being able to complete transactions/transfer payment to Jordanian companies.

### Rules of Origin (ROO)

According to the World Trade Organization (WTO), rules of origin are "the criteria needed to determine the national source of a product, and their importance is derived from the fact that duties and restrictions in several cases depend upon the source of imports". In other words, there can be more than one country contributing to material, labour or both to its production.

Jordanian exporters consider conformity assessments to ROOs to be difficult and perceive that officials lack comprehensive knowledge, capacity, and resources of ROOs and expertise about the procedures; this delays the process of preparing the conformity documents. Hence Jordanian exporters face challenge in obtaining ROOs / certificates of origin for exporting to partner countries<sup>73</sup>.

<sup>71</sup> | Euromonitor International trade analysis, 2019

<sup>72</sup> | Euromonitor International trade analysis, 2019

<sup>73</sup> | [http://www.intracen.org/uploadedFiles/intracenorg/Content/Publications/NTM%20Jordan\\_final\\_Low-res.pdf](http://www.intracen.org/uploadedFiles/intracenorg/Content/Publications/NTM%20Jordan_final_Low-res.pdf)

## SWOT Analysis

The following section highlights the strengths and weaknesses of local manufacturers in Jordan and the opportunities and threats that are present in the industry.

### Strengths and Weaknesses

**Table 13:** Strengths of local players in the pharmaceutical sector

STRENGTH	IMPACT ON SECTOR
1. STRONG SPECIALIZATION IN GENERICS	Companies specialise in antibiotics and cardio-vascular drugs. On average, 280 generics were introduced in 2017 by local manufacturers
2. QUALITY CONTROL IN MANUFACTURING FACILITIES	Companies not only comply with current Good Manufacturing Practices but also implement quality and risk management tools to ensure quality control towards zero defects in their manufacturing facilities. This enables them to meet international production standards towards exports.
3. AVAILABILITY OF GRADUATES FROM DIFFERENT SCIENCE MAJORS	Availability of skilled human resource in surplus with graduate degrees in chemistry, biology, and pharmacology to address workforce needs in production, packaging and storage, distribution, marketing, and pharmacies.
4. HIGH PRODUCTION POTENTIAL CURRENT CAPACITY EXCEEDING US\$2 BILLION	Manufacturers have a total installed capacity estimated to be almost double the utilised capacity, suggesting large room for growth in the sector.
5. STRONG CONTRIBUTOR TO ECONOMY	The entire pharmaceutical sector (considering different areas including production, clinical studies, exports etc.) accounted for 3% of the country's GDP in 2018 which makes it a strategic contributor to the economy.
6. REGULATIONS AND STANDARDS	The sector is regulated by Ministry of Health and JFDA. Local regulations and standards governing the performance of the sector is compatible with that of other international regulatory bodies such as USFDA, EMA. This enables the ease of exports for Jordanian manufacturers.
7. TRADE AGREEMENTS	Jordan's free trade agreements with countries and regions such as U.S, EU, GCC and other Arab countries makes it an open market trade internationally and facilitates export of pharmaceuticals for Jordanian manufacturers.
8. PREFERENTIAL TREATMENT FOR LOCAL PLAYERS	Preferential treatment is given to local manufacturers in public tenders. 15% pricing advantage is available for local manufacturers in public tenders.

Source: Euromonitor International from Trade Analysis, 2019

**Table 14:** Weaknesses of local players in the pharmaceutical sector

WEAKNESS	DESCRIPTION
1.STRONG COMPETITION	Competition in domestic market due to both local companies' products and imported drugs and in export markets as Jordan is primarily producing generics.
2. PRICE PRESSURES	Government regulations cap prices, which limits manufacturer profit margins. Thus, volume share is more important for companies than value.
3. INCREASING COSTS	Increase in labour costs and utility costs impacts the cost of production in the sector and negatively impacts Jordan's competitiveness in the export markets. In addition to energy costs, compliance and regulatory costs are a huge burden on manufacturers.
4. LACK OF DIFFERENTIATION - RELIANCE ON GENERICS	Manufactures rely only on generic drugs, resulting in a lack of differentiation which in turn impacts the sustainability of the sector.
5. PREPARATION OF REGISTRATION FILE	Companies commonly receive deficiency letters upon submission of files to the JFDA which adds to the long registration process. Investment by companies in trainings to R&D and regulatory personnel is minimal.
6.TALENT ACQUISITION IN SPECIALISED AREAS	Shortage of highly trained human capital specifically in IP and R&D is a hindrance to differentiation among local companies
7. PACKAGING & STORAGE REGULATIONS	Differences in packaging requirements (labelling, colour, language, type of container etc.) for various export markets imposes additional costs on manufacturers and increases operational challenges. Storage regulations in Jordan requiring cold chain management and adhering good distribution practices will add to the costs in the domestic market.
8. MARKETING	Most companies fall short of marketing professionals with techniques and technologies in marketing pharmaceuticals and rely on general business marketing methods.

## Opportunities and Threats

**Table 15:** Opportunities in the pharmaceutical sector

OPPORTUNITY	DESCRIPTION
1. AUTOMATION OF REGISTRATION PROCESS (ECTD)	Adoption of eCTD is expected to increase efficiency of the registration process
2. INVEST IN INNOVATION	For manufacturers to be able to differentiate themselves and stay competitive as well as penetrate new markets, innovation in new patents is key.
3. VALUE ADDED MEDICINE	Global decline in pipeline of new chemical entities for value added medicines is an opportunity for Jordanian manufacturers to work on addressing key health issues such as Asthma in export markets such as the EU. Manufacturers can focus development of antineoplastic, anti-cancer drugs, and injectables.
4. WIN MARKET SHARE OVER IMPORTED BRANDS	A significant share of imported pharmaceuticals are generics which means Jordanian companies have the potential to expand their market share and reduce reliance on imports.
5. EXPLORE NEW EXPORT MARKETS	Moving away from traditional export markets and exploring new markets has become inevitable as regional governments are limiting imports from Jordan to protect their respective local industries.

Source: Euromonitor International from Trade Analysis, 2019



**Table 16:** Threats to the pharmaceutical sector

THREAT

DESCRIPTION

1. RIGOROUS REGULATORY ENVIRONMENT
2. SHIPPING AND LOGISTICS
3. TAXES
4. LIMITATIONS TO EXPORT TO TRADITIONAL MARKETS

The lengthy registration process is a key obstacle to manufacturers. Certain procedures and processes under the regulations can be obstacles and a hindrance to local players. The growing number of regulations further adds to this challenge.

Challenges in shipping on road via Syria to Turkey and Eastern European countries force exports via the port of Aqaba. This adds to both shipping costs and transport costs involved from Amman to port of Aqaba, impacting competitiveness of manufacturers by affecting the lead time.

Change in corporate tax rates from flat 14% to different tax slabs with a gradual increase from 10% for 2019 to 20% in 2024 is expected to impact cash reserves much needed for R&D

As governments in traditional export markets continue to protect respective local pharmaceutical industries, exports from Jordan will face more challenges

Source: Euromonitor International from Trade Analysis, 2019

74 | <https://www.ey.com/gl/en/services/tax/international-tax/alert--jordan-amends-income-tax-law>

## Potential New Export Markets

To enhance exports in Jordan's pharmaceutical sector, a list of 33 countries was evaluated across regions such as Central Africa, East Africa, and Commonwealth Independent States. Each country was evaluated against four broad factors:

- 1) Business dynamics and economy
- 2) Demographics and expenditure
- 3) Trade
- 4) Shipping duration time

### Business Dynamics and Economy

Each country's business dynamics and economy were evaluated to understand the strength of the country to trade with Jordan. Business dynamics and economy were evaluated based on:

- 1) Corruption Perceptions Index
- 2) Trading Across Borders
- 3) Logistics Performance Index Score
- 4) GDP Measured at Purchasing Power Parity
- 5) Real GDP growth
- 6) Unemployment
- 7) Inflation
- 8) Exchange rate of each country's currency against the Jordanian Dinar

### Demographics and Expenditure

Each country's potential buying power was assessed to determine which markets would be a better matched to trade with Jordan. Demographics and expenditure of the countries were evaluated based on:

- 1) GDP per capita
- 2) Private final consumption expenditure
- 3) Consumer expenditure on pharmaceutical products, medical appliances and equipment
- 4) Population density
- 5) Population living below international poverty line
- 6) Total population

- 7) Urban population

### Trade

The trade scenario of each country was analysed to understand the export potential for Jordan to that target country. Trade was analysed based on:

- 1) Trade balance
- 2) Applied tariffs
- 3) Untapped potential trade

### Shipping Time

It was important to gauge the shortest shipping route and associated shipping time in order to understand the involved shipping costs between Jordan and each target country.

### Assessment of Target Countries

Each sub-factor of each country was ranked relative to other countries' data for the respective sub-factor. Weights were assigned for each broad factor considered and an aggregate score for each broad factor was calculated for each country. An overall score was calculated as the sum of aggregate scores and each country's relative rank at the level of broad factors was calculated compared to all countries. The countries ranking 1, 2, 3, and 4 were recommended as target export markets.

## Export Profiles - Belarus

### Background

Economic stability and anti-corruption measures assure minimal market risks to trade with Belarus. However, regulations remain unpredictable and taxes are high by regional standards. Exports are driven by stronger demand in the European Union (EU) and Russia and constant commodity prices. Low inflation and exchange rate stability exist because of strong policy frameworks.

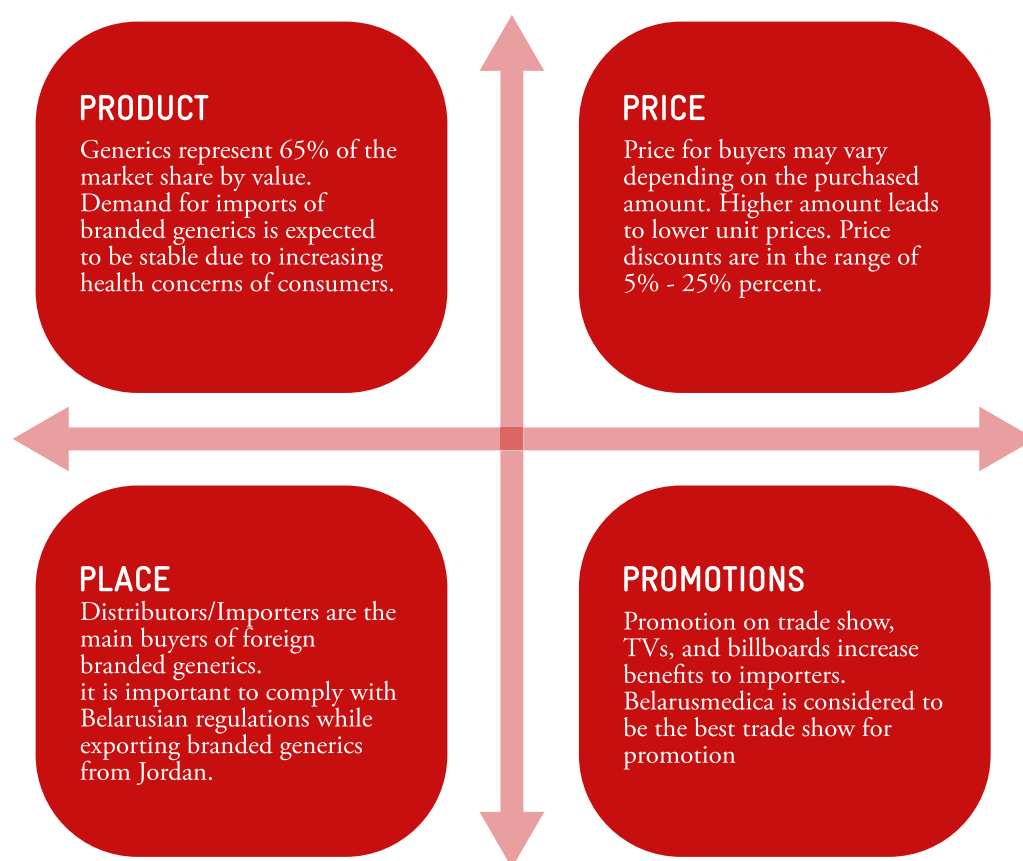
Pharmaceutical market has been growing consistently from 2013 to 2018, except during 2015 and 2016, when the country was affected by the financial crisis. The key demand and growth drivers for the overall sector are the broadening varieties of drugs as well as the increasing number of domestic products at competitive prices. The key trends affecting the pharmaceuticals sector are:

- Developing healthcare system and increasing health concerns of consumers.
- Consumers' trust is gradually increasing in locally produced pharmaceutical products.

### Market Highlights

- The demand for imported pharmaceutical products is higher than that for local products because of marketing campaigns of imported branded generics and perception of Belarusian consumers is better towards imported products.
- However, government's initiative to increase the share of locally manufactured drugs in the domestic market and development in local manufacturing of generics can impact the demand for imported drugs.
- The key supplying countries for Belarus are Russia, Germany, and Ukraine and their competitive advantages are trade terms in the framework of Eurasian Economic Union and the reputation of high-quality products. Shorter lead times from pharmaceutical companies will be key to penetrate in the Belarus market.

**Chart 3:** Marketing mix of pharmaceutical products in Belarus



### Access to Market

- Distribution in the local market occurs via short supply chain from importers / distributors to pharmacies. More than 50% of pharmaceutical products are distributed by one state-owned company, 'Pharmacia'.
- Pharmaceutical products are examined by the center for examinations and tests in the health service and confirmation of State Registration at the Ministry of Health for sales in the domestic market.
- Export of pharmaceutical products via land is the recommended route to access Belarus market due to cost effectiveness.

### Recommendations and Next Steps

- To overcome any common challenges or avoid unneeded costs, it is recommended to partner with importer / local distributor companies, possessing special warehouses and transportation for storage and distribution of pharmaceutical products across the country.
- It is important to cooperate with big pharmacy chains for product marketing, which would improve consumer awareness about advantages of particular brand.
- Product promotion should be creative for good brand recall among consumers. Television is the most influential method of promotion in Belarus.
- Besides identifying partners for importing medicines, pharmacies and doctors are the key retail channels to promote the product brand. Hence, they could be targeted via trade shows.
- In terms of pricing, Jordanian drugs could be slightly more expensive comparing to Belarusian, since consumers believe that local drugs are too cheap to be good.

## Export Profiles - Russia

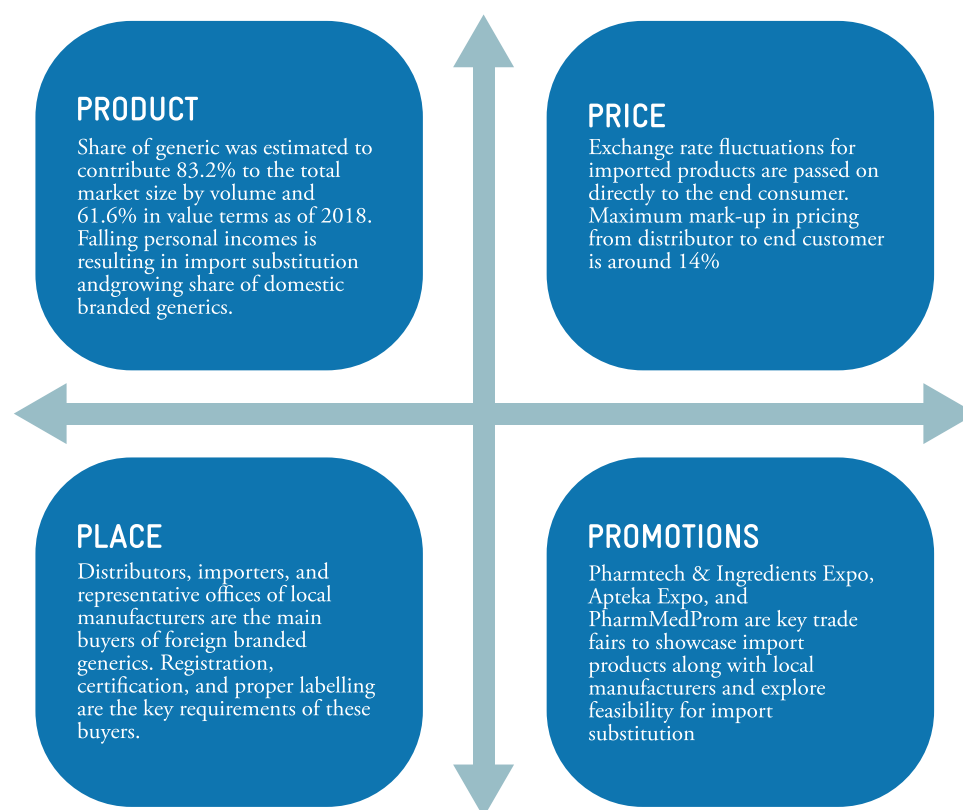
### Background

The Russian economy is experiencing moderate growth after a recession of two years. Banks have become vulnerable to money laundering and illegal origin of money. There are no significant restrictions for payments related to the import of goods. However, the bank of the Russian importer is obliged to ensure compliance of payments with currency regulations. The Russian importer and its bank

need to set up a "transaction passport" for each contract. The foreign exporter is not directly involved but may be affected due to the need of the Russian importer to obtain documents and information from the exporter. Exchange rate volatility remains an issue given the volatility of oil and gas prices and the effect of sanctions.

### Market highlights

- The health care system in Russia suffers from underfunding, red tape and corruption which results in reduced efficiency. This trend is unlikely to change in the coming years.
- The country encourages local production. As a result, it is expected that exporters of large volumes could collaborate with local entities to establish manufacturing entities and achieve government subsidies.
- The pharmaceutical sector will continue to integrate vertically among Russian firms with primary focus on production, distribution and retail.
- The commercial drugs market grew by 11% in volume terms driven mainly by the increase in domestic production of generic and cheaper drugs.
- Regional pharmacy retail chains and small independent pharmacies have been consolidating through mergers and acquisitions resulting in stable quality of service and product prices rendered to consumers.
- The key supplying countries for Russia are Germany, France, and USA. The key competitive advantages of these supplying markets are wide portfolio of pharmaceutical products, well established logistics, and innovative, premium offerings.
- Active promotion of the medicines by the leading suppliers such as Bayer, Sanofi, and Novartis, in the Russian market has aided their penetration across all major channels.
- The country's depreciating currency against the US dollar is likely to impact import prices which may not always be passed on to end-consumers. Hence, importers might be sceptical in venturing into new brands.
- Medicines registered under certain rules can be circulated and offered for sale throughout the EAEU - in the territories of Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan without undergoing registration procedures in each of these member states.

**Chart 4:** Marketing mix of pharmaceutical products in Russia

### Access to Market

- Distribution in the local market occurs via short supply chain from importers / distributors to pharmacies.
- Product registration and approvals are to be obtained before imports into Russia
- Identifying a suitable partner who is well integrated in the supply chain could help reduce intermediaries and improve margins.
- Export of pharmaceutical products via land is the recommended route to access Russian market due to cost effectiveness.
- The best trade routes recommended are either through Moscow or St. Petersburg due to infrastructure, developed retail and solid consumer base.
- Subsequent expansion plans should include other major cities such as Novosibirsk, Nizhny Novgorod, Rostov, Krasnodar.
- Branded generics should be marketed as affordable and equivalent alternatives to domestic brands.
- It is important to price the exported branded generics to give attractive profit margins to intermediaries in the supply and to be included in the list of vital drugs and be included in government drug programs.

### Recommendations and Next Steps

- Identification of multiple distributors who are willing to expand a new brand is important for penetrating different states in the country.
- Exporters need to plan their shipments well in advance due to delays in drug registration and approval by local health authority.
- Establishing a representative office or partnering with local distributor is recommended as the best route to penetrate the market.
- New products should be promoted at trade shows and backed by aggressive media campaign aimed at industry professionals and the business community.

## Export Profiles - Ukraine

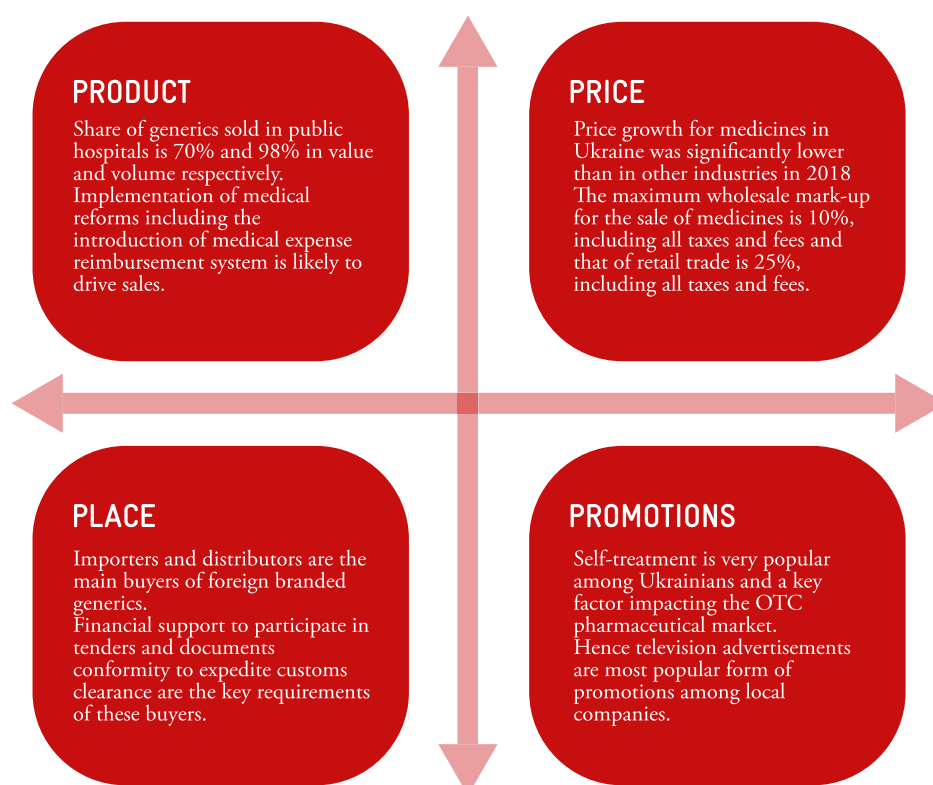
### Background

Unstable macro-economic condition poses trading risks with Ukraine. Improvements in trade competitiveness are threatened because of increasing labour costs. High external debt payments can affect national currency leading to defaults in payments.

### Market Highlights

- There is a growing trend for consumption of dietary supplements such as fructose, lecithin, fiber, omega3. This is pushing market value given the higher price points of the supplements.
- Prescription drugs witnessed a growing trend in the past 10 years. In 2018, high-value drugs' share increased both in volume and value due to rising prices and consumption shift to more expensive drugs.
- Value sales grew better than volume sales in the past few years with consumers preferring high-quality international brands instead of the locally made brands.
- The internet is playing a major role in not only educating the consumers with the appropriate medicines but also in drug trade and electronic prescriptions
- Germany, India, and France were the key supplying countries for Ukraine. The competitive advantages of these supplying markets are access to high-grade technology resulting in high quality products, products are perceived to be 'Value for money' resulting in the right price-quality ratio, wide range of products.
- Innovation, price, and volume discounts are the key competitive advantages of the key supplying companies such as Farmak, Arterium, and Teva.

**Chart 5:** Marketing mix of pharmaceutical products in Ukraine





## Access to Market

- If a drug is registered under one (or several) of the countries: USA, Switzerland, Japan, Australia, Canada, European Union the company can use fast-track registration which can take up to 1 working day.
- It is common to register drugs and get licenses (such as import, wholesale etc.) via specialized consulting companies, this will help to simplify and optimize the process for the importer and exporter.
- Producers and importers prefer to distribute pharmaceuticals via distributors to cover all regions and ensure an uninterrupted supply of drugs
- Export of pharmaceutical products via air is the recommended route to access Russian market due to cost effectiveness.

## Recommendations and Next Steps

- Importers with strong financial background is recommended for partnership to cover market risks and on-time payments.
- Chemists and pharmacies are recommended to be targets for promotion as most OTC products are sold on their advice to end consumers.
- Focusing on volume-sales at pricing closer to competition will ease initial market entry.
- Digital channels are recommended to promote Jordanian drugs to health care professionals and end consumers because of increasing online trade.

## International Case Study: Bulgaria

### Background

The pharmaceutical industry in Bulgaria has evolved remarkably since 1990, from a fully vertically integrated sector involved in developing, producing, and licensing patented medicines, to a manufacturing hub of generic pharmaceuticals, which takes advantage of their low-labour cost in comparison to other EU-member states<sup>75</sup>. Being an EU member, the country benefitted from access to the European market, opening business opportunities in Germany, the UK and France, while preserving pre-existing business rapports with nations, such as Russia and Romania. This advance allowed pharmaceutical exports to grow from USD0.9 billion in 2013 to USD1.02 billion in 2018 at a CAGR of 2.9%.

Bulgaria and Jordan boast a significant pharmaceutical industry (in comparison to their respective GDP), which is overwhelmingly focused on the production of cost-efficient generic lines; for this purpose, their best resource is to maintain their costs low, this by paying low-wages to their respective workers and minimizing their R&D activities to less than 5% of their budget.

Bulgaria shares demographic similarities with Jordan, with both countries boasting less than 10 million inhabitants. This results in both countries having a limited local target market, which limits their pharmaceutical industry's exponential growth nationwide and forces stakeholders to look at foreign market opportunities.

### Macroeconomy

Bulgaria's population is in freefall due to a combination of negative natural changes, such as lower birth rates and high death rates, plus high rates of emigration. Lower birth rates are resulting in a rapidly-aging population, with Bulgaria expected to become the 9th oldest country in the world by median age of 33, by 2030<sup>76</sup>. In terms of economics, the country continues to benefit from EU funding, especially for the development of infrastructure. Domestic demand should continue to be a driver of growth in the short-term, along with increased investment in export-focused manufacturing and improvements in the labour market.

In 2018, inflation reached 2.8% and the same rate of inflation is expected in 2019. Strong domestic demand and higher energy and commodity prices pushed inflation up, and it is expected to rise again in the future if energy prices rise further. Unemployment is experiencing a secular decline, due to emigration and population ageing; an estimated 30,000 people are thought to be leaving each year and the figure has been much higher in years past<sup>77</sup>.

**Table 17:** Bulgaria, Macro-economic indicators 2014-2023

Indicator	Unit	2014	2018	2023
Population	000	7,245.7	7,050.0	6,782.8
GDP	US\$ mn	47,878.6	61,892.9	81,711.9
Inflation	%	-1.4	2.8	2.3
Unemployment rate	%	11.4	5.2	6.0

Source: Euromonitor International

<sup>75</sup> | Euromonitor International trade analysis, 2019

<sup>76</sup> | Euromonitor International

<sup>77</sup> | Euromonitor International

## Market Demand and Supply

### Local production

Bulgaria has established itself as a hub for on-contract production of generic medicines, benefitting from low-cost labour, the large installed manufacturing capacity of their three largest players (Sopharma, Teva (Teva acquired Actavis Generics of Allergan Plc globally) and Huvepharma) and their preferential access to the EU. Another reason for the strong supply of generics by local manufacturers is that consumers nowadays have a better perception of generic medicines made in Bulgaria, as a result of compliance with EU production requirements.

This extensive supply of generic products caters both to their local market and foreign exports, to Russia, Germany and Romania mainly. Sources indicate that generic products represent an estimated 80% of the market by volume and 50% of the market by value<sup>78</sup>; this is explained by their low-cost in comparison to branded products.

In 2018, local production reached a total value of USD0.97 billion, of which 25% accounted for local sales. Total consumption in the sector is USD2.1 billion, of which 85% was attributable to imports. Consumption grew by a CAGR of 8.5% over 2013-2018<sup>79</sup>; this fast rate was primarily driven by higher disposable incomes in the country, which increased by a CAGR of 7.3% from 2013-2018<sup>80</sup> to reach USD39,472 in the latter year. Higher cash availability resulted in higher consumption of both generic and premium OTCs, and faster development of pharmacy outlets, which complement their retail offering with cosmetics, beauty and hygiene products. The OTC market also performed positively, due to increasing health awareness among consumers, strong advertising and the focus on cost containment in healthcare<sup>81</sup>.

Other important factors include Bulgaria's rapidly-aging population, with the 65+ age segment increasing from 1.4 million in 2013 to 1.5 million in 2018, a CAGR of 1.2% over this period. In 2018, Bulgaria's senior population represented 2.01% of the total population, with this percentage expected to increase to 22.7% by 2023<sup>82</sup>.

Production capacity is 20 billion tablets/year, of which 20 million is accounted for by Sopharma and 7 billion by Teva (formerly Acatavis)<sup>83</sup>.

### Labor market needs

The industry is currently facing a shortage of both educated (pharmacists, medical representatives) and non-educated personnel (production/packaging, logistics). In multiple cases, the pharmaceutical sector has been forced to use the services of personnel who have reached retirement age or very inexperienced specialists. Higher education institutions have tried to marginally increase their education offering, however this is not expected to provide significant changes given Bulgaria's depopulation process, caused by low local wages in comparison to other EU member states<sup>84</sup>, which tends to result in the migration of skilled workers. Distributors and manufacturers are constantly running marketing and sales trainings for their sales teams; as the industry must often rely on inexperienced sales agents who require an intensive induction to the pharmaceutical sector<sup>85</sup>.

### Key manufacturers

Sopharma, Teva, and Huvepharma are the three leading manufacturers. Sopharma is a public company which achieved high profitability by combining high volume production of generic medicines and partnering with a large medicine wholesaler working on a franchise model with pharmacies. Teva acquired Actavis' production and retail facilities and achieved growth and expansion. Huvepharma is owned by the Domustchiev brothers who also own Biovet, a former state company. It has advanced its manufacturing capacity, supported by own investment and a €200 million EU grant.

Foreign companies are represented either by local subsidiaries, which produce drugs under license, or by offices with 10 to 30 employees who carry out only trade, marketing activities, and clinical trials. GSK and Novartis, for example, have only trade and clinical trials operations. As of 2013, there are more than 100 foreign pharmaceutical companies represented in Bulgaria<sup>86</sup>.

### Imports

Over the last 6 years imports have represented an average of 78-85% of the local market<sup>87</sup>. Hungary, Germany and the Netherlands have been Bulgaria's main suppliers. Foreign drugs are largely demanded for the treatment of chronic diseases, such as hypertension and diabetes.

<sup>78</sup> | Euromonitor International trade analysis, 2019

<sup>79</sup> | Euromonitor International trade analysis, 2019

<sup>80</sup> | Euromonitor International

<sup>81</sup> | Euromonitor International trade analysis, 2019

<sup>82</sup> | Euromonitor International trade analysis, 2019

<sup>83</sup> | Euromonitor International trade analysis, 2019

<sup>84</sup> | Euromonitor International trade analysis, 2019

<sup>85</sup> | Euromonitor International trade analysis, 2019

<sup>86</sup> | Euromonitor International trade analysis, 2019

<sup>87</sup> | <http://www.thekuriers.com/Bulgaria.pdf>

**Table 18:** Bulgaria, declared imports trade value (USD million), including main markets

	2013	2014	2015	2016	2017	2018
<b>Total Imports</b>	<b>1,016.8</b>	<b>1,158.6</b>	<b>1,018.8</b>	<b>1,019.7</b>	<b>1,179.1</b>	<b>1,286.1</b>
<b>Hungary</b>	191.5	207.2	183.1	193.1	229.2	273.0
<b>Germany</b>	128.0	156.4	139.3	151.1	159.9	176.3
<b>France</b>	69.9	103.8	93.3	82.1	85.9	84.4

Source: Trademap (HS codes: 3003 – unpackaged medicaments and 3004 – packaged medicaments)

## End users

Pharmacy chains such as Apteki Mareshki (21.4% of pharmacy retail sales, 2018), Ceiba (6.9%), Medeya (4.1%) and Sopharmacy (2.6%) represented the largest distributors/retailers of pharmacy products in 2018. In total, pharmacy retail sales amounted USD1,466 million in 2018, rising from USD1,125 million in 2013<sup>88</sup>, representing 69.5% of pharmaceutical retail sales in 2018. As stated previously, pharmacies are large distributors of generic OTC drugs, which are not covered by the public system and must be purchased in full by end-consumers. Pharmacies must procure pharmaceutical products from licensed wholesalers and only licensed drugs are allowed for retail sales. Patients are allowed to buy prescription drugs only with prescription and cannot resell or export them.

The public and private hospital/healthcare system represented the remaining 30.5% of consumption in 2018. The medicines that public and private hospitals use are price controlled, hence hospitals can buy them without tender. For other products, state or municipal hospitals must set a public tender. The state health fund pays hospitals per service rendered. Hospitals have a dedicated pharmacy which is for their own use only and they cannot sell medicine to patients. Both private and public hospitals must buy pharmaceutical products from licensed wholesalers.

Doctors and dentists are not allowed to sell medicine directly to patients and can procure only a permitted list of medicines that they need to use solely for the procedures on patients that they carry out. Doctors are paid from the

health insurance fund per service rendered and thus buy medicines at their expense for the procedures. Vaccines are provided by the health ministry.

## Government role

The Bulgarian pharmaceutical sector is regulated by the Bulgarian Drug Agency (BDA), which reports to the Ministry of Health; the BDA is responsible for:

- Authorisation and oversight of manufacturing, import, wholesaling and retailing of pharmaceuticals
- Authorisation and oversight of clinical trials
- Pharmacovigilance and drug information
- Classification (scheduling) of pharmaceuticals
- Authorisation of marketing/advertising

Companies are eligible to gain EU financing to increase the skill level of their workforce. As Bulgaria is predominantly a generic-drug producer, the key needs of the industry are ensuring bioequivalence of the drugs and safety related procedures to comply with GMP standards. The government does not provide any significant support to tackle this vocational deficit, given their restricted budget for both education and health<sup>89</sup>. The government focuses instead on cost-containment measures, which leads to public-health prescriptions of low-cost generics.

<sup>88</sup> | Euromonitor International

<sup>89</sup> | Euromonitor International trade analysis, 2019

## Value Chain Analysis

The pharmaceutical sector in Bulgaria has the same stages as the Jordanian pharmaceutical sector.

### - Research and Development (R&D)

Overall, the Bulgarian pharmaceutical industry generates about 25,000 jobs, of which about 3,000 are in R&D and clinical trials. Large domestic producers, such as Teva and domestically owned Sopharma, spend only a small fraction of their annual turnover (about 5%) on development activities. Most studies undertaken by Bulgarian companies remain focused on proving bioequivalence between generic and patented drugs. Bulgarian producers have substantially modernised their production facilities using high level of automation such as automated tablet production, pelleting, primary packaging, secondary packaging, and transport packaging, and expertise from PhD holders in pharmacology on sites to oversee and optimize production lines. In essence, one machine that produces ready to ship packages is used, but R&D is not a priority<sup>90</sup>.

### - Sourcing

Most APIs required for pharmaceutical production are sourced from EU countries, given their preferential access compared to those of non-EU origin. The largest API suppliers include large companies such as Teva (from Hungary), Boehringer Ingelheim (Germany) and Interchemie (Netherlands)<sup>91</sup>. These companies provide competitive prices and a vast portfolio to produce depot tablets and fast-dissolving tablets. Some suppliers offer R&D support for implementing physical form, others offer a branded active ingredient.

Similar to Jordan, suppliers do not need to have local representation in Bulgaria, as they can trade from anywhere in the EU; this reduces administrative costs and increases business flexibility. It is also easier for the local drug manufacturer to get a license to import the active ingredient if coming from the EU. Drug manufacturers must register as importers to import directly, saving on logistic costs through direct purchases. However, for smaller drug manufacturers, minimum order quantities can be too high, as content of an API per package is low.

### - Registration

The BDA oversees drug registration, which is considerably fast if the product is already registered within the EU (less than 30 days). If the product is not registered in another EU country, the registration process takes up to 240 days. Non-generic drugs must pass through full clinical testing while generics must only prove bioequivalence with reference products. Packaging, leaflets and advertisements also need to be approved. Registration of drugs is applicable for domestic sale only, with no registration needed for exports.

Although costs for drug registration are much higher than Jordan, it is considered affordable by local players, €7,500-10,000 for new drugs depending on the processes and tests required, while registration fees for products already registered within the EU are €3,500-7,000 for generics and €1,000-2,500 for homeopathic medicine. The registration process has been digitalised and companies register their drugs using e-CTD for more transparency<sup>92</sup>. The e-CTD was launched in 2014, enabling companies to save time and manpower. This online registration process allows companies to track the status of their registration process and diminishes the risk of delays in launching the products in the market.

### - Production

Manufacturers are continuously making significant investments in the modernisation of their production facilities to comply with EU GMP requirements for production, packaging and storage. Bulgarian manufacturers have invested particularly in production areas, improving self-contained area conditions, airlocks, pressure differentials, and air supply and extraction systems. Moreover, producers have improved their QA measures, minimising the risk of contamination by wearing protective clothing where products or materials are handled and using cleaning and decontamination procedures of known effectiveness<sup>93</sup>.

<sup>90</sup> | <https://www.mi.government.bg/files/useruploads/files/innovations/input3s.pdf>

<sup>91</sup> | Euromonitor International trade analysis, 2019

<sup>92</sup> | <https://www.bda.bg/en/>

<sup>93</sup> | Euromonitor International trade analysis, 2019

**Table 19:** Key conversion costs in Bulgaria's pharmaceutical industry, 2018

METRIC	SHARE OF REVENUE (%) - JORDAN	SHARE OF REVENUE (%) - BULGARIA
Labour & fixed costs	15%	12%
Transportation & logistics	3%	3%
Raw materials (APIs and excipients)	5%-15%	5%-30% (Depending on APIs used)
Packaging	6%	7%
R&D	1%	5%
Registration	1%	1%
Marketing	20%	10%-30%
Utility costs	4%	Absorbed in packaging and fixed costs
Exports & agent costs	20%	N/A
Profit margin	15%	20%

Source: Euromonitor International from Trade Analysis, 2019

## - Packaging and Storage

Local manufacturers have invested in their facilities to comply with GMP requirements for packaging and storage. Once again, local manufacturers have invested in quality control measures such as precision controlled packaging automation, to guarantee correct labelling and safety of drugs when being packaged. In terms of storage, every warehouse needs a registered pharmacist in charge of storage and employment size in this stage is about 10 workers per location. Packaging and storage must remain in-house as it is otherwise difficult to meet GMP standards<sup>94</sup>.

## - Distribution and Marketing

There is increasing consolidation among distributors who most of them are small and medium-sized, currently Bulgaria has over 150 distributors of medicines. These companies' operations tend to mix pharmaceuticals with other lines, such as food additives, sanitary materials and cosmetics. Large manufacturers, such as Sopharma, and pharmacy chains, such as Apteki Mareshki, act as wholesale distributors, for both their brands and other companies<sup>95</sup>. Marketing activities must comply with GMP standards.

Local manufacturers have introduced written procedures. Written procedures is an EU system in which every package has a unique code through which its source can be traced to produce reliable distribution records, which can be regularly reviewed and updated, in case product recalls are required<sup>96</sup>.

<sup>94</sup> | Euromonitor International trade analysis, 2019

<sup>95</sup> | Euromonitor International

<sup>96</sup> | Euromonitor International trade analysis, 2019



## - Exports

Sources estimate that 85% of current production (2018) was destined for the export market, with 90% of these exports being generic products. Bulgaria's main manufacturers are also responsible for the largest export operations. Sources estimate that Huvepharma accounted for 42.5% of exports in 2018, Teva accounted for 27.5% and

Sopharma for 17.5%<sup>97</sup>.

Increase in exports were driven by the successful compliance of Bulgarian manufacturers to EU-GMP standards, which opened market opportunities in Western European nations. EU regulations are not expected to experience significant changes in the short-to-medium term; Bulgarian manufacturers must simply continue complying with EU-GMP standards by employing an effective quality assurance system, to secure access to the EU single market.

**Table 20:** Bulgaria, declared exports trade value (USD million), including main markets

	2013	2014	2015	2016	2017	2018
<b>Total Exports</b>	798.3	961.3	808.0	794.1	923.2	956.9
<b>Russia</b>	220.6	233.7	130.2	105.4	139.1	132.7
<b>Germany</b>	85.3	86.7	87.1	86.3	86.4	86.4
<b>Romania</b>	70.3	69.9	56.5	47.9	79.4	75.3
<b>UK</b>	28.3	43.4	49.2	47.4	72.4	57.0
<b>Netherlands</b>	28.0	32.4	31.0	37.6	39.7	57.2
<b>France</b>	20.4	22.5	25.2	34.3	32.3	42.6

Source: Trademap (HS codes: 3003 – unpackaged medicaments and 3004 – packaged medicaments)

<sup>97</sup> | Euromonitor International trade analysis, 2019

## Challenges

The main challenge the sector faces is the government's program to restrain price growth in order to decrease public sector expenditure. This type of measure has proven to restrict companies' economic growth, limiting their capacity to develop R&D studies to introduce new drugs and gradually reduce the country dependency on costly imports. Moreover, price restriction tends to shift preferences towards foreign markets, with Bulgarian manufacturers becoming low-cost generic producers supplying Western Europe<sup>98</sup>.

## Recommended Experiences

Bulgaria has gained experience in the production of cost-efficient generic pharmaceutical products, benefitting from its low labour and production costs. Additionally, Bulgaria has successfully complied with the GMP standards set by the EU, achieving greater transparency in the market as well as opportunities for more foreign firms to enter the market through acquisitions (Teva for example)<sup>99</sup>.

Bulgaria's adoption of EU-GMP standards has brought positive results in both local and foreign markets. In the local market, end-consumers feel more confident about the quality of products offered by local manufacturers, while in foreign markets it has opened doors for the supply of generics to large European economies such as Germany, the UK and France.

Bulgarian and Jordanian manufacturers' profit is also affected by pre-established government price-caps, sustained by their local health authorities, to decrease public sector expenditure. This has forced the industries of both countries to search for foreign business opportunities, based on exports of competitive-priced generics to neighbouring countries. Despite the relative success of this strategy in both nations, their local pharmaceutical markets still depend on heavy imports of specialised/premium drugs, to treat advanced diseases. Moreover, both countries are still dependant on the supply of foreign APIs, given the lack of resources, technology and education to be able to produce these products locally.

The Bulgarian government's lack of support, strict control on generic-prices and on-going corruption continues to deter foreign investment. Jordan must continue providing a positive business atmosphere to attract overall investment into the country.

Packaging, leaflets, and advertisements also need to be approved. Registration of drugs is applicable for domestic sale only, with no registration needed for exports. This reduces the lead time to importers in the export markets and cuts down the additional cost for registration of drugs in domestic health authority. This could benefit Jordan in exports to unregulated African export markets.

Strong dependency on generic drugs by both Bulgaria and Jordan limits the capabilities of skilled human resource from R&D and innovation. As a result, they face strong competition from Asian countries such as India and China in the generics drugs segment, as these countries also have API manufacturers supplying to the local market.

Setting up packaging industries in Jordan similar to Bulgaria's PET bottle industry will support internal reliability for packaging material and decrease costs involved in importing the packaging from China. Special focus on packaging material that can be recycled should be adopted by Jordan to adhere to medical waste management laws in the export markets.

Bulgaria, as a country, utilises a good mix of both renewable and non-renewable energy to supply power to its manufacturing sector. In 2017, renewable energy sources such as nuclear, water, wind, solar, biomass accounted for 57% of energy mix of Bulgaria<sup>100</sup>. It is recommended that, Jordan can focus on renewable energy sources to address the electricity costs impacting the domestic pharmaceutical industry.

Jordan's pharmaceutical manufacturers can adopt end-to-end automation in production lines for manufacturing shipments that are export ready from the factories. This will reduce the time and additional labour costs involved in production and packaging and meet shorter delivery times to end buyers in export markets. As regulated in Bulgaria to employ PhD degree holders in pharmacology at the production sites will ensure to address inspection issues by local health authorities and seamless production.

Bulgarian Small and Medium Enterprises Promotion Agency worked on a dedicated export strategy project for chemical and pharmaceutical products to develop competitiveness for Bulgarian economy. The project was funded by European fund for regional development. The project involved strategies towards the following action plan:

<sup>98</sup> bulgarien.um.dk/da/.../Sectoranalyses\_Pharmaceutical%20and%20Healthcare.pdf  
<sup>99</sup> bulgarien.um.dk/da/.../Sectoranalyses\_Pharmaceutical%20and%20Healthcare.pdf  
<sup>100</sup> <https://www.globallegalinsights.com/practice-areas/energy-laws-and-regulations/bulgaria>

**Table 21:** Export Strategy Development Program, Bulgaria, 2012

OBJECTIVES AND MEASURES	EXPECTED RESULTS
Development and implementation of programs for improving the qualification of export specialists in SMEs	Train over 1,000 export specialists from SMEs during 2014 -2020`
Development and implementation of training program for participation in international exhibitions	Train experts from minimum of 400 SMEs
Financial support for certification of enterprises in quality management, environment management and implementation of system for safe and healthy working conditions	increase number of enterprises which obtains certificates to access foreign markets and partners
Development of mechanism for financial assistance of the participation of foreign partners at local fairs and exhibitions	Finalise contracts for exports as a result of the participation of foreign trade partners.
Development of working procedures for the Bulgarian trade representatives abroad in favour of SMEs in the sector	Increase the number of export contracts for products from the sector.
Development of working procedures for the Bulgarian trade representatives abroad in favour of SMEs in the sector	Improve the brand image of Bulgarian products and awareness of foreign customers to them.

Source: Bulgarian Small and Medium Enterprises Promotion Agency

It is important for GIZ to facilitate and to create an export development plan by working along with Jordan Enterprise Development Corporation (JEDCO), Ministry of Industry and Trade, JAPM, and Jordanian manufacturers in the key sectors of focus to enhance exports and Jordan economy.

**Table 22:** Similarities and differences between Jordanian and Bulgarian pharmaceutical industries**THEME****COMPARISON OF JORDAN AND BULGARIA****R&D**

Both countries do not invest more than 5% of its annual turnover in the pharmaceutical industry towards R&D. R&D activities are limited in the two nations as both are dominantly generics industry

**SOURCING**

Most APIs are sourced within the EU given the preferential access for Bulgaria within the EU. This gives competitive prices for Bulgaria as compared to Jordan which is sourcing from India and China.

**REGISTRATION**

Bulgaria launched eCTD for drug registration was in 2014 and Jordan piloted eCTD in 2016 and was mandated only in 2019. This has enabled Bulgaria to decrease delays in registration and time to market for drugs. However, there is no requirement to register drugs meant for exports in Bulgaria as in Jordan. This has a huge impact on lead times and export of drugs, where Bulgaria has been successful.

**PRODUCTION**

Bulgaria's production lines are far more automated than Jordan's where the level of automation is high to the extent of manufacturing export ready products (including packaging). Further, the production lines of Bulgaria are managed by PhD. holders in pharmacology which gives higher level of quality assurance in production. Jordan does not employ many PhD. holders in production lines.

**PACKAGING & STORAGE**

Both packaging and storage of produced drugs are controlled in-house by pharmaceutical companies in Jordan and Bulgaria to ensure quality assurance and meet GMP standards.

**DISTRIBUTION & MARKETING**

Bulgaria adheres to EU's written procedures to facilitate traceability of drugs in distribution. Such traceability features were not identified in Jordan's distribution system. Marketing activities and associated costs were identified to be high in Bulgaria's pharmaceutical industry as compared to Jordan. This is very important for the industry to expand both in domestic and export markets.

**EXPORTS**

70% of the local production accounted for exports in Jordan as compared to 85% of the local production translated to exports in Bulgaria. Exports grew by 4% between 2013 and 2018 for Bulgaria whereas it declined by 2% during the same period for Jordan. Bulgaria's access to EU financing to upgrade its manufacturing facilities and access to EU market has aided to sustain its export growth as compared to Jordan, which is currently witnessing non-tariff trade barriers from its key export markets in the MENA region. Further, a dedicated strategic export development plan for the sector is yet to be devised in Jordan as compared to Bulgaria.

Source: Bulgarian Small and Medium Enterprises Promotion Agency

## Recommendations: Opportunities for Growth and Development

### Overview

The following section aims to provide effective recommendations, which can be realistically implemented by the different stakeholders with low-to-moderate investment and achieve results in the short-to-medium term (2-5 years).

### Strategic Directions Road Map

#### Strategic Direction 1: Support local manufacturers in using eCTD

STAGE IN VALUE CHAIN	REGISTRATION
DESCRIPTION	<ul style="list-style-type: none"> <li>• Through eCTD submission, review and approval of new drug applications will be faster and more cost-efficient. This will encourage new market entry as eCTD has become a global requirement in most markets.</li> <li>• The current pricing of eCTD is Euro 6,000 per year for a company to ease uptake of eCTD by companies. This is expected to become expensive in July 2019. The Support local manufacturers with competitive costs for eCTD.</li> <li>• Assist JFDA in training regulatory personnel of companies to complete CTD with less deficiencies.</li> </ul>
INVOLVED STAKEHOLDERS	Manufacturers, JFDA
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• Manufacturers will be able have faster entry into local and export markets.</li> <li>• JFDA could benefit from decision support tools that can capture historical orders, actual delivery times, prices and comparisons against international published price lists to create quick, at-a-glance views of the supply market dynamics (average price, number of suppliers, installed capacity, typical lead time) for each product and therapeutic category .</li> <li>• JFDA reviewers could be provided with communication tools to rapidly interact with manufacturers or exporters if case specific documentation/information is missing from applications, streamlining the registration process.</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY

**Strategic Direction 2:** Provide funds to improve current labs, support JFDA to accredit external labs, and increase full-time assessors

STAGE IN VALUE CHAIN	REGISTRATION
DESCRIPTION	<ul style="list-style-type: none"> <li>• Modernising and improving JFDA lab conditions to implement lean testing processes</li> <li>• Accredite outside domestic labs to support JFDA for testing.</li> <li>• Increase the number of assessors by increasing meetings to twice a week and increase their fees.</li> </ul>
INVOLVED STAKEHOLDERS	JFDA
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• The JFDA could benefit from financial aid to modernise their labs to improve testing of drug samples for registration.</li> <li>• By accrediting external labs, JFDA and industry could benefit from reducing the registration queue of drugs and improving the time to market.</li> <li>• Additional hours spent on assessment of registration files will expedite the process. Supporting JFDA with financial aid to increase fees for assessors will help retain assessors on a regular basis.</li> <li>• Separate registration committees at JFDA for local manufacturers to offer them preferential or faster registration process over non-Jordanian companies will support local companies market and export their products faster.</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY

**Strategic direction 3:** Support JFDA towards approval of Pharmaceutical Inspection Co-operation Scheme (PIC/S)

STAGE IN VALUE CHAIN	EXPORTS
DESCRIPTION	JFDA's application to be a part of PIC/S has been accepted. Qualify JFDA authorities via trainings and seminars for GMP inspection towards international GMP harmonisation for PIC/S approval.
INVOLVED STAKEHOLDERS	JFDA
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• Approval for JFDA to be part of PIC/S will aid the industry to:               <ul style="list-style-type: none"> <li>◦ Facilitate exports</li> <li>◦ Expand to new export markets</li> <li>◦ Save registration costs in export markets</li> <li>◦ Minimize the number of inspections from JFDA</li> </ul> </li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY



**Strategic Direction 4:** Set- up training programs on super-generic drugs production

STAGE IN VALUE CHAIN	PRODUCTION
DESCRIPTION	Foreign cooperation could invest in training programs and scientific support for sample studies focused on the production of super-generic drugs.
INVOLVED STAKEHOLDERS	Manufacturers, International Donors (GIZ, USAID, DFID, JICA, AFD)
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• Global trends indicate upcoming demand for super-generic products, which combine multiple generic APIs, to enable improved and more synergistic treatment regimens.</li> <li>• Foreign cooperation could organise production training courses with industry specialists, which could introduce manufacturers to the possibility of testing new API combinations, which might lead to improvements in performance, tolerability and ease of administration.</li> <li>• Focus on reformulating and producing value added medicines or super-generics is anticipated to provide new export opportunities in the export markets such as EU and the U.S because of the prevalence of chronic illnesses.</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY

**Strategic Direction 5:** Support in setting up export intelligence team to monitor business opportunities and support Jordanian companies financially for international trade fairs

STAGE IN VALUE CHAIN	PRODUCTION
DESCRIPTION	Jordanian pharma companies represented by JAPM should promote their products in dedicated pavilions at international fairs such as CPhi andACHEMA.
INVOLVED STAKEHOLDERS	JAPM, Manufacturers, GIZ
POTENTIALIMPACT	<ul style="list-style-type: none"> <li>• An export-dedicated team could implement the use of inventory management software to monitor and forecast future foreign market needs, in both existing and new markets.</li> <li>• Exposure to international market, new export markets and potential buyers would aid increase the leads and exports for Jordanian manufacturers.</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY

**Strategic Direction 6:** Diploma programs in the pharmaceutical industry and mandate hiring PhD holders in Jordan

STAGE IN VALUE CHAIN	PEOPLE/HUMAN RESOURCES
DESCRIPTION	One-year diploma degree is needed for B.Sc. graduates specialised for pharmaceutical industry in cooperation with JAPM and universities. Regulation is required to mandate hiring of PhD degree holders by manufacturers in the all stages of the value chain.
INVOLVED STAKEHOLDERS	Manufacturers, GIZ, JAPM
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• There is lesser number of pharmacology graduates working in the production stage of the value chain compared to R&amp;D or marketing. Diploma programs is expected to get potential employees with B.Sc. degree in pharmacology industry-ready and specialize for production stage of the value chain.</li> <li>• As a key learning from Bulgaria, if PhD degree holders are employed in the production stage of the value chain to oversee production lines, it is expected to ensure seamless operations and knowledge transfer to the industry.</li> </ul>
OPPORTUNITY TIMELINE	MEDIUM-TERM

**Strategic Direction 7:** Implementation of cost analysis on API suppliers

STAGE IN VALUE CHAIN	SOURCING
DESCRIPTION	Local manufacturers could benefit from Big Data applications that could deliver analysis on the cost-benefits of specific API suppliers. Facilitation of joint purchase of APIs along with JAPM if necessary.
INVOLVED STAKEHOLDERS	JAPM, Manufacturers
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• A wider understanding of the global offering of APIs would allow local manufacturers to diversify their supply chain structure and evaluate possible alternatives.</li> <li>• The application could provide API supplier evaluations based on questionnaires, interviews and on-site inspections.</li> <li>• Aggregating requirements and orders for APIs from more than one manufacturer will help reduce the purchase cost of APIs and hence the profits of the industry.</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM

**Strategic Direction 8:** Implementation of renewable energy sources to decrease electricity costs

STAGE IN VALUE CHAIN	COSTS
DESCRIPTION	Local manufacturers could benefit from financial AID/donations for the implementation of renewable energy sources, such as solar panels.
INVOLVED STAKEHOLDERS	Jordan's Ministry of Energy and Mineral Resources International Donors (GIZ, USAID, DFID, JICA, AFD) Manufacturers
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>Local manufacturers could reduce their production costs by using renewable energy, such as solar panels; this would be of great benefit if this could be used for their process heating supply, which accounts for approximately two thirds of the total energy demand in manufacturing sites.</li> <li>This type of initiatives would require the support of the Ministry of Energy, in order to secure a legal framework that allows energy sourcing from renewable energy.</li> </ul>
OPPORTUNITY TIMELINE	MEDIUM-TERM

**Strategic Direction 9:** Training courses on advertising and marketing

STAGE IN VALUE CHAIN	MARKETING
DESCRIPTION	Foreign cooperation could invest in conventions (short courses) on advertising, marketing, business development, and sales targeted separately to both domestic and international markets
INVOLVED STAKEHOLDERS	Manufacturers Foreign Cooperation (GIZ, USAID, DFID, JICA, AFD)
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>Foreign market guidance could address significant challenges, such as how to overcome cultural/language barriers when trying to communicate with clientele from other geographical areas.</li> <li>Tailored pharmaceutical marketing and business development compared to traditional marketing using medical representatives to provide samples and leaflets to pharmacies and doctors is expected to build a strong business and client base for Jordanian manufacturers</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY

**Strategic Direction 10:** Facilitate improvement in transparency of trade and streamlining of border clearance procedures

STAGE IN VALUE CHAIN	EXPORTS
DESCRIPTION	Promote the existing “Partnership council” between Jordan Customs, JAPM, and the Chambers of Commerce and Industry to facilitate customs clearance and ROO. Train involved authorities to gain comprehensive knowledge on ROO of different export markets for Jordan’s pharmaceutical industry.
INVOLVED STAKEHOLDERS	Ministry of Industry, Trade and Supply, Ministry of Foreign Affairs, JAPM, Jordan Customs, and Chambers of Commerce and Industry
POTENTIAL IMPACT	<ul style="list-style-type: none"> <li>• Promotion of the Partnership Council will aid minimize delays and high costs involved due to the involvement of multiple agencies to issue the Certificates of Origin (CoO).</li> <li>• Exporters’ expectations could be matched by streamlining procedures for the granting of CoO.</li> </ul>
OPPORTUNITY TIMELINE	SHORT-TERM OPPORTUNITY

## Other Recommendations

- Introduce fast-track registration process at a premium fee while keeping the normal registration process.
- Invest in clinical studies to pursue venturing into super-generic drugs.
- Conduct a study to analyse the return on investment in venturing into R&D of originator drugs
- A central export entity is recommended to centralise marketing and branding activities in target export markets

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