

ARMENIA PHARMA MARKET REPORT

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Demography

SL. No	Parameter	Description
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1	Region	South western Asia
2	Country	Armenia
3	Capital	YEREVAN
4	Population	30, 38,217 (July 2018 est.)
5	Population growth rate (%)	-0.25% (2018 est.)
6	GDP (purchasing power parity)	\$28.34billion (2017 est.)
7	GDP - real growth rate (%)	7.5% (2017 est.)
8	GDP - per capita (PPP)	\$9,500 (2016 est.)
9	Exchange rates	
10	Population below poverty line	32% (2013, No Update available)
11	Age structure (%)	0-14 years: 18.86%
		15-24 years: 12.37%
		25-54 Years: 43.31%
		55-64: years 13.77%
		65 years and over: 11.7%
Source: CIA World Fact Book updated to July 2018(on 23rd June 2019)		

Introduction

Country's economic growth trajectory is expected to moderate, it is forecasted to grow above historical levels and thus be conducive to healthcare system development. This is further boosted by international support for improvement initiatives. However, the underdeveloped infrastructure and the high private share of overall spending is likely to retard the expected growth.

Market was of \$ 177 million in 2018 and is expected to grow by 16% in 2019 and touch \$ 206 million.

Updates

- In May 2019, ARKA reported that Armenia and USAID extended two existing bilateral agreements that aim to support improvements in the former's governance and public administration and that have now also received USD8.5bn in additional funding.

- In April, the Initiatives for Development of Armenia (IDeA) Foundation unveiled a new platform that aims to support healthcare innovation and sustainability, which was developed following discussion with research centres such as the UCLA, Phillips and Russian Skolkovo Healthcare Development Centre, specifically target Dilijan-Sevan, Tatev-Goris, Yerevan- Etchmiadzin, Stepanakert-Shushi and Gyumri areas.

Strength

- Government support for domestic pharmaceutical industry
- Underdeveloped market provides for a relatively high growth potential
- Some multinationals already have representative offices in the country
- Market entirely reliant on imported patented medicines

Weaknesses

- Market size limited by small population
- Limited Public Sector Funding

Opportunities

- Regulatory harmonisation and tariff-free trade within the Eurasian Economic Union (EAEU) will lead to greater access to markets within the region(Advantage for JNs and subsidiaries)
- Introduction of a compulsory health insurance scheme potentially to enable greater access to healthcare services and medicines
- Armenia-EU deal will lead to greater policy and regulatory harmonisation, increasing regulatory transparency

Threats

- EAEU single medicine market will result in greater price competition, placing increased pressure on price margins(would be difficult to Export from outside EAEU)
- Out-of-pocket spending remains highly vulnerable to wider economic fluctuations

Market summary

Armenia's pharmaceutical market is calculated to have reached USD177mn in 2018, which translated into a modest USD60 per capita (below the regional average) and around 14% of the country's healthcare expenditure. By 2023, the market is forecast to reach USD323mn, with a five-year annual growth rate (CAGR) of 12.8%.

Generally speaking, Armenia's pharmaceutical market may not much offer revenue-generation opportunities for multinational pharmaceutical firms on account of its small market size, and unfavourable demographic trends. In addition, growth within the market has been negatively

impacted by the country's sluggish economic recovery from recession in 2016 and its impact on healthcare spending as a whole, though the situation has improved.

However, improved regulatory environment - exemplified by amendments to the Law on Medicines passed in May 2016 - will create greater hope in the market, boosting its attractiveness. Most pertinently, the law introduced pricing regulations for state-reimbursed medicines. The government has also tried to improve healthcare system spending and its allocation.

Following the lead of some of its regional peers - Georgia, Kazakhstan, Azerbaijan and Ukraine - Armenia is looking to implement a compulsory health insurance system to replace the current model. It is hoped that this system will increase the efficiency of healthcare funds whilst enabling greater accessibility to higher-quality treatments. This new system is expected to be assessed by parliament in 2020, though political and economic factors are bound to influence the change.

Armenia's disease burden, in line with its peers in the former Soviet Commonwealth of Independent States (CIS), is dominated by non-communicable diseases. Cardiovascular diseases accounted for approximately a quarter of the total burden of disease and more than half of all deaths in 2016. After cardiovascular diseases, the most prominent causes of death and injury are cancers and diabetes.

Armenia's pharmaceutical sector has been declared by the government as a priority sector for its economic diversification programme, and its 'export-led industrial policy 2010-2020'. As such, production of medicines has surged in recent years and is anticipated to continue this rapid growth through to 2020. Although Armenia remains highly reliant on pharmaceutical imports, this is likely to decline over the long term. Domestic production, which is almost exclusively based on generic medicines, is dominated by three main drugmakers: Liqvor, Arpimed and PharmaTech.

Pharma Trade

Pharmaceutical imports reached USD137mn in 2018. For the current year, forecasts say imports to grow by 15.3% and reach USD158mn. The figures are forecast to grow over the next five years at a compound annual growth rate (CAGR) of 12.8% to reach (USD250mn by 2023).

Pharmaceutical exports were worth USD30mn in 2018 and are forecast to increase by 33% to USD40mn in 2019. Forecast is pharmaceutical exports to grow at CAGR of 30.6% to a value of USD115mn by 2023. This would mean a widening of the trade balance, from USD106mn in 2018 to USD136mn in 2023, despite the fact that the import mix is likely to increasingly favour generics.

The government aims to increase pharmaceutical production from the USD15mn in 2015 to USD75-100mn by 2020. With the adoption of Good Practice (GxP) standards within the manufacture of pharmaceuticals by the end of 2019, Armenia's exports will be able to compete for the significant growth opportunities in emerging markets of the Commonwealth of Independent States (CIS) region and further abroad. The government hopes that exports will reach approximately USD45-50mn by 2020.

Regulatory

Armenia's pharmaceutical market is governed by the Ministry of Health, which proposes the country's national drug policy, while the Scientific Centre of Drug and Medical Technologies Expertise (SCDMTE) implements this policy to provide safe, effective and quality medicines to the market. The most recent update to the regulatory landscape was the Law on Medicines (No Zr-86), which was adopted on May 17 2016. The new law aligns the much of the regulatory landscape with

international norms, including the harmonisation of regulations with Eurasian Economic Union (EAEU) members in order to access the EAEU single medicines market.

According to local sources, the Ministry of Health carries out monthly updates of the medicines registered in the country, for monitoring and budgeting purposes.

The law also describes regulations for the registration of medicines on the market. The maximum time for medicine registration is set at 150 calendar days, with an examination period of 140 days. In reality, it is unclear whether the authorities will be able to maintain these timelines. Once a medicine has been approved, its marketing authorisation lasts for five years. Re-registration of medicines will take a maximum of 31 calendar days, with a maximum 21-day examination period. Once re-registered, the medicine is granted authorisation for an additional five years.

The Ministry of Health provides pharmaceutical manufacturer licences according to the provisions within the Law on Medicines.

In November 2010, Armenia adopted the EU Good Manufacturing Practices (GMP) guidelines. As of February 2017, there were 1,059 over-the-counter (OTC) medicines and 3,051 prescription medicines registered. Five local companies produce medicines, with imports handled by an additional handful of foreign players authorised to operate in Armenia.

In August 2018, the Eurasian Economic Commission finalised regulations governing the single medicines market that will provide for simplified registration and market access for EAEU. While the single market is positive for drugmakers, providing more severe penalties for the import of counterfeit medicines and better business certainty.

Local Industry

Of the 19 licensed pharmaceutical manufacturers in Armenia, none produces innovative medicines. The country is therefore entirely dependent on pharmaceutical imports to meet its patented drug demand. The EU is the largest importer of medicines into Armenia on an absolute basis, accounting for 67% of all imports in 2016. Germany, France and Russia are the leading suppliers, accounting for 15.1%, 11.5% and 6.7% of total imports in the same year.

Pharmaceutical production is almost exclusively centred on generic medicines, with the vast majority of drugs produced domestically on the country's Vital and Essential Drugs list. Generic medicines produced domestically cost a reported 10-30% less than imports. Therefore, the growth of the domestic industry will continue to be incentivised. Local companies export to regional markets. Key importing partners of Armenia are Russia, India, Belarus and Ukraine, though more sophisticated products have to be imported from the EU and the US.

The domestic market itself is very small with limited growth potential. Drugmakers therefore seek to export products to neighbouring markets. The easy access to neighbouring markets in the Commonwealth of Independent States (CIS) and Central Asia region provides significant export opportunities, particularly as many of these emerging markets are set to expand considerably over the coming years. Major emerging markets in the Middle East also represent potential for exploitation.

Currently, the CIS region (primarily Moldova, Belarus, Russia, Tajikistan, Uzbekistan, Kazakhstan and Georgia) is the largest beneficiary of pharmaceutical exports from Armenia, accounting for 57% of all

medicinal exports in 2015, led by Georgia (36% of exported drugs). The formation of the Eurasian Economic Union (EAEU) single medicine market in May 2017 supports the potential for further export growth within the CIS region through the reduction of trade tariffs and harmonisation of medicine registration legislation.

There are 19 licensed drugmakers in Armenia, of which 3 contributed to more than 70% of all production in 2015. The key manufacturers are Liqvor, Arpimed, and PharmaTech. According to March 2018 statements made by Hakob Topchyan, director of the Medication and Medical Technology Expert Center within the Ministry of Health, five pharmaceutical companies operate in the country, suggesting not all licensed companies are still operational. Some 8.0% of medicines are made locally, with the rest needing to be imported.

Statistics

India's exports

India Pharma exports to ARMENIA by Category \$ Million					
Category	2015-16	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	0.02	0.06	0.06	0.05	-6.12
Drug Formulations & Biologicals	0.71	0.48	0.66	0.64	-2.45
Ayush	0.02	0.01	0.02	0.04	54.39
Herbal Products	0.00	0.00	0.00	0.00	-100.00
surgicals	0.08	0.15	0.09	0.12	38.25
Vaccines	0.01	0.07	0.00	0.02	6832.30
Total	0.85	0.77	0.83	0.88	5.70

Armenia's Import

Top Ten Importing Partners of Armenia \$ Million						
Rank	Country	2015	2016	2017	Gr%	Share%
1	Canada	0.36	1.12	53.53	4666.95	28.96
2	Germany	14.28	15.86	19.43	22.46	10.51
3	France	10.58	10.60	11.66	10.06	6.31
4	Switzerland	12.40	3.63	10.39	186.12	5.62
5	Russian Federation	4.96	6.68	9.71	45.29	5.25
6	Netherlands	6.21	10.33	8.83	-14.47	4.78
7	USA	5.79	6.36	7.45	17.10	4.03
8	United Kingdom	2.73	4.31	6.21	44.25	3.36

9	Hungary	5.17	4.72	5.67	20.10	3.07
10	Slovenia	4.38	4.23	5.48	29.46	2.96
12	India	3.38	2.43	3.88	59.93	2.10
	World	111.58	110.73	184.85	66.94	100.00