



2008

# Armenian Pharmaceutical Industry Investment Handbook



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Union of Medicine  
Producers &  
Importers



Armenian  
Development  
Agency

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**Disclaimer:**

The contents of this Handbook are derived from a variety of sources, have been researched with the utmost care and are believed to be accurate as of the beginning of August 2008. The purpose of the Handbook is to provide brief guidance to potential investors. It must not be used in place of professional advice. The Competitive Armenian Private Sector Project, the Armenian Development Agency and the Union of Medicine Producers & Importers cannot be held liable for the accuracy or implications of use of the information contained within.

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# Preface



With a tradition of fine chemical production, Armenia's pharmaceutical industry has blossomed over the past decade into one of the country's most dynamic sectors of the economy. Exports of pharmaceutical products, for instance, have grown at an impressive compound annual growth rate of 50% during the past five years.

Such growth has been largely founded on several critical factors: the skilled and highly educated workforce, an open and cooperative cluster comprised of enthusiastic entrepreneurs, significant domestic and foreign direct investment, and an appreciation and willingness to adopt international standards.

Current producers focus largely on the production of generic drugs, although there are those producing branded products as well, which are gaining in popularity among both domestic and foreign markets. Quality assurance is a high priority and the industry has demonstrated a strong commitment to adopt internationally accepted standards. Three producers are currently audited to good manufacturing practice (GMP) standards and others are at various stages in the process to implement GMP in the near future. The industry also benefits from a modern testing and inspection laboratory, which is ISO 9001-2000 certified and approved by the World Health Organization and International Pharmaceutical Federation.

Although current production volumes are relatively small, opportunities exist for potential investors in: penetrating the large and growing markets of the CIS through existing free trade agreements, and utilizing small to moderate scale production facilities – ideal for low volume, high value production.

We believe Armenia's pharmaceutical industry will continue to expand and grow, and we welcome your participation in this emerging and vibrant sector.

A handwritten signature in black ink, appearing to read 'N. Yeritsyan'.

Nerses Yeritsyan  
Minister of Economy

## Introduction

This Pharmaceuticals Investment Handbook has been prepared for foreign investors considering entry into the Armenian pharmaceuticals market and is designed to provide enough information to make a decision on whether investment is a potential option for you. It is intended to highlight industry potential and recent performance, backed up by quantitative and qualitative data. The handbook also suggests investment competitive advantages & opportunities and provides details of investment incentives.

Given the country's prominent history in the fine chemicals industry, the success of existing pharmaceutical manufacturers and the high skill levels of the workforce, Armenia is worth your consideration for investment; particularly in the areas of equity investment and contract manufacturing for local distribution and export.

Armenia's domestic market may be small but it neighbors the large and fast-growing market of the CIS. Additionally, only 10% of the local market is currently served by domestic production. Opportunities also exist for manufacturing low-volume specialized drugs that larger producers find uneconomical to produce. Whilst it is appreciated that investors will need to carefully consider a wide variety of factors, this guide should give the reader enough background information to assess investment potential, and enable them to move forward quickly with further research. Contact details of useful organizations are provided to assist with gathering further industry insights.

A general analysis of the economic environment and investment incentives is followed by a detailed review of pharmaceutical industry performance, the regulatory environment, recent investments and investment opportunities. The third part of the handbook focuses on general information on the business environment.

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# 1. Armenia's Economic Performance

## International Rankings

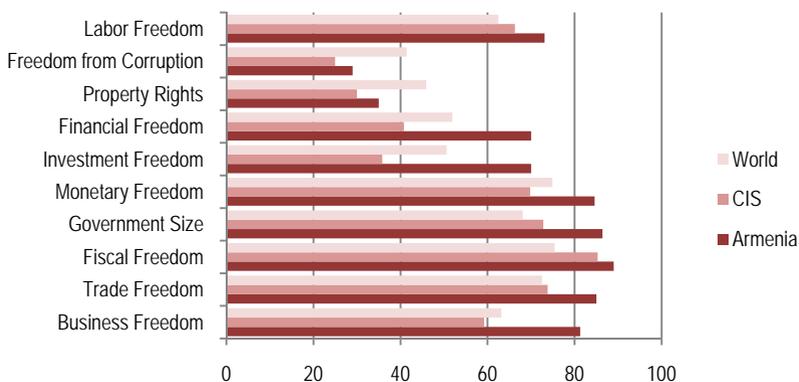
Armenia's Standing in International Rankings	
Index of Economic Freedom (Heritage Foundation), 2008	28 (Rank among 157 countries), Mostly free
Ease of Doing Business (The World Bank), 2008	39 (Rank among 178 countries)
Best Countries for Doing Business (Forbes), 2008	63 (Rank among 121 countries)
Human Development Index (UNDP), 2007/2008	83 (Rank among 177 countries)
Global Competitiveness Index (World Economic Forum), 2007/2008	93 (Rank among 131 countries)

According to the Heritage Foundation's 2008 Index of Economic Freedom, **Armenia is classified as 'Mostly Free' and ranks 28<sup>th</sup> place** (out of 157 countries) ahead of Austria, Spain, Georgia, Norway, the Slovak Republic, the Czech Republic, Hungary, Israel & France. Such an impressive ranking results from the following:

- 1) Short period of time in starting a business – 18 days versus the average of 43 days
- 2) Quick turnaround on issuing a business license – only 19 procedures and expected time for completion is half the world average of 234 days
- 3) Low average trade tariff of 2.5%
- 4) Low taxation – overall tax revenue as percentage of GDP is 17.3%
- 5) Low government spending – only 21.3% of GDP
- 6) Low inflation – averaging 2.3% between 2003 and 2005 (3.7% between 2001-2007)
- 7) Equal rights for Armenian and foreign investors
- 8) Liberal trade regime
- 9) Flexible labor market

**In fact for eight out of the ten indicators used by the Heritage Foundation, Armenia scores higher than the world average and CIS average.**

Economic Freedoms – Average Rankings for Armenia, the CIS and World



Source: Heritage Foundation, 2008

Armenia's position in the Index of Economic Freedom increased by 2 places compared to 2007. Five years ago it was ranked in 37<sup>th</sup> place. Ten years ago it was in 117<sup>th</sup> position – remarkable progress in a relatively short period of time.

Armenia's position in the World Bank's Doing Business Report (<http://www.doingbusiness.org/ExploreEconomies/?economyid=10>) **increased by 7 places in 2008 to 39<sup>th</sup> position**. It ranks 6<sup>th</sup> position out of 28 countries in the Eastern Europe and Central Asia region behind Estonia, Georgia, Latvia, Lithuania and Slovakia. Within the 10 indicators that make up the overall ranking, the 'Getting Credit' indicator increased by 25 places and 'Trading Across Borders' indicator by 15 places. **Armenia ranked 2<sup>nd</sup> in the world with the 'Registering Property' indicator.**

Forbes, in their report of 'Best Countries for Doing Business', rank Armenia in 63<sup>rd</sup> position in the world (out of 121 countries); the **highest ranked country from the CIS**. The rankings are based on GDP growth, GDP per capita, trade balance, population and unemployment.

Armenia is ranked 93<sup>rd</sup> among 131 countries in the Global Competitiveness Report. The assessment is based on over 100 factors defining the competitiveness of economies and their ability to increase prosperity of the nation within a midterm timeframe. From that perspective, Armenia's key advantages are:

#	Factor	Rank Among 131 economies
1	Business costs of terrorism	40
2	Business costs of crime and violence	35
3	Low Inflation	39
4	Low level of government debt	32
5	HIV prevalence	25
6	Time required to start a business	39
7	Trade-weighted tariff rate	5
8	Flexibility of wage determination	36
9	Rigidity of employment	42
10	Hiring and firing practices	40
11	Firing costs	17
12	Pay and productivity	50
13	Female participation in labor force	38
14	Legal rights index	47

Note: 1 indicates the highest (best) ranking, whereas 131 is lowest

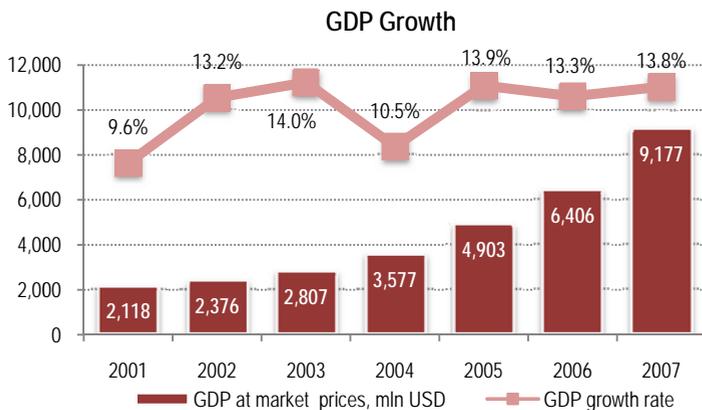
The efficiency of the labor market and macroeconomic stability, key fundamentals of economic growth, place Armenia in a strong position. Improvements in regulations related to company registration have cut down the cost and time required to start a business in Armenia. The country also benefits from high levels of safety and security, in terms of low cost of terrorism and low crime.

Areas of concern, in relation the country's competitiveness include the size of the local market, physical and financial infrastructure, extent of market dominance and intensity of competition, innovation and technological advancement, and sophistication of business processes. However, these issues are the focus of the newly-appointed Government's second-generation reforms intended to turn the country's business climate into a center of excellence in the region. Armenia is trying to neutralize the disadvantage of the small local market through establishing free trade zones and free trade agreements, particularly with the CIS.

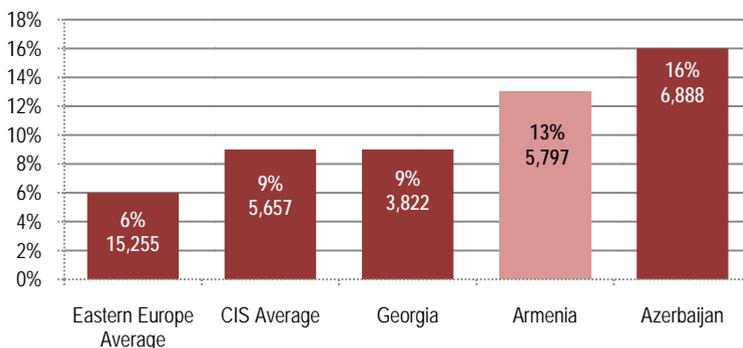
## Economic Performance

With **CAGR of almost 14%**, real GDP for Armenia has demonstrated rapid and sustainable growth over the last 6 years. This strong growth places **Armenia second among the CIS countries and the first among countries without oil**

**reserves.** Per capita incomes matched Armenia's growth, with purchasing power parity reaching \$5,178.4 in 2007, allowing growing "discretionary spending" levels. GDP per capita in 2006 slightly exceeded the CIS average.



### CAGR of GDP Per Capita 2000-2006 (and PPP at current rate in US\$)



Source: National Statistical Service, World Development Indicators (WB)

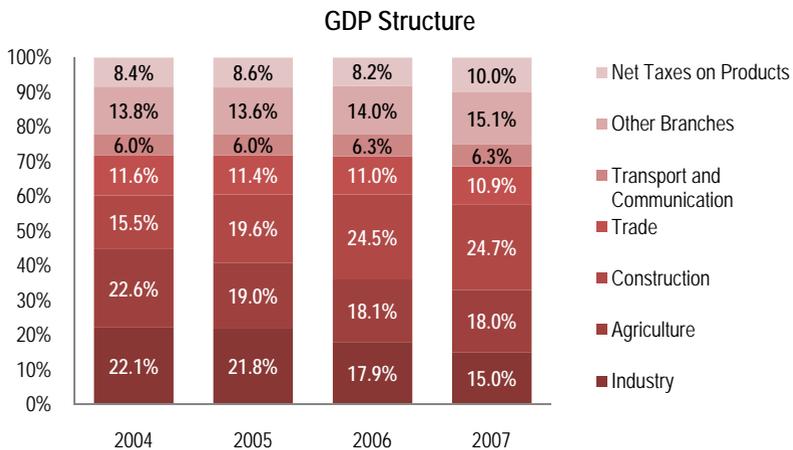
The key drivers of economic growth include:

- ✓ Large government and donor-supported construction and infrastructure upgrade projects
- ✓ Residential construction projects in Yerevan

- ✓ Large-scale foreign investment in infrastructure and mining
- ✓ Significant and growing private transfers from the Diaspora
- ✓ Fast growing service sector (IT, tourism and retail)
- ✓ Expansion of traditional sectors (agriculture, food processing, production of building materials and metal processing)

**GDP growth is forecasted to continue at rates of 8-10% per annum in the short term.**

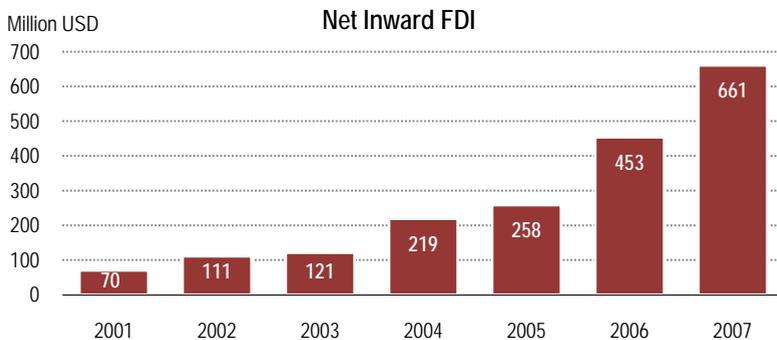
During the past four years, there has been a visible shift in the structure of the GDP away from industry and agriculture towards construction and services. High growth rates have been seen in the construction, mining, retail, food processing, ICT and financial intermediation sectors.



Source: National Statistical Service

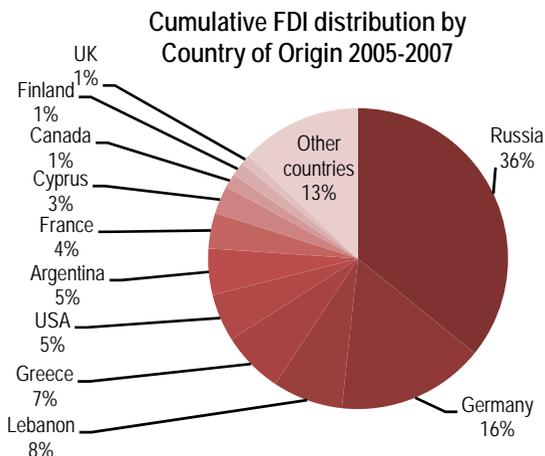
## Foreign Trade & Investment

External financial inflows to the economy have grown significantly in the past five years; **growing about six times since 2001** and reaching US\$ 661 million in 2007. As of 1 January 2008, there were 3698 companies with foreign capital investment in Armenia.



Source: National Statistical Service, Balance of Payments

During the last three years, major source countries for FDI have included Russia, Germany, Lebanon, Greece, the USA, Argentina and France. Russia took the lead owing to large-scale privatization deals in utilities and the energy infrastructure, while investors from Western Europe and America were largely concentrated in the manufacturing and service sectors of the Armenian economy. Germany, the second highest FDI contributor, invested heavily in the mining industry (copper and molybdenum).



45% of cumulative inward FDI in the real sector (1998-2007) was channeled to infrastructure (telecommunications and gas/electricity generation and distribution) followed by mining (13%) and food processing (8%). A significant proportion of FDI is generated by Diaspora or Diaspora-related investors.

Industries	Cumulative FDI in Real Sector (1998-2007), Share in Total, %
Electricity/Gas/Water Generation and Distribution	25.3
Telecommunications	19.8
Mining and Quarrying	14.6
Food/Beverage/Tobacco	8.2
Real Estate-related Activities	4.6
Air Transportation Activities (incl. Airport construction)	4.1
Wholesale and Distributive Trade	3.5
Precision Equipment	3.1
IT and R&D	2.8
Hotels & Restaurants	2.4
Financial Intermediation/Insurance	1.2
Furniture	1.0
Construction	0.8
Chemicals	0.7
Metal Processing	0.6
Other	7.2
Total	100

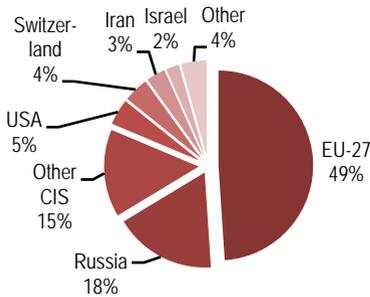
Source: National Statistical Service

Export and import volumes have doubled in the past five years. Despite the large merchandise trade deficit, the current account deficit is lower due to positive service trade, growing tourism receipts and increasing private transfers.



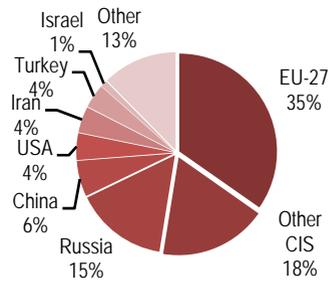
Source: National Statistical Service

### Exports from Armenia 2007



Source: National Statistical Service

### Imports to Armenia 2007



Source: National Statistical Service

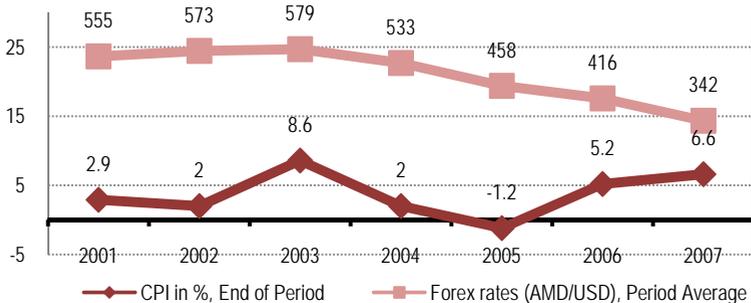
Armenia's major export items include base metals (copper, molybdenum, gold) and cut diamonds, and food & beverages (canned and fresh food, brandy). High tech exports, as a share of merchandise exports, is 1.1% (WB, 2004).

The major import commodities include natural gas, petroleum, tobacco products, food items and diamonds. The share of equipment, machinery and technologies is increasing as a result of modernization in some industries.

### Inflation / Currency / Country Debt

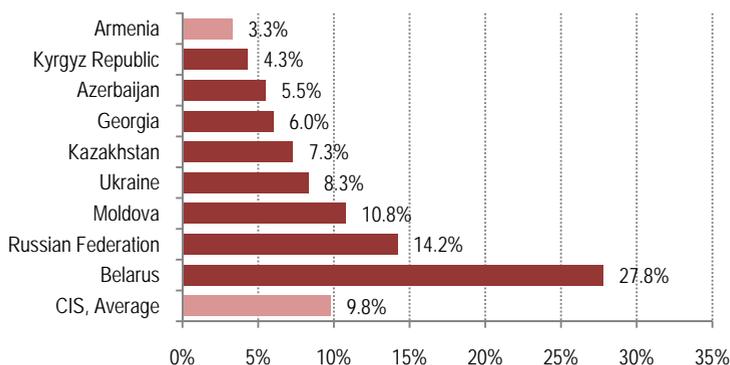
Armenia has benefitted from **very low levels of inflation in the past decade**; price stability being the main target of the independent, strong and professional Central Bank. Average inflation for the past five years was 3.5% per annum. The Bank maintains a strict monetary policy combined with a long-term development strategy. Recent Dram appreciation is linked to Diaspora investment in real estate and private transfers. Foreign reserves have doubled in the last two years despite limited intervention from the Central Bank.

#### Exchange Rate and CPI Dynamics



Source: National Statistical Service

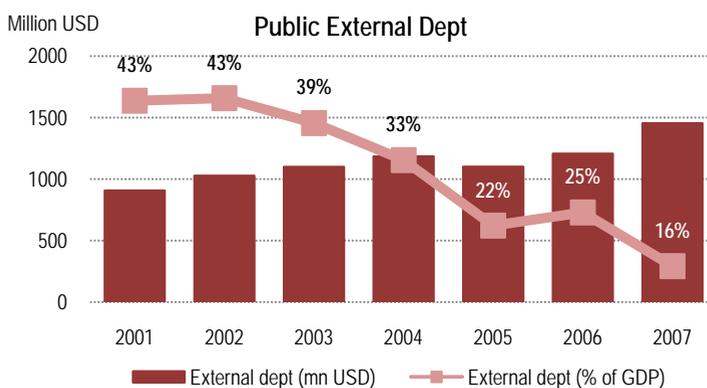
## Average Consumer Price Index in Selected CIS Countries - Average 2001-2006



Source: World Development Indicators

The World Bank considers Armenia to be a low indebted country. The level of debt is manageable. The main areas of external debt financing are defense, education, infrastructure, health care and public sector reform.

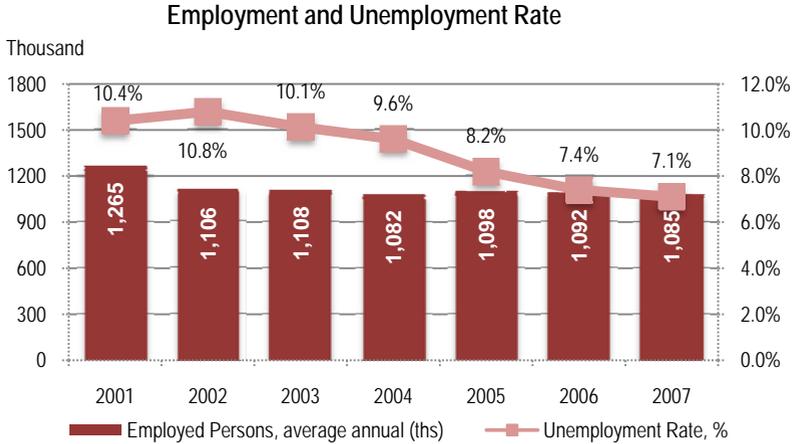
Moody's Investors Service says its Ba2 rating for local and foreign currency debt obligations and "stable" outlook balances the low debt burden of the government and economy as a whole against the country's evolving institutional capacity and modest level of economic development.



Source: National Statistical Service

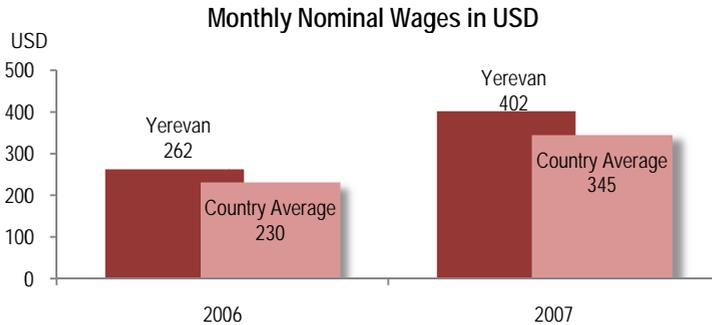
## Workforce and Unemployment

Recent economic growth has coincided with a decrease in the level of unemployment. In 2007, 7.1% of the working age population was unemployed. Falling levels of employment at the beginning of this decade were a hangover from emigration during the 90s; although employment levels have since stabilized.



Source: National Statistical Service

Wages in Armenia have increased both in USD and in local currency terms leading to an increase in the population's real disposable income, on average by 18% annually, between 2001 and 2007.



Source: National Statistical Service

## 2. Investment Incentives

The overall objective of the Government of Armenia is to provide an investment and business framework which, combined with global opportunities, can substantially and qualitatively change the pace of development and accelerate the catch-up process with developed markets. To this end, the Government of Armenia believes that the current managerial & business knowledge gap can be reduced, and that foreign entry of reputable institutions will help bring the necessary know-how and management culture.

Low tax rates, low government expenditure, and limited share of government-owned enterprise revenue in the GDP contribute to impressive fiscal and government freedom rankings. Inflation is low, and commercial regulations are flexible and relatively simple. Armenia's investment climate is one of its great strengths.

The Law on Foreign Investments outlines the rights, guarantees and privileges for foreign investors. The government's policy towards foreign investment is one of the most liberal in the CIS.

### **Specific investment incentives:**

- ✓ 100% foreign ownership allowed
- ✓ Lack of screening and authorizations for making investments (unless related to financial sector, defense or public utilities)
- ✓ No restrictions on sectors or geographical locations
- ✓ Investment guarantees on nationalization, confiscation and property seizure. Compensation for damages and losses as a result of unlawful acts of State bodies or officials
- ✓ Grandfathering provisions for five years
- ✓ No export duty, and VAT refunds on exported goods and services
- ✓ No import duty on capital and raw materials in relation to the investment
- ✓ Free conversion of foreign exchange and operation of foreign currency accounts
- ✓ Unrestricted profit repatriation
- ✓ No restrictions on remittances
- ✓ A cost efficient, well educated, skilled and easily trainable labor force
- ✓ No restrictions on foreign staff recruitment
- ✓ Losses can be incurred and carried forward for up to five years
- ✓ Competitive energy costs
- ✓ Easy access to CIS markets where Armenia has traditional close ties

- ✓ Although foreigners can only lease land, a company registered by a foreigner as an Armenian business entity does have the right to buy land
- ✓ Signatory to the International Convention on Investment Disputes and member of the International Center for Investment Dispute Settlements
- ✓ Member of the Multilateral Investment Guarantee Agency
- ✓ Signatory to the CIS Multilateral Convention on the Protection of Investor Rights.

The positive aspects of Armenia's investment environment can also be highlighted through further analysis of the Heritage Foundation's Index of Economic Freedom. Armenia's overall score is 1 percentage point higher than last year, reflecting some improvements in the investment regulations. Armenia is now ranked 15<sup>th</sup> freest among the 41 countries in the European region, and its score puts it above Europe's average - an impressive feat.

Armenia rates significantly higher than the average in eight of the 10 freedoms.

**Business Freedom - 81.3%** - The freedom to start, operate, and close a business is relatively well protected by Armenia's national regulatory environment. Starting a business takes an average of 18 days, compared to the world average of 43 days. Obtaining a business license requires about the world average of 19 procedures and about half of the world average of 234 days. Closing a business is easy.

**Trade Freedom - 85%** - Armenia's weighted average tariff rate in 2001 was a relatively low 2.5 percent. The Government is currently undertaking large scale reforms of the Customs Service that until now has resulted in unpredictable customs valuations, improper implementation of the customs code, an inefficient customs administration, and corruption.

**Fiscal Freedom - 89%** - Armenia has low tax rates. The VAT and personal and corporate income tax rates are all 20%. During 2007, overall tax revenue as a percentage of GDP was 17.3 percent.

**Freedom from Government - 86.4%** - Total government expenditures, including consumption and transfer payments, are low. During 2007, government spending equaled 21.3% of GDP. Despite some delays, privatization has accelerated over the past two years in sectors such as mining and metals.

**Monetary Freedom - 84.6%** - Inflation is relatively low, averaging 3.5 percent between 2002 and 2007. Relatively stable prices explain most of the monetary freedom score.

**Investment Freedom - 70%** - By law, foreign and domestic investors are accorded equal rights in establishing businesses in nearly all sectors of the economy. Armenia maintains a liberal trade regime, receiving the highest classification from the IMF. Commercial arbitration laws passed in December 2006 allow

a wider range of settlement procedures for parties contracting in Armenia. The IMF reports that there are no restrictions or controls on the holding of foreign exchange accounts, invisible transactions, or current transfers and no repatriation requirements.

**Financial Freedom - 70%** - Armenia's underdeveloped financial sector is dominated by banking. Following a banking crisis in the 1990s, the government embarked on a process of privatization and regulatory reform that included the adoption of International Accounting Standards. Under the revised rules and standards, many banks have closed or merged. In 2001, there were 31 banks—by the end of 2007, there were 22. The remaining banks are more liquid and profitable. The state no longer has a stake in any bank, and all 22 are privately owned. The Central Bank has intervened in the market to encourage dram transactions, but without much success. The Central Bank of Armenia regulates the small insurance industry. Foreign banks are permitted to operate in Armenia.

**Property Rights - 35%** - Armenian law provides substantial protection for intellectual property rights and is in compliance with the WTO's Trade Related Aspects of Intellectual Properties (TRIPS) Agreement. The government has increased enforcement of IPR laws.

**Freedom from Corruption - 29%** - As is the case with many former-Soviet countries, corruption is perceived to be widespread. In recent years, however, the government has introduced a number of significant reforms to combat this problem. Armenia ranks 93rd out of 163 countries in Transparency International's Corruption Perceptions Index for 2006.

**Labor Freedom - 73.1%** - Armenia's labor market operates under relatively flexible employment regulations. The non-salary cost of employing a worker is moderate, and dismissing a redundant employee is relatively simple.

To provide an effective mechanism to monitor the improvement in the investment climate, the Business Support Council (BSC) was established by a Presidential Decree in early 2001. Chaired by the Prime Minister, the evenly balanced private/state membership represents a powerful and influential vehicle to improve the business and investment environment and eliminate administrative barriers to investment.

On December 10, 2002 Armenia joined the WTO. All rules and regulations related with foreign trade are harmonized with international standards.

Bilateral treaties on investment promotion and protection (BITs) have been concluded with 37 countries (34 of which have been ratified) and with the OPEC International Development Fund. These countries comprise:

Argentina	Austria,	Belarus	Belgium-Luxemburg Economic Union
Bulgaria	Canada	China	Cyprus
Egypt	Finland	France	Georgia
Germany	Greece	India	Iran
Italy	Israel	Kazakhstan	Kyrgyz Republic
Latvia	Lithuania	Lebanon	The Netherlands
Qatar	Russian Federation	Romania	Sweden
Switzerland	Tajikistan	Turkmenistan	Ukraine
United Kingdom	Uruguay	USA	UAE
Vietnam			

Armenia has Free Trade Regimes with:

Georgia	Kyrgyzstan	Moldova	Russia
Tajikistan	Turkmenistan	Ukraine	

Under the terms of free trade agreements, tariff exemptions are extended to goods traded between Armenia and:

Belarus	Georgia	Kyrgyzstan	Moldova
Russia	Tajikistan	Turkmenistan	Ukraine

Most-Favored-Nation Trade Regimes have been established with:

Argentina	Bulgaria	Canada	China
Cyprus	EU	Iran	India
Hungary	Lebanon	Poland	Romania
Syria	Switzerland	USA	Vietnam

### 3. Investor Assistance

The Armenian Development Agency (ADA) – [www.ada.am](http://www.ada.am) - is Armenia's one-stop full service investment promotion agency and provides the following services to investors:

- ✓ Provision of Quality Information – tailored information packages according to the needs of the foreign investor

- ✓ Organization of Site Visits – planning and preparation of visits from foreign investors, arranging appointments with private and public organizations, accompanying investors to meetings, assisting in site selection, providing translation support, identification of business service providers
- ✓ Brokering Business Partnerships – finding the appropriate partners in Armenia
- ✓ Follow Up Support – managing post-visit support, preparation of additional information and documentation, explaining legislation
- ✓ Investment Project Implementation – assisting with company registration and staff recruitment (job announcements & holding interviews)
- ✓ Representing Investor Views – to the government
- ✓ Liaising with Government institutions

## 4. Pharmaceutical Industry at a Glance

Indicator	Pharmaceutical Cluster
<i>Industry Size</i>	<ul style="list-style-type: none"> <li>✓ 17 licensed manufacturers</li> <li>✓ 20 wholesalers and 800 retailers</li> <li>✓ 4 major retail chains</li> <li>✓ More than 170 pharmaceutical product importers</li> </ul> <p>Local Production: AMD 2.3 billion - approximately US\$7.6 million (2007, NSS)            Exports: US\$3.7 million (2007, National Statistical Service)            Imports: US\$100 million (2007, National Statistical Service)</p>
<i>Export Performance</i>	<p>US\$3.7 million in 2007 with a CAGR of 51% between 2004 and 2007</p> <p>Major export markets: Russia, Georgia, Turkmenistan, Uzbekistan, Ukraine and Belarus.</p>
<i>Workforce</i>	<p>Cluster workforce (including distribution): 4,800-5,000</p> <p>Employment in Manufacturing: c. 600</p>
<i>Average Monthly Salaries (gross)</i>	<p>Managerial Staff: &gt; US\$600</p> <p>Pharmacist/Engineer/Technologist: \$450 - \$600</p> <p>Support Staff: \$200-300</p>
<i>Academia and R&amp;D</i>	<p>6 universities and 5 colleges providing degree programs in pharmaceutical-related disciplines</p> <p>R&amp;D is conducted largely by state-owned research institutions</p> <p>Companies spend up to 10% of expenditures on R&amp;D</p> <p>ISO certified state-of-the-art laboratory facilities with cutting-edge equipment and highly skilled staff (ExLab - Laboratory of the Scientific Center Of Drug And Medical Technology Expertise)</p>

Indicator	Pharmaceutical Cluster
<i>Unions and Associations</i>	Union of Medicine Producers and Importers (10 members) Armenian Pharmacological Society
<i>Product Lines</i>	Production of largely generic drugs and probiotic complexes: <ul style="list-style-type: none"> <li>✓ Sterilized liquid preparations, including intravenous infusion solutions</li> <li>✓ Antiseptic preparations (largely covering local demand)</li> <li>✓ Cardio vascular medicines</li> <li>✓ Galenic preparations</li> <li>✓ Herbal extracts and liquid preparations</li> <li>✓ Ophthalmological preparations</li> <li>✓ Probiotic complexes (Narine)</li> <li>✓ Bioactive food additives</li> <li>✓ Dosage forms: tablets, capsules, ointments and solutions.</li> </ul>
<i>Application of International Standards</i>	GMP audited and ISO certified: 3 companies
<i>Foreign Investment</i>	Two manufacturing companies and one retail chain attracted FDI investors: European Bank for Reconstruction and Development, Armenian Diaspora

Sources: NSS, CAPS Pharmaceutical Cluster Assessment 2007

## 5. Key Competitive Advantages

Pharmaceuticals are one of the fastest growing business sectors in Armenia. Recent development trends and current company investments have created a sound basis to ensure further growth of the sector.

- ✓ High market growth evidenced in both domestic and Armenia's major export markets within the CIS
- ✓ Old traditions and rich experience in fine chemical industry
- ✓ Highly educated workforce, complemented every year by new graduates from Armenia's internationally-recognized universities that have close partnerships with well-known foreign universities

- ✓ State-of-the-art testing and laboratory facilities with cutting-edge equipment and highly skilled staff, conducting all types of laboratory testing and research
- ✓ Open and collaborative cluster with enthusiastic entrepreneurs
- ✓ Willingness of companies to adopt international standards and a readiness to invest and be certified by local and international accreditation bodies

## 6. Armenian Pharmaceutical Industry

The fine chemical industry has been a prominent part of the Armenian economy for many years. In the 1980's, approximately 10% of manufacturing output was generated by the chemical sector, to which pharmaceutical production belongs. The first Armenian pharmaceutical company, Yerevan Chemical-Pharmaceutical Firm (earlier Yerevan Chemical-Pharmaceutical Plant), was founded in 1967. A year later, the company had started production of ten different medical preparations. The company was privatized in 1995.

A new wave of extended pharmaceutical industry development commenced with the upturn of country's economy in the mid 1990's when Armenia succeeded in gaining macroeconomic stability and sustained economic growth. It was in this period that Armenia received its first foreign investment in the pharmaceutical manufacturing industry.



Currently there are 17 pharmaceutical companies with licenses to produce drugs in Armenia. They are all specialized in the production of generic drugs, although a few (e.g. Liqvor, Pharmatech, Arpimed and Vitamax-E) are producing branded products; in high demand both in the domestic and export markets. Contract manufacturing is also taking place to a limited extent (e.g. Arpimed, Pharmatech). The number of stakeholders in the wholesale and retail market is larger, although consolidation is underway. As of July 2008, there were more than 170 pharmaceutical importers, 10 wholesalers, and approximately 800 retail outlets and pharmacy shops. There are 4 major retail chains (AlfaFarm, NataliFarm, 911 and Esculap).

Product quality is a high priority amongst Armenian manufacturers. Most raw materials and chemical compounds used in production are therefore bought from EU and US suppliers. Additionally, the well developed and internationally recognized Drug and Medical Technology Expertise Center of Armenia, with its state-of-the-art laboratory equipment, assures the appropriate testing of both inputs and outputs of the pharmaceutical industry. The presence of such capacity in the country is one of the industry's key advantages.

The implementation of internationally-accepted quality standards, which is in process, will further support quality assurance and reduce the risk of substandard products entering the market. Three major producers have been successfully audited by Western companies and one has already reorganized their company structure and processes in accordance with GMP standards and will be certified after completion of a new factory.

The total cluster workforce is estimated at 4,800-5,000 out of which 550-600 are employed directly in pharmaceutical and biotech production. Most production jobs require skilled specialists with higher education. Pharmaceutical companies are largely small and medium-sized companies. The number of employees varies from company to company ranging from 30 to 100.

Compared to other productive sectors in Armenia, the pharmaceutical industry has a greater potential for further growth resulting from: high forecasted CIS market growth, the available knowledge and technology base, possibility of import substitution, a skilled workforce, transparency in the sector, openness for investment, and a well-developed national drug agency.

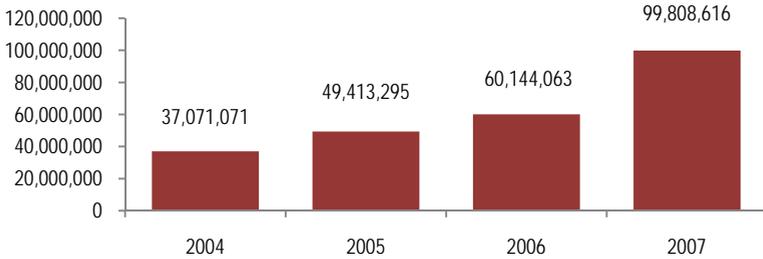
Spending on R&D is limited. Research is largely undertaken by public sector institutions. There are 5 scientific research institutes undertaking research in the pharmaceutical and related areas, although they are in substantial need for technological upgrade.

Armenia's major pharmaceutical manufacturers comprise:

Company	Product line	Year of Establishment	Major Export Markets	Certification
Liqvor Pharmaceuticals cjsc	Intravenous Infusion Solutions, Ophthalmological Preparations, Injection Solutions, Local Haemostatic Preparations <i>Branded products</i>	1991	Russia Belarus Kazakhstan Uzbekistan Tajikistan Turkmenistan Moldova Georgia	GMP implementation in process
PharmaTech cjsc	Intravenous Infusion Solutions, Ophthalmologic al Preparations (Eye drops) <i>Branded products</i>	1997	Georgia	GMP audited and ISO certified
Arpimed cjsc	Various tablets, ointments, capsules, solutions, disinfectants, dietary supplements, veterinary preparations <i>Branded products</i>	2001	Belarus Georgia Uzbekistan Ukraine	GMP audited and ISO certified
Esculap LLC	Various tablets, ointments, capsules, solutions, Herbal solutions, etc.	1998	Georgia	N/A
Yerevan Chemical Pharmaceutical Firm ojsc	Injection preparations, solid and liquid medicines	1967 Privatized in 1995	Georgia Uzbekistan Russia Turkmenistan	N/A
Vitamax-E LLC	Various probiotics (capsules, tablets, powder, fruit, vegetable and meat powder, baby foods, etc) <i>Branded products</i>	1997	Japan USA Belarus Ukraine Baltic States	GMP audited and ISO certified

The Armenian pharmaceutical market is highly dominated by imports. According to estimates, the domestic market exceeded US\$130 million in 2007. Imports accounted for 90% of the local market where the first-tier multinational companies, such as Bristol-Myers Squibb, Novartis, Schering-Plough, GlaxoSmithKline and Pfizer have substantial representation. Most agree this situation presents a tremendous opportunity for locally based producers to make sales inroads, via improved marketing and distribution, resulting in import substitution.

### Armenia's Imports of Pharmaceutical Products in Current USD



Source: National Statistical Service

Major challenges currently facing the Armenian pharmaceutical industry include:

- ✓ Establishment of a regulatory framework and inspection structures concerning pharmaceutical production and distribution
- ✓ Investment in upgrading production facilities for quality assurance & certification (GMP)
- ✓ Marketing, packaging and branding of own products
- ✓ Effective export marketing
- ✓ Growing but still small-scale home market

## 7. Export Markets & Opportunities

The pharmaceutical industry is one of few export-oriented industries in Armenia. Approximately 30% of locally produced drugs are exported. Key foreign markets for Armenian companies comprise the CIS, with a predominance of Central Asian countries (Uzbekistan, Kazakhstan, Turkmenistan, and Tajikistan). Armenian companies also compete successfully in the Georgian, Belarusian, Russian and Ukrainian markets. These market links are, of course, historical in nature but continue due to the common use of the Russian language and the free trade regime among CIS countries.

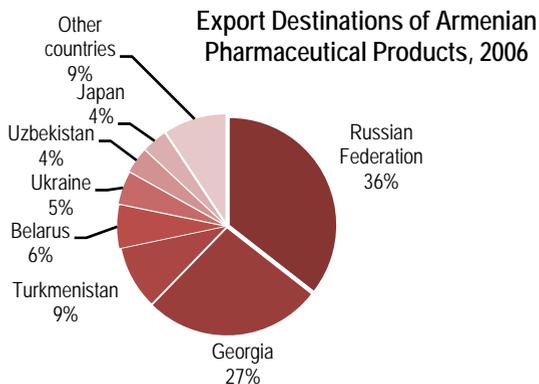
Within traditional markets, market growth is driven by budget growth (tax base, energy revenues), increased standards of living (higher disposable income), a large free market (lower health insurance coverage), and old habits (over prescribing and over consumption of medicines).

Exports of pharmaceutical products from Armenia reported significant growth during last five years, with a CAGR of 50%, although actual volumes remain fairly low.



Source: National Statistical Service

The geography of exports of biotechnology companies is wider and includes also economically advanced countries such as the US, Japan and countries in the EU.



Source: United Nations Commodity Trade Statistics Database, Statistics Division



## 8. Pharmaceuticals FDI

Due to the outstanding industry performance and viable business projects, the pharmaceutical industry has managed to attract foreign direct investment from both private and institutional investors.

Major foreign investment projects in the Armenian Pharmaceutical Manufacturing Industry include:

Company	Field of Activity	Investor	Investment Size	Year
PharmaTech	Production of intravenous solutions and eye drops	Diaspora	N/A	1998
Liqvor Pharmaceuticals	Production of infusion, injection and ophthalmological preparations	European Bank for Reconstruction and Development	EUR 850,000	2005
AlfaPharm	Wholesale, distribution and retail	European Bank for Reconstruction and Development	EUR 4.2 million	2007

There are also several foreign investment companies engaged in import and distribution activities.

Armenian producers currently dominate in the infusion and injection preparations segment of the pharmaceutical market. Liqvor Company was established in 1991 and modernized with equity investment from EBRD in 2005. Pharma-Tech was established and setup a modern production facility in 1998 with Diaspora investment. Both companies completely reshaped the high quality infusion and injection preparations market through import substitution. In parallel, they



penetrated the regional markets; largely comprising CIS countries. These companies recorded high growth rates both in terms of total turnover and exports. In addition to the abovementioned products, the companies expanded their markets in the segment of branded ophthalmological preparations. Recently, Pharma-Tech investors decided to expand production facilities, putting four new production lines in to operation.

EBRD is confident with its contributions to the development of Armenia's pharmaceutical industry, through its direct investment facility. We are sure that this sector will become one of Armenia's dynamically developing industries, having substantial expertise in this field. EBRD has invested in a pharmaceutical manufacturing company and a retail chain, anticipating higher than average returns on investment, based on high growth perspectives for the industry and well-grounded business projects. EBRD is optimistic for project outcomes.

Artashes Tonoyan

Principal Banker, Private Equity

European Bank for Reconstruction & Development, Yerevan Office

## 9. Legal Framework & Regulations

Due to the specific nature of the products, the Pharmaceutical industry is well-regulated.

### Major Regulatory Documents

	Document Name	Description
1.	The Law on Medicines of the Republic Of Armenia, adopted on October 27, 1998	The Law sets the legal basis for the pharmaceutical sector in Armenia. It includes general rules referring to pharmaceutical production and supply: production, import and export, shipment, advertisement, state registration, etc.
2.	Government Decree 581 Of September 20, 2000 on "Rules on Import and Export of Medicines and Pharmaceutical Entities in the RA"	<p>This decree ensures that drugs can only be imported to and exported from Armenia based on a certificate issued by the Ministry of Health.</p> <p>Documents required for issuance of the certificate are stipulated by normative acts of the Ministry.</p> <p>Only drugs which have state registration in Armenia can be imported; limited exceptions to the rule apply.</p> <p>Imported drugs should have a manufacturer's quality certificate.</p> <p>The minimum expiration date of imported drugs should be 1 year.</p> <p>The Decree sets specific rules for the export and import of drugs relating to humanitarian assistance programs.</p>

	Document Name	Description
		<p>The Decree has separate sections on technical and procedural rules with regard to the import and export of Drugs (e.g. application for getting the MOH certificate, terms of the expertise, types of laboratory and documental expertise, the legal and technical bases for rejection of import or export, etc.).</p>
3	<p>Government Decree 347 of April 25, 2001 on "Rules on State Registration of Pharmaceuticals and Fees for Expertise of State Registration Of Pharmaceuticals"</p>	<p>This decree is based on the requirement of the Law on Medicines (Article 15). It has 2 sections. Section 1 sets the rules for the registration procedure, the basis for rejection of registration, and the rules for invalidation of registration. It establishes that registration is processed only upon positive expert assessment of the safety, quality and effectiveness of the medicine. The expert assessment is conducted by the Scientific Center of Drug and Medical Technology (SCDMT, Drug Agency). Application and required materials for assessment should be submitted by the producer to the SCDMT. Assessment is provided to the Pharmacological Council in the Ministry of Health within 180 days of paying the assessment fee. The final decision on approving or rejecting the drug is made by the Pharmacological Council. If the medicine passes the assessment, the applicant pays the state duty, and receives a certificate of registration. The registered medicine is then included in the State Register of Medicines; a public document published periodically.</p> <p>The Decree provides a procedure and basis for refusal to register a medicine. The Ministry must send an official notice upon rejection which can be challenged through court process. The Decree has detailed provisions on the procedure to declare invalid the registration of certain medicine. Section 2 of the Decree is devoted to the types of registration and relevant fees. Fees range from AMD 60 thousand to AMD 2250 thousand (US\$ 200 – US\$7500) depending on the type of drug (new, generic, combination, homeopathic, herbal, additional dosage form or strength)</p>
4	<p>Government Decree 867 of June 29, 2002 on "Rules on Licensing Production of Medicines, Pharmacy Practice, Health Service, Implementation Of Medical Professional Education Curricula, as well as on approval of Licensing Forms for Implementation of Mentioned Activity"</p>	<p>General terms of licensing are established by the Law on Licensing. This Decree specifies the detailed procedural rules for licensing several types of activities, including the production of medicines. The first step for obtaining a license is to file an official application, accompanied by several other documents specified in Decree. A sample of the application is attached to the Decree. The application package is reviewed by the Ministry, to identify compliance of the submitted documents and information to the legislation. Grounds for refusal to grant a license are included and are stipulated in the decree. The decree has also a sample of the License.</p>

Additional important regulatory documents include:

1. Law on Narcotics and Psychotropic Substances, adopted December 26, 2002
2. Law on Licensing, adopted on May 30, 2001, amended 2002-2008
3. Law on Advertising, adopted April 30, 1996, amended 2006
4. Government Decree #1608-N of November 2, 2006 on Rules of Advertisement of Medicines
5. Government Decree #63 of January 24, 2002 on Rules of Implementation of Clinical Trials of New Medicines

## Licensing

According to the Law on Licensing, the production of medicines is subject to licensing. The licensing authority is the Ministry of Health. According to the Law, there are two types of licenses: (1) licenses issued by simple procedures (simple license) and (2) licenses issued by compound procedures (compound license). The law on Licensing defines that a license for the production of medicines is a compound license. Compound licenses shall be issued based on the conclusions drawn by the licensing commissions established by the licensors. A simple license is issued through a simplified procedure: without the decision of the licensing commission and within three days upon submission of the required documents. A compound license is issued with no time limits.

Requirements for licensing are defined by the Law on Licensing and Government Decree #867 of June 29, 2002. The annual fee (state duty) for obtaining a drug production license is AMD 200 thousand (US\$667) per year (provided by the Law on State Duties, Article 19.2.2).

## Drug Registration

The Law on Medicines requires state registration of all produced, imported and distributed medicines. Government Decree 347 of April 25, 2001 regulates details of the registration procedure; "Rules on State Registration of Pharmaceuticals and Fees for Expert Opinions of State Registration of Pharmaceuticals". The fee for state registration differs and is stipulated in the Government Decree. The maximum duration for providing expert assessment is 180 days.

Marketing authorization is issued for a 5 year period. The MoH approves the list of variations that do not require a registration.

## Main Regulatory Institutions

The industry *regulating authority* is the Ministry of Health (MoH) of the Republic of Armenia, which has a wide range of rights and responsibilities relating to their role of initiator of the law; supervision and regulation, developing public policy in the health care sector, etc. The MoH has the sole authority to license certain activities in the pharmaceutical industry - licensing production of medicines, pharmacy practice, health service, etc. The MoH is also the state authorized body to issue and cancel drug registration certificates as well as medicine import and export certificates. Other institutions that participate in the state reg-

ulation of the health care sector are the State Health Care Agency, and the Scientific Center Of Drug And Medical Technology Expertise (Drug Agency).

## **Public Procurement of Drugs**

The public procurement of drugs is implemented by the general system for public procurement, defined by the Law on Public Procurement. This law defines the State Procurement Agency (SPA) of the Ministry of Finance ([www.procurement.am](http://www.procurement.am)) as the responsible state agency for conducting bids for acquisition of medicines on behalf of state agencies and state-owned organizations (e.g. state owned hospitals). The SPA conducts bids for contracts when the value of those contracts exceeds a certain amount defined by legislation. Mechanisms of tendering are defined by the Law. The centralized procurement of medicine is one of the major programs in the primary healthcare system of Armenia. The State also implements the centralized procurement of drugs for the treatment of specific conditions such as diabetes and TB. The Law on State Budget defines, each year, the amount to be allocated for public health and includes a special provision for financing the centralized procurement of medicines.

## **10. Quality Control & Assurance**

Quality control and assurance is crucial in the pharmaceutical sector. The Armenian government is in the process of establishing a quality assurance system, in accordance with internationally accepted quality standards, by adopting and implementing Good Manufacturing Practices in Armenia. EU GMP guidelines are translated and in the process of approval.

Most Armenian pharmaceutical companies have already implemented Quality Management Systems in accordance with ISO 9001 and have been certified by well known accreditation bodies such as SGS, QMI and TUV, etc. This indicates the pharmaceutical sector's readiness and willingness to work according to international standards and requirements.

## **11. Workforce and Education**

Armenia's long history of educational excellence has resulted in a skilled and qualified workforce. Literacy is almost 100% and Armenia has one the highest percentages of graduates in the former Soviet Union. Education is seen as an incentive for progress. There are currently 16 public and 83 private universities in Armenia. The Armenian education system participates in the Bologna process in compliance with international standards.

The following educational institutions provide degree programs in pharmaceutical disciplines:

### Universities:

- ✓ Yerevan State Medical University after M. Heratsi
- ✓ Yerevan State University
- ✓ Yerevan Medical Institute after Mehrabyan
- ✓ Armenian Medical Institute
- ✓ Medical University after Saint Teresa
- ✓ "Haybusak" Yerevan University
- ✓ University of Traditional Medicine

### Colleges:

- ✓ "Grigoris" Medical-Humanities College
- ✓ "L.Orbeli" Medical College
- ✓ Medical College after Prof. K.B. Akunts
- ✓ Yerevan State Basic Medical College
- ✓ Yerevan State Medical College "Erebuni"

The Yerevan State Medical University after M. Heratsi remains the leading medical institution. It is recognized by the WHO as the main medical university in Armenia. In Pharmacology, it provides several fields of study, including Pharmaceutical Chemistry, Pharmacology, Clinical Pharmacology, Pharmacognosy and Botany, Drug Technology, etc. Due to its reputation, the university attracts a large number of foreign students from India, Iran, Georgia and other countries. The number of graduates from the Pharmacy Faculty increased over the past six years and totaled 90 in 2006. Approximately 25% are foreign citizens.

Students in their final years of study undertake internships with pharmaceutical companies. These internships often lead to full-time employment.

A comprehensive Skills & Knowledge Needs Assessment will shortly be undertaken to analyze specific areas for university curricula enhancement and professional development improvements.

University	Pharmaceutical-related Departments	Key Courses (Pharmaceutical-related Programs)
<b>Yerevan State Medical University (YSMU)</b> Founded in 1930 YSMU is a member of the International Association of Universities (IAU). Number of students: c. 2,900	Pharmacy	Pharmacy Dept: Pharmaceutical Chemistry, Pharmacology, Clinical Pharmacology, Pharmacognosy and Botany, Drug Technology, Pharmacy Organization

University	Pharmaceutical-related Departments	Key Courses (Pharmaceutical-related Programs)
<p><b>Yerevan State University (YSU)</b>            Founded in 1919            The university has collaborative agreements with 58 universities in 23 countries, including: United States (Northeastern, Michigan, Fresno, Riverside, and George Mason); France (University of Paris, Lyon, Marseilles, and Montpellier); United Kingdom (University of London); Germany (Rostock University).            Number of students: c. 8,200</p>	<p>Chemistry, Applied Chemistry, Biology, Biochemistry, Biophysics, Pharmacology, Ecology</p>	<p>a) Chemistry Dept: Organic &amp; Inorganic Chemistry, Analytical Chemistry, Catalysis, Physical/Colloidal Chemistry, Pharmaceutical Chemistry            b) Biology Dept: Biochemistry, Biophysics, Botany, Zoology, Ecology, Genetics &amp; Cytology, Plant Anatomy &amp; Physiology, Human &amp; Animal Physiology, Environmental Protection</p>
<p><b>State Engineering University of Armenia (SEUA)</b>            Founded in 1933            SEUA provides majors in 63 disciplines and hosts several advanced and extensive R&amp;D facilities.            Number of students: c. 10,800</p>	<p>Chemical Technologies, Ecology, Engineering, Chemistry, Biology</p>	<p>a) Chemical Technologies Department:            Technology of Fine Chemicals, Biotechnology, Electrochemical Production Technology, Chemical Technology of Bioactive Synthetic Chemicals</p>
<p><b>Armenian State Agrarian University (ASAU)</b>            Reorganized in 1994            Number of students: 7,500</p>	<p>Agrarian</p>	<p>Agrarian Dept:            Agronomy, Plant Protection, Selection and Genetics of Crops</p>
<p><b>Russian-Armenian (Slavonic) State University</b>            Founded in 1997            Slavonic University was established according to a bilateral agreement between the Armenian and Russian Governments.            Number of students: c. 2,400</p>	<p>Medical-Biological</p>	<p>Biochemistry, Chemistry, Biotechnology, Biology, General Pathology, Bioengineering, Information Technology, Applications of Genetic Engineering and Cloning in Medicine</p>

## 12. Business Opportunities

Based on the existing growth of the industry, market opportunities and professionalism of the workforce, the following investment opportunities are proposed:

### Green-field Investment

- ✓ There are no restrictions for foreign investors/companies interested in operating a business in the Armenian pharmaceutical industry. Investors/companies are treated equally to local companies regarding permits and licenses.

### Equity Investment

- ✓ Foreign investors/companies are able to buy and sell the shares of local companies. Investors may consider the following exit strategies: a) sale of shares to strategic investors, b) IPO, c) management-buy-out (MBO) or d) management-buy-in (MBI). In 2007, the Armenian Stock Exchange was bought by Swedish OMX, and later acquired by NASDAQ.

### Contract Manufacturing for Local Distribution and Export

- ✓ Through contract manufacturing, investors/companies may gain in terms of:
  - a) Cost efficient production
  - b) Utilizing the knowledge and connections of local producers in the local and CIS markets; having access to dynamically developing and vast markets
  - c) Free trade agreements while accessing CIS markets
  - d) Utilizing the advantage of small scale and flexible production capacities of Armenian producers; cost efficient for production of small volume products

## 13. Pharmaceutical Industry Organizations

### Scientific Center of Drug and Medical Technology Expertise CJSC

The center was established in 1992 and is one of the pharmaceutical sector's key state institutions. Based on recommendations from the World Health Organization (WHO) and substantial support by donor organizations, the Center has created modern laboratory facilities; unique in the region and within CIS countries.

The Center's Laboratory received quality management ISO 9001-2000 certification from the Swiss SGS company in 2003 and is included in the WHO's and International Pharmaceutical Federation's (FIP) lists of leading laboratories.

The Center's professional staff consists of over 80 employees, including experts in pharmacology, pharmacy, clinical pharmacology, toxicology, chemistry, biotechnology.

The Center's major activities include:

- ✓ Expertise and evaluation of medicines and medical devices required for state registration
- ✓ Expertise aimed at the certification of imported and exported pharmaceutical products
- ✓ Certification of drugs and psychotropic substances, calculation of quotas
- ✓ Professional inspection of pharmaceutical activities
- ✓ Expertise of clinical trial materials
- ✓ Monitoring of drug adverse effects
- ✓ Development of Optimal Pharmacotherapy schemes
- ✓ Publication of National Drug Formulary.
- ✓ Expertise on advertising materials
- ✓ Evaluation of drug treatment efficiency
- ✓ Pharmacoepidemiological research
- ✓ Development of draft legislative documents
- ✓ Information provision
- ✓ Educational activities

The Laboratory offers the following services:

### **In Pharmaceuticals:**

- ✓ Quality control of medicines, substances, herbs & dietary supplements
- ✓ Pharmacokinetic studies in animals and humans
- ✓ Bioequivalence and bioavailability studies
- ✓ Drug interaction studies

### **Other chemical tests**

- ✓ Iodine, chlorides, nitrates, nitrites, sulphates & sulphites determination
- ✓ Detection of heavy metals
- ✓ Bacterial contamination detection
- ✓ Endotoxin detection (LAL test)
- ✓ Determination of proteins, lipids, vitamins and metals in poultry feed
- ✓ Food expertise (honey, juices, milk, alcohol and mineral drinks)

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## Union of Medicine Producers and Importers

The Union was formed in 2003 to promote and protect the interests of pharmaceutical producers and importers and includes 6 producers and 5 importers as members. So far, MPI's major service has been to provide member companies with information about legislative changes and disseminate information about major tenders organized by the Central and Regional Governments and hospitals for procurement of pharmaceutical products. The Union is currently undertaking a strategic planning process; defining goals and activities for the medium term. Major upcoming projects include the creation of a pharmaceutical industry web portal and the establishment of a resource and training center, focusing on GMP/GDP training.

## Contacts

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## 14. Sources of Pharmaceutical Industry Information

- ✓ Ministry of Health of the Republic of Armenia – [www.moh.am](http://www.moh.am)
- ✓ Scientific Center Of Drug And Medical Technology Expertise – [www.pharm.am](http://www.pharm.am)
- ✓ Armenian Development Agency – [www.ada.am](http://www.ada.am)
- ✓ Armenian Customs Service – [www.customs.am](http://www.customs.am)
- ✓ Armenian State Tax Service – [www.taxservice.am](http://www.taxservice.am)
- ✓ World Economic Forum, Global Competitiveness Report - <http://www.gcr.weforum.org>
- ✓ World Bank Doing Business Indicators - [www.doingbusiness.org](http://www.doingbusiness.org)

- ✓ Forbes, Best Country for Business Report - [www.forbes.com/lists/2008/6/biz\\_bizcountries08\\_Best-Countries-for-Business\\_Rank.html](http://www.forbes.com/lists/2008/6/biz_bizcountries08_Best-Countries-for-Business_Rank.html)
- ✓ Heritage Foundation, Index of Economic Freedom - [www.heritage.org/research/features/index/index.cfm](http://www.heritage.org/research/features/index/index.cfm)
- ✓ The official website of the Armenia - Diaspora Conference: [www.armeniadiaspora.com](http://www.armeniadiaspora.com)
- ✓ Central Bank of Armenia: [www.cba.am](http://www.cba.am)
- ✓ Official site of Central Electoral Commission of the Republic of Armenia: [www.elections.am](http://www.elections.am)
- ✓ Official Site of Constitutional Court of the Republic of Armenia: [www.concourt.am](http://www.concourt.am)
- ✓ Government of Republic of Armenia: [www.gov.am](http://www.gov.am)
- ✓ Ministry of Privatization of Republic of Armenia: [www.privatization.am](http://www.privatization.am)
- ✓ Web Site for Parliament of Armenia: [www.parliament.am](http://www.parliament.am)
- ✓ President of Republic of Armenia – Sergh Sargsyan: [www.president.am](http://www.president.am)
- ✓ Ministry for Foreign Affairs of the Republic of Armenia: [www.armeniaforeignministry.com](http://www.armeniaforeignministry.com)

## 15. Forms of Business Organization

Foreign investors may establish operation in Armenia through a range of legal business entities:

- ✓ Entrepreneurs/Sole Proprietors
- ✓ Partnerships (full or limited)
- ✓ Companies (open joint stock, closed joint stock, limited liability, supplementary liability)
- ✓ Cooperatives (commercial and non commercial)
- ✓ Branches
- ✓ Representative Offices

Details of the different types of business organizations can be found in various pieces of legislation – the Civil Code, the Law on Joint Stock Companies, the Law on Limited Liability Companies; copies of which can be downloaded from [www.parliament.am](http://www.parliament.am). At the same time, assistance can be obtained from the Armenian Development Agency ([www.ada.am](http://www.ada.am)). The majority of business entities are limited liability companies (55%).

All business entities must be registered on the State Register of Legal Entities - details are outlined in the Law on the State Registration of Legal Entities, also available from [www.parliament.am](http://www.parliament.am) or [info@ada.am](mailto:info@ada.am).

## 16. Corporate Taxation<sup>1</sup>

There are a number of laws and regulations governing taxation in Armenia. Foreign companies are subject to the same tax regimes as Armenian companies. The new Government is intent on simplifying the tax system and creating greater transparency and service for tax payers. The major taxes are

- ✓ Profit Tax – Corporate Income Tax
- ✓ Income Tax - Personal
- ✓ Value Added Tax
- ✓ Excise Tax
- ✓ Property Tax
- ✓ Land Tax
- ✓ Presumptive Taxes – paid for particular activities such as gambling

The texts of the various laws can be downloaded from [www.parliament.am](http://www.parliament.am).

### Profit Tax

Profit tax is based on the profit obtained through the sale of goods, services, property and assets, less any expenses allowed by legislation. Deductible expenses include advertising, training, foreign trips, corporate hospitality, marketing, research and the maintenance of fixed assets.

The annual profit tax rate is 20%. The tax year ends on December 31<sup>st</sup>. Resident and non-resident companies are both liable for the tax. Losses may be carried forward for resident companies for up to five years. Depreciation periods vary according to the type of asset.

Tax holidays will become obsolete in 2009. Profit tax exemptions are available for those involved in agricultural production or in free trade zones.

### Value Added Tax

The basic rate of VAT is 20% and is applied to the sale of goods and services, and donations (based on the value of the goods and services).

The amount of VAT to be paid is calculated by subtracting any VAT paid to suppliers from VAT received from customers. The amount of VAT to be charged is based on the price stated on an invoice, plus any applicable excise taxes for excisable goods. The amount of any customs duties is added for imported goods.

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<sup>1</sup> On August 19, 2008, an extraordinary session of the Armenian Parliament was convened to discuss a package of tax amendments submitted by the Government. The goal of the amendments was to improve the legislation and administration of SME taxation and trade activity. In total, 17 pieces of legislation will be affected by the amendments. On August 21, the Parliament adopted all pieces of legislative in the package. The newly adopted laws will be sent to the President for approval and later to the Official bulletin for publication. The majority of amendments are expected to be in to force by January 2009. The Law on Simplified Tax will be eliminated under these legislative changes, amongst many others.

The following products and services are exempt from VAT:

- ✓ Agricultural products
- ✓ Newspapers & magazines
- ✓ Precious and semi-precious stones (outlined by legislation)
- ✓ Tourist Services provided to foreign citizens
- ✓ Financial Services (banking, insurance, foreign currency trading)
- ✓ Research activities

Zero rating is applied to goods and services purchased by foreign embassies and their staff, products in transit, and export goods.

## **Excise Tax**

Excise tax is payable on beer, wine, spirits, tobacco and fuel. Payments are dependent upon quantity and are made to the Customs Administration.

## **Property Tax**

Property tax is payable on privately owned buildings and vehicles and is based on the value of the property. Individuals and legal entities are both liable for the tax. The tax on buildings is 0.3% of the property value per year. Revaluation of building values is undertaken every three years. Vehicle taxes decrease with the age of the vehicle (discounts of between 10% and 50% apply).

## **Land Tax**

Landlords of private land, and temporary and permanent users of state-owned land are subject to annual Land Tax. Agricultural land is taxed at 15% of the estimated net revenue, which is established by the government. For non-agricultural land the tax rate varies from 0.5% on rural land used for industry, communications, defense, etc to 1% for land in urban areas, forests and other land.

## **Presumptive Tax**

Presumptive tax replaces VAT and Profit Tax for shops with a small turnover, catering businesses, hairdressing salons, garages and car repair establishments and casinos.

The method of calculation depends on the type of activity but can be based on the trading space, number of employees, and working days in a month.

## **Import Duty**

Import duties are calculated based on the value of the goods, transportation and any other related expenses. Exemptions are provided for imported capital goods forming part of an investment, goods temporarily imported or exported for the purpose of processing or reprocessing, currencies, humanitarian aid and goods in transit. Free trade zone imports will either be taxed at reduced rates or tax exempt. Import duties are typically zero or 10%.

## **Export Duty**

All export goods are zero rated.

## **Taxation Treaties**

Double taxation treaties (DTTs) are in force with Austria, Belarus, Belgium, Bulgaria, Canada, China, Egypt, Estonia, France, Georgia, Greece, India, Indonesia, Iran, Italy, Latvia, Lebanon, Lithuania, Moldova, Poland, The Netherlands, Qatar, Romania, Russia, Switzerland, Syria, Tajikistan, Thailand, Turkmenistan, UAE and Ukraine. The number of new DTTs is rapidly increasing.

## **17. Individual Taxation**

Individual taxation is governed by the Law on Income Tax. Foreign citizens that have spent more than 183 days in Armenia, or who have family, property or business interests in Armenia are considered to be residents and therefore become liable for income tax on worldwide income. Armenia has dual taxation agreements with many countries so income already taxed from overseas can be taken into account. Non-residents are only liable for tax on Armenian income.

Income legally comprises wages, salaries, donations, royalties, business income, property income and benefits in kind. The personal allowance for Armenian citizens is currently AMD 25,000 per month. Income of up to AMD 80,000 is taxed at 10%. Income over AMD 80,000 is taxed at 20%. Income from property leasing, royalties and interest is taxed at 10% but without the AMD 25,000 allowance. Employers are to withhold employee income tax at source.

There are a few exemptions from income tax:

- ✓ Income from trading government securities
- ✓ Dividends
- ✓ Interest on government securities
- ✓ Property or money inherited or received as gifts from individuals
- ✓ Donations from non-profit and foreign organizations
- ✓ Insurance payments
- ✓ Scholarships & Educational allowances

## **Social Security Payments**

Employers and employees are obligated to pay social security contributions at the following rates.

Paid by Employer – Gross Income (AMD per month)	Mandatory Payment
< AMD 20,000	AMD 7,000
AMD 20,000 – 100,000	15% of the amount exceeding AMD 20,000 PLUS AMD 7,000
> AMD 100,000	5% of the amount exceeding AMD 100,000 PLUS AMD 19,000
Paid by Employee – Gross Salary (AMD per month)	
In all cases	3%
Paid by Individual Entrepreneurs – Gross Income (AMD per year)	
< AMD 1,200,000	15% but not less than AMD 60,000
> AMD 1,200,000	5% of amount exceeding AMD 1,200,000 PLUS AMD 180,000

Foreign citizens are not liable for social security payments.

## 18. Labor Relations

Labor relations are governed by the Labor Code, adopted in 2004. The Code includes provisions relating to working hours, vacations, employment termination, special leave (maternity, study, etc), employment contracts and the calculation of salaries. The Labor Code was given a positive assessment by the Venice Committee and is in line with European standards and guidelines.

Labor agreements are typically either long-term/open-ended employment contracts or time-stipulated consulting contracts; the latter also being regulated by the Civil Code.

Employers and employees both have the right to terminate contracts early. Employees should provide 14 calendar days written notice. Employers should provide between 14 calendar days and 2 months notice, depending on the reason for the termination. Reasons for termination are outlined in the Labor Code. Employers cannot terminate labor contracts with pregnant employees, employees with children less than one-year of age, and with employees taking sick or vacation leave. In case of termination, the employer should provide severance payment equal to one month's salary.

All employees are entitled to vacation leave. The minimum requirement is 28 calendar days, applicable after 6 months of employment. For some types of employment, longer vacation periods are provided. The list of occupations and the vacation time is regulated by the Labor Code. 140 days are provided for maternity leave; 70 days before birth and 70 days after. Based on medical need and evidence, maternity leave can be extended to 180 calendar days.

Wages are governed under market conditions, although a minimum wage of AMD 25,000 (US\$ 82) per month applies. Salaries of civil servants increased in recent years, pushing up salaries in the private sector. Salaries broadly range from US\$100 to several thousand dollars per month.

The Labor Code limits the amount of overtime that can be undertaken by an employee. Overtime is voluntary for pregnant women and employees with children under one year of age. An employer must notify employees in advance if overtime is required. Overtime must be paid at 1.5 times the employee's contractual wage, although higher amounts are allowed according to the rules and policies of the employer.

Foreign citizens can work in Armenia with little restriction, although they must be registered for employment.

Employees are protected by the Armenian Constitution, the Civil Code, the Labor Code and other government legislation. Disputes can be resolved through due legal process.

## 19. Intellectual Property

Armenia has a sound legal basis for the protection of intellectual property rights, patents, know-how, trade secrets, trademarks, and service marks. However enforcement mechanisms remain underdeveloped due largely to a lack of action on the part of infringed parties. Although Armenia's legislation is in compliance with the WTO Trade Related Aspects of Intellectual Properties (TRIPS) Agreement, strengthening enforcement mechanisms is one of the key goals for Armenia in meeting its WTO commitments.

The "Law on Copyright and Related Rights" provides for the legal protection of literary works, musical works, paintings, films, software, and other intellectual property rights as well as the legal protection of the rights of performers, producers of sound recordings and broadcasting organizations. Among the legal instruments for the protection of copyright and related rights are international conventions, which Armenia has ratified: the Berne Convention for the Protection of Literary and Artistic Works; the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations; the WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty, etc.

The registration and protection of trademarks, service marks and geographical indications is defined by the "Law on Trademarks, Service Marks and Designation of Origin". A trademark or service mark is subject to legal protection in the Republic of Armenia by virtue of international treaties or acknowledgement of its renown or after its State registration, which is carried out by the Intellectual Property Agency. Designations of origin are also subject to legal protection by virtue of international treaties or after their State registration. Armenia is a sig-

natory to such international treaties, as the Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods, the Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks, and the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks.

The rules for registration and legal protection of inventions, industrial designs and utility models are set by the “Law on Patents”. It provides patent protection for inventions (20 years), industrial designs (15 years) and utility models (10 years). Armenia has also ratified several international conventions in this area, such as the Patent Cooperation Treaty, Paris Convention for the Protection of Industrial Property, Strasbourg Agreement Concerning the International Patent Classification, etc.

The specialized state agency - the Intellectual Property Agency of the Ministry of Economy - is responsible for granting patents and for overseeing other IPR related matters. In January 2005, the government created an IPR Enforcement Unit in the Organized Crime Department of the Armenian Police.

## 20. Insurance

The insurance sector and legal framework in Armenia has changed substantially in the last couple of years. In 2007, new insurance legislation was enacted (Law on Insurance and Insurance Activities, adopted on 09.04.2007). This law introduced certain provisions which are in line with international standards: e.g. solvency ratios, investment policies, reserve management, consumer protection and related provisions. The biggest innovation was the introduction of new a classification of the types and classes of insurance that are similar to European classification. Other positive innovations refer to management, internal audit, responsible actuary, insurance secrecy, merging and liquidation of insurance companies, transferring insurance portfolios, etc. The advantage of the new regulation is that the business community and consumers now have modern and clear rules of action in the insurance sector.

According to the new law, the supervisory, regulatory and licensing functions related to insurance companies, were transferred from the Ministry of Finance to the Central Bank of Armenia. The new insurance legislation is aimed to protect the lawful rights and interests of consumers.

Currently, a wide range of products are available from insurance companies operating in Armenia: life, accident, illness, cargo, property, motor vehicle, aviation risk, general liability, etc. Armenia currently does not have any compulsory insurance. Liability insurance is not widely taken up amongst Armenian companies.

## 21. Business Financing

Armenia's financial system consists of 22 banks (with 347 branch offices), 11 insurance companies, 21 non-bank credit institutions (with 40 branch offices) and 18 securities broker-dealers.

The banking sector dominates the financial system; holding over 90 percent of system assets. They also have significant and geographically widespread foreign ownership. Institutional investors include HSBC, Credit Agricole, VTB (Russia), AmeriaBank, Byblos Bank (Lebanon) and GazpromBank (Russia). High net worth individuals also own significant portions of other Armenian banks. Interest rates are currently between 10% and 16% for commercial lending.

Growth amongst the banks has been strong. Since 2002, banking sector capital and assets showed a CAGR growth of 34% and 25% respectively. Banks are expanding into new financial products' markets, especially into different types of consumer credit and mortgage markets. Mortgage lending has accelerated markedly since 2004, with the volumes increasing by 170% over the last year. In 2007, the banking sector experienced more than 82% growth of credits to the private sector against a 35% growth in deposits. All of the above reflects increased public demand and competition within the banking sector.

The strong growth in the Armenian banking sector is shown in the table below, with total assets reaching AMD 784 billion (US\$ 2.6 billion) at the end of 2007:

Period	Total Assets AMD (billion)	% Increase
2001	239	-0.2%
2002	257	7.7%
2003	292	13.2%
2004	369	26.7%
2005	455	23.2%
2006	544	19.5%
2007	784	44.1%

Year	Banking Assets as % of GDP
2001	19.3%
2002	18.1%
2003	17.4%
2004	18.3%
2005	20.0%
2006	20.4%
2007	25.0%

While the banking sector in Armenia has been growing at an impressive rate over the past five years, the level of banking assets held by Armenian banks remains relatively constant as a percentage of the country's GDP:

## 22. Zoning, Land Use & Building Permits

The Armenian Constitution provides certain limitations on the right to own land – foreign individuals can only lease but not own the land in Armenia. Exceptions are provided only for those foreigners who hold a special permit. The status of the special permit is defined by the Law on Foreigners. However a company registered in Armenia by a foreign individual or company has the right to own a land.

Foreigners have the right to use land under long term lease. They have also the right to use Armenian natural resources under a concession agreement.

Owners and users of state land are subject to Land Tax. Owners of real estate are subject to Property Tax.

Certain activities in urban development areas are subject to licensing (e.g. civic construction, preparation of documents in engineering, expertise construction documents). This requirement is defined by the Law on Licensing. The license is considered to be a special permit to conduct a certain business activity. To obtain a Construction License, a state duty has to be paid to the state budget. However, construction activities also require permission from local administrations – a permit for construction and a permit for demolition. The fee for obtaining the permits is paid to the local budget.

There are a number of legislative acts relating to the environment and natural resources. These include the Land Code, Water Code, Code on Entrails of the Earth, the Law on Concession of Entrails for Extraction and Research Purposes, the Law on Waste Products, the Law on Payments for Environmental Protection and Use of Natural Resources and the Law on the Assessment of Environmental Impact.

## 23. Business Costs

Business Start Up Costs	
Company Registration (incl. tax and social security registration)	\$50 - \$100
Office Space in Yerevan	\$10 - \$50 per sq. m.
Operating Costs	
Staff – Pharmaceutical Company – average monthly salary	\$200 - \$600
Electricity	\$0.08 per kw
Gas	\$0.32 per m <sup>3</sup>
Water	\$0.40 per m <sup>3</sup>

Operating Costs	
Telephone – Land Line - local call	\$0.03 per minute
Telephone – Land Line - international call	\$1.00 - \$1.30 per minute to the US
Mobile Telephone - local call	\$0.13 - \$0.40 per minute (prepaid)
Mobile Telephone - international call	\$1.00 - \$1.30 per minute to the US (prepaid)
Internet	\$0.05 - \$0.08 per Mb
Broadband	starting from \$40 per month
Property Tax (Real Estate)	0% - 1%
Property Tax (Vehicle)	\$0.30 - \$3.30 per hp – dependent on vehicle type
Fuel	\$1.50 per liter
Imports	0% or 10% of the CIF value
4* Hotel	\$100-\$150 per night in standard single room, breakfast incl.
Air Transport	\$1100 - \$2500 - round trip to the US
Living Costs	
3 Bedroom Apartment - Central Yerevan	\$1700 - \$2500 per month rent
Utilities (electricity, gas, water, telephone)	\$100 - \$200 per month (monthly average)
International School Education	\$1400 per month
Taxis	\$0.27 - \$0.40 per kilometer

## 24. Country Information

### Geography

The Republic of Armenia is a small country in the South Caucasus, approximately the same size as the States of Massachusetts or Maryland (11,500 sq. miles). It borders Iran to the South, Turkey to the West, Georgia to the North and Azerbaijan to the East. The land border is 779 miles. Yerevan, the capital city, is situated at an elevation of just below 1000 meters.

The country is administratively divided into eleven marzes including Yerevan.

Armenia is rich in a number of natural resources including copper, iron, molybdenum, zinc, bauxite, silver, lead and gold. Substantial deposits of pumice, marble, tufa, perlite, limestone, basalt and salt also exist.

## **Climate**

Summers are hot and dry; and winters are cold. The coldest month is January, with the average daily temperature ranging between -13°C and 1°C. The hottest months are July and August with the average daily temperature ranging between 30°C and 35°C.

## **Population and Language**

The population of Armenia numbered 3.2 million as of July 2008. Only 2% of the population is ethnically non-Armenian. The capital city, Yerevan, has a population of approximately 1.1 million. An estimated Diaspora population of 6.6 million is spread around the world but with high concentrations in Russia, North America, Argentina, the Middle East and Western Europe.

The national language is Armenian with its own unique script. Russian is widely spoken. English is becoming popular as the language of business and more and more young people are learning additional European languages – French, German, Italian and Spanish.

## **Currency and Payments**

Armenia's national currency is the Dram (AMD). The current exchange rate (August 2008) is AMD 300 = USD 1. Most of the Armenian commercial banks operate ATMs, accepting MasterCard, Visa, and Maestro.

## **Public Holidays**

Armenian public holidays are as follows: 31 December to 2 January - New Year; 6 January - Christmas; 28 January – Army Day; 8 March – Women's Day; 24 April - Armenian Remembrance Day; 1 May – Labor Day; 9 May – Victory & Peace Day; 26 May – Memorial Day; 5 July – Constitution Day; 21 September – Independence Day.

## **Time Zone**

The time in Armenia is four hours ahead of Greenwich Mean Time (GMT+4). Daylight saving is in place between March and October.

## **Government**

Armenia is a republic. The new constitution was adopted on 5 July 1995. The President of Armenia is elected for a period of five years by popular vote. The President appoints the Prime Minister and Members of Government who are nominated by the Prime Minister. The 131 members of the National Assembly (Armenian Parliament) are elected through a general election once every five years.

## **Entry Visas & Residency**

Foreign citizens, except those from some CIS countries, travelling to Armenia should obtain an entry visa from an Armenian embassy or consulate abroad,

electronically through the Ministry of Foreign Affairs website: [www.armeniaforeignministry.am/eVisa](http://www.armeniaforeignministry.am/eVisa), or upon arrival at the border (airport and road borders). A tourist visa at the border costs AMD 15,000 and is valid for 120 days. Electronic visas cost US\$60 and can only be used for entering via the airport in Yerevan.

For stays longer than 3 months, a one-year temporary residency permit must be obtained through the Ministry of Foreign Affairs in Yerevan. A translated and notarized copy of the passport and a medical examination are required. There are no fees for visas issued to children under 16.

### **Business Hours**

Typical business hours are from 9am to 6pm from Monday to Friday. Some banks are open on Saturday mornings. Business hours for retail stores vary depending on their size and location. Most retail outlets are open from 8.00 a.m. to 9.00 p.m. There are also 24-hour stores.



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