

Investment Guide

Opportunities in Georgia's Pharmaceutical Sector

June 2012



prepared by **KOMSA INTERNATIONAL**
www.komsa-international.com

CONTACTS

Keti Bochorishvili

Director

+995 32 2 991 098

k.bochorishvili@investinggeorgia.org

George Tsikolia

First Deputy Director

+995 32 2 106 392;

g.tsikolia@investinggeorgia.org

Rati Anjaparidze

Investment Project Manager

+995 32 2 433 433;

r.anjaparidze@investinggeorgia.org

Disclaimer

This report is presented for informational purposes and does not constitute an offer to sell, or a solicitation of an offer to buy, any securities. The information contained in this report is not guaranteed as being accurate and does not purport to be a complete statement or summary of the available data. Distribution of this report in certain jurisdictions may be prohibited by law. Recipients are required to inform themselves of and comply with all restrictions and prohibitions in such jurisdictions. This report may contain statements that constitute "forward-looking statements". While these forward-looking statements represent our judgments and future expectations, a number of risks, uncertainties and other factors could cause actual developments and results to differ materially from our expectations. We are under no obligation (and expressly disclaim any such obligations) to update or alter our forward-looking statements whether as a result of new information, future events, or otherwise. The recipients hereof are permitted to further disseminate this report or key facts and statements contained herein, provided that they do so with the proper attribution to the relevant government agency as the source of such information.



Government of Georgia

11 July 2012

Dear Prospective Investors,

Emerging markets are expected to drive growth in the global pharmaceutical market over the coming decade, and the industry is expected to undergo a shift toward localization of production to accommodate for production and monitoring of biotechnologies, as well as a trend towards consolidated, vertically integrated supply chains.

Already, pharmaceutical exports from Georgia have grown at an average 47% per year over the past six years, and Georgia's own demand for pharmaceuticals has experienced rapid growth, averaging 16% per year over the past six years. Continued growth can be expected due to rising incomes and overall economic growth.

Georgia offers a strategic base for production, with easy access to surrounding CIS countries and other major emerging markets such as the Middle East. Georgia is a leader in the CIS and emerging markets for the ease of its business environment and rooting out of corruption, as demonstrated by Georgia's ranking as #16 in the World Bank's global Ease of Doing Business report (2012). In addition to a favorable tax regime and a simple regulatory environment, Georgia has an attractive and efficient customs regime that can give pharmaceutical producers assurance about their ability to import active ingredients and other ingredients from their preferred global suppliers.

Also making Georgia an attractive strategic base for pharmaceutical production are its low costs of energy and labor (average wages approximately 30% less than in nearby Turkey) and an established pharmaceutical production industry totaling USD 48 million in 2011.

Recognizing Georgia's future potential in this sector, the Georgian Government is pleased to support and facilitate investments undertaken in the pharmaceutical industry. This is in addition to our commitment to improve healthcare access in Georgia, to support our country's medical education institutions, and to work towards establishment of a local GMP certifying agency in Georgia by 2016.

Lastly, among current global economic challenges, I am pleased to highlight that the Georgian economy has been undergoing strong economic growth, with real GDP growth of 7.0% in 2011 and annual projections over 6% for 2012-2016. Foreign investment and exports are up in 2011 compared to prior years, and the products and countries represented in trade and investment are diverse. At the same time, we are maintaining a healthy level of external public sector debt (estimated 29.0% of nominal GDP in 2011) and a stable exchange rate. Confidence in the future of Georgia is reflected by our BB- long-term credit ratings in foreign and local currencies (S&P and Fitch) and the successful Eurobond placement in April 2011 (5.3x oversubscribed). We are confident about the direction in which our country is moving as an attractive, vibrant, and welcoming base for business and trade in the region.

Yours sincerely,

Nika Gilauri
Prime Minister of Georgia

Contact Us

The Government of Georgia is ready to cooperate and support individuals, companies, agencies and governments interested in making investments into the pharmaceutical sector in Georgia.

Through the Georgia National Investment Agency (GNIA), we are equipped and ready to provide information about the business environment in Georgia, and to support investors every step of the way with assessing, entering and navigating in the local market, whether it be from a legal, tax, regulatory, market, or operational perspective.

GNIA and the Government of Georgia are also ready for constructive dialogs with potential foreign investors in order to assess areas where the Government can play a specific role to improve the investment environment and the competitiveness of the sector.

About GNIA: GNIA is the sole public agency responsible for promoting and facilitating foreign direct investment in Georgia. GNIA plays a moderators role between foreign investors and the Government. Responsible for export promotion as well, the Agency serves as a bridge between investors, foreign companies and Georgian companies. GNIA also serves as a “directory” to render relevant free services to investors, including arrangement of forums and conferences to raise awareness of Georgia’s potential and to disseminate overall, sector-specific and project-specific information about Georgia’s investment climate. Our team consists of multilingual (Georgian, English, Turkish, Russian, Italian, French, German and Korea) and dedicated professionals who ensure guidance for successful business development in Georgia.

Interested investors may contact GNIA for inquiries and support at:

Keti Bochorishvili

Director

k.bochorishvili@investingeorgia.org

George Tsikolia

Deputy Director

+995 32 2 106 392

g.tsikolia@investingeorgia.org

Rati Anjaparidze

Investment Project Manager

+995 32 2 433 433

r.anjaparidze@investingeorgia.org

General Contact

+995 32 2433 433

enquiry@investingeorgia.org

Table of Contents

1. Executive Summary	3
2. Georgia’s Pharmaceutical Sector at a Glance	6
3. Why Georgia?	7
4. Pharmaceutical Retail & Wholesale	11
Historical Growth Performance	
Potential Market Growth	
Market Structure & Key Players	
Company Highlights	
Source of Imports	
Pricing	
5. Pharmaceutical Production	17
Historical Growth Performance	
Key Players	
Types of Production	
Phages Production	
Natural & Herbal Medicine Production	
Producer Highlights	
Export Markets & Potential Growth	
Contract Research & Contract Manufacturing	
6. Overview of Healthcare in Georgia	25
7. Taxation, Regulation & Quality Control	30
Tax Exemptions	
Key Reforms & Liberalization of Regulation	
Licensing & Regulatory Procedures	
Registering Exports Abroad & Issue of GMP	
8. Human & Other Resources	37
9. Foreign Investment & Partnerships	41
10. Investment Opportunity Highlights	43

Appendices:

- A. About Georgia: Macro-economy & the Business Environment
- B. List of Countries Eligible for Simplified Recognition of Pharmaceuticals
- C. List of Georgian Laws Relating to Pharmaceutical Sector

1. Executive Summary



Emerging markets are expected to drive growth in the global pharmaceutical market over the coming decade, and Georgia and the surrounding region have significant room for growth. In this context, Georgia offers the following key growth opportunities:

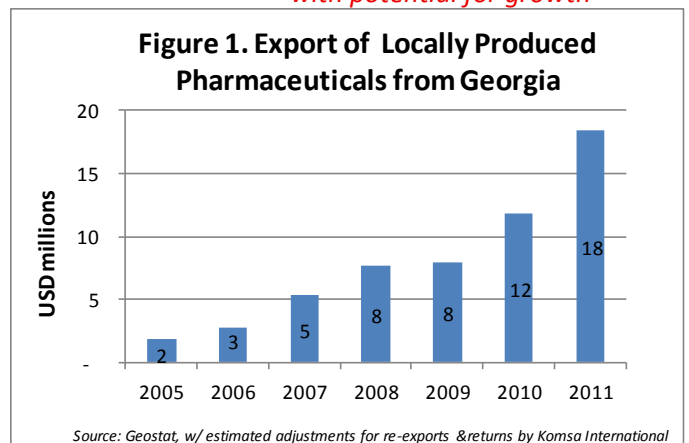
35% average annual growth in pharmaceutical production over the past 6 years

Growth Opportunities in Georgia’s Pharmaceutical Sector:

- Track record of pharmaceutical production and double digit export growth.** Pharmaceutical exports from Georgia have grown at an annual rate of **47%** from 2005 to 2011. Georgia exports pharmaceuticals to **16** countries, with **USD 18.5 million** in exports of locally produced pharmaceuticals in 2011. Exports to CIS countries are well established and growing robustly, and in the past two years Georgia has begun exporting to a several new countries in the Middle East, Africa and Asia.
- Growth potential in surrounding CIS countries and other major emerging markets.** Georgia’s existing CIS export markets have also had fast growing pharmaceutical retail sectors over the past six years. These markets still have very low per capital pharmaceutical consumption in comparison with the West, and there is potential to enter other major, fast growing markets such as Asia and the Middle East.
- Strong historical and projected growth in Georgia’s retail pharmaceutical market.** As a result of overall economic growth and a

Established and growing exports to CIS countries as well as recent new markets in Asia, Africa and the Middle East

Proximity to CIS countries and other markets with low per capita pharmaceutical spending with potential for growth



government commitment to advancing Georgian health care, the total pharmaceutical retail and wholesale market has grown at an average rate of 16% per year over the past six years. With strong real GDP growth of over 6% per annum projected for the coming 5 years and currently low per capita pharmaceutical spending, continued strong growth rates are expected.

16% average annual growth in Georgia's pharmaceutical market over the last 6 years

Competitive Advantages for Pharmaceutical Production in Georgia:

Projected real GDP growth over 6% per annum for coming 5 years

In addition to the attractive growth opportunities in Georgia and its surrounding region, Georgia's business environment offers the following competitive advantages making it attractive for investment in the pharmaceutical sector and serving as a regional hub for pharmaceutical production and sales:

Attractive base or hub for a regional pharmaceutical business

- Favorable business environment and simplified pharmaceutical regulation with no pharmaceutical price controls.** Georgia is a leader in the CIS and emerging markets more broadly for its business environment, as demonstrated by Georgia's ranking as #16 in the World Bank's global Ease of Doing Business report (2012). There are absolutely no pricing regulations on pharmaceuticals in Georgia, and Georgia also recently streamlined regulation of the pharmaceutical sector, including automated recognition of pharmaceuticals registered in certain countries, to enhance free competition and competitiveness. In addition to a favorable business environment, Georgia also offers an attractive, Western-style living environment, including the charming capital of Tbilisi, Black Sea coast, a burgeoning wine industry and Caucasus mountain winter resorts.
- No VAT or customs taxes on pharmaceuticals:** Pharmaceuticals are excluded from Value Added Tax (VAT) and customs taxes in Georgia. This is in contrast to a number of CIS and other developing countries.
- Attractive import/export regimes.** With an efficient, reliable and transparent customs department, pharmaceutical distributors can operate trade routes with ease, and pharmaceutical producers can be assured of smooth functioning of imports from their preferred global suppliers.
- Low cost of labor and energy inputs.** The average wage in Georgia is less than that in China, and approximately 30% less than in nearby Turkey. Average gross monthly wages in the pharmaceutical industry are in the USD 300-600 range, and typically up to USD 1,800 for senior technical staff and management. In terms of skills, Georgia carries a legacy of focus on the medical field from Soviet times, and operates with an established production industry currently with 70 pharmaceutical manufacturers. Electricity costs, which are also critical to pharmaceutical production, are also low compared to other countries in the region.

Ranked #16 in World Bank's Ease of Doing Business Report

No pricing regulation of pharmaceuticals

Recently simplified regulation for the pharmaceutical sector

Attractive, Western living environment with Black Sea coast and Caucasus mountains

No VAT or customs tax on pharmaceuticals

Efficient customs and trade regimes

Low labor and energy costs along with pharmaceutical skill sets

- **Recently established USD 150 million national referral laboratory:**
In cooperation with the United States, the Georgian government recently established a national laboratory with biosafety level (BSL) 2 and level 3 designations according to international standards. The laboratory will be ready this year to partner with or provide contract services to governments, international organizations, institutions, and private companies for research, training, testing or storage.

BSL-2 & BSL-3 national laboratory recently establish with US support

- **Competitive advantages in phages and natural/herbal medicines:**
Since the 1930s, Georgia has been a leader in R&D and production of bacteriophages, used for treating various bacterial infections. Now with the rise of drug resistant strains of bacteria, the potential role of phages is garnering new attention in the West. There are also a number of producers of natural based and herbal based medicines, with growing sales within the CIS and potential to break into the EU market with investment into standards and licensing. The Caucasus mountains have over 40 varieties of unique medicinal and herbal plants, and Georgia offers pristine, underutilized agricultural land for cultivation.

Phages and natural medicines are sub-sectors attractive for investment

- **Commitment to improve healthcare access in Georgia.** Since Georgia's transition to a privatized healthcare system, significant efforts have been made to improve the quality and efficiency of healthcare, including privatization of hospitals, increasing public expenditures on healthcare and establishing new programs to insure the poor, children and pensioners. With the new government programs and a growing popularity of private insurance, the health insurance industry is experiencing new growth, and improving healthcare will be a main focus of the government administration in the years to come.

Track record and commitment to advancement of health care

- **Government commitment to establish a GMP certifying agency and support for the development of Georgia's pharmaceutical sector.** Recognizing Georgia's future potential in the pharmaceutical sector, the Georgian Government is committed to continual enhancement of the regulatory environment, including plans to introduce a GMP certifying agency by 2016, which will enhance the ability of Georgian pharmaceutical producers to export to other countries. It is also committed to supporting other efforts to achieve enhanced competitive advantages and attracting investments in the sector into the country.

Plans for establishing a GMP certifying agency

2. Georgia's Pharmaceutical Sector at a Glance

Industry Players (July 2011)

- **70** manufacturers (of which an estimated 50-60 are operating)
- Approximately **2,000** retail pharmacy companies & 3,000 pharmacy outlets
 - **46** companies own more than 3 pharmacy outlets
 - **5** are major chains (own more than 30 outlets)
 - **2** dominate the market (with 600 outlets combined)
- Imports from **92** foreign manufacturers
- **75** companies importing pharmaceuticals (mix of wholesalers and retailers)
- **4** global contract research organizations (CROs) with representation in Georgia for clinical trials

Market Size

- **USD 48 million** local production (2011)
- **USD 18 million** locally produced exports (2011)
- **USD 210 million** imports (2011)

Market Growth

- **35%** average annual growth rate in local production (2005-2011)
- **47%** average annual growth rate in locally produced exports (2005-2011)
- **15%** average annual growth rate in imports (2005-2011)

Major Export Markets (2011)

Caucasus	Ukraine	Russia
Central Asia	Belarus	Bulgaria

Recently New Export Markets (in past 2 years)

Moldova	Sierra Leone
Libya	Australia/India (samples)

Production Type

Tablets	Injections	Ingredients
Sprays	Extracts	Balms
Syrups	Capsules	Eye drops
Powders	Gels	Granules

Workforce (2010)

- **13,767** employees in the industry
 - 2,409** in production
 - 8,120** in retail
 - 3,328** in wholesale
- Average gross monthly wage statistics
 - USD 322** production
 - USD 265** retail
 - USD 528** wholesale

R&D, Academia, & Associations

- Central Public Health Reference Laboratory (CPHRL), with high biosafety BSL-2 and BSL-3 labs and vivarium, offers services and cooperation for research and testing to the private and public sectors.
- 13 universities with degree programs in pharmaceutical related disciplines
- Association of Pharmaceutical Company Representatives in Georgia (APCRG)

Regulation & Standards

- No pharmaceutical pricing regulations
- No VAT on pharmaceuticals
- Agency for State Regulation of Medical Activities (licensing/monitoring of production, trade, prescribing, disposal)
- Law on Medicines and Pharmaceutical Activity (1997) as later amended
- Various related laws (health care, patents, consumer rights, etc.)
- Simplified licensing for import of FDA and GMP certified pharmaceuticals (for certain countries)
- New legislation allowing for parallel imports of pharmaceuticals
- Plans for GMP certifying agency by 2016

Foreign Investment

- ABC Pharmacia, Gama, Euromedical, Iveriapharm, CPHRL, plus various CROs and pharmaceutical distributors

Sources for statistics: Geostat and Ministry of Health. Sources referenced later in the report.

3. Why Georgia?



Leader among Peers for Ease of Doing Business

Georgia is globally recognized for the economic reforms it has achieved over the past seven years, making it an attractive, open and easy emerging market in which to do business, and a model of success, and a leading destination in the region.

Ease of Doing Business: Georgia is ranked 16th among 183 countries in the World Bank's "Ease of Doing Business" report for 2012, ranking ahead all of its neighboring countries and many EU countries and has been continually placed among the "Top Reformers" among CIS countries by the World Bank since 2006. The Heritage Foundation's 2011 Index of Economic Freedom ranked Georgia as the 29th freest economy in the world.

Attractive and Efficient Tax Regime: Georgia offers a simple, unified tax code with low tax rates and greatly improved tax administration and enforcement. The corporate income tax rate is 15% and the personal income tax rate is 20%. There is no separate capital gains tax, wealth tax or social insurance tax, and by 2014 interest and dividends taxes will be reduced to 0%. Customs taxes are usually 0%, with a tax on certain limited product types only, and the customs process is simple and transparent, particularly in comparison to other countries in the region. In 2008, Forbes Magazine designated Georgia as the 4th "Least Tax-Burdened Country in the World." Georgia also has 20 OECD-model double taxation treaties, other bilateral tax treaties, and several free industrial zones with minimal tax burdens for international companies.

Ranked #16 in World Bank's 2012 "Ease of Doing Business Report"

Ranked as the 34^h freest economy in the world by the Heritage Foundation in 2012

Low tax rates

Low Corruption & Bureaucratic Burdens: Also, as a result of a major effort by the Government to combat corruption, Georgia has improved its ranking on Transparency International's *Corruption Perception Index* from 133rd in 2004 to 64th in 2011, and low level corruption, for example among police and customs officials, has been virtually rooted out completely. Georgia has also passed important reforms that have brought administrative and bureaucratic burdens down to very low levels. For example, it has dramatically simplified licensing and permitting requirements, introduced a liberalized labor code, and modernized civil services (simple processes for registering businesses, filing taxes, etc.). There are almost no restrictions on foreign ownership in Georgia and no restrictions on repatriation of profits from Georgia other than compliance with tax law. According to the World Bank's assessment it takes only 3 days to establish a business in Georgia.

Low level corruption virtually non-existence as a result of 2004 reforms

Very low bureaucratic and administrative burdens

3-days to register a business

Attractive trade regime: Georgia has abolished import tariffs on almost 90% of goods, including pharmaceuticals. Georgia has most-favored trading relationships with all WTO members and has GSP arrangements with all EU countries (GSP+ status) and several other countries including the US and Japan. Georgia has a free trade agreement with Turkey and has signed a number of economic cooperation agreements with neighboring CIS countries, including bilateral free trade agreements with Armenia, Azerbaijan, Kazakhstan, Turkmenistan, Ukraine and Russia. Georgia has on-going negotiations on DCFTA with the EU and USA.

Member of the WTO with numerous trade agreements and free trade agreements

Potential for Robust, Sustainable Growth

The Georgian economy has been undergoing strong and steady economic growth despite the economic slowdown in most of the world over the past several years, and at the same time is maintaining a healthy macro-economic situation. With this foundation, Georgia is positioned for strong and sustained economic growth.

7.0% real GDP growth in 2011

GDP Growth: Real GDP growth was 7.0% in 2011 and is expected to be 5.0% in 2012. Real GDP growth in 2008 and 2009 was 2.3% and -3.8% respectively, a result of the August 2008 conflict with Russia and the global financial crisis in 2009, but this was in stark contrast to double digit contractions in much of the CIS and other emerging markets. Georgia is on track with robust growth performance in 2010 and 2011 and annual real growth rates in the range of 5.0-6.5% projected for 2012-2016.¹

Projected real GDP growth over 6% per annum for 2011-2016

Positive FDI growth projected for 2011 and following 5 years

Increasing Foreign Investment: Net foreign direct investment (FDI) was to be USD 980 million in 2011, an increase over the 2010 level of USD 814 million. With steady increases projected for the coming five years, FDI is on its way to return to its pre-crisis peak of USD 2.1 billion in 2007.¹

Exports rising, with diverse product and country destination range

Export Growth: Exports are also up, at USD 2.2 billion for 2011, up from USD 1.67 billion in 2010.² Moreover, products and countries represented in trade and investment in Georgia are diverse, without reliance on any one country or sector.

¹ Source: International Monetary Fund (IMF) June 2011 Georgia report.

² Geostat.

Macroeconomic Health

Strong International Credit Ratings and Eurobond Placement: Georgia's external public debt is at a healthy level, at estimation of 29.0% of nominal GDP in 2011 and projected to decrease steadily over the next five years.³ It also has a stable exchange rate (maintaining a range of approximately GEL/USD 1.5-1.8 over the past five years, with a stable level of foreign reserves. Georgia holds BB- long-term credit ratings in foreign and local currencies (S&P and Fitch) and achieved a successful Eurobond placement in April 2011, which was 5.3x oversubscribed.

Bilateral and Multinational Engagement: Georgia enjoys strong political and financial support from the international community, and the IMF, World Bank, ADB and the EBRD are active in the country. Since privatization in areas such as energy and telecommunications which have brought foreign private investors, Georgia is experiencing growing interest and investments from private foreign investors across a diverse range of sectors.

Leading Hub for Doing Business in the Region

"Silk Trade Route" Connecting Europe and Asia: Georgia has a strategic geographical position at the western end of the Silk Route connecting Europe and Asia. With Black Sea access, Georgia is the main gateway for land transportation of goods through to the Caucasus and the land-locked Central Asian countries, mainly from Turkey and its several Black Sea ports.

Headquarters Base for Doing Business in the Region: Georgia's role as a base for doing business in the region is also garnering attention, given its location, attractive trade regimes, and ease of doing business in Georgia comparison to that of the other countries in the region, as well as the safe and Western lifestyle experienced in Georgia that is attractive to expatriate staff. With ski resorts, spas, a wine industry, and the Black sea coast, Georgia is garnering attention as a new tourism destination. Its capital Tbilisi is charming and ripe with restaurants, cafes, and nightlife.

Synergies with Turkey and the Mid-East: Georgia also borders Turkey, which has booming economy and open and constructive trade and investment relations with Georgia. With significantly lower labor costs in Georgia, Georgia offers an additional location for basing business to focus on Turkey and other countries in the region. Proximity with mid-east nations also opens opportunities for trade links and a role as a hub for the region.

Low Input Costs

While offering an open, Western environment for business and an attractive quality of living, the cost of labor and other input costs are competitive in Georgia. The average gross monthly salary in Georgia was USD 346 in 2010. The prices of oil, gas and electricity in Georgia are also competitive in the

BB- sovereign credit ratings in long-term foreign and local currencies

5.3x oversubscribed Eurobond placement in April 2011

Bilateral and multilateral engagement for economic development

Silk Road trade route linking East to West

Preferred base for doing business in the region

Shares southern border with Turkey, emerging market star with GDP growth of 6.6% projected for 2011

Low labor, energy and utility costs

³ Source: IMF June 2011 Georgia report.

region, for electricity in particular due to Georgia's water resources that are increasingly being developed for hydropower. Lastly the affordability of land, due to the relatively undeveloped market in Georgia as well as government incentives for buying land through privatizations.

Additional Macroeconomic & Business Information

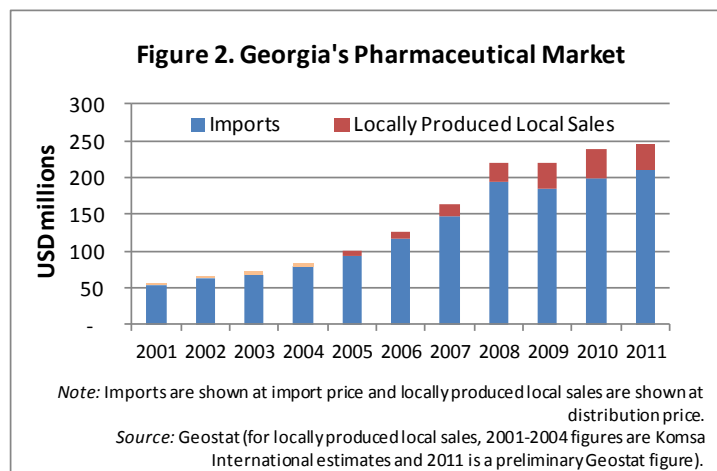
For more extensive information about Georgia the macro-economic and business environment in Georgia, please refer to Appendix A.

4. Pharmaceutical Retail & Wholesale



Historical Growth Performance

The Georgian pharmaceutical market is one of the fastest growing markets in the country. In fact the Georgian pharmaceutical market has grown dramatically from approximately **USD 57 million** in 2001 to **USD 245 million** in 2011, based on the value of pharmaceutical imports plus the value of locally produced pharmaceuticals sold in Georgia, as shown in the figure to the right.⁴ This represents a compound annual growth rate of **16%**. Though growth subsided in 2009 and 2010 due to the global economic situation, growth has already begun to recover in 2011, with a growth rate of **9%**.



The vast majority of the total market size is comprised of commercial private purchases. A small portion of 2010 imports consists of humanitarian aid (5%) and state purchases (3%) as well as pharmaceutical inputs for local production (5%).⁵

Potential Market Growth

⁴ Calculated from Geostat data, as shown in Figure 2. It is noted that the total retail market size is larger than the quoted amounts since the value of imports represents the costs to importers rather than the retail sale price, and local sales of locally produced pharmaceuticals are also quoted at distribution price.

⁵ Breakdown of imports in USD for 2010 from the Ministry of Health.

Strong growth in demand of pharmaceutical products in Georgia is expected for the future as a result of what is still a very nascent market, the overall economic growth expected in Georgia (annual real GDP growth of approximately 5-5.5% projected for the coming 4 years), and an ongoing government commitment by the government to advancing Georgian health care.

Furthermore, the per capita consumption of pharmaceuticals in Georgia is quite low, at **USD 35** per year, versus **USD 62** in Ukraine and **USD 99** in Russia, and a range of **USD 200-400** in Europe, demonstrating that there is significant potential for growth in the coming years⁶. It is noted that the percent of household income spent on pharmaceuticals is higher in Georgia than in most develop countries, but this is in part a result of low incomes and prioritization of spending on health. Plus, approximately only 30% of the Georgian population is covered by health insurance⁷, the vast majority of which is via a publicly funded insurance program for the poor, which does not cover pharmaceuticals except in limited amounts in some cases such as cancer treatment. This program will be covering a greater range of pharmaceuticals starting in 2012, but still in limited amounts for certain diseases only. Also recently announced is that the government program will cover all children under 5 years old and all pensioners over 65 starting sometime in 2012. As the percentage of the population covered by insurance increases, and as pharmaceutical coverage is incorporated into insurance programs, and as household incomes increase, expenditures on pharmaceuticals in Georgia can be expected to increase.

Market Structure & Key Players

The pharmaceutical retail and wholesale market in Georgia is largely dominated by two companies: Aversi and PSP, which are estimated to account for approximately **45%** of the market in 2010, based on USD amount of pharmaceutical imports. There are other key players, with 10 companies including Aversi and GM Pharmaceuticals dominating approximately **85%** of the market, also in terms of USD amount of pharmaceutical imports.⁸

In comparison to Western Markets, pharmaceutical shops in Georgia are smaller scale (approximately 30 sq m each on average) and also more prevalent in cities and even rural areas. In fact there are approximately **3,000** pharmaceutical retail outlets in Georgia, which is approximately one shop for every **1,500** people in the country.⁹ Part of the reason the large number of shops in Georgia is a result of very high profit margins given the lack of competition in the sector, allowing retailers to expand the number of their shops without cost concerns. Despite greater competition due to recent regulatory changes, there has been a shift to larger, more consolidated shops, but the many small shops continue to exist.

There are approximately **2,000** pharmaceutical retail companies in Georgia owning these retail outlets (that is, chains and owners of individual shops), but only **46** have more than two shops. The largest chains

Figure 3. Top 10 Pharmaceutical Retail Chains in Georgia (based on number of shops in 2011)

- | | |
|------------------------|---------------------|
| 1. Aversi | 6. PharmaDepot |
| 2. PSP | 7. Neopharm+ |
| 3. GPC | 8. Saaptiako Sakhli |
| 4. Sakhalkho Aptiaki | 9. Krystali |
| 5. Narinjispheri Pharm | 10. Hekate |

Source: Ministry of Health & other data

Figure 4. Top 10 Pharmaceutical Retailers and/or Distributors (based on USD amount of pharmaceuticals imported in 2010)

- | | |
|------------------|---------------|
| 1. PSP | 6. Impexpharm |
| 2. Aversi | 7. GEA |
| 3. Globalpharm | 8. Tonusi |
| 4. GPC | 9. Medinservi |
| 5. ABC Pharmacia | 10. Lilo |

Source: Ministry of Health

⁶ <http://cispharma.blogspot.com/2011/06/georgia-pharmaceutical-market-trends-in.html#more>.

⁷ <http://www.psidiscourse.ge>.

⁸ Based on 2010 import data from the Ministry of Health, breaking out commercial private imports only (that is, excluding humanitarian aid and commercial state purchase which together account for 7% of pharmaceutical imports in 2010).

⁹ Source: Ministry of Health. Figure is of 3,000 is approximate, based on a total of 2480 registered retailer companies as of July 2011 according to the Ministry of Health data, adjusting the figure estimating that a portion of these are registered but non-operating.

are Aversi and PSP, with a combined total of approximately **600** shops. The next two largest chains are GPC and ABC Pharmacia, which have a combined total of **140** shops. The other six companies among the top ten largest chains (in terms of number of shops) own and operate a range of approximately **20** and **40** retail outlets each.¹⁰

Many of the larger, leading pharmaceutical retailers are also engaged in pharmaceutical distribution in Georgia as well. There are also stand alone distributors not engaged in wholesale. While statistics detailing the number of wholesalers and the overlap with retailers is not available, statistics show that in 2010 there were **75** companies in Georgia that imported pharmaceuticals on a commercial basis (as opposed to humanitarian and state purchases). **44%** of commercial imports in 2010 were imported by the leading pharmacy companies PSP and Aversi (both operating as both retailers and wholesalers). PSP, Aversi, and 8 additional companies accounted for **85%** of imports in 2010 (see list of top 10 importers above). Importers/wholesalers benefit from the presence of many individually owned pharmacies in Georgia that are not in a position to import directly (approximately **1,950** companies own two or less pharmacy outlets).

Over the past several years, the leading pharmacy chains in Georgia have become integrally engaged in other parts of the healthcare system, including direct or indirect related ownership of insurance companies, hospitals and medical clinics. Please refer to Section 6 of this report for an overview of Georgia's healthcare system.

Company Highlights

Aversi: Aversi was founded in 1994, initially as an importer and distributor, eventually establishing a pharmaceutical chain. Today Aversi operates with roughly 250 pharmacy outlets, as well as an online Aversi pharmacy. Aversi also founded Aversi-Rational, which produces pharmaceuticals (mainly importing of bulk products and conducting packaging) and established a network of modern, well equipped clinics under the Aversi brand name. There are currently 7 Aversi Clinics throughout Georgia, construction of two more will be finished in nearest future, and Aversi has built and manages hospitals that were bought from the state under the hospital reform and privatization plan. It also established its own insurance company, Alpha. Aversi is one of the largest taxpayers within Georgia, contributing tens of millions of GEL to the state budget, on an annual basis.

PSP: PSP is the second largest pharmaceutical distributor and retail chain in Georgia, operating with roughly 250 retail outlets. PSP owns pharmaceutical producer GM Pharmaceuticals, which supplies to PSP retail chains and other pharmacies and chains as well. PSP owns one multi-profile hospital in Tbilisi which was bought from the state under the hospital reform and privatization plan. The hospital was recently reconstructed according to International standards. Like Aversi, the company also established an insurance company, PSP Insurance.

GPC: GPC is the third largest pharmaceutical company in Georgia. One of the new directions of the company is the import and sale of nutritional supplements in the Georgian market. Currently GPC contracts local and international manufactures to produce various OTC drugs and nutritional and dietary supplements with its own brand name (private labeling). The drugstore network GPC includes 37 drugstores in Tbilisi, and the company has 7 branch offices throughout Georgia. The company also has a recently new franchise network under the name "Red A" and in 2010 GPC opened a new chain called Citypharm (larger scale pharmacies) and plans to expand this line further. Along with its own drugstores GPC operates as a distributor and cooperates with more than 330 independent pharmacies.

¹⁰ Source: Ministry of Health. This counts individual outlets, including outlets owned individually and by chains. Figure is approximate, based on a total of 3,786 registered outlets according to Ministry of Health data, estimating that a portion of these are registered but non-operating.

ABC Pharmacia & PharmaDepot: ABC Pharmacia, the fourth largest distributor of pharmaceutical goods in Georgia, has been in existence for 10 years, initially as a pharmaceutical importer/distributor and eventually operating with handful of pharmaceutical shops under various names (including ABC Pharmacia and Mkurnali). As a result of regulatory reforms for Georgia’s pharmaceutical adopted in 2009 that encourage greater and more fair competition), ABC Pharmacia established a new discount pharmacy chain, PharmaDepot. PharmaDepot opened a number of large scale, discounted pharmaceutical shops in Georgia. The company has brought some of its other pharmacies into the PharmaDepot brand name and now operates with 32 retail outlets. As a result of PharmaDepot, the prices of a number of pharmaceutical products have dropped, and other retailers have begun to follow suit in establishing larger scale, discount pharmacy outlets. ABC Pharmacia also engages in some production of herbal medicines, outsourcing most parts of the production to other local producers. The company’s mission is to provide prescription medications for customers at the lowest prices on the market nationwide and they expect to increase number of our stores to 50 by the end of 2012 nationwide. Most recently, the European Bank for Reconstruction and Development (EBRD) provided ABC Pharmacia with a USD 4 million loan (via a local bank, partially drawn down) for further expansion throughout Georgia.

Availability of Products and Products Consumed

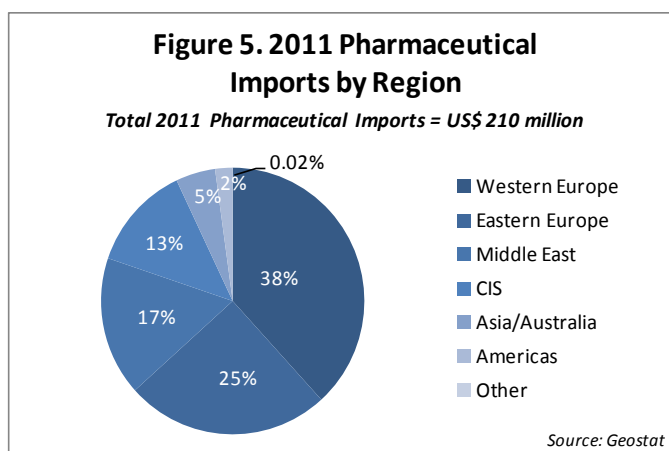
All routinely required pharmaceuticals are readily available in Georgia. There are approximately **10,000** types of prescription (Rx) and over-the-counter (OTC) medicines registered in Georgia. In 2010, it was reported that **1,000 to 1,200** applications for registration had been approved. However, in rural areas of Georgia, where pharmacies and healthcare facilities are smaller and less stocked, not all needed pharmaceuticals are always immediately or readily available. In addition, though under regulation hospitals are required to stock certain quantities of certain drugs, they are often under-stocked due to budgetary constraints and require patients to purchase their own drugs from pharmacies.

The ratio of Rx drugs to OTC drugs consumed in Georgia is **67% to 33%**. The top five drug types are A (Alimentary tract and metabolism), C (drugs affecting the cardiovascular system), J (anti-infectives for systemic use), N (drugs acting on the nervous system), and R (drugs acting on the respiratory system).¹¹

Source of Imports

Imports accounted for approximately **86%** of local pharmaceutical sales in Georgia in 2011, and imports of pharmaceuticals to Georgia have grown rapidly over the past five years, at a rate of **15%** per year from 2005 to 2011.

As demonstrated in Figure 5, imports are coming from a diverse range of countries, mainly from Western Europe, Eastern Europe and the Middle East. In 2011 pharmaceuticals were imported to Georgia from **60** countries, and the leading importer was Turkey, accounting for **16%** of imports based on USD import amount, followed by Germany, Hungary, Switzerland, France, and Ukraine with **10%, 7%, 6%, 6%** and **5%** respectively.¹²



¹¹ <http://cispharma.blogspot.com/2011/06/georgia-pharmaceutical-market-trends-in.html>.

¹² Source: Geostat.

In 2010 imports came from a total of 92 different foreign manufacturers (2011 data not yet available), with no set of manufacturers dominating the market (the highest single manufacturer market share was 10%). A number of these manufacturers have representation established in Georgia, or have given permission to a Georgian company to represent them in Georgia, to handle imports and/or to conduct brand marketing and monitoring, 13 of which are members of the Association of Pharmaceutical Companies Representative in Georgia (APCRG). The top 10 manufacturers of imports, based on USD amount imported in 2010, are presented in Figure 6.

Figure 6. Top 10 Countries Importing Pharmaceuticals to Georgia (based on USD imports in 2011)

- | | |
|----------------|-------------|
| 1. Turkey | 6. Ukraine |
| 2. Germany | 7. Poland |
| 3. Hungary | 8. Bulgaria |
| 4. France | 9. Austria |
| 5. Switzerland | 10. Russia |

Source: Geostat

Sale of branded pharmaceuticals used to dominate the market in Georgia, due to limited import supply channels and domination by branded, higher margin pharmaceuticals. In recent years, however, sales between branded and generic pharmaceuticals are more balanced. This is explained by a general growth of generics globally, as well as the result of liberalized regulation in Georgia allowing for parallel imports putting downward pressure on profit margins as a result of new competition, leading to a shift by some importer/distributors to towards import of alternative products including generics.

Figure 7. Top 10 Manufacturers of Pharmaceuticals Imported to Georgia (based on USD amount in 2010)

- | | |
|--------------------|-----------------------------|
| 1. World Medicine | 6. Berline Chemie |
| 2. Hoffman LaRoche | 7. Shering Bater |
| 3. NYComed | 8. Pfizer |
| 4. GlaxoSmithKline | 9. Les Laboratories Servier |
| 5. Sanofi Aventis | 10. Novartis |

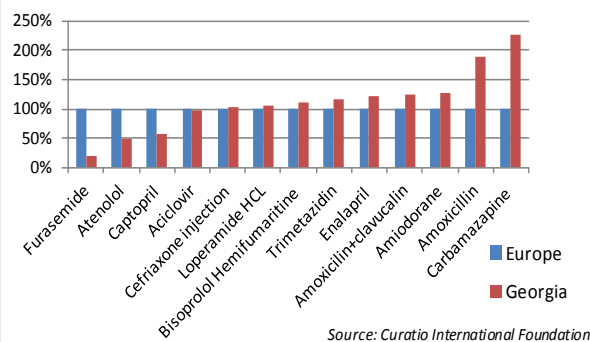
Source: Geostat

Pricing

As stated in the Section 7 of this report (Taxation, Regulation, & Quality Control), there is no regulation of pharmaceutical prices or mark-ups in Georgia.

According to an October 2010 study conducted on availability, price and affordability of pharmaceuticals in Georgia by the Curatio International Foundation, the prices of pharmaceuticals in Georgia are higher than in selected European countries in 70% of cases and are lower than in Europe in 30% of cases. This is based on a comparison of the prices of original brand and generics in Georgia with the average prices from selected European countries (Czech Republic, Hungary, Poland and Italy), as presented in Figure 8.

Figure 8. Average Georgian Pharma Prices as % of European Pharmaceutical Prices, 2009 Survey

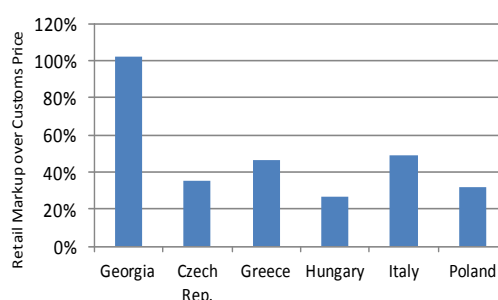


Source: Curatio International Foundation

The report also noted that when it analyzed the same set of drugs but for branded and generics separately, branded drugs more often cost more in Georgia than in Europe, while generics more often cost less in Georgia than in Europe.

The study also concluded that overall on average, the mark-ups on pharmaceuticals in Georgia are higher than the markups in Europe, based on a survey comparing Georgia to five European countries, as shown in the figure below. As presented in Figure 9,

Figure 9. Average Pharmaceutical Mark-Up Prices in Georgia vs. European Countries, 2009 Survey



Source: Curatio International Foundation

the average mark-up (from customs price to retail price) in Georgia is approximately 102% whereas in Europe the markup ranges from 27% to 49%.

As a result of regulatory reforms adopted in 2009 (mainly simplification of pharmaceutical regulation to encourage greater and more fair competition among), pharmaceutical prices have begun to come down from what were high prices. The main, visible impact thus far has been the entrance of a new pharmacy retail chain, PharmaDepot (owned by ABC Pharmacia), which opened a number of large scale, discounted pharmaceutical shops in Georgia, leading to what has been observed by the industry as a drop in prices of some pharmaceutical products by 25%. Some further drop in prices can likely be expected.

5. Pharmaceutical Production

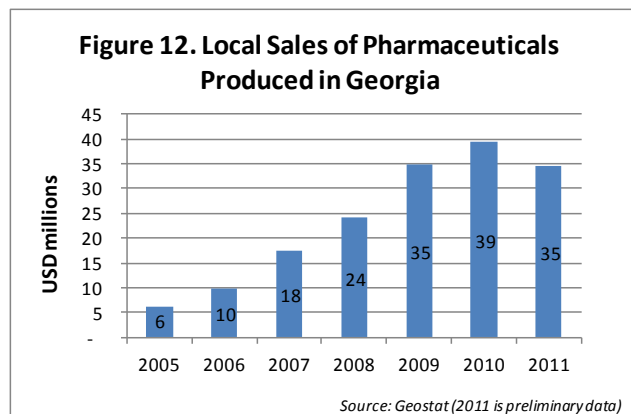
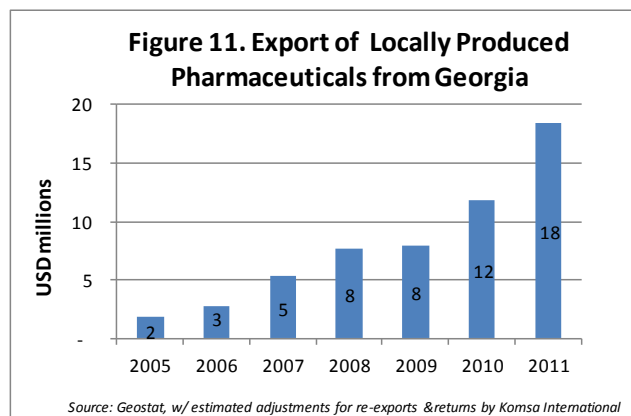
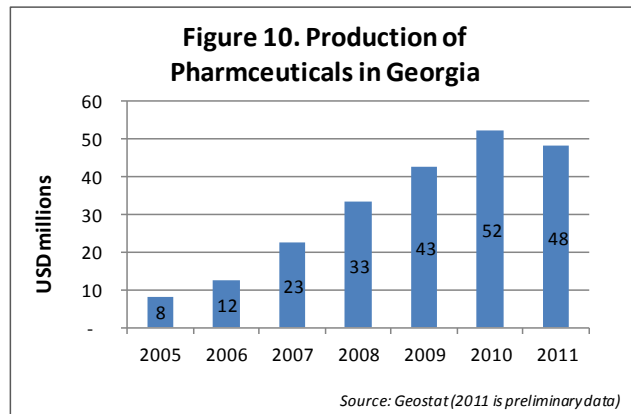
Historical Growth Performance

Local production of pharmaceuticals in Georgia, while still relatively a nascent sector, has been growing at an extremely fast pace, growing at an average annual rate of **35%** over the past six years. The total value of local production in Georgia in 2011 was **USD 48 million**, versus just **USD 8 million** in 2005.¹³

The value of exports of pharmaceuticals from Georgia was equivalent to **37%** of the value of total production in Georgia in 2011, up from a range of roughly 20-25% over five years prior. Like production, pharmaceutical exports from Georgia have grown at an extremely fast pace over the past five years, with a compound annual growth rate estimated at **47%** from 2005 to 2011. While growth was only an estimated **3%** in 2009 likely due to the local and global economic situation, growth in 2010 and 2011 was strong, at an estimated **48%** and **57%** respectively.

The above figures are for exports of locally produced pharmaceuticals only. Also of note is that Georgia has a market as a pass-through entity for sales of pharmaceuticals in the region, roughly estimated at USD 15 million in 2011.¹⁴

Growth of local sales of pharmaceuticals produced in Georgia has also been strong, with a compound annual growth rate of **33%** over the past six years (2005-2011). The ratio of local sales to exports has been decreasing, as a result of faster growth in exports. The existence of a robust market for local sales and exports of locally produced pharmaceuticals offers balanced risk for investors.



¹³ Source: Geostat (preliminary data for 2011).

¹⁴ This is an estimate because it is not possible to distinguish import returns versus re-exports in the data available.

Key Players

There are 70 pharmaceutical manufacturers registered in Georgia (as of July 2011), but it is believed that approximately only 50-60 of these are actively operating and most are quite small, as the two largest producers represent almost 90% of total local production in Georgia (in terms of revenue amount). These two largest producers are Aversi-Rational and GM Pharmaceuticals, both associated with leading pharmacy chains in Georgia. Neither company is engaged in primary production (that is, production of active ingredients, but they are engaged in secondary production. Aversi Rationale engages mainly in packaging, whereas GM Pharmaceuticals conducts both formulation and packaging. Both have certifications confirming compliance with European Good Manufacturing Practices (GMP), but from private European consulting firms rather than an actual EU government GMP certifying agency. While some other producers claim to follow European GMP standards, no other producers are reported to hold GMP certification, neither from private consulting firms or government certifying agencies. A summary of the key pharmaceutical producers in Georgia is presented below in Figure 13, followed by highlights on selected companies on the following page.

Figure 13. Key Players in Pharmaceutical Production in Georgia

Two Largest Producers:

- **Aversi Rational** (conducts packaging, broad range of products, associated with Aversi pharmacy chain, holds ISO, European GMP and US FDA certification but from private auditor rather than government certifying agencies)
- **GM Pharmaceuticals** (conducts formulation and packaging, broad range of products, associated with PSP pharmacy chain, holds European GMP certification but from private auditor rather than government certifying agencies, but expects to receive French GMP agency certification in 2012)

Other Major Producers:

- **Biopharm** (broad range of products)
- **Neopharm** (focus on and leader in herbal and dietary supplements, associated with Neopharm+ pharmacy, state-of-the-art factory, seeking investment/expansion)
- **Kamelini** (producer focused on herbal medicines and dietary supplements, including some patented products derived from honey)
- **Naturopharm** (focus on natural medicines)
- **BioChimPharm** (phages production)
- **Salkhino** (natural based dietary supplements)
- **Gama** (recently established with foreign investment)
- **Farconi** (focus on herbal medicines, as well as raw herbal materials)
- **TbilChimPharm** (regular and some natural pharmaceuticals)
- **Davati** (mainly veterinary medicines in partnership with InVet)
- **Pharmimpexi** (regular pharmaceuticals)

Other Notable/Niche Producers

- **Biopolus** (recent start-up based in Batumi already producing, spin-off from older historical producer in Batumi, with capacity/know-how to produce range of quality products and a new state-of-the-art facility currently under construction)
- **Apipharm** (newly established state-of-the-art facility, in start-up phase, focus on antibiotics)
- **Tbilisi Pharmaco-Chemistry Institute** (research institute engaged in production with unique drug innovation/brand)

Producers with Foreign Investment

- **Euromedical** (recently established with foreign investment, but still in early stages)
- **Gama** (recently established with foreign investment, but not yet grown in scale)
- **Iveriapharm** (small niche manufacturer of two naturally-based branded products)

Companies Producing Phages

- **Biopharm-L**
- **BioChimPharm** (mentioned above)
- **Bacteriopagi Biopreparatebi** (associated with Eliava Institute and engaged in production of phages and other products)

Some of the Leading Companies Producing Herbal-based Pharmaceuticals

- **Main players:** Neopharm, Kamelini, Naturopharm, Salkhino, Farconi, Kardu
- **Smaller niche players:** Phitopharm, Iveriapharm, Turmanidze, Khalkhur Medicina, Eskulapi

Types of Production

Among traditional pharmaceutical manufacturers (i.e., chemically based drugs), none of the producers in Georgia, not even GM Pharmaceuticals and Aversi (as noted above), are engaged in primary production (that is, production of active ingredients). However, in the areas of natural and herbal medicines and phages, two pharmaceutical areas niches where Georgia can be considered to have strong competitive advantages, producers are engaged in primary production.

Also of note, out of the 70 producers in Georgia, only 20 are importing substances (pharmaceutical ingredients). The others are either buying substances from companies among these 20, or are producing biological or herbal medicines where active and non-active ingredients are produced in Georgia.

Among traditional pharmaceutical products (i.e., other than herbal medicines and phages), production conducted in Georgia includes secondary manufacture (mixing active ingredients with other ingredients) and primary and secondary packaging.¹⁵ Almost all packaging materials are imported, with the exception of outer paper packaging and some other basic packaging. While some of these producers engage in secondary manufacturing, some engage in primary and/or secondary packaging only. Some of the companies engaged in secondary manufacturing do have their own dedicated small scale R&D programs.

The types of pharmaceuticals produced in Georgia, by illness types treated and by product form, are quite diverse, as presented in Figures 14 and 15.

Phages Production

In pharmaceutical R&D and production, Georgia has a special niche in the area of bacteriophages. Discovered in France in the early 1900s, bacteriophages are viruses that infect bacteria, and they have been used for over 90 years as an alternative to antibiotics in the former Soviet Union and Eastern Europe as well in France. Though more R&D is needed, they are seen as playing a potential role as a therapy against multi drug resistant strains of many bacteria. In 1923, the Eliava Institute was opened in Tbilisi, Georgia, to research this new science and put it into practice, which lasted through Soviet times, though never garnering attention in the West as a viable therapy. Now with the rise of drug resistant strains of bacteria, the potential role of phages is gaining new attention in the West.

The Eliava Institute continues to operate today with close collaboration with a number of local and international research institutions, universities, and medical and industrial organizations. There are also three private companies that manufacture phage pharmaceutical products, include ampoules and tablets.

Figure 14. Types of Pharmaceuticals Produced in Georgia by Form, 2010

- Tablets
- Sprays
- Syrups
- Powders
- Injections
- Extracts
- Capsules
- Gels
- Ingredients
- Balms
- Eye drops
- Air drug forms
- Granules

Source: Ministry of Health

Figure 15. Types of Pharmaceuticals Produced in Georgia by Illness Treated, 2010

- Gastrointestinal tract
- Cardiovascular system
- Central nervous system
- Pain & consciousness (analgesic drugs)
- Musculo-skeletal disorders
- Eye
- Ear, nose and throat
- Respiratory system
- Endocrine problems
- Reproductive system or urinary system
- Obstetrics and gynecology
- Skin
- Infectious diseases
- Immune system
- Allergic disorders
- Oncologic diseases
- Dietary supplements, herbal products, vitamins

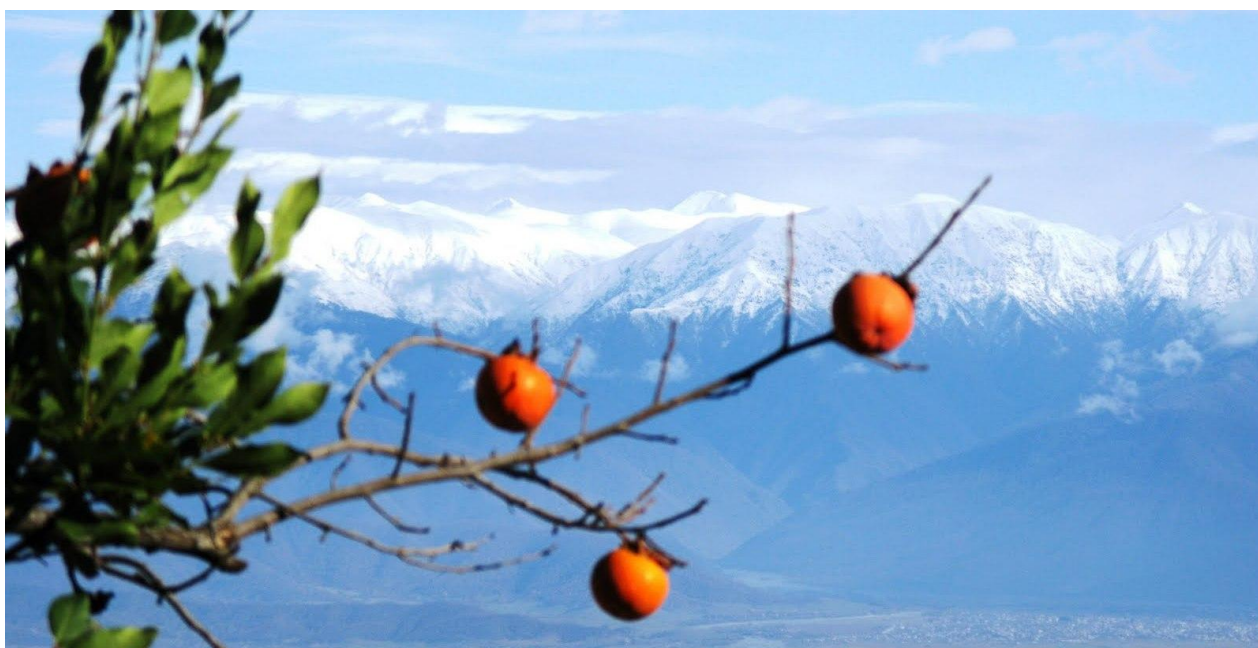
Source: Komsa International Survey/Interviews

¹⁵ Primary packaging is the packaging of pharmaceuticals into the packaging that is directly in contact with the pharmaceuticals, whereas secondary packaging is the outer packing on top of primary packaging.

Their products are sold in Georgia, Kazakhstan and Kyrgyzstan. Their bacteriophage preparations are used for treating typhus, salmonella, dysentery, food intoxications, gastroenteritis, urinary tract infections, and certain bacterial infections, as an alternative to antibiotics. Phages are also under development and/or under production in Russia, Israel, India, Canada and Australia, however Georgia holds a historical and competitive edge in the breadth and depth of its research and breadth of specimens.

With further R&D and marketing, bacteriophage preparations have in some cases the potential to gradually substitute antibiotics and gain share of the worldwide market of medications against bacterial infectious diseases. Phage therapy is harmless, risk-free and effective biologic alternative to antibiotics. Phage preparations, having no side effects, qualify as over-the-counter prescription-free drug in any health system.

Natural & Herbal Medicine Production



There are a number of manufacturers in Georgia that focus on natural and herbal medicines and dietary substances, and these producers are engaged in primary production (production of active ingredients, with such being herbal extract) and secondary production, and operation with R&D units for product development. These producers are selling in the domestic market and exporting, mainly within the CIS region. The larger players in this field are Neopharm, Kamelini, Naturopharm, Salkhino, Farconi, and Kardu. All of these companies are producing mainly liquid extracts for oral consumption, powdered herbal medicines (for example for cold and flu), and dietary supplements. Kamelini produces medicines derived from honey using their own innovations, and Salkhino is a well known dietary supplement brand. Some other notable players are Phitopharm, Biopolus (which does general pharmaceuticals but also some herbal), Khalkhur Medicina and Turmanidze (produces natural skin ointments based on the traditional herbal recipes of a famous, historical Georgian doctor).

Global demand for medicinal herbs and plants is currently growing at 8-10% annually, according to the International Council for Medicinal and Aromatic Plants. Georgia can be considered to have a competitive advantage in the area of herbal medicine production. Georgia has over 40 varieties of medicinal herbs and berries growing wild in its high mountainous regions, and there has been focus on and knowledge of herbal medicines dating back centuries in Georgia. Also adding to Georgia's competitive advantage are the prevalence of uncultivated agricultural land (whereby unused land can be easily established for

pristine, organic production of herbs) and Georgia's low labor and energy costs associated with agriculture.

Despite the handful of players mentioned above and significant demand from within the CIS and the EU, the medicinal herbs and plant sub-sector remains largely underdeveloped in Georgia. The main reason for this is that under the current 2005 Forestry Law only collection of wild herbs and berries for personal use is permitted, and because of the strict regulatory barriers for exporting to the EU (EU regulations for hygiene, labeling, marketing, plant health and importing licensing).

While there is a strong base of pharmaceutical manufacturers producing herbal/natural based products, it is also noted that much of the medicinal herb exports are going to Ukraine, Azerbaijan, Armenia, and Latvia as semi-finished products (in the form of dried herbs), and thus there is significant room for greater value added within Georgia, and for penetration of new, high demand markets such as the EU. Also of note is that just four herbal products account for approximately 80% of the total tonnage of herbs collected in Georgia: Eucalyptus, Bilberry, Dwarf Everlast Flower and Rosehip. Meanwhile, interviews with Georgian businessmen indicate that final product manufacturers and importers of herbs and medicinal plant products in Eastern Europe and EU countries are increasingly interested in establishing direct relationships for sourcing herbs and herbal medicines.

With investment into R&D, cultivation, processing and marketing, there are opportunities to increase sales (both quantities and varieties) of raw medicinal herbs and plants and finished products to the CIS and penetrate EU markets (where wholesale prices are as much as 50% higher than in Eastern European markets).

Producer Highlights

Aversi-Rational: Associated with Aversi pharmacy chain, Aversi-Rational is one of the two largest pharmaceutical producers in Georgia, producing almost 60% of the total locally produced supply in terms of US dollar value and also exporting, mainly to CIS countries. Aversi-Rational buys finished pharmaceuticals in bulk and conducts packaging only. It produces 107 medicines with 175 varieties. The company operates with new medical equipment of American, Japanese, and European origin and a modern fully equipped laboratory to perform chemical analyses on raw materials. Aversi-Rational holds an ISO Certificate from TUV SUD Management, a reputable European auditing firm (awarded in 2006), and a certification from the same company confirming compliance with European GMP and US Food and Drug Administration (FDA) standards (awarded in 2008). The company is fully Georgian owned, established without foreign investment.

GM Pharmaceuticals: Associated with PSP pharmacy chain, GM Pharmaceuticals is one of the two largest pharmaceutical producers in Georgia, producing approximately 30% of total locally produced supply in terms of US dollar value and also exporting, mainly to CIS countries. GM Pharmaceuticals also holds a private certification confirming compliance with European GMP (also from TUV SUD Management) and expects to achieve GMP certification from an official government certifying body (France) in early 2012. GM Pharmaceuticals is engaged in production (e.g., formulation, mixing, etc), not just packaging, and sells within Georgia and exports, mainly to CIS countries. GM Pharmaceuticals produces a broad range of products, including a mix of branded and generic drugs and covering a range of illnesses and in the forms including tablets, syrups, powders, extracts, capsules, gels and eye drops (though mainly solid forms, such as tables). GM Pharmaceuticals is based in the capital Tbilisi and is fully Georgian owned (e.g., no foreign investment).

Biopolus: A recent start-up located in Batumi, established as a spin-off from Batfarma (see below), this company has been producing a range of pharmaceutical products for domestic sale and export since 2010. The company is in the process of constructing a state-of-the-art production facility that will be in

compliance with GMP requirements. The company produces 60 pharmaceutical products approved with the government of Georgia. While it produces products with a range of such as tablets, capsules and powders, its main focus is production of ampoules, and claims to be the leading ampoule producer in Transcaucasia. The company sells throughout Georgia and exports, and is fully Georgian owned (that is, no foreign investment to date).

Neopharm: Like Aversi Rational and GM Pharmaceuticals, Neopharm is also a producer that is associated with a retail pharmacy chain: Neopharm+. Neopharm focuses on herbal and dietary supplements with biological active ingredients. In addition to sales in Georgia, Neopharm exports to Belarus and Ukraine, mainly substances for example powders for injections) and syrups of herbal recipes sold to manufacturers in those countries. Neopharm has been producing pharmaceuticals since 1991 and has a strong and well qualified management team. For the future, they seeking to cultivate their own lands for production of herbs, upgrade or build a new factory, and achieve GMP standards and certifications.

Apipharm: This is a newly established company that will focus on antibiotic production. While some other producers in Georgia are importing antibiotics and conducting packaging only, this will be the first case of full antibiotic production in Georgia (aside from importing of active ingredients). Construction of the facility is nearly completed, after which the company will enter its production test trial stage. The company's strategy is to operate as a contract manufacturing organization (CMO), with contracts to produce on behalf of Georgian pharmaceutical retailers and eventually for foreign companies as well, mainly in the CIS but potentially for European companies as well. The company has experienced, high quality management coming from other Georgian producers and with international experience and European GMP standards expertise. While the company does not have GMP certification, management holds that production will be carried out according to European GMP standards and all equipment is new and state-of-the-art, from Germany, Croatia and China.

BioChimPharm: This is one of the three private companies that manufacture phage pharmaceutical products, including five product types in the form of ampoules and tablets. Their products are sold in Georgia, Kazakhstan and Kyrgyzstan. The company seeks to expand sales to other markets, which requires R&D and marketing efforts, but most recently obtained positive lab result from Australia. The company has worked in partnership or with grants from foreign institutes over the years and welcomes investment or partnership to support R&D, marketing, and export expansion.

Batfarma: This is the former Batumi Chemical-Pharmaceutical Factory, which was founded in 1939 and manufactured natural caffeine from tea and other substances from plants in the region. Today, the company produces a wide spectrum of pharmaceuticals (approximately 40 products), both regular and natural/herbal products, including tablets, ampoules, and capsules. Products are sold in Georgia and exported to Caucasian and Central Asian countries.

Export Markets & Potential Growth

In 2011, Georgia exported locally produced pharmaceuticals to 16 countries. As shown in Figure 16, the bulk (93%) of Georgia's exports go to the other Caucasus Countries and Central Asia. 6% goes to other CIS countries percent goes to other countries, and 1% goes to other countries, mainly new export markets in Africa, Asia and the Middle East. Figure 17 presents Georgia's new markets for pharmaceutical exports over the past two years.

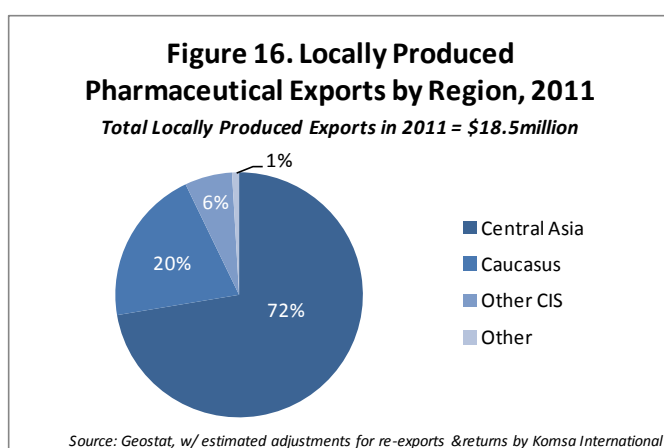


Figure 17. Export Markets for Locally Produced Pharmaceuticals

Main Export Markets (established and growing)	Smaller Export Markets (established and growing)	Recently New Export Markets (in past two years)
1. Uzbekistan	13. Turkmenistan	8. Moldova
2. Armenia	14. Belarus	9. Libya
3. Tajikistan	15. Russia	10. Sierra Leone
4. Kyrgyzstan	16. Bulgaria	11. Australia (believed to be small/special orders of phages)
5. Azerbaijan		12. India (believed to be samples or small initial orders)
6. Ukraine		
7. Kazakhstan		

Based on USD export amounts for 2005-2011. Data from Geostat, with estimated adjustments by Komsa International to remove re-exports and import returns.

Contract Research & Contract Manufacturing

Contract Research Organizations (CROs)

With rising R&D costs and shorter cost-recovery periods, Western pharmaceutical companies seek cost effective solutions for bringing drugs to market. The average cost of clinical trials, for example, has risen to nearly 60% of total development costs in recent years, compared to just over 30% in the 1980s.¹⁶

While the amount of contract research outsourcing in Georgia is still limited, the level of activity is on the rise. Individual groups of doctors and hospitals have historically been offering contract research services in Georgia, primarily later stage and phase 3 clinical trial services. There are also four global clinical research CROs that have either branch offices or local partnerships in Georgia. These are Worldwide Clinical Trials, Parexel, MB Quest and Cromos. Now with a growing set of well equipped new hospitals and research labs, CROs are positioned to research contracts other than for clinical trials alone.

While not a complete data set, the World Health Organization's (WHO) International Clinical Trials Registry Platform (ICTRP) shows 16 clinical trials registered in Georgia in 2010 and 19 in 2011. Most of these clinical trials are led by major U.S. and European companies, where Georgia is represented among a total of 2-20 countries per trial. Though still low in number in comparison to that of many Eastern European Countries, this is a steady increase since 2004 and 2005 with just 5 and 2 trials registered in the database respectively.¹⁷

Latin America, Eastern Europe and Asia have experienced rapid growth in FDA-regulated clinical trials in recent years, a result of offering lower study costs as well as increasing comfort in working in emerging markets due to harmonization of good clinical practice guidelines, increasing availability of well trained professionals, and treatment-naïve patients. Most of these clinical trials are for confirmatory, later stage studies, as is the case in Georgia. Central and Eastern Europe is the largest non-Western region for clinical trials, with 8.5% of all active FDA-regulated investigators being based there.¹⁸

In comparison to Eastern Europe, Georgia offers lower labor costs, high patient recruitment rates, and an increasing ability to meet Western standards for research and testing efficacy and safety. Normally in the Western world patients are paid to participate in clinical trials, but participation is mostly unpaid in

¹⁶ The Center for Information and Study on Clinical Research Participation, http://www.ciscrp.org/professional/facts_pat.html.

¹⁷ <http://apps.who.int/trialsearch/AdvSearch.aspx>.

¹⁸ The Center for Information and Study on Clinical Research Participation, http://www.ciscrp.org/professional/facts_pat.html.

Georgia as patients are motivated to participate and provide consent in order to receive free-of-charge medical services as part of clinical trials such as diagnostic tests, provision of drugs, and sometimes transportation cost reimbursement.

Contract Manufacturing Organizations (CMOs)

With growing competitiveness in the pharmaceutical market and a focus on cutting costs, pharmaceutical companies are increasingly turning to specialized, niche contract manufacturing organizations (CMOs) as well, with lower-cost international CMOs capturing an increasing portion of the CMO market. While no Georgian producers are currently contracting for international pharmaceutical companies, some producers are contracting for the leading pharmaceutical retailers in Georgia, and are beginning to pursue contracts for production for companies in Ukraine and other parts of the CIS. With a rapidly growing pharmaceutical production industry, increasing capital investment and a commitment to achieving international standards by both the government and the private sector players, it is expected that the CMO role in Georgia, for serving the CIS and elsewhere, will increase.

6. Overview of Healthcare in Georgia



Background

Until 1991, the Georgian health system was part of the Soviet system, which was characterized by almost complete public ownership of healthcare services. After the Soviet collapse, while the country struggled with economic and political hardship during the transition to a market system, real per capita public expenditures on healthcare rapidly declined, and the physical condition of facilities severely deteriorated, as did medical technology and equipment.

Since independence, Georgia has made significant strides to reestablish and reform its health care system. In 2004, Georgia changed from a social health insurance system to a privatized health insurance system, as part of an overall liberal approach of lessening the role of government in providing, financing, and managing public services.

Figure 18. Georgia Population Health Statistics (2009 & 2010)

Population:	4.4 million
Over 60 years old:	19%
Median age:	37
Life expectancy:	71
Fertility Rate:	1.6 children per female
Adult Mortality Rate:	164 deaths between 15-60 year age per 1,000
Infant mortality rate:	20 deaths before age 1 per 1000 live births
Under-5 mortality rate:	22 deaths before age 5 per 1000 live births

Leading causes of death: Diseases of the circulatory system, neoplasms, accidents and injuries, diseases of respiratory and digestive systems and “other”. Tobacco a major contribution to disease.

Sources:

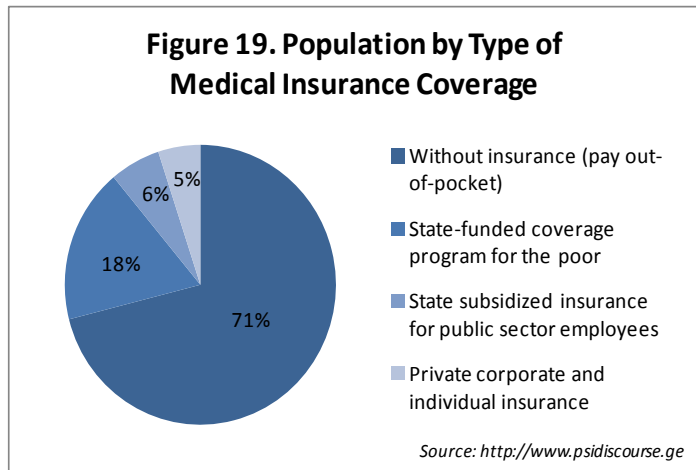
Population: International Monetary Fund (IMF), 2010.

Health Statistics: WHO Global Health Observatory Data Repository, mix of 2009 & 2010.

Leading causes of death: WHO.

Medical Insurance Coverage

Health care and medical insurance in Georgia is privatized; however, since 2007 the government provides health care coverage for Georgians who live below the established poverty line (which currently covers approximately 18% of the population) and provides public sector employees (such as teachers, police and military) with state subsidized insurance programs (which currently covers approximately 6% of the population). A limited set of people are covered by private health insurance programs purchased by private corporations, state agencies and individuals (currently 5% of the population). In total, approximately 29% of the population is currently covered by medical insurance. The remaining 71% of the population pays for health care out-of-pocket.



The state program that provides coverage for the poor is called the Medical Insurance Program for the Poor (MIP). Public funds from the Ministry of Labor, Health and Social Affairs (MoLHSA) are used to provide vouchers to Georgians who are eligible under certain poverty level measurements and can then purchase health insurance for approximately USD 5 per month. Per agreement with and the subsidy from the MoLHSA, the insurance is provided by private health insurance companies in Georgia. The benefit package includes primary health care services but without drug benefits except in some very limited cases such as cancer treatment. Other benefits include limited diagnostics, emergency outpatient and inpatient services, physiologic services, planned hospitalization, and chemo or radiotherapy for oncology patients within certain limits.

Fully private insurance (for corporations and individuals) offer packages with varying scope of coverage, some of which include pharmaceuticals and some of which do not. Primary care doctors typically act as gatekeepers for patients covered by private health insurance; patients are free to self-refer to more specialized inpatient services. With economic growth, private insurance companies in Georgia are positioned to increase business, and in fact has attracted the attention of investors. Recently the International Finance Corporation (IFC), the World Bank’s investment arm, has co-invested with Archimedes Global into health insurance ventures in Georgia, in an aim to make health insurance and sufficient health services more accessible to the population.

Private & State Expenditures on Health Care

Over the years, chronic under-funding and instability of financial resources persisting throughout the reform process has affected the functioning of health care system and is the main reason for the substantial shift of expenditures to out-of-pocket systems. As a share of public financing, health sector allocations remain low, but recently improved fiscal revenues have allowed the government to increase state allocations to health sector, as demonstrated in Figure 20, and future expenditures are expected to rise further.

Figure 20. Public expenditure on health in Georgia

	2006	2007	2008	2009	2010
Public expenditure on health (USD millions)	144	153	230	251	na
as % of total government expenditures	7%	5%	6%	8%	na

Source: Ministry of Labor, Health & Social Affairs – National Health Accounts

Figure 21. Statistics on Health Expenditures in Georgia, 2009

Per capita total expenditure on health	US\$ 256
Per capita government expenditure on health	US\$ 73
Private expenditure on health as a percentage of total expenditure on health	71%
Social security expenditure on health as a percentage of general government expenditure on health	65%
Out-of-pocket expenditure as a percentage of private expenditure on health	94%
Total expenditure on health as a percentage of gross domestic product	10%
General government expenditure on health as a percentage of total government expenditure	8%

Source: WHO Global health Observatory Data Repository

As shown in Figure 21, private expenditures on health are still quite low and can be expected to rise significantly with income growth. This is also true for pharmaceutical expenditures, which as mentioned earlier in the report are quite low, at an average of **USD 35** per year per person, and can be expected to rise.

As noted earlier in the report, approximately 3% of the pharmaceutical retail market is state purchases. These purchases are for the following patient groups under state-funded public health programs:

- Adults with diabetes mellitus (insulin provision);
- Children and young adults with diabetes mellitus (insulin and glucagon);
- Children and adults with hemophilia (anti-hemophilia factor concentrates);
- Terminal oncology patients (painkillers);
- Organ transplant patients (immunosuppressants);
- Patients with diabetes insipidus;
- Anti-rabies vaccine for children aged 0–15 and vulnerable populations;
- Immunization (vaccine procurement, storage and cold chain maintenance);
- Food supplements for children with phenylketoneuria;
- Patients with the cystic fibrosis;
- Substitution therapy for dependent drug users (methadone programs).

Health Care Reform Efforts

Aside from the recently launched MIP program, the role of government in regulating healthcare and financial transactions has been greatly reduced since 2003. For the 71% of the population without healthcare coverage, high costs in comparison to incomes reduce the majority of the population's access to healthcare and pharmaceutical drugs. The government's approach has been to allow market mechanisms to regulate the relationships between patients, providers, and third-party purchasers, and with a limited government role in regulation, measuring and ensuring quality of care is limited.

Also of note is that healthcare system in Georgia has had an over capacity in terms of human resources and hospital space – a legacy left from Soviet times. There has been an extremely high number of doctors and hospital beds per capita in Georgia compared with other European countries. There have been three

times as many physicians in the nation's capital city, Tbilisi, than in rural areas. Lastly, there have been low utilization rates of both inpatient and outpatient services, as well as pharmaceutical drugs, suggesting that there are barriers, primarily cost-related, to healthcare access. With reforms, however, these characteristics have been changing.

Earlier health care system reforms have focused on reducing overcapacity of health care infrastructure and human resources inherited from Soviet times, allowing the private sector to occupy a greater role in the provision of medical services, establishing a system of medical insurance, strengthening the provision of primary and preventive health care services, and reforming the sanitary-epidemiology system. More recent reforms were directed towards offering increased financial protection to poor (including the MIP program of purchasing private insurance for the poor, described above), promoting private insurance to reduce the incidence and volume of out-of-pocket payments, and increasing investments in infrastructure. Part of recent efforts to make higher quality medical services available and affordable to the population has been investment to remodel and equip primary health care facilities and re-train staff into family doctors and nurses. Clinical guidelines were developed and approved by the MoLHSA and providers trained in these guidelines.

Currently in Georgia a new health strategy document is under development which will guide the MoLHSA activities over the next five years (2011-2015). The health strategy identifies objectives with the outcome targets set by 2015. Reduction of child morbidity and mortality remains among the key health outcomes which should be achieved by introduction of new vaccines in the National Immunization Program. Specifically the goals will focus on the following:

- Reducing mortality rates primarily among children and the working age population
- Reducing overall morbidity:
 - By reducing the incidence of diarrheal and respiratory illnesses among children through the introduction of new vaccines in the national EPI program and improved management of delivery services and childhood illnesses;
 - Through adequate screening and provision of quality curative services for cardio-vascular diseases and neoplasms;
 - Through prevention, timely detection and treatment of TB and HIV/AIDS;
 - Through the implementation of preventive programs aimed at reducing trauma and promoting a healthy lifestyle to reduce tobacco and alcohol consumption and improve diet.

Throughout the period of reforms, the government has been closely engaged with the international community, working with financial, policy and technical assistance from the World Bank, the United Nations Children's Fund (UNICEF), WHO, UNFPA (United Nations Population Fund), the American International Health Alliance (AIHA) and other government donors.

Hospital Privatizations

The latest development in healthcare reform has been in the area of hospital reform, namely privatization, optimization of hospital beds and improvement of infrastructure. According to the hospital master plan, all types of investors were allowed to participate in tenders for hospital privatization, including pharmaceutical and private medical insurance companies (typically whereby bidders can buy older hospitals in prime real estate locations for development for other commercial purposes with the agreement to build and operate a state of the art hospital in an alternative area). By 2013 up to 150 new small, medium and large sized hospitals will be constructed or renovated throughout the country with support of private investments. As part of this, the private insurance companies that won the government tenders to insure the poor population for at least three years are required to build new hospitals in the regions of Georgia (i.e., outside of the capital). To date, USD 103 million has already been

invested in the hospital sector by private investors from Georgia, as well as from Canada, Poland, Israel, Check Republic and UK, and several of these new hospitals, fully equipped and state-of-the-art, have already been built and opened for operation. The program has faced some challenges in its earlier stages, in terms of the speed and quality of new hospital development and management by some tender winners, but is now on track with qualified and properly incentivized partners.

Links between Pharmaceutical Companies, Insurance Companies, Clinics and Hospitals

The two largest pharmaceutical retail and distribution companies in Georgia – Aversi and PSP – were founded as distributors, but over time they have opened pharmacy networks, clinics, insurance companies, hospitals, and have begun to manufacture pharmaceuticals (Aversi owns pharmaceutical manufacturers Aversi Rational and PSP owns pharmaceutical manufacturer GM Pharmaceuticals). Some people have viewed this to represent oligopolistic business involving collusion to set the prices in their pharmacies, but as described above, government regulation has been reformed to facilitate greater competition and there are indeed other players coming into the market and now operating with significant market share. Though these two pharmaceutical companies are also engaged in insurance, there are a number of other insurance companies not involved in the pharmaceutical industry. Also as noted above, as part of the agreement by the insurance companies who are handling the government's insurance program for the poor, the insurance companies have been required to build and operate hospitals.

7. Taxation, Regulation, & Quality Control



Since independence, the pharmaceutical sector has undergone many reforms and changes, starting with general reform of health care in 1994. The aim of reforms in the pharmaceutical sector has been to provide the population of the country with safe, effective and high-quality drugs and to ensure their appropriate prescription and use, and in comparison with other post Soviet countries has been quite successful in achieving good results in the sector.

Tax Exemptions

One of the first reforms was the introduction of a business friendly tax base. There is currently no import tax and no Value Added Tax (VAT) on pharmaceuticals. There is no VAT charge to the consumer when purchasing pharmaceuticals, nor to companies purchasing pharmaceuticals for resale (e.g., pharmaceutical retailers do not have to pay VAT to pharmaceutical distributors). The VAT exemption for pharmaceuticals was adopted as a policy in order to achieve better prices for customers (as the VAT charge in Georgia would otherwise be an additional 18% charge to customers).

There is also no VAT or import charge on medical devices, as well as on any inputs that are determined to be exclusively for the pharmaceutical industry (for example, blister packaging or equipment specifically for pharmaceutical production).

However, it is noted that the VAT exemption does not exclude pharmaceutical companies from paying VAT on non-pharmaceutical inputs (ongoing operational expenses such as petrol, office supplies and rent and initial capital expenditures such as blister packs, certain lab equipment and other pharmaceutical production equipment). Although pharmaceutical companies benefit from the policy in that they can offer better prices to the customer, it can also create a greater tax burden because there is no mechanism for getting reimbursed for VAT paid on inputs if the company itself is not collecting VAT on sales from which it can then deduct such VAT expenses. A regular, non-pharmaceutical company is ultimately “VAT neutral” in that it can deduct VAT expenses from the VAT it collects, paying the government only the difference. However, if a company sells pharmaceuticals only and therefore does not collect any VAT on sales, there is no mechanism for deducting VAT expenses and thus such VAT expenses on ongoing

operating expenses and capital expenditures is a permanent cost. Some companies (for example, pharmaceutical retailers) also sell a number of non-pharmaceutical products such as toiletries. In such cases the company calculates the percent of sales on which it collects VAT and can then deduct the same proportion of VAT paid on inputs from its VAT payments due to the government.

Key Reforms & Liberalization of Regulation

In the wake of early reforms and the tax exemptions adopted for the pharmaceutical sector, three dominating players emerged in the retail and wholesale pharmaceutical market – Aversi, PSP, and GPC – and the market became characterized by high pharmaceutical retail prices and high profit margins. These players began as distributors and then pharmacy networks (and producers), and over time also began opening medical clinics, insurance companies, and hospitals. This resulted in a general view that the industry was oligopolistic and colluding to set prices in their pharmacies.

In reaction to this, in March 2009, the government introduced amendments to pharmaceutical laws in an effort to induce greater competition in the sector. Amendments were adopted by the Parliament of Georgia to simplify the registration procedures for pharmaceuticals and to allow for greater competition in the pharmaceutical sector. Most significantly, the amendments included simplified registration procedures for drugs recognized by the European Medicines Agencies and certain other countries (prior to this amendment, the registration process was far more lengthy, burdensome and time consuming, including significant product documentation from the drug producer), allowing for parallel imports, simple notification procedures for parallel imports, and simplified registration and regulations for pharmacies.

These amendments are considered to have been quite effective, and indeed have led to greater competition. As a result of these changes, a number of new wholesalers/importers have emerged, the number of registered drugs has increased, and several new pharmaceutical chains have entered the market. Most notably, the end result of this, and primarily the result of the new pharmaceutical retail chain PharmaDepot, which opened a number of larger scale, discounted pharmaceutical shops, the retail prices of some pharmaceuticals in Georgia have dropped 25%, according to observation by some people in the pharmaceutical industry.

Overall the results of these changes have been viewed positively, with a few caveats. With the introduction of parallel imports in Georgia, some companies have stated that they believe that although this has led to improvements in competition, it has also opened the door for greater instances of counterfeit drugs and lack of control about the origin and quality of drugs. However most companies stated that counterfeit drugs is not a major issue in Georgia. Also, some producers have noted that the simplifications for importing drugs from the EU and other selected countries had had a negative impact on the competitiveness of locally produced drugs, which still require lengthy, case by case approvals. Lastly, there have been some reports from companies that have attempted to or gone through the process of registering drugs to import that they still face challenges or bureaucratic barriers despite the simplified regulation.

Also with regard to quality control and consumer rights, it is required in Georgia that the name of the company and the country of the final manufacturer are placed on pharmaceutical product labels. However, there is no requirement that the origin of the active ingredients or imported finished products (for example, tablets where only packaging is done in Georgia) is placed on labels. Thus for pharmaceuticals packaged in Georgia, consumers are not necessarily aware of where the origin of products or where most of the manufacturing is done (for example, pharmaceuticals packaged in Georgia but sourced from India). This impacts consumers, as well as producers trying to compete with such products.

Key Licensing & Regulatory Procedures:

The Agency for State Regulation of Medicine Activities is responsible for state quality control of pharmaceutical product safety, which handles the regulations and procedures outlined below.

Pharmaceutical Producers:

Pharmaceutical producers must obtain an initial license, for which documents must be submitted outlining facility construction plans, technical plans, and staffing plans. There are no annual registration or license renewal procedures, and there is no GMP type certification process in Georgia that looks at the condition and processes taking place at the production facility and there is no annual licensing or registration renewal process. Only products produced are subject to a review and registration process, which is outlined below. However, there is a range of regulations and standards specified in Georgian law about pharmaceutical production to which companies are expected to adhere, and the products are subject to selective control testing by the Agency for State Regulation of Medicine Activities (the agency is authorized to purchase products at the retail level to take for laboratory testing).¹⁹

Pharmacies:

The March 2009 amendments changed procedures for pharmacy operation from a lengthy licensing procedure to a simple notification procedure with the exception of Category 3 pharmacies.

In Category 1 pharmacies, only OTC drugs can be sold. These can be set up in supermarkets/convenience stores, and it is not necessary to have a pharmacist or any other employees with medical education on staff. For licensing, there is a simple notification procedure. In Category 2 pharmacies, prescription and OTC drugs can be sold, and as for Category 1 there is a simple notification procedure only. Other than the notification, there are no annual registration renewals or notifications required, but there is a range of regulations related to pharmacy operation, for example related to shop design, sanitation, product storage, product traceability, disposal of expired pharmaceuticals, and staffing. Pharmacies are also subject to selective control inspections by the Agency for State Regulation of Medicine Activities to check for compliance with these regulations and standards. Also of note is that as part of the amendments made in March 2009, a medical degree or a pharmacy degree is sufficient to work as a pharmacist.

In Category 3 pharmacies, prescription and OTC drugs can be sold, as well as drugs under special control such as psychotropic drugs and sleeping pills. Category 3 pharmacies require special permission from the Agency for State Regulation of Medicine Activities and are subject to special, ongoing regulation as well.

Distributors (Importers/Wholesalers):

There are no specific registration and licensing procedures for distributors at time of formation other than notification and the drug registration regulation for each specific type of drug imported, summarized below. However, there are regulations and standards to which distributors must comply, similar to those areas for pharmacies, for example, in areas such as storage conditions and product traceability, and distributors are also subject to the random inspections as described for pharmacies.

Registration of Drugs:

1. Simple recognition procedures for drugs recognized by the European Medicines Agency and certain other countries (please see Appendix B for a list of countries included): For the first import

¹⁹ The Ministry of Health has approved of the handbook of selective control and is responsible to ensure that the agency complies with it. According to the handbook, selective control is based on risk assessment (technical regulations, guidelines, which include rules and conditions on when and how to conduct selective control).

of such a drug (branded or generic), the importer or manufacturer must submit documentation for administrative review by the Agency for State Regulation of Medicine Activity, and within 7 days the government issues approval and publishes information about the approved drug in the publicly available agency registry.

2. Registration of drug products to be imported to Georgia that are not eligible under item 1 noted above: The importer or manufacturer must submit a set of registration documents based on which the agency will then carry out administrative, scientific and technical review. This applies equally to branded and generic drugs. Based on discussion with industry players, this registration typically takes an average of 3 months.
3. Licensing and registration of pharmaceuticals produced in Georgia: The process for approval involves submission of various administrative, scientific and technical documents as well as sample products, and the approval process, assuming all documentation is in place, also typically takes 3 months.
4. Simple notification procedures for parallel imports. After approval of a new drug by the initial importer (that is, per item 1 or 2 above), any other importer may import the same drug through a simple notification process rather than another registration/approval process, provided that with notification the importer submits the required documentation demonstrating authorization and approval of the provider, the product, and its packaging and marking under the laws of the source country). Within 5 working days, the government is obliged to accept the parallel import notification and add it to the registry, or otherwise notify the importer of a refusal and grounds for refusal.

The cost for registering a drug in Georgia is currently GEL 500 (approximately USD 300), with the exception of new innovative drugs which is GEL 2,500 (approximately USD 1,500). This applies to products covered under items 1 and 2 above, and for registration of drugs produced in Georgia. There is no fee for notification of parallel imports.

Pricing:

There are absolutely no pricing or price mark-up regulations related to pharmaceuticals in Georgia. This is in line with Georgia’s liberal and free market policy approach, as well as the idea that the greater competition introduced as a result of simplified pharmaceutical regulation would lead to self-regulation of pricing and lower, fair retail prices for the Georgian population.

Pharmaceutical Classifications:

The range of products that falls under pharmaceutical classifications is generally in line with typical classifications in Western markets. Dietary supplements, vitamins and certain herbal medicines are not subject to pharmaceutical registration requirements but can be done so voluntarily. Likewise, for local producers seeking to export these kinds of products, they can at their own option go through the pharmaceutical



registration process so that they may present the certification to the regulation authorities of the export country. Also of note is that dietary supplements, vitamins and certain herbal medicines are also not exempt from VAT and customs fees.

Also of note is that according to regulations, a doctor's prescription is required for prescription drugs but in practice this is not followed. Most pharmacies sell prescription drugs without requiring customers to furnish a drug prescription (except for certain highly regulated drugs such as psychotropic pharmaceuticals, which are sold at specialized pharmacies only). As a result, and because the out-of-pocket costs of doctors visits are financially prohibitive vis a vis salaries, many Georgians self-prescribe.

Other Regulations:

Other aspects of regulations carried out by the Agency for State Regulation of Medicine Activities are issuing the permission of clinical studies of pharmaceutical agents, approving export or import of pharmaceutical products subject to special control, and ensuring the systemic control of pharmaceutical product series registration.

Intellectual Property Rights

Several foreign manufacturers and local pharmaceutical manufacturers stated that they are very comfortable with intellectual property rights in Georgia and believe their patents to be safe. While the prevailing view in Georgia about the judiciary system overall is that further development is needed, there do not seem to be concerns within the pharmaceutical sector. Also of note is that Georgia has a national intellectual property office (Sakpatenti) with strong capacity and knowledge.²⁰

Reference of Relevant National Regulations & Laws

Please see Appendix C for a list of the laws in Georgia that relate to the pharmaceutical sector in Georgia.

Registering Exports Abroad & Issue of GMP

Planned Adoption of Good Manufacturing Practices (GMP)²¹ in Georgia

While Georgian pharmaceutical production regulation covers some elements of GMP standards (that is, technical regulations about process and production), but not to the extent of those covered in GMP, and there is no certifying agency in Georgia that reviews or provides GMP certification. As mentioned earlier in this section, the Agency for State Regulation of Medicine Activities reviews, tests and certifies individual

²⁰ "Georgia's Intellectual Property Rights (IPR) Environment, by Deloitte Consulting LLP for USAID, May 9, 2011

²¹ Good Manufacturing Practices (GMP) are a series of guidelines on practices and systems required to be adapted during manufacturing (in the areas of pharmaceuticals, active pharmaceutical ingredients, diagnostics, foods, and medical devices) with the goal of ensuring product quality and the health of the patient or consumer. The guidelines cover areas such as quality control, process control, documentation of clear procedures, testing, and record keeping. Many countries and organizations have created their own GMP guidelines that correspond with their legislation. The US FDA has a GMP (cGMP), the EU has a GMP (EU-GMP), and WHO has a version of GMP that is used by pharmaceutical regulators and the pharmaceutical industry in over 100 countries, primarily in the developing world. Other countries such as Australia, Canada, Japan and Singapore have highly sophisticated GMP requirements, all of which are recognized by the EU and US and vice versa (through an informal recognition scheme referred to as PIC/S). Countries such as India, China and Iran have their own versions of GMP but not as stringent as EU and other guidelines and not recognized by the EU. Cross recognition is an important theme in terms of the ability to register drugs in other countries for export. As GMP is incorporated into national law, GMP inspections are typically carried out by national regulatory agencies, as opposed to associations which provide common certifications for some other industries. There are some private firms that provide GMP review/certification, but not the official state agency regulation that is typically required for recognition by national authorities.

drugs and conducts selective control inspections and issues licenses to manufacturers, but does not issue any kind of GMP-type certification for the manufacturing process itself.

Georgia has announced that it would adopt GMP standards by 2016 (that is, adopt GMP standards into legislation and establish a certifying body). The government is currently engaged in developing policies and plans for adopting such a certifying agency, taking into consideration what standards and approaches will be from a public policy perspective and the business environment perspective.

It is possible that the Ministry of Health will implement a policy whereby for several years the GMP certification would be optional and would give a timeline of several or more years for pharmaceutical producers in Georgia to come into compliance. This will give companies the time to obtain the expertise and financial resources required to invest into equipment, infrastructure and personnel to achieve compliance, while at the same time allowing those producers that do obtain the certification to benefit from the ease it will provide for exporting to any markets that will recognize the Georgian GMP certification.

It is also possible that the GMP standards to be adopted would not be as stringent as EU and PIC/S member GMP standards. Rather it may adopt the WHO GMP standards, which are very similar but not quite as stringent as that of the EU. Countries such as India, China and other developing countries generally follow the WHO standards. This will still be a valuable step for the development and competitiveness of the pharmaceutical production in Georgia. This is because most of the countries to which Georgia exports or would export are also developing countries (CIS countries, African countries, Vietnam, India, etc.) and do not demand PIC/EU/US level GMP certifications but demand at least some national, government agency GMP certification. A Georgian GMP certification would be sufficient for obtaining approval for export to such countries. Currently, in lieu of this, Georgian producers go through more complicated, timely approval processes with each country to which they export for each product, including product testing and sometimes on site inspection visits to Georgia. Such process can sometimes take up to a year.

If the above approach is taken, it would then be likely that Georgia would at some point later advance its GMP certification standards in order to sign on to the PIC/S scheme which would achieve automatic recognition by the PIC/S scheme countries (the EU, the US, Japan, Singapore, etc.). Another option that could be considered by the government is to offer EU and WHO-based GMP certification and give local manufacturers the option to select which standard they seek for certification.

Analysis and decision-making by the Government to plan for the establishment of a GMP agency is currently underway and the government welcomes feedback and recommendations from local producers and foreign companies that seek to establish themselves in Georgia.

Obtaining Foreign GMP Certifications

Of note, two Georgian pharmaceutical producers are reported to hold GMP certifications from private auditing companies (Aversi Rational and GM Pharmaceuticals), but not from official GMP certifying agencies of foreign governments (as explained in the footnote on the previous page, while there are private firms that provide GMP review/certification, a certification from a given country's state GMP agency is required for official recognition/registration of drugs in the given country). There are also a number of pharmaceutical manufacturers in Georgia that claim to comply with GMP, but without any kind of certificate. Many pharmaceutical manufacturers would require investment to come into compliance with GMP and/or to be able to achieve a GMP certificate, whether from a private auditing firm or a foreign government certifying body.

One Georgian pharmaceutical producer, GMP, is in the process of obtaining GMP certification from France, expected to be official in early 2012. The process will certify the company's production process as

well as the product which it has registered for approval in France. Once obtained, the company will be in a position to export its products to all countries that recognize EU-GMP. The process has been a major effort, both in terms of establishing the production facility, processes and procedures and the certifying process.

GMP Plans for Other CIS Countries

Other CIS countries have either announced or launched efforts to establish GMP certifying agencies, and as well to accept import of pharmaceuticals with GMP certification only, but have not yet implemented such plans. Russia announced plans to achieve this by 2005, 2008, and then 2012, but it is unlikely to take place. The Russian pharmaceutical market is large and lacks motivation to encourage imports, and therefore likely will continue with its own particular drug import approval process rather than recognizing imports with GMP certification. Ukraine has local GMP regulation and had plans to recognize foreign GMP certifications for import, but plans to move forward on this have also been tabled.

9. Human & Other Resources



Workforce & Wages

The total number of people employed in the pharmaceutical sector in Georgia is 13,767. The vast majority is employed in retail, but as can be seen in Figure 22, employment growth in production has been rapid, at an average of 30% per year since 2006.

Wages in Georgia are competitively low with an average gross monthly wage of USD 346 in 2010. As can be seen in the Figure 26, wages in the Caucasus countries (Georgia, Armenia and Azerbaijan) are significantly lower than wages in Western and Eastern Europe, Russia, Ukraine, Turkey, and even China.

Average wages in the pharmaceutical sector are in line with the overall average national wage, with average gross monthly wages of USD 322, 265, and 528 in the production, retail and wholesale components of the pharmaceutical sector respectively.

Wages are higher in wholesale we believe as a result of competitiveness in the area of sales (i.e., higher wages for MBA type employees for sales and marketing). Wages are typically higher than these average figures for more experienced and high quality pharmaceutical experts and managers in the field working in labs and production, with the higher bracket of salaries in the area of USD 1,500-2,000 (gross monthly).

Figure 22. Georgia’s Pharmaceutical Sector Workforce Data, 2010

	Number of Employees	Average Annual Growth (2006-2010)	Average Gross Monthly Wage
Production	2,409	30%	USD 322
Retail	8,120	12%	USD 265
Wholesale	3,328	10%	USD 528
Total	13,767	13%	NA

Source: Geostat

Figure 23. Other Pharmaceutical Sector Salary Insights

USD 190-300: Typical minimum starting salary (gross monthly) for pharmaceutical B.A. graduates entering pharmacies

USD 375: Typical minimum gross monthly starting salary for pharmaceutical M.A. graduates (usually hired for research production)

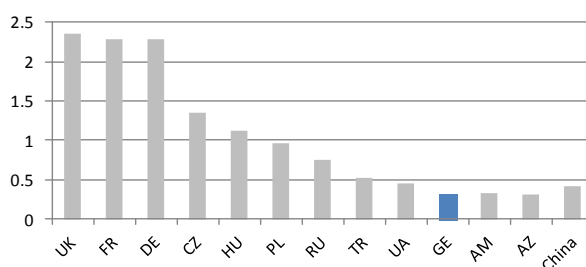
USD 615: Typical average gross monthly salary for experienced skilled pharmaceutical professionals working in labs, research, production, and management (with top managers often earning a USD 1900 gross monthly salary with bonuses or ownership shares)

Source: Komsa International Survey & Interviews

Figure 25. Overall Employment Statistics for Georgia

Average gross monthly salary: USD 342
Population: 4.4 million
Labor force: 1.9 million
Unemployment rate: 16% (approx. 50% is between 20-34 years old)

Source: Geostat

Figure 26. Average Gross Monthly Salary 2009, US\$ thousands


Source: National Statistics Office, World Bank

Skills & Ease of Hiring

The quality of pharmaceutical skills among the workforce is solid in terms of pharmaceutical education basics, but most companies find it necessary to provide modern, up-to-date professional training or specialized training to pharmaceutical employees. Companies typically provide employees with formal training, sometimes with company testing, and often with use of foreign pharmaceutical specialists. Most companies believe it is “somewhat difficult” to hire properly qualified pharmaceutical staff, but with reasonable hiring efforts combined with internal training, companies are able to meet their needs.²²

The study of pharmacy (particular for the pharmacist profession) has become quite popular in Georgia over the past several years, but because of growth in the industry, demand and supply for pharmacists seems to remain in balance. Among retailers, the company GM Pharmaceuticals, for example, provides a formal training program for newly hired pharmacists but some smaller retailers typically do not have formal training programs, as the quality of education of new staff coming in is typically considered sufficient by them. Also of note is that since 2009, medical doctors are allowed to work in pharmacies with pharmacist responsibilities, with the requirement being that employees with pharmacist responsibilities be either a Bachelor of Pharmacy or an M.D.

There is less supply of qualified pharmaceutical professionals who are able to work in manufacturing, especially at newly constructed plants that are more in line with international standards. Manufacturers therefore typically provide training to their staff, both in house and with use of foreign specialists. Particularly for manufacturers striving for or in compliance with GMP principles, at least some staff needs training abroad before they are able to manage, implement and monitor procedures in accordance with GMP principles. With industry growth, rising popularity of pharmaceutical study, and rising standards of higher education in Georgia, the quality and supply of human resources for pharmaceutical production will improve.

Education

Among the legacies of the Soviet Union are high literacy rates and high quality education at all levels of higher and lower education. Though the quality of education in Georgia weakened after the fall of the Soviet Union, the foundation of the historical legacy is still in place and quality has been improving over the past five years. Particularly at the university level, and particularly in the pharmaceutical field (which is becoming more and more popular among students each year), there is a clear track record and continuing trend of rising educational standards in Georgia.

²² Out of a range of “easy, somewhat easy, somewhat difficult, and difficult” in a limited survey conducted by Komsa International.

There is a total of 11 public and private universities and institutes in Georgia that offer medical degrees, with a total of 560 graduating students each year (2011 figure). In terms of reputation, infrastructure, and standards, the leading medical universities are Tbilisi State Medical University (TSMU), Tbilisi State University (TSU), and Tvildiani Medical University. After the fall of the Soviet Union, a number of medical schools appeared in the 1990s, but the weaker programs have been closed, leaving the 11 programs today, and the number is expected to decrease further, with this consolidation allowing for better economies of scale and improved quality.

There is a total of 13 public and private universities and institutes in Georgia that offer degree programs in pharmacy (9 of which are also offer medical degrees and 4 of which are at universities and institutes that do not offer medical degrees). As in the case of medical programs, several programs recently closed and it is expected that the weaker still among these programs (at least 4 in the near future) will close (whereby students in those programs are transferred to the stronger, remaining programs). The strongest pharmacy program, in terms of reputation, facilities and standards, is considered to be that at TSMU, which is featured below, and is the only program in Georgia to offer a Masters in Pharmacy and Ph. D. in Pharmacy (other programs offer Bachelor degrees only). Aside from TSMU, there are three other pharmacy degree programs in Georgia with reasonable reputations, but smaller in scale. These are Tbilisi State Technical University, Akaki Tsereteli State University, and Sokhumi State University.

Pharmacy Program at Tbilisi State Medical University (TSMU). TSMU has the strongest pharmacy program in Georgia, in terms of reputation, facilities and standards, as well as size. It graduated 127 pharmacy students in 2011, all of which obtained jobs in the pharmaceutical sector after graduation. Since 2006, TSMU has offered a Bachelor of Pharmacy Degree, a Masters of Pharmacy (with varying specialities within pharmacy), and a Ph.D. of Pharmacy. The university recently came into compliance with the Bologna Process (European education structures and standards), as Georgia is working towards compliance among all its universities. TSMU uses a combination of English language and Georgian text books, noting that the Georgian text books authored by a Georgian professor are quite strong and up to date. The university often works in cooperation with the government (e.g., forensics lab), research institutes, and private sector pharmaceutical companies in Georgia (shared lab research and internships for students at both pharmaceutical producers and pharmacies). TSMU has a renovated training lab, but which could benefit from greater investment to become fully state of the art and up to date and for this reason depends on its relationships with private sector producers in Georgia.

Research Institutes & National Laboratories

Georgia also has historically had strong scientific research institutes, which still operate today. Two of these, related to the pharmaceutical industry, are the I. Kutateladze Pharmaco-Chemistry Institute under Tbilisi State University and the George Eliava Institute of Microbiology (directly under the Ministry of Education) which plays a strong role in Georgia's phages industry (covered earlier on page 19). Also of note is that there are 7 universities in Georgia which have faculties of natural science.

The I. Kutateladze Institute of Pharmaco-Chemistry. Founded in 1932 focusing on the plethora of natural products and minerals found in Georgia, the focus of the institute today is research of plant substances and accumulating biologically active compounds of various chemical classes and drug development using these substances. This has resulted in the development of a number of new medicinal preparations suitable for various curative indications and the establishment of chemical - pharmaceutical production facilities in Tbilisi and Batumi. Among the drugs that the institute developed is Caripazim, a mixture of phytogenous protein-degrading enzymes, prepared from proteolytic enzyme latex of papaya, which has since been commercially manufactured since 1987.

Also very central to Georgia's pharmaceutical industry capabilities and capacity is the Central Public Health Reference Laboratory (CPHRL), operated as a not-for profit government owned institution, established with financial and technical support from the United States. The laboratory has a very large, state-of-the art high biosafety level (BSL) laboratory with BSL-3 designation, along with a BSL-2 lab and a vivarium. The CPHRL was established for the purpose of safe storage of dangerous pathogens and biological threat prevention research. The laboratory is a potential partner for cooperation with foreign governments for research of dangerous pathogens and virus risk management strategies, and a potential partner for academic institutions and organizations for research and training, and as a contractor for private pharmaceutical companies for R&D and clinical studies.

Central Public Health Reference Laboratory (CPHRL), www.cphrl.org

The CPHRL is the result of cooperation between the Government of Georgia and the United States Department of Defense (DoD), aimed to achieve secure storage and threat reduction of dangerous pathogens. A project of over USD 150 million, the CPHRL is a not-for-profit legal entity owned by the government of Georgia, with oversight by a Board of Governors consisting of five Georgian ministries and liaisons from the US Army Medical Research and Material Command represented by the Walter Reed Army Institute of Research (WRAIR), and the US Defence Threat Reduction Agency. The laboratory's mandates are to serve as a repository for consolidated national collections of dangerous pathogens (which had previously been spread throughout the country in less secure environments), a national reference laboratory, an academic research center, and an education and training center and allow for research of human, animal, food borne and water specimens without field separation.

The CPHRL is equipped with laboratories, repository rooms, and a vivarium, all with BSL-3 designation, the second highest biosafety level ranking according to international standards. It also has laboratories and a vivarium with BSL-2 ranking. The laboratories will be fully operational in 2012 and will operate according to the standards of and with the approval of the US DoD, the US Food and Drug Administration (FDA), the World Organization for Animal Health (OIE), and the World Health Organization (WHO). Additionally, the CPHRL will be integrated into Georgia's integrated disease surveillance network of human and veterinary labs throughout the country.

The laboratory cooperates with the US DoD and its agencies and contractors, which are helping in capacity building and commercialization of the CPHRL. WRAIR, one of the world's most reputable institutes in the area of infectious disease pathogen research, is in the process of establishing a long-term scientific presence at the CPHRL, and cooperation with EU institutions is also now under consideration. The Science Advisory Council (SAC), which was established to link science across the world, is conducting an academic review of the facility and is assisting the CPHRL in development of sound research strategies.

The laboratory is equipped to cooperate with other foreign governments for research and testing in areas such as pathogen outbreak risk mitigation, drug resistant diseases, genomes, phages, virology, and microbiology, and is equipped to partner or contract with research institutes and private pharmaceutical companies in areas of R&D and clinical testing. Aside from the laboratory facilities, the CPHRL offers potential partners a team of international staff, a rich collection of pathogens for research, a reputable network of collaborating and supporting institutions, government support, affordable human resources and energy costs, and flexible regulations.

Industry Associations

The Association of Pharmaceutical Companies Representative in Georgia (APCRG) was established in 2007 and is quite active, with 13 members currently. The main goals of the association are to support the development of an open pharmaceutical market in Georgia, to promote harmonization with international standards to achieve high quality and safe pharmaceutical products in Georgia, and to promote improvements to regulations, compliance and ethical conduct in the industry. This is currently the only pharmaceutical association in Georgia.

9. Foreign Investments & Partnerships

In Georgia there are a number of representatives of foreign manufacturers of pharmaceuticals in Georgia (with 13 members in the association APCRG as mentioned earlier), several foreign companies in Georgia doing clinical trials, and a number of distributors/wholesalers that are foreign owned or with foreign investment. There are also a number of institutes and private companies that have had foreign support or cooperation for pharmaceutical research. However, there has been less foreign investment in pharmaceutical retail and production in Georgia, thus with the rapid growth in the sector to date being driven by local investment. There is a lack of comprehensive data on the foreign investment into the pharmaceutical sector in Georgia, but highlights of some of the foreign investments and partnerships are presented below.

ABC Pharmacia and PharmaDepot: Highlighted earlier in the report ABC Pharmacia is the fourth largest distributor of pharmaceutical goods in Georgia and recently launched the successful PharmaDepot chain of discount pharmacies, now operating with 32 outlets. In 2011, the European Bank for Reconstruction and Development (EBRD) provided ABC Pharmacia with a USD 4 million loan (via a local bank, partially drawn down) for further expansion of PharmaDepot throughout Georgia.

Gama (pharmaceutical producer): Gama is a Georgian pharmaceutical producer established in 1993 in part with investment from a private US investor of approximately USD 740,000. The company produces a variety of branded and generic products and operates with 30 employees. The company is open to further investment to support registration of drugs in nearby CIS countries.

Euromedical (pharmaceutical producer): Euromedical was founded in August 2010 as a Georgian-British partnership. Still in its early stages, 80% of production is planned to be exported to CIS and Eastern European countries, with the remainder to be sold on the local market. The company has partnership relations with American pharmaceutical marketing group Unimed Group Corporation, which organizes the introduction of Euromedical's generic and brand products CIS and Eastern European markets.

Iveriapharm: A small-sized, niche manufacturer with 25 employees, Iveriapharm currently produces two branded products (a naturally based sinusitis product and a naturally based product for herpes and skin infections) for sale in Georgia and for export (to Belarus, Ukraine and Kazakhstan). The company was founded in 2000 and in 2002 built a manufacturing plant with an investment from Hartington Business S.L., based in Spain and dedicated to developing natural based medicines to tackle prevalent diseases. Likewise, Iveriapharm's mission is to develop new products to treat highly prevalent diseases that are unsatisfactorily treated by existing medicines, and which have an enormous socio-sanitary impact. The company's team works on and develops effective treatments. The production plant is equipped with state-of-the-art production lines and technological equipment manufactured by leading manufacturers in the USA and Western Europe and is built in accordance with GMP standards. In addition, the medicinal plants are treated following the Good Agricultural and Collection Practices (GACP).

Central Public Health Reference Laboratory (CPHRL): As featured earlier in the report, the Georgian government recently established, in cooperation with and with funding from the United States government, this national laboratory with biosafety level 2 and level 3 designations according to international standards. A project of over USD 150 million, the CPHRL is a not-for-profit legal entity owned by the government of Georgia, with oversight by a Board of Governors consisting of consisting of Georgian government and US government representation. The CPHRL will operate according to WHO and US FDA standards and is in the process of establishing ongoing presence of the Walter Reed Army Institute of

Research (WRAIR). Once fully operational in 2012, the laboratory is ready to partner with or provide contract services to governments, international organizations, institutions, and private companies for research, training, testing or storage.

Global Contract Research Organizations (CROs): As mentioned earlier in the report, there are four global CROs with either representative offices or partners in Georgia for conducting clinical trials. The number of clinical trials being conducted in Georgia is on the rise, offering high volunteer participation rates and low costs.

Pharmaceutical Wholesalers: While the leading players have not had foreign investment to date, there are various examples of small and medium sized wholesalers (i.e., revenues in the USD 500,000 - 4 million range) that are foreign owned or have foreign investment. Examples include Actapharm (Turkish owned) and Marji, which engage in a mix of import and export of imported and Georgian produced pharmaceuticals.

10. Investment Opportunity Highlights

With recent liberalization and simplification of regulations, it is an ideal time to invest and enter the market. Liberalization can be expected to tighten up eventually, making new entry more difficult, and those players that will already be established in the market will possess significant market advantages. Investment opportunities are strong in the areas of local production for the Georgian market, CIS markets and other emerging markets, for contract manufacturing, contract research – through partnerships with existing Georgian players or as stand-alone start up ventures. The areas that are attractive for investment are presented below, along with highlights of companies known to be seeking financing.

Pharmaceutical Production and Contract Manufacturing Organizations (CMOs)

Georgia already has a strong base of pharmaceutical producers, some well established and some recently established over the past one or two years with which foreign investors can partner. Pharmaceutical production has been growing at a fast pace, at an average of 46% per year for the past five years, with production at USD 52 million in 2010. Exports have also been increasing, reaching USD 30 million in 2010 (nearing Georgia's exports for wine in 2010 at USD 39 million, a much talked about industry attracting foreign investment), and there are a number of new countries to which Georgia has just begun exporting over the past few years. With rising incomes and still relatively low expenditures on pharmaceuticals in Georgia and neighbouring countries, it is believed that the growth in Georgia's pharmaceutical sector is just beginning. In order to seize expansion opportunities, many of the main producers in Georgia are open to or actively seeking investment. The size range for investment opportunities ranges from just a few hundred thousand US dollars (for example, for laboratory upgrade or export registration) to several million new facility construction. There are opportunities with some of the smaller or newer companies with annual revenues in the range of USD 500,000 to USD 2 million, as well as with some of the larger players with revenues of USD 10 million and more. Several producers known to be open to investment are highlighted to the right, and other key players that can serve as local partners (both for new ventures or investing into existing businesses) are presented on pages 18-22 of this report.

Gama: See Section 9 of this report (Foreign Investments & Partnerships). The company has already received an investment from a US investor, and is seeking further investment for expansion at this time, namely to register drugs in Ukraine.

Apipharm: A recent start-up, Apipharm has constructed the first antibiotic production facility in Georgia and is expected to launch production in the coming months, serving mainly as a CMO. While fully funded for the time being, the company will potentially seek an investor in the near future, preferably a pharmaceutical company as a partner, to finance the establishment of a microbiology laboratory and a chemical lab (currently such lab services are contracted out) and to purchase additional machines for production. The company is also interested in partners with networks and expertise in the industry to enhance and expand its contract manufacturing. Investment needs are as low as a few hundred thousand US dollars in the near future and more for later stages.

Biopolus: Recently established as a spin-off from Batfarma, a long-standing Georgian pharmaceutical producer based in Batumi, this company has strong capacity and know-how and has been producing since 2010. The company seeks financing to complete construction of its new state-of-the-art production facility and to obtain GMP certification.

Natural & Herbal Medicine Production

Global demand for medicinal herbs and plants is currently growing at 8-10% annually, and Georgia offers a number of competitive in this sub-sector. In addition to underutilized, organic agricultural land, Georgia has over 40 varieties of medicinal herbs and berries growing wild in its high mountainous regions, and there has been focus on and knowledge of herbal medicines dating back centuries in Georgia as well as a handful of existing natural/herbal medicine manufacturers in Georgia today. Some of the larger producers are manufacturing herb/plant based pharmaceuticals and dietary supplements, and there are also a number of smaller players that have been experiencing significant growth and seek investment, some of which are highlighted below. Most of the exports of these companies are to CIS countries, and there is an opportunity to penetrate new markets with high demand such as the EU through partnerships with foreign investors to achieve required licensing and certifications. Also of note is that there is also a significant amount of export of raw and semi-finished medicinal herbs and plants, also mainly only to CIS countries. There is a strong opportunity to export these kinds of products to new market and to achieve greater value added within Georgia. Investment opportunities in this sub-sector can include both start-up ventures and partnerships with existing Georgian players, some of which are highlighted below (see page 20 for information on sub-sector players), as well as potential consolidation of some of the many players in this segment.

Neopharm: Neopharm focuses on production of herbal and dietary supplements with biological active ingredients. In addition to sales in Georgia, Neopharm exports to Belarus and Ukraine. Neopharm has been producing pharmaceuticals since 1991 and has a strong and well qualified management team. Neopharm seeks to cultivate their own lands for production of herbs, upgrade or build a new factory, and eventually achieve GMP standards and certifications and is interested and open to investment partners.

Iveriapharm: See Section 9 of this report (Foreign Investments & Partnerships). The company has already received an investment from Spain based Hartington Business, and is seeking further investment move from leased space to purchase its own land/building and expand.

Eskulapi: Eskulapi is a small producer (revenues under USD 400,000) with 9 employees that produces various types of branded herbal products including extracts, ointments and syrups. The company sells its products in Georgia and in Kyrgyzstan and is seeking investment for further development and expansion.

Turmanidze: Turmanidze produces herbal based skin ointments for various skin complications based on the traditional recipes of Turmanidze who was a renowned historical medical figure in Georgia. The company is the extension of his descendants' family practice during Soviet times. Products are sold in Georgia, and the company is seeking investment to expand production and to finance marketing to launch exports. The brand name is already known in other CIS countries from Soviet times.

Salkhino: This company produces herbal medicines, currently with two products, the raw materials for which are collected and harvested in Georgia. Also a small player, the company has 30 employees and has been experiencing high growth rates for the past several years and seeks financing to sustain growth, namely to finance marketing in Georgia and its export markets.

Similia: Established in 2010, the goal of company is to innovate and produce Georgian homeopathic and phyto-herbal pharmaceutical products. The company manufactures various types of homeopathic syrups and tablets, dietary supplements and vitamins originated from bee and honey products. The company is a small player but has experienced strong initial growth and is seeking financing for increasing drug production and market in new CIS export markets.

Phages R&D and Production

Since the early 1900s, Georgia has been a leader in phages research, development and production. Phages are also under development and/or under production in Russia, Israel, India, Canada and Australia, however Georgia holds a historical and competitive edge in the breadth and depth of its research and breadth of specimens. With the rise of drug resistant strains of bacteria, the potential role of phages is gaining new attention in the West. Companies and investors seeking to capitalize on the potential of this unique industry have the opportunity to cooperate or partner with several institutions and producers in Georgia. The Eliava Institute, established in the early 1900s, continues to operate today with close collaboration with a number of local and international research institutions, universities, and medical and industrial organizations. There are also three private companies that manufacture phage pharmaceutical products (one associated with Eliava Institute), which are sold in Georgia, Kazakhstan and Kyrgyzstan. With further R&D and marketing, bacteriophage preparations have in some cases the potential to gradually substitute antibiotics and gain share of the worldwide market of medications against bacterial infectious diseases. Key players are presented on pages 19-20, and one company open to investment is highlighted below.

BioChimPharm: This company manufactures seven phage product types in the form of ampoules and tablets. Their products are sold in Georgia, Kazakhstan and Kyrgyzstan. Though the company's annual revenues are less than USD 1 million, the company has sustained annual revenue growth rates of more than 20%. The company seeks to expand sales to other markets, which R&D and marketing efforts, but most recently obtained positive lab results from Australia. The company has worked in partnership or with grants from foreign institutes over the years and welcomes investment or partnership to support R&D, marketing, and export expansion.

Pharmaceutical Packaging

There are currently no specialized pharmaceutical packaging companies in Georgia, and almost all of the packaging for pharmaceutical products produced in Georgia is imported, mainly from Turkey. While the local and regional market is not large enough likely to sustain an investment into vials, blister packaging and other more complex packaging components, there is a strong opportunity to establish production of paper carton packaging for the pharmaceutical industry in Georgia and in the CIS region. In Georgia alone there are estimated to be more than 70 million paper cartons imported for pharmaceutical packaging each year. There are already paper packaging companies in Georgia, but none producing packaging to meet the specific needs of pharmaceutical companies (aside from a few locally produce products with more simple packaging), with proper sanitary standards, special labelling capabilities, sanitary standards, etc. Thus there are opportunities to establish a stand-alone pharmaceutical packaging facility, or to partner with existing packaging companies in Georgia.

Investing in Georgia as a Hub for Regional Distribution

With an attractive environment for doing business, an easy and efficient customs regime, and low levels of regulation, Georgia is well positioned to serve as a hub for distribution of pharmaceuticals in the region. Georgia's existing CIS export markets have also had fast growing pharmaceutical retail sectors over the past five years, and these markets still have very low per capital pharmaceutical consumption in comparison with the West. There is also potential to enter other major, fast growing markets such as Turkey and the Middle East. Investors may partner with existing pharmaceutical distributors to support expansion of sales throughout the region, or foreign manufacturers or distributors may set up in Georgia to establish their own distribution in the region.

Pharmaceutical Retail Chains

With greater competition in the retail market as a result of recent streamlining of regulation, a number of players are looking to establish themselves in the market alongside leading players and offer better pricing and cost efficiencies. Some of these players are open to investment for consolidating, reformatting or expanding retail outlets (see pages 12-14 for featured retailers).

ABC Pharmacia: As mentioned in the previous section of this report (Pharmaceutical Retail & Wholesale), ABC Pharmacia is one of the main pharmaceutical distributors in Georgia and recently launched the successful PharmaDepot chain of discount pharmacies, now operating with 32 outlets. The company received a USD 4 million loan from the European Bank for Reconstruction and Development (EBRD) in 2011 (via a local bank) and seeks additional financing to fund further expansion of its retail chain within Georgia, to expand distribution regionally, and potentially for production.

Contract Research Organizations (CROs)

Investors and pharmaceutical companies have the opportunity to establish their own CROs in Georgia or invest in or partner with existing CROs, research institutions or pharmaceutical producers with CRO capabilities. There are already four global CROs with either representative offices or partners in Georgia for conducting clinical trials, as well as a number of doctors and hospitals that conduct clinical trials, primarily late stage and Phase 3 trials. While the number of clinical trials being conducted in Georgia is limited, with 16 and 19 registered on the WHO's online database for 2010 and 2011 respectively, the number being conducted in Georgia is on the rise, offering high volunteer participation rates and low costs, while at the same time rising standards. Aside from clinical trials capabilities, there are a number of research institutes and local production companies with the skills to handle contract work, and the recently established USD 150 million CPHRL national laboratory is a potential resource for private companies.



Appendix A

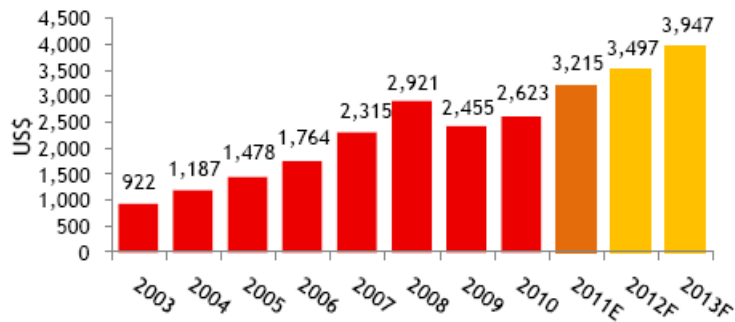
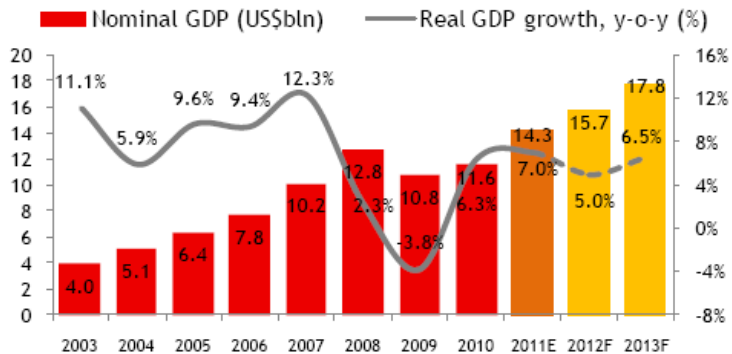
About Georgia: Macroeconomy & the Business Environment



Macroeconomy

Georgia has been undergoing strong and steady economic growth despite the economic slowdown in most of the world over the past several years, and at the same time is maintaining a healthy macro-economic situation. With this foundation, Georgia is positioned for strong and sustained economic growth.

The International Monetary Fund (IMF), in its most recent review under the Stand-By Arrangement it has with Georgia, painted a positive scenario. GDP growth in 2011 was 7.0%, with a projection of 5.0% and 6.5% for 2012 and 2013 respectively. The country’s balance of payment developments have been more favorable than anticipated in the owing to higher private inflows, including tourism. The IMF also noted that the successful Eurobond issue of April 2011 marks a significant improvement in market confidence and eases considerably debt rollover risks and that its success with substantial downward re-pricing of Georgia risk embedded in the Eurobond issue is all the more remarkable as it came at a time of unsettled market conditions for sovereign paper.



Source: National Statistics Office of Georgia-GeoStat, Ministry of Finance of Georgia

Georgia has undertaken major economy wide reforms since early 2000. These have yielded impressive results. Economic expansion averaged ten percent per annum from 2003-2007. The business environment improved drastically, lifting Georgia from #112 in the World Bank’s 2006 Doing Business Index to #16 in 2012. Corruption has also been reduced sharply, and important steps have been taken to reform the role of the state vis-à-vis the private sector.

While the shocks from the August 2008 conflict with Russia and the global economic downturn somewhat hurt economic performance in 2008 and 2009 (growth slowed to 2.3 percent in 2008, and sank into negative territory in 2009, and trade, transport volumes and FDI were reduced), the economy was impacted far less severely than the global crisis affected many other emerging markets, and the economy has shown strong recovery in 2010 and 2011. Georgia’s recovery from the twin shocks of 2008 were partly due to official balance of payments (BOP) support from the IMF and contributions from other donors, but quick and disciplined return to stability has led to confidence, a healthy macro-economic situation and a prognosis for rapid economic expansion. This confidence is reflected in the country’s agreement to exit from official BOP support well before repayments peak in 2013-2014.

Foreign Direct Investments

Net foreign direct investment (FDI) is projected to be USD 980 million in 2011, an increase over the 2010 level of USD 814.5 million. With steady increases projected for the coming five years, FDI is on its way to return to its pre-crisis peak of USD 2.01 billion in 2007.

Georgia has attracted significant amounts of FDI in the past, evenly distributed between Industry, Transport, Construction and other services. While low productive agriculture has been unable to attract much investor interest to date, there is clear potential in this sector that has begun to garner investment attention.

There are no restrictions on foreign ownership of property or assets in Georgia, except that a foreign natural or legal person may only own agricultural land through a Georgian registered legal entity. There are no restrictions on the repatriation of profits from Georgia, subject to compliance with applicable tax laws.

Also of note is that according to the World Bank, Georgia is one of the most open countries to foreign equity ownership as measured by the Investing Across Sectors indicators. All of the 33 sectors covered by the indicators are fully open to investment. There are neither sectors with monopolistic or oligopolistic market structure nor any perceived difficulties in obtaining any required operating licenses. With only 4 procedures and 4 days, Georgia is among the fastest countries in the world in terms of establishing a foreign-owned limited liability company (LLC).

World known brands in Georgia:



State Budget Revenues

Taxes are the Government’s main source of revenues. Total revenues increased during the past five years from GEL 3,695 million in 2006 to GEL 5,866 million in 2010, an increase of 59% year to year. Total revenues increased by 34.6% in 2007 and 17.7% in 2008, before declining by 10.1% in 2009 due to the combined effects of the 2008 Conflict and the global financial crisis on Georgia. Total revenues increased in 2011 up to GEL 6,870 million, as compared to GEL 5,865 million in 2010 respectively an increase of 17.1%.

Government revenues increasing at a rate of 59% per year

The overall growth of the state budget since 2006 is a result of the Government’s improved revenue collection capacity. In 2011, tax revenues accounted for 89.0% of total revenues. Tax revenues include personal income tax, profit tax, VAT, excise, import tax and property tax.

The IMF noted in its June 2012 report that tax revenues and projected tax revenues are improved, in part as a result of greater compliance as a result of streamlined tax procedures such as web portals and online payment systems.

Fundamental Policies and Reforms

Georgia has created and continues to strengthen fundamental policies that reflect a forward looking liberalized economic environment for the country.

Broad areas of focus have included a range of opportunities to support efficiency and encourage growth. Some of these include the following.

- Rule of Law
- Property Rights
- Reduction of the state’s fiscal footprint
 - Few, low and flat tax structures
 - Minimal social security burden for business
- Inflation targeting (single digit inflation)
- Free trade; no customs tariffs or non-tariff barriers
- Flexible labor market with minimal state interference
- Limited government
 - Aggressive deregulation
 - Dramatically reduced and simplified licensing
 - Transparent privatization
- Means tested and focused social assistance
- Lean, efficient and modernized civil service sector

Leader in implementing liberalized yet responsible economic and business reforms

Few, low and flat tax structures

Minimal labor laws and regulation

Georgia’s commitment to driving favorable market conditions in general, is admirable. The country has been recognized over the past several years for its aggressive approach to redefining its economic and financial structure – and its future outlook.

Modern and efficient civil service sector

Recognition of Georgia’s reforms are reflected vis-à-vis the following indicators.

**STANDARD
& POOR'S**

November 22, 2011

Foreign Currency

- Long Term: BB-
- Short Term: B

Local Currency

- Long Term: BB-
- Short Term: B

Outlook: Stable

FitchRatings

December 15, 2011

Foreign Currency

- Long Term: B+
- Short Term: B

Local Currency

- Long Term: BB-
- Country Ceiling: BB

Outlook: Stable

**MOODY'S
INVESTORS SERVICE**

October 6, 2010

Foreign Currency

- Long Term: Ba3
- Short Term: Not-Prime

Local Currency

- Long Term: Ba3
- Short Term: Not-Prime

Outlook: Stable

Major Rating Strengths:

- Government’s political commitment to market oriented policies and structural reforms
- Relatively strong economic structure and growth prospects
- Low tax regime and business friendly environment
- High potential growth rate
- Moderate levels of government debt

Major Rating Strengths:

- Strong economic recovery with strong GDP growth prospects
- Reduction in both budget and current account deficits
- Long track record of low and stable inflation
- Strong banking sector due to improvement in asset quality, growth in deposits and rising profitability
- Favorable business climate, low corruption, sound governance and easing of political risk
- High level of human development
- Strong support from the international community

Other Rating Indicators:

Bond (Country) Ceiling

- Foreign currency: Ba1
- Local Currency: Baa3

Bank Deposits Ceiling

- Foreign Currency: B1
- Local currency: Baa3

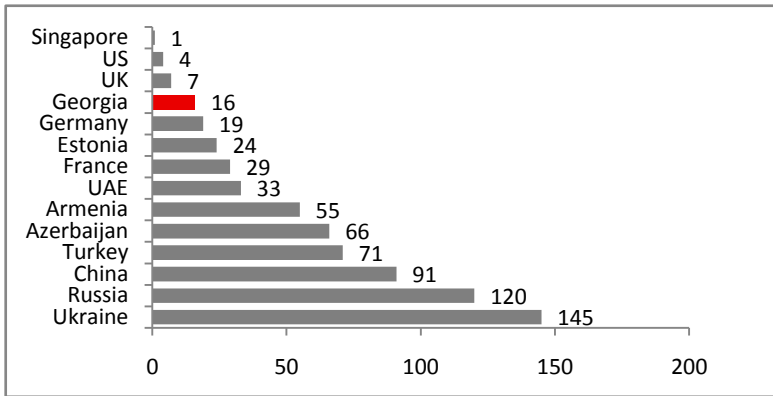
Major Rating Strengths:

- Marked progress in building social, political and economic institutions
- Healthy operating business environment that is unique in the region
- Credible fiscal and monetary framework
- Government debt at affordable levels on very favorable terms

Also noteworthy is that in July 2010, government adopted the Economic Liberty Act. The law is expected to enter into force on 31 December 2013 and will contain (1) a coherent package of bold measures to constitutionally enshrine our basic policies, reassuring investors that no policy reversal or policy drift is possible, (2) returning to citizens to the power to tax – no new taxes or tax rate increases without a nationwide referendum and (3) fiscal responsibility, such as:

- Government expenditure capped at 30% of GDP
- Budget deficit capped at 3% of GDP
- Government debt capped at 60% of GDP
- No budget earmarks.

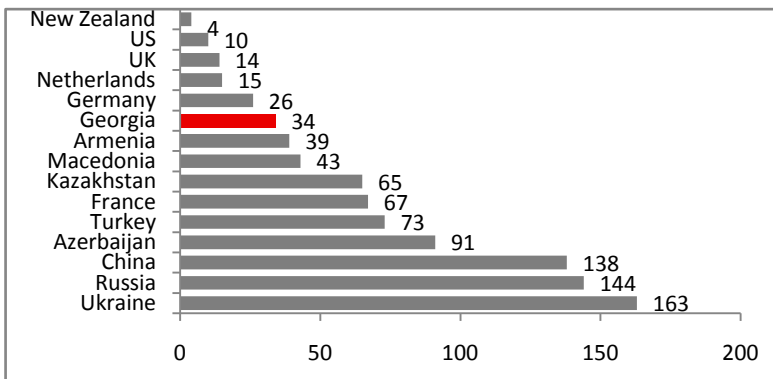
Ease of Doing Business, 2012



Up from 112 in 2005 and now ranked 16 in 2012

Source: World Bank, 2011 (Rank out of 183 countries)

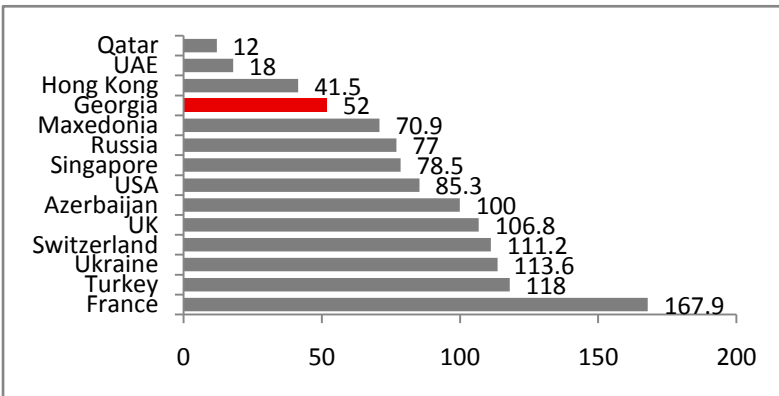
Economic Freedom Index, 2010



Up from 99 in 2005

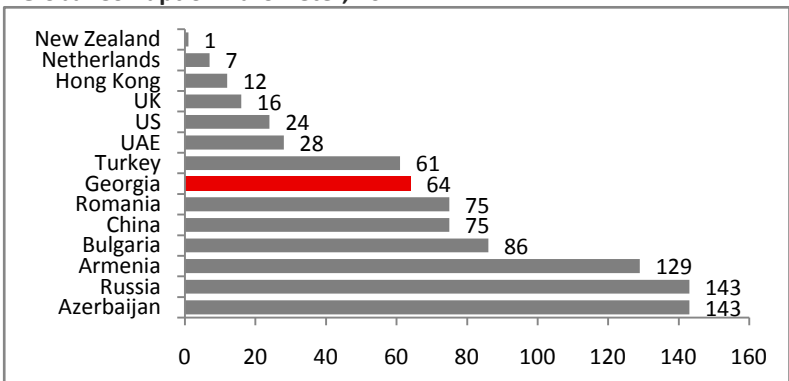
Source: The Heritage Foundation, 2011 (Rank out of 183 countries)

Forbes Tax Misery 2009



Source: Forbes Tax Misery, 2009 (Rank out of 183 countries)

Global Corruption Barometer, 2011



Source: Transparency International 2011 (Rank out of 125 countries)

Labor and Other Input Factors

Labor Regulations

As mentioned earlier in the report, Georgia has no minimum wage regulations and very few other regulations for labor. Labor Freedom Index for Georgia is 92.1 (6th place) according to the Heritage Foundation’s Index of Economic Freedom for 2011. Georgia has a score of zero in difficulty of the hiring & firing indices, according to the World Bank Doing Business Survey 2011. Aside from a flat tax of 20%, there is no social or pension tax.

Georgia takes 3th place in the Heritage Foundation’s Labor Freedom Index for 2012

Score of zero in “difficulty of hiring & firing” according to the World Bank Doing Business Survey 2011

Availability & Quality of Labor

Georgia’s total population is 4.44 million as of 2011. Among the workforce, total unemployment is estimated at 15.1%. The rate has ranged between 13% and 17% since 2004.

Unemployment rate of 15.1%

Approximately 50% of the population and 27.5% of the population is aged between 20-34 years. Thus, there is a high percentage of young labor availability in Georgia.

Literacy rate of 99.7%

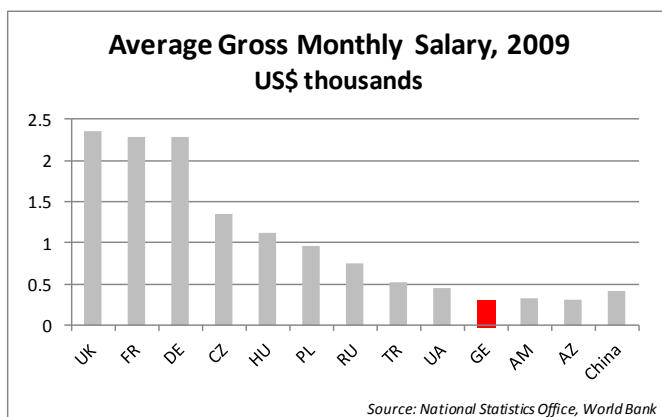
As a legacy from the Soviet Union, Georgia has a well educated workforce, with a 99.7% adult literacy rate. In 2009 and 2010, there were approximately 102,000 students enrolled in tertiary education courses, which represents approximately 31% of the population in the 20-24 age group. Although official statistics are unavailable, anecdotal evidence suggests that approximately two-thirds of Georgians speak Russian and 1/3 speak English. The knowledge of English is prevalent among the young generation, and the government recently launched several initiatives to eventually make Georgia a fully English speaking country. Work ethics of the labor force, another important factor for consideration, is also relatively high, and would thus represent a point of confidence for investors.

Labor Costs

Georgia has highly competitive labor costs specially compared with neighboring countries, including Turkey. As can be seen in the chart below, average wages in Georgia are less than in Russia, Turkey, Ukraine and even China. The average gross monthly wages in 2009 was USD 317, and in 2010 USD 342. Salary levels differ across regions in Georgia, with the highest average salary in Tbilisi at USD 455.

Average wages lower than in nearby Russia, Turkey, and Ukraine and even China

Average gross monthly wage of USD 342 in 2010



Other Input Costs

In addition to labor, energy costs represent another important factor for most businesses. Also in this regard, Georgia compares favorably with other countries in the region in terms of prices of petrol (lower than in Turkey), gas (lower than in Turkey, Ukraine and Armenia) and electricity (lower than in Turkey, Russia and Armenia). The price of electricity in Georgia is extremely low (thanks to significantly availability of water reservoirs for hydropower generation) at about 0.065 USD/kwh²³ (including taxes). This is roughly half of the average price in Turkey (at 0.146 – 0.154 USD/kwh²⁴ including taxes). Natural gas prices on the other hand are almost equal in the two countries. Also of note is the ease of buying land and property in Georgia, noting the government incentivizes foreigners to buy land for the purposes of investment.

*Electricity - 0.065
USD/kwh (incl. taxes)*

*Natural Gas - 0.43 USD/m³
(incl. taxes)*

Water - 0.118 USD/ 1m³

Quality of Living

Just as important of a consideration for FDI as local labor costs is the quality of living for attracting any key foreign management staff to relocate to Georgia. In addition to a favorable business environment, Georgia also offers an attractive, Western-style living environment, including the charming capital of Tbilisi, Black Sea coast, a burgeoning wine industry and Caucasus mountain winter resorts.

Traditional Food, Wine & Culture



“When you come to do business in the Caucasus-Caspian region, Georgia is probably the best starting point for a foreigner also in terms of quality of life.”

*David Lee,
President of the
American Chamber of
Commerce in Georgia*

Seaside, Mountains, Georgian Spa



In terms of other living needs, reasonable long-term accommodation rental is very common in the main business areas (Tbilisi, Batumi, Kutaisi and Poti) and ranges from USD 600-3000 per month depending on size, amenities and of course, location. Although the healthcare system in Georgia is still in transition, high quality private medical care, concentrated primarily in Tbilisi, has been rapidly developing. Lastly, there are 130 universities and other higher education institutions in Georgia, as well as a growing number of

²³ Based on 1 GEL: 0,578 USD

²⁴ EPDK, TEDAS. Based on 1 USD: 1.6 TL

international schools for children, including English, Russian German, Turkish and other schools. Many courses are taught by international and multilingual tutors.

World Trade Organisation and Other Trade Regimes

Georgia joined the WTO in 2000 and immediately entered a round of multilateral trade negotiations, as well as bilateral negotiations with the other member states.

After signing the Protocol on Accession to the Marrakesh agreement establishing the WTO, Georgia joined several WTO agreements and made commitments under the WTO Annexes to this Protocol. Georgia is therefore bound by the maximum customs tariff rates on imports, subject to special consent of the WTO members. Since its accession to the WTO in 2000, Georgia has been working on reducing tariffs and non-tariff barriers to trade. In 2006, the government abolished import tariffs on almost 90% of goods.

Georgia has most-favored-nation trading relationships with all WTO members and has GSP arrangements with all EU countries (GSP+ status), Japan, Canada, Norway, the United States and Switzerland. In 2008, Georgia's GSP+ privileges granted by Turkey were replaced by a free trade agreement between Georgia and Turkey, pursuant to which customs tariffs on industrial products have been fully eliminated, although a number of agricultural products are excluded by both parties. In 2007, Georgia and the United States signed a Trade and Investment Framework Agreement and, in January 2009, Georgia signed the Georgia-U.S. Charter on Strategic Partnership, which, *inter alia*, covers issues of trade between the two countries.

Georgia's GSP+ status with the EU has had a favorable result on the volumes of trade with EU member states, which has increased significantly between 2006 and 2010. Despite the global financial crisis on Georgia during the period, from 2006 to 2010 imports from EU countries increased by 30.3% and exports to EU countries increased by 32.0%. In 2010, imports from EU countries increased by 10.3% as compared to 2009, while exports to EU countries increased by 24.8%.

Georgia has signed a number of economic cooperation agreements with neighboring CIS countries. The most significant of these agreements are bilateral free trade agreements with Armenia, Azerbaijan, Kazakhstan, Turkmenistan and Ukraine, as well as Russia. The volume of trade with CIS countries has increased in recent years. Despite the combined effects of the 2008 conflict with Russia and the global financial crisis on Georgia, as well as the impact of the Russian embargo, during the period, from 2006 to 2010 imports from CIS countries increased by 10.9% and exports to CIS countries increased by 64.7%. In 2010, imports from CIS countries increased by 23.6%, as compared to 2009, while exports to CIS countries increased by 54.8%.

In June 2007, a Trade and Investment Framework Agreement was signed between Georgia and the United States. Georgia has signed double taxation treaties with 30 countries.

In order to further liberalize its foreign trade relations, Georgia is actively

MFN Tariffs with WTO Members

In 2006, Georgia abolished import tariffs on almost 90% of goods

Georgia benefits from a Generalized System of Preferences (GSP) when trading with the USA, Canada, Switzerland, Japan and Norway; accordingly lower tariffs are applied on goods exported from Georgia to those countries

GSP+ status with the EU allows Georgia to Export apparel and textile products to the EU market duty free

Free Trade Regime with CIS (Including Russia) Countries and Turkey

Georgia is actively working with the EU and the USA to promote free trade negotiations

working with the EU, the European Free Trade Association (the “EFTA”) and the Gulf Cooperation Council to negotiate free trade agreements. In 2008, a feasibility study on potential future free trade agreements between the EU and Armenia and Georgia, respectively, concluded that such an agreement could bring significant economic benefits to both countries. Negotiations are expected to commence within the framework of the negotiations in respect of the two countries’ bilateral association agreements with the EU, which were launched in July 2010.

Duty free trade opportunities with large consumer markets such as US and Russia are certainly critical, for instance to potential investors from Turkey. Russia is one of the key markets that Turkish investors would like to export to and the customs duties are significantly high, limiting Turkey’s export capacity. Georgia thus represents a great platform to reach to high growth potential economies in the greater region.

Serves as an attractive trade platform for production for global export for countries that face higher trade barriers

Tariffs

Georgia does not apply quantitative restrictions or non-tariff barriers, except when justified by health, safety and environmental protection considerations. VAT and excise tax apply equally to imported and local products, but there is no VAT on exports. Licensing requirements remain in effect for the import of certain medicine, weapons, explosive materials and radioactive products. Before September 2006, Georgia had 16 tariff rates ranging from 0% to 30%. The Law on Customs Tariffs, adopted in September 2006 and incorporated into the Customs Code passed in 2007, reduced customs tariffs, in most cases, to 0%. In 2010, the Customs Code was combined with the existing tax code to create the unified Tax Code, which came into effect on 1 January 2011. Pursuant to the Tax Code, tariffs on most agricultural products and certain construction materials that are produced in Georgia are subject to rates of 5% and 12%. Georgia’s weighted average import tariff is among the lowest in the world.

No VAT on exports

Georgia’s weighted average import tariff is among the lowest in the world

Georgia does not have import tariffs on machinery and equipment

International Trade

Georgia is an open economy, and the value of foreign trade in goods and services represented approximately 65% of GDP in 2011. Georgia's trade balance has been characterized by a structural deficit, as a result of the high prices for imported energy and commodities and the import of capital goods as Georgia re-industrializes with the benefit of increased private capital inflows. Georgia's external trade balance in services has been positive, as a result, in part, of the growing tourism sector. Turkey, the EU, Ukraine, the United States and Azerbaijan have been among Georgia's five largest trading partners over the past five years. Of note is that Georgia's trade environment is diverse, without reliance on any one country or product type.

No quantitative restrictions on import and export

Few export/import licenses and permits

Simplified export and import procedures

Imports

Georgian imports are primarily comprised of petroleum and petroleum products, motorcars, medicines and food products. Due to Georgia's status as a regional hub for trade, some of the goods imported into Georgia, such as motorcars, are subsequently re-exported to neighboring countries.

Over the period 2006-2010, the value of Georgia's imports of goods increased significantly from USD 3,675 million in 2006 to USD 7,057 in 2011. The increase over the period was principally due to the continued liberalization of trade policy, generally increased FDI inflows, import tax reforms and increases in the price of oil products and other international commodities. Imports peaked at USD 6,302 million in 2008, before falling to USD 4,500 million in 2009. This represented a year-on-year decrease of 29%, which was followed by a 16.8% year-on-year increase in 2010 to USD 5,257 million. The NBG estimates that total imports, including both goods and services and after certain statistical adjustments, amounted to USD 7,057 million in 2011, as compared to USD 5,257 in 2010.

Exports

In 2011, Georgia's principal exports were ferro-alloys, motor cars, ferrous waste and scrap, gold, mineral or chemical fertilizers and copper ores and concentrates. Due to Georgia's geographic location, the transport services (including transit fees generated by the pipelines that traverse Georgian territory) and logistics sector has become a significant generator of export revenues, enabling Georgia to become a net services exporter.

Over 2006-2010, the value of Georgia's exports of goods increased significantly from USD 936 million in 2006 to USD 2,189 million in 2011. The increase was principally due to increased exports of ferro-alloys and motor cars and continued liberalization of trade policy and import tax reforms.

No customs tariff on export and re-export

Notwithstanding the overall increase in the past five years, exports decreased by 24.1% in 2009, from USD 1,495 million in 2008 to USD 1,134 million in 2009. In 2010, exports recovered to surpass 2008 levels increasing by 39.6%, as compared to 2009, to USD 1,583 million. Total exports, including both goods and services amounted to USD 4,048 million in 2010, as compared to USD 3,208 in 2009.

Georgia as a Trade Hub, Transportation and Logistics

Georgia is located between Europe and Central Asia and is considered to be a bridge connecting several important economic regions with a total population of more than 827 million people. It is bounded to the west by the Black Sea, to the north by Russia, to the southwest by Turkey, to the south by Armenia, and to the southeast by Azerbaijan.

Since 2004, investment in Georgia's transport infrastructure has focused on reconstruction and rehabilitation in order to modernize the infrastructure after years of underinvestment. Transport services and communication systems are in need of further modernization. In 2010, the transport sector's contribution to Georgia's nominal GDP grew by 25.6% to GEL 1,429 million, as compared to GEL 1,138 million in 2009, primarily due to the implementation of a number of infrastructure projects, including the construction of road systems, continuing projects involving Georgian Railway and work on the construction of the new Baku-Tbilisi-Kars railway line.

Located at the crossroads of Europe and Central Asia, Georgia is a bridge connecting several important economic regions, including the EU, the CIS, Turkey and the Caucasus Region. It is a key link in the shortest transit route between Western Europe and Central Asia for the transport of oil and gas, as well as dry cargo. Georgia's oil and gas pipelines, Black Sea ports (just recently, Maersk's company APM Terminals purchased shares in Georgia's Poti Port on the Black Sea), railway systems and airports are playing an increasingly important role in linking East and West.

In order to facilitate easy transport of goods through Georgian territory, the Government, in cooperation with private enterprises, continues its liberalization of regulations on international transport; development of transport infrastructure including roads, railways, sea ports and airports; simplification of customs and other administrative procedures; and the introduction of a number of economic reforms in this sphere.

The Georgian road network is comprised of 22,490 km of international roads (with cross-border links), secondary roads (between major cities and regional centers) and local roads (between villages and regional centers). In 2010, 28.5 million tons of cargo and 317.9 million passengers were carried by road transport. Approximately GEL 708 million was invested in the construction and rehabilitation of Georgian roads in 2010, as compared to GEL 553 million in 2009, and more than GEL 500 million is budgeted for 2011.

Approximately 80 km of a four-lane highway connecting eastern and western Georgia have been constructed, which was jointly financed by the World Bank and the Government. In addition, the Japanese International Cooperation Agency has provided loans for a highway improvement project to upgrade the 40-km section of the East-West Highway in western Georgia and build a bypass around Kutaisi. The Asian Development Bank has also provided loans for the construction of the Adjara bypass road, part of the East - West Highway with cross-border links to Turkey.

Georgia has good sea, air, rail and road connections to the main apparel market EU, Russia and Turkey

Two international airports in Georgia

There are three operating sea ports in Georgia

Key link in the shortest transit route between Western Europe and Central Asia for oil and gas as well as cargo

Liberalization of regulations and investment into infrastructure to make Georgia a leading trade hub

Noteworthy that, since 2003, more than 3,000 km of roads have been improved and refurbished

The Georgian railway, which is state-owned, runs on 1,554 km of track. In addition to serving the Georgian market, the Georgian railway connects with Azerbaijan State Railway to form part of the shortest rail link between the Black Sea and the Caspian Sea. In 2010, Georgian Railway carried 19.3 million tons of cargo, including 11.1 million tons of oil and oil products and three million passengers

In 2010, 22.7 million tons of cargo were processed at Georgia’s sea ports and terminals on the Black Sea, Batumi Sea Port (8.0 million tons), Poti Sea Port (7.3 million tons), Kulevi Sea Terminal (3.4 million tons) and Supsa Sea Terminal (4.0 million tons).

In 2008, JSC National Company KazMunayGas, the Kazakh state-owned oil company, leased the Batumi port and oil terminal. In addition, in 2007, the Kulevi oil terminal, situated between Poti and Batumi on the Black Sea, was completed. The Kulevi oil terminal is majority-owned by SOCAR, the Azeri state-owned oil company. Georgia’s ports and terminals serve as key links in the transportation corridor between Asia, the Caucasus and Europe. Additionally, they contribute to the growth of the Georgian railway, since oil and oil products originating in Central Asia and Azerbaijan and exported through the seaports are transported, *inter alia*, by rail across Georgia.

Georgian sea ports are linked with the ports of Ilychevsk and Kerch (Ukraine), Varna (Bulgaria) and Kavkaz (Russian Federation) by direct railway-ferry lines and with Novorossiysk (Russia) and Burgas (Bulgaria) ports by direct Ro-Ro lines. In addition, Georgia is currently in negotiations with Turkey and other countries to establish direct ferry connections.

In 2010, over 918,660 passengers passed through Georgia’s three main international airports, Tbilisi International Airport (822,818 passengers), Batumi International Airport (88,627 passengers) and Kutaisi International Airport (7,221 passengers). In early 2007, each of Tbilisi International Airport and Batumi International Airport were significantly upgraded. These airports are currently served by Georgian Airways, the national airline, and 12 foreign airlines, including, *inter alia*, Aerosvit, Air Baltic, Austrian Airlines, British Midland International, CZA, LOT Polish Airlines, Lufthansa, Pegasus Airlines, S7 Airlines, Turkish Airlines and Ukraine International Airways. Direct air connections are available from Tbilisi to, *inter alia*, Amsterdam, Athens, Baku, Dubai, Frankfurt, Istanbul, Kyiv, London, Minsk, Moscow, Munich, Odessa, Paris, Riga, Tel Aviv, Vienna and Vilnius.

In 2005, the Government announced a civil aviation “open sky” policy under which new air service agreements were entered into with the aim of abolishing restrictions in relation to the number of air carriers permitted to operate flights, the capacity, frequency and destinations for such flights and the establishment of a liberal international tariff regime. Since 2005, Georgia has entered into new air service agreements and protocols amending existing agreements with Armenia, Austria, Azerbaijan, the Czech Republic, Latvia, Poland, Switzerland, Turkey, the United Kingdom and the United States.

57 flights to Europe weekly

55 flights to CIS weekly

Direct flights between Georgia and nine EU member states

Over the last five years, passenger traffic between Georgia and the EU has increased by an average of 10% per year, while cargo traffic has increased by an annual average of 26%

Transportation Routes

	Western Europe	Central Asia	Russia
<u>Road</u>	Georgia-Turkey-Bulgaria-Romania-Hungary-Austria-Germany	Georgia-Azerbaijan-Kazakhstan	Georgia-Azerbaijan-Russia
	Georgia(Poti by Ferry)-Bulgaria-Romania-Hungary-Austria-Germany	Georgia-Azerbaijan-Kazakhstan-Central Asia	
	Georgia (Batumi by Ferry)-Ukraine-Poland-Germany	Georgia-Turkey-Middle East	
<u>Sea</u>	Georgia(Poti)-Turkey-Nederland or Germany		Georgia (Poti/Batumi)-Turkey-Russia
	Georgia (Batumi)-Turkey-Nederland or Germany		Georgia (Poti)-Egypt-Germany-Russia
	Georgia (Poti)-Egypt-Nederland or Germany		
<u>Air</u>	Tbilisi-Frankfurt	Georgia-Azerbaijan-Kazakhstan	Georgia-Russia
	Tbilisi-London		Georgia-Azerbaijan-Russia
	Tbilisi - Moscow		
	Tbilisi-Vienna		
<u>Rail</u>	Georgia-Turkey-Europe (under construction)	Georgia- Azerbaijan-Kazakhstan	Georgia-Azerbaijan-Russia
			Georgia (Poti)-Ukraine-Russia
			Georgia (Poti/Batumi)-Russia

Taxes and Tax Rates

There are six taxes currently in force in Georgia.

Income Tax

The personal income tax rate is 20% .

Corporate (Profit) Tax

Legal entities carrying out activities in Georgia are subject to corporate profit tax which is 15%. Georgian entities, meaning entities incorporated or managed in Georgia, pay corporate profit taxes on their worldwide income.

In contrast, foreign entities pay corporate profit taxes only on Georgian-sourced income. Taxable profit of Georgian entities, as well as that of foreign entities operating in Georgia through their permanent establishment, is equal to the difference between taxable income and tax-deductible expenses.

Foreign entities earning Georgian-sourced income without a permanent establishment in Georgia are subject to withholding tax on this income at the source of payment (i.e. by the company paying income) at the rate of 10% or 15%. Certain relief on non-resident income withholding tax may be available through applicable Double Taxation Avoidance Treaties, if any.

Georgia has no separate tax on capital gains. Capital gains of resident natural persons, as well as Georgian-source capital gains of non-resident natural persons arising from the sale of any asset (including securities), are taxable at the flat personal income tax rate of 20%. The sale of tangible assets (including securities) held by an individual for more than 2 years is exempted from personal income tax.

Capital gains of Georgian entities, as well as Georgian-source capital gains of foreign entities, are taxable similarly to other taxable profit at the flat profit tax rate of 15%.

Withholding Tax on Dividend

At present 5% (0% by 2014) withholding tax is imposed on dividends paid to natural persons and foreign entities, subject to certain relief which may be available through applicable Double Taxation Avoidance Treaties. Dividends paid to Georgian entities or Georgian permanent establishments of foreign entities are not subject to withholding tax and are not included in taxable profit.

By the initiative of the Government of Georgia, decision regarding the increase of taxes can only be made after countrywide referendum.

Corporate Income Tax: 15%

Personal Income Tax: 20%

Withholding Tax: dividends distributed to individuals and non-residents are subject to 5% (decreasing to 0% by 2014)

VAT: 18%

Property Tax: up to 1%

Import/Customs Tax: 0%, 5%, 12%

No payroll tax or social insurance tax

No capital gains tax

Withholding Tax on Interest

A 5% (0% by 2014) withholding tax is imposed on interest payments made by Georgian entities or Georgian Permanent Establishments of foreign entities, provided that the source of interest income is in Georgia. Interest received from licensed financial institutions is no longer taxed at the source and is not included in the gross income of the recipient unless it is also a licensed financial institution. If the recipient is a licensed financial institution, the interest is not taxed; it is however included in its gross income.

No wealth tax, inheritance tax or stamp duty

Relief on withholding tax on interest income may be available through applicable Double Taxation Avoidance Treaties.

Property Tax

Georgia applies property tax at a flat rate of up to 1% on the annual average net balance sheet value of tangible and intangible non-current assets of Georgian entities and Georgian permanent establishments of foreign entities. The property tax is a local tax. As such, its exact rate is determined by Units of Local Self Governance. Notably, land and certain movable property (cars, yachts, etc.) are taxed based on specific rules set out by domestic tax law.

Foreign-source income of individuals fully exempted

Value Added Tax

The Tax Code of Georgia sets the value added tax at the rate of 18%. Taxable operations include supply (and import) of goods and services in Georgia. Certain business activities, such as, for instance, financial services, are exempt from VAT. The Tax Code of Georgia establishes a mechanism to, on a monthly basis, offset input VAT (VAT on purchase and import) against output VAT (VAT on sale). Surplus VAT payments can be reclaimed or offset against future VAT payments or current tax liabilities pursuant to the special provisions of the Tax Code of Georgia.

Tax rates reduction timetable has been further accelerated in 2008

With respect to the electricity sector, VAT exemption applies to the import of goods and/or construction-installation, renovation, rehabilitation, testing and/or geological exploration services financed by the favorable credits issued by the foreign states and/or international organizations under international agreements ratified by the Parliament of Georgia for the purposes of rehabilitation of the Georgian electricity sector. Supply of electricity to the consumers (except to the retail consumers) is exempt from VAT until January 1, 2012.

Withholding Taxation and Double Taxation Avoidance Treaties

Income earned by foreign companies and individuals from Georgian sources not having a Permanent Establishment (PE) in Georgia is subject to withholding tax at the source of payment. Double taxation treaties may reduce the tax rates. In general, double taxation treaties provide relief from the payment of non-resident income withholding tax (such as on interest payments, for instance), as well as withholding tax on dividends and capital gains in Georgia when the non-resident has invested in the Georgian company in excess of a certain investment threshold, while taxing dividends and capital gains in other cases at lower tax rates compared to the statutory rates.

Currently Georgia has 31 OECD model double taxation avoidance treaties with: Armenia, Austria, Azerbaijan, Belgium, Bulgaria, China, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, India, Iran, Ireland, Italy, Kazakhstan, Latvia, Lithuania, Luxemburg, Malta, The Netherlands, Poland, Romania, Singapore, Turkey, Turkmenistan, Ukraine, The United Kingdom, Uzbekistan.

Treaties with: State of Kuwait, State of Qatar, United Arab Emirates, Spain, State of Israel, Switzerland and Egypt are ratified by Georgia and will enter into force after ratification by a contracting state.

Treaties with: Cyprus, Kingdom of Norway, Kingdom of Bahrain, India, Slovenia, Slovakia, Hungary, Portugal are in line for the official signature.

Georgia has 31 OECD model double taxation avoidance treaties in place

Because Double Tax Avoidance Treaties vary from country to country, they must be analyzed in the light of the investor's specific circumstances.

Customs Duties

Newly adopted Tax Code of Georgia (TCG) regulates both tax and customs issues. The TCG defines various customs regimes under which goods are brought in or taken out of the customs territory of Georgia. Taxpayers of customs duties are persons who cross the customs border of Georgia holding the goods.

Where imported goods are subject to customs duties, the importer or the importer's authorized representative is responsible for the payment of any customs duties due at the time the goods are released by customs for free circulation within the territory of Georgia.

Customs duties include taxes and fees payable upon bringing goods in or taking them out of the customs territory of Georgia, and for some special goods a license fee is payable.

Taxes payable upon import include customs (import) tariff, VAT (payable on imported goods by both VAT registered and non-VAT registered persons) and excise tax (if applicable).

Customs Tax (Tariff)

Customs tax is based on either customs value or per physical unit of goods. The rate applicable to the customs value of the goods is fixed at 0%, 5% or 12%, depending on the classification of the goods. Most goods fall into the 0% rate. Most food products and construction materials fall under the 5% or 12% tax rates.

Customs Fees

Customs fees are payable at the time of declaration of the goods to customs and are due on import, export, or transit of goods into, out of, or through Georgian customs territory, as well as upon the registration of temporarily imported transportation means.

Tax Free Regimes in Georgia

Specialized tax rates and procedures have been adopted for 3 types of Tax-Free Regimes in Georgia. These include: 1. Free-Industrial Zones (FIZs); 2. Free Warehouse Enterprise; and Entities designated as *International Finance Companies*. These innovations are intended to establish new international financial institutions within the country, to attract inward investments and to encourage economic growth and sustainable development. The introduction of free warehouses and international enterprises into the tax and legal systems is intended to encourage the trade-transit function within Georgia.

Free Industrial Zones

Free Industrial Zone legislation was introduced in Georgia in 2007 for the purpose of encouraging foreign investments, stimulating exports and developing Georgia's international trade-transit activities. A favorable tax and customs framework for FIZ is intended to provide incentives for international firms to develop their production bases within such zones. As of December 31, 2010 there are 3 FIZs in Georgia, which entitle FIZ-incorporated International Companies to operate in a tax-free environment. In Free Industrial Zones firms can process, produce and export goods with minimal tax burden; export goods free of trade barriers to global markets; and export more than 7,200 types of goods under GSP+ terms to the EU.

*Free Industrial Zones can be established on any territory **exceeding 10 hectares**, except for the protected territories under the Georgian Land; the decision on the creation of Free Industrial Zones is made by the Government of Georgia*

Currently two FIZs are operated in Georgia – the Poti FIZ and Kutaisi FIZ

Free Warehouse Enterprise

Due to its geographic location, of Georgia's goals is to facilitate *shortest and fastest transit route* between Europe and Central Asia. This goal is supported by the legislation which enables incorporation of Free Warehouse Enterprises. Such an entity is intended to be an integral part of an international transit company and to benefit from exemptions from profit tax applied to income received from re-exporting goods from an independent warehouse via Free Warehouse Enterprise. The VAT rate on the supply of goods by a Free Warehouse Enterprise to a VAT taxpayer is 0%.

International Finance Company

Georgian tax legislation offers incorporation of an International Finance Company. An International Finance Company is defined as an entity whose revenues received from financial operations implemented or financial services provided in Georgia do not exceed 10% of its gross revenues. An IFC is not required to obtain a license from the National Bank of Georgia. Activities of IFCs are exempt from taxes (i.e., it operates under a Tax-free Regime).

Comparative Table of Tax Exemptions

Tax	FIZ Int'l Company	Free Warehouse	Int'l Finance Co
Corporate Income Tax	0%	0%	0%
Value Added Tax	0%	0%	0%
Customs Tariff	0%	up to 1%	up to 1%
Property Tax	0%	0%	up to 1%
Personal Income Tax	20%	20%	20%

Appendix B

List of Countries Eligible for Simplified Recognition of Pharmaceuticals

Drugs registered under the European Medicines Agency or registered in the following countries are eligible for the simplified recognition procedures for drugs that was introduced per a government decree in March 2009 (see Section 7 of this report for details):

- | | | |
|-------------------|----------------|---------------------|
| 1. Australia | 13. Greece | 25. Norway |
| 2. Austria | 14. Hungary | 26. Poland |
| 3. Belgium | 15. Iceland | 27. Portuguese |
| 4. Bulgaria | 16. Ireland | 28. Romania |
| 5. Canada | 17. Italy | 29. Slovakia |
| 6. Cyprus | 18. Japan | 30. Slovenia |
| 7. Czech Republic | 19. Korea | 31. Spain |
| 8. Denmark | 20. Latvia | 32. Sweden |
| 9. Estonia | 21. Lithuania | 33. Switzerland |
| 10. Finland | 22. Luxembourg | 34. The Netherlands |
| 11. France | 23. Malta | 35. Uk |
| 12. Germany | 24. New zeland | 36. USA |

Appendix C

List of Georgian Laws Relating to Pharmaceutical Sector

The following are the laws in Georgia that relate to the pharmaceutical sector in Georgia:

- Law on Medicines Drugs and Pharmaceutical Activities (1997)
- Law on Product and Service Licensing (1996)
- Law of Georgia on Health Care
- Law of Georgia on Patents
- Law on Licensing of Entrepreneurial Activity and Permissions (1999)
- Law on License and Permission fee
- Law on Licensing Medical and Pharmaceutical Activity (2003)
- Law on Protection of Consumers' Rights
- Law on Rights of Patients in Health Care (2000)
- Law on Physicians Activities (2001)
- Law on Narcotic Means, Psychotropic, Precursors and Narcologic Care (2003)

The Georgian Law on Drugs and Pharmaceutical Activities (1997) is the primary legislation affecting the sector. The legislation is comprehensive and divided into the following areas:

- Main provisions and definitions
- State policy in area of medicines turnover
- State regulation in the area of medicines turnover
- Pharmaceutical product admission to the Georgian market
- Therapeutic Agent manufacturing
- Creation of medical remedies and pharmacological research
- Ensuring quality of medicines
- Production of medicines
- Issuance, application and destroying of medicines
- Import, Export, Re-export and Transit
- Substances, remedies and forms of medication under special control
- State system of quality control of medicines
- Monitoring of side effects of medicines
- Information about medicines and advertisement
- Pharmaceutical specialist and pharmaceutical institution
- Transition provisions

It was this Law on Drugs and Pharmaceutical Activities that was amended in March 2009 as described above.