

# Opportunities in Georgia's Pharmaceutical Sector

**HIGHLIGHTS  
FROM FULL  
INVESTMENT GUIDE**

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# About Georgia

## Snapshot

- Area: 69,700 sq km
- Population: 4.4 million

## Healthy, Growing Macro-economy

- **6.4%** real GDP growth in 2010 and range of **5.0-5.5%** annual real GDP growth projected for 2011-2016.
- FDI of **US\$ 815 million in 2011**, a **43%** increase over 2010 and continued growth expected thru 2016.
- **\$2.2 billion** in exports in 2011, up from **\$1.6 billion** in 2010.
- **BB-** long term local and foreign currency credit ratings (S&P and Fitch) and a successful Eurobond placement in April 2011, **5.3x** oversubscribed.

## Attractive Business Environment

- **#7 of 183 countries in the World Bank's 2011 "Ease of Starting a Business" report**
- Main **gateway** for land transportation from Europe and Turkey to Central Asia and most attractive **hub** for doing business in the region.
- **Attractive and efficient tax and customs regimes** with one of the most liberal economies in the world, and various newly established **free economic zones**.
- Numerous bilateral and multilateral **trade agreements**. Negotiations on DCFTA with US and EU- to be completed by 2014
- **Low cost but well qualified labor** (average wages less than in Turkey and China, 97% literacy, and growing English speaking population)
- Attractive, Western **living environment** with charming, welcoming and safe capital Tbilisi, vino-culture as birthplace of wine, Black Sea coast, and Caucasus mountains.





# Why Pharmaceuticals in Georgia?

## Strong Growth Track Record

- Significant and steady growth over the past five years in local production, exports and local sales of locally produced pharmaceuticals, and import of pharmaceuticals as shown in the table to the left
- Growing role as hub for distribution, reaching an estimated **\$15 million** in re-exports to other/surrounding countries in 2011

## Georgia's Pharmaceutical Sector Statistics

	Average annual growth rate (2005-2011)	Amount, US\$ millions (2011)
Production	35%	\$48*
Export (of locally produced)	47%	\$18
Local sales (of locally produced)	33%	\$35*
Imports	15%	\$210

Source: Geostat (\*denotes preliminary figures)

## Strong Growth Opportunities

- Emerging markets widely considered to be the driver for growth in the global pharmaceutical market over the coming decade, and Georgia and the surrounding region have significant room for growth
- Expected growth in Georgia due to currently low per capital pharmaceutical expenditures along with rising incomes, and strong projected GDP growth

## Competitive Sub-Sector Niches:

- Bacteriophages, Natural and herbal medicines, R&D and Clinical Testing

## Attractive business environment

- No price controls (no regulation related to pricing or price mark-ups)
- No VAT or customs taxes on pharmaceuticals
- Recently simplified pharmaceutical regulation (attractive time to invest during liberalized period, before regulation becomes more balanced with the West in the long run)
- Low cost but well qualified labor in the pharmaceutical industry

# What Kinds of Investment Opportunities Exist?

## Pharmaceutical Manufacturing

- For local market and export
- Opportunities to invest in existing companies or new joint/independent ventures
- Niche sub-sector opportunities: bacteriophages and natural/herbal medicines
- Contract Manufacturing Organizations (CMOs)

## Pharmaceutical Packaging

- Opportunity to establish pharmaceutical packaging (paper cartons) manufacturing in Georgia for import substitution and sales in the region

## Pharmaceutical Retail Chains

- Room for consolidation or support for up-and-coming 2<sup>nd</sup> tier players

## Hub for regional distribution

- Opportunity to seize retail growth opportunities in neighboring and other CIS countries, with Georgia as a hub with the most attractive business environment and regulation in the region

## Contract Research Organizations (CROs) and R&D

- Increasing number of clinical trials being conducted in Georgia
- Access to new high bio-safety BSL 2 & BSL 3 National Laboratory

**Companies specifically known to be open to or actively seeking investment partners**

### General Production

- Biopolus
- Apipharm
- Gama

### Bacteriophages Production

- BioChimPharm

### Herbal/Natural Production

- Neopharm
- Iveriapharm
- Eskulapi
- Turmanidze
- Salkhino
- Similia

### Pharmacy retail/wholesale

- ABC Pharmacia  
(PharmaDepot brand)

# Pharmaceutical Manufacturing: Industry Snapshot

## Statistics

- **70** manufacturers (of which an estimated 50-60 are operating and of which 15 have annual revenues of US\$ 230,000 or more) as of July 2011
- **US\$ 48 million** local production in 2011 (**35%** annual growth from 2005 to 2011)
- **US\$ 18.5 million** exports of locally produced pharmaceuticals in 2011 (**47%** annual growth from 2005 to 2011)

## Types of Production

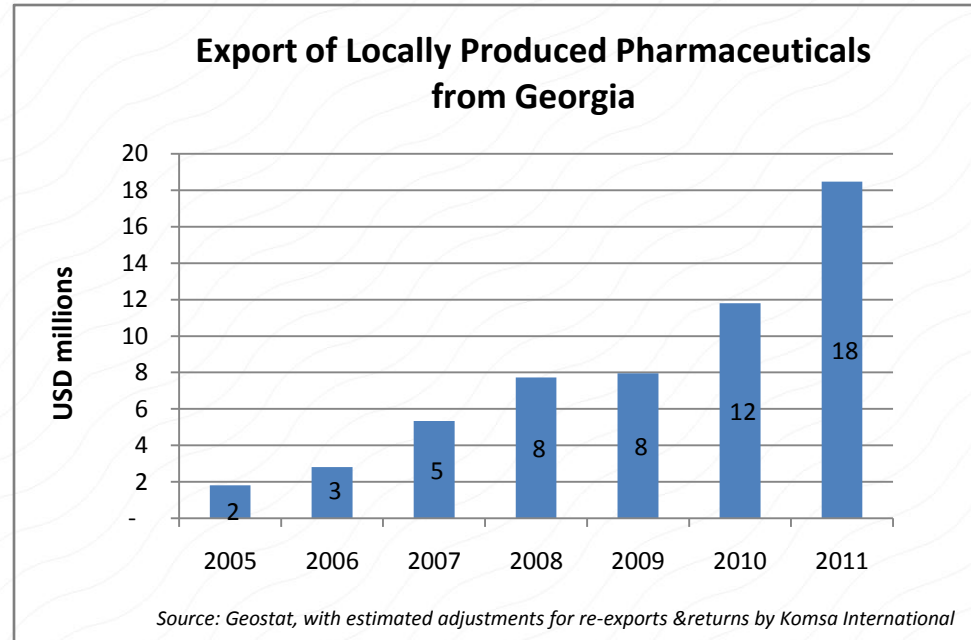
- **Level of manufacturing:** Secondary manufacturing and packaging (primary manufacturing in herbal/natural medicines and bacteriophage production only)
- **Forms:** Broad range (tablets, sprays, syrups, powders, injections, extracts, capsules, gels, balms, eye drops, granules)
- **Ailments Treated:** Broad range (gastrointestinal, cardiovascular, pain, ear/nose/throat, respiratory, etc.)
- Almost all packaging materials are imported, with exception of outer paper packaging and some other basic packaging. in some cases only.
- **Largest Producers (account for 90% of production):** Aversi Rational (conducts packaging, associated with Aversi pharmacy chain, holds ISO, EU GMP and US FDA certification from private auditor) and GM Pharmaceuticals (conducts formulation and packaging, associated with PSP pharmacy chain, holds EU GMP certification from private auditor, expects to receive French government agency GMP certification in 2012)
- **Other Major Producers:** Biopharm, Neopharm, Kamelini
- **Some Notable/Niche Producers:** Naturopharm, BioChimPharm, Salkhino, Farkoni, Tbilqimfarmi, Davati, Farmimpexi, Kardu, Apipharm, Tbilisi Pharmaco-Chemistry Institute, Biopolus.
- **Producers with Foreign Investment:** Euromedical, Gama, Iveriapharm



# Pharmaceutical Manufacturing: Export Growth

## Statistics for Exports of Locally Produced Pharmaceuticals:

- Average annual growth rate of **47%** from 2005 to 2011
- **US\$ 18.5 million** in exports in 2011.
- Exports to **16** countries in 2011
- **Main export markets established and growing:**  
Uzbekistan, Armenia, Tajikistan, Kyrgyzstan, Azerbaijan, Ukraine, Kazakhstan
- **Smaller established markets:** Turkmenistan, Belarus, Russia, Bulgaria
- **Recently new export markets (in past 2 years) :** Moldova, Libya, and Sierra Leone, as well as Australia and India (both for small and/or sample orders)





# Pharmaceutical Manufacturing: Competitive Niche Sub-Sectors

## Bacteriophages

- Since the 1930s, Georgia has been a pioneer and leader in R&D and production of bacteriophages.
- Used for treating various bacterial infections.
- Development of phages hindered, as a result of political and economic transition and lack of funding.
- With rise of drug resistant strains of bacteria, potential role of phages is garnering new attention in the West.
- 3 companies focusing on phages production (Biopharm-L, BioChimPharm, and Bacteriopagi Biopreparatebi).
- Well established exports within the CIS region, and room for new markets with further R&D and marketing.

## Natural/Herbal Medicines

- 40 varieties of unique medicinal and herbal plants in the Caucasus mountains
- Underutilized pristine/organic agricultural land available for cultivation.
- Already a number of producers of natural based and herbal based medicines, including unique/innovative branded products.
- Growing sales within the CIS.
- Potential to break into the EU market with investment into EU-demanded standards, licensing, and marketing.



## R&D and Clinical Testing

- Increasing number of clinical trials registered in Georgia, due to low costs and prevalence of volunteers. 4 global contract research organizations (CROs) have representation in Georgia for clinical trials.
- Recently established US\$ 150 million national laboratory (Central Public Health Reference Laboratory ) with biosafety level 2 and 3 laboratories and vivarium, ready to cooperate with governments and private sector.



# Pharmaceutical Retail/Wholesale Market: Industry Snapshot

## Statistics

- **US\$ 210 million** pharmaceutical imports, **\$35 million** local sales of locally produced pharmaceuticals (2011)
- ~**2,000** pharmaceutical retail companies with total of ~**3,000** pharmacy outlets (as of July 2011)
  - **46** companies own more than 3 pharmacy outlets
  - **2** companies dominate the market (with 600 outlets combined)
- Imports from **92** foreign manufacturers (2010 data)
- **75** companies importing pharmaceuticals, mix of wholesalers and retailers (2010 data)
- Imports from **60** countries, with largest proportion from Western Europe. Top importing country in USD terms is Turkey, followed by Germany, Hungary, France, Switzerland, and Ukraine (2011 data).

## Market Characteristics

- Two largest pharmacy chains in Georgia dominating approximately **45%** of the market
- In comparison to Western markets, pharmaceutical shops in Georgia are **smaller scale and more prevalent**
- Prices have generally been **high**, due to domination of the market by just a few players
- With **simplified regulation** aimed to encourage competition, a **new player** (PharmaDepot) has entered the market establishing discount, larger scale pharmacy shops and other players are beginning to follow suit.
- Association of Pharmaceutical Company Representatives in Georgia (APCRG) active with 13 members (foreign manufacturers or representatives of foreign manufacturers).

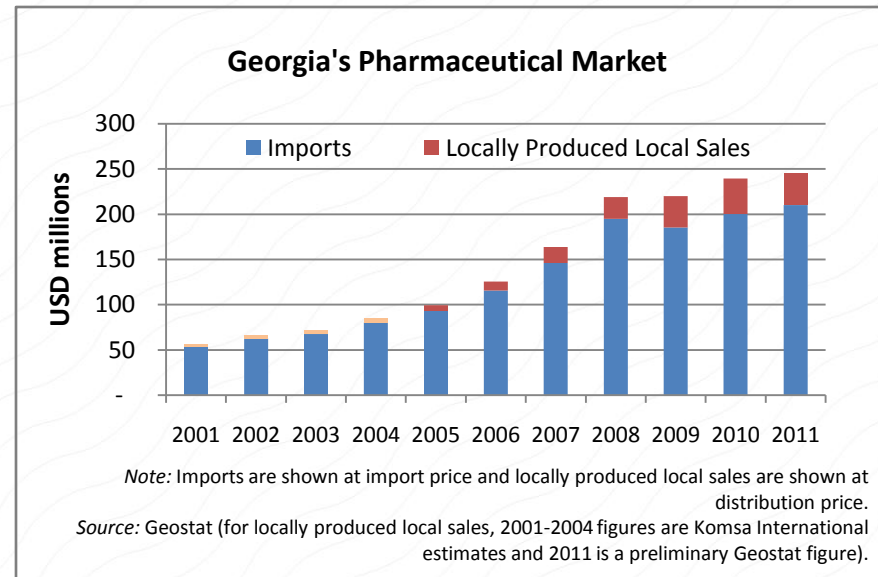
## Key Players

- **Largest pharmacy chains:** Aversi & PSP
- **Other Key Pharmacy chains:** GPC, ABC Pharmacia (PharmaDepot brand) Sakhalko Aptiaki, Narinjispheri Pharm, Neopharm+, Saaptiako Sakhli, Krystali, Hekate
- **Key Distributors:** PSP, Aversi, Globalpharm, GPC, ABC Pharmacia, Impexpharm, GEA, Tonusi

# Pharmaceutical Retail/Wholesale Market: Growth Performance

## Strong Growth Track Record:

- **15%** average annual growth in imports (2005-2011)
- **33%** average annual growth in local sales of locally produced pharmaceuticals (2005-2011)



## Significant growth expected (in Georgia and the surrounding region) as incomes continue to rise:

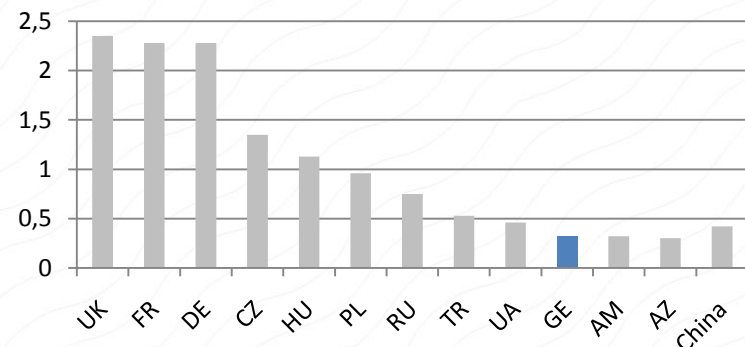
- Annual per capita consumption of pharmaceuticals in Georgia is only **US\$ 35** per year, versus **US\$ 62** in Ukraine and **US\$ 99** in Russia, and a range of **US\$ 200-400** in Europe (2010 data), which along with income and GDP growth suggests room for growth
- Track record and commitment to advancement of health care, with growing percent of the population being insured (currently only **30%** and expected to rise) and a growing percentage of public expenditures going towards healthcare

# Human & Other Resources:

## Low Labor & Energy Costs

- The average wage is less than that in China, and approximately **1/3 less** than in nearby Turkey.
- Average gross monthly wages in the pharmaceutical industry are in the **US\$ 300-600** range, and typically up to **US\$ 1,800** for senior technical staff and management.
- Electricity costs, which are also critical to pharmaceutical production, are also low compared to other countries in the region due to vast hydro resources.

**Figure 2. Average Gross Monthly Salary 2009, US\$ thousands**



Source: National Statistics Office, World Bank

### Overall Employment Statistics for Georgia (2010)

**Average gross monthly salary:** USD 342

**Population:** 4.4 million

**Labor force:** 1.9 million

**Unemployment rate:** 16%

Source: Geostat



# Human & Other Resources:

## Education, Skills & Research Institutes

### Education & Skills

- High literacy rate (97%) and good quality education (legacy from Soviet times).
- Study in the pharmaceutical field becoming more and more popular.
- 13 public and private universities and institutes offering degree programs in pharmacy, with a consolidation taking place whereby weaker programs are closing.
- Strongest program at Tbilisi State Medical University (TSMU).
- Students graduate with a solid foundation of skills, but many pharmaceutical companies (particularly in the area of manufacturing) find it necessary to provide additional training and depend on some managers with foreign education/experience.



### Research institutes

- Has historically had strong scientific research institutes which still operate today.
- Those operating with in the pharmaceutical field:
  - I. Kutatelaze Institute of Pharmaco-Chemistry
  - George Eliava Institute of Microbiology (including focus on phages)
  - Central Public Health Reference Laboratory (CPHRL) previously mentioned

# Regulatory Environment

## Overview

- No price controls (absolutely no pricing or mark-up regulation related to pharmaceuticals)
- No VAT or customs tax on pharmaceuticals, inputs and equipment specifically for pharmaceutical production, and medical devices (however VAT must be paid to vendors on non-pharmaceutical inputs)
- Agency for State Regulation of Medical Activities (licensing and monitoring of production, trade, prescribing and disposal)
- Law on Medicines and Pharmaceutical Activity (1997) as later amended
- Various related laws (health care, patents, licensing, consumer rights, physicians, etc.)
- New simplified licensing for import of GMP certified (for certain countries) and FDA certified pharmaceuticals
- New legislation allowing for parallel imports of pharmaceuticals
- Plans for national GMP certifying agency by 2016

## Key Licensing & Regulatory Procedures

- Manufacturers: Obtain initial license based on documentation of plans. Review and registration process for each product developed for sale. Products subject to selective control testing.
- Pharmacies: Simple initial notification procedure for Category 1 (OTC) & Category 2 (OTC and prescription) pharmacies. Special initial licensing procedures and regulations for Category 3 pharmacies (specially controlled drugs). Staff with medical degree or pharmacist degree required for Category 2 & 3 pharmacies. Pharmacies subject to selective control inspections for compliance with regulations and standards.
- Distributors: Registration for each product imported/sold. Subject to selective control inspections.
- Registration of drugs: 7 days for drugs with GMP (certain countries) or FDA certification, typically 3 months for other drugs and drugs produced in Georgia, simple notification procedures for parallel imports.

# Contact GNIA for Investment Support

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.

## Georgian National Investment Agency (GNIA)

- Sole public agency responsible for promoting and facilitating foreign direct investment in Georgia.
- As a moderator between foreign investors and the Government, 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.
- We are also ready for constructive dialogues 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.
- 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:

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