

Transparency International Georgia

The Georgian Pharmaceutical Market



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This report is the first of three reports that describe the status of the health care sector in Georgia. The goal of this project is to examine and raise awareness of ongoing reforms and developments in the health care sector. The project focuses on the pharmaceutical, insurance and hospital sectors. The content and opinions expressed herein are those of Transparency International Georgia and do not necessarily reflect the views of the Embassy of the Kingdom of the Netherlands in Tbilisi, Georgia.

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Executive Summary

This report describes the situation within the pharmaceutical sector of Georgia. It assesses the market environment, and discusses other issues of importance in this sector with regard to quality safeguards.

The pharmaceutical market is characterized by a lack of effective governance and a strong concentration of market power of a few large companies. During the last decade, three well-established companies: Aversi, PSP and GPC have acquired a position where they are able to dominate the import/distribution, the retail and the manufacturing sector of the pharmaceutical market. We found that:

- The pharmaceutical market is best described as an oligopoly and vertical monopoly of two companies that use their strong concentration of market power in the import/distribution, the retail and the manufacturing sectors to dominate the market.
- The 2009 legislative amendments designed to promote competition have only had a limited effect on the market. While the barriers to competition created by previous legislation have been removed, other barriers—such as the dominance of large companies—have not been adequately dealt with.
- The situation in the market leads to increasingly high expenditures on pharmaceuticals. The Georgia Health Utilization and Expenditure Study 2010 shows that the expenditures on medical goods in 2010, made up for 60% of the total health care expenditures per household. From 2007 to 2010 the expenditures on pharmaceuticals have grown at the pace of 23.7% each year.
- The market dominance of a few companies leads to high markups for medicines which explains the high expenditures of pharmaceuticals. The markup for medicines in Georgia is far above the average markup for medicines in other European countries.
- A recent study by the Curatio Foundation shows that, while a general price decrease for medicines occurred during the last three years, only 30% of these medicines truly decreased in price.
- The prescription behavior of doctors appears to be influenced significantly by financial or other incentives offered by large pharmaceutical companies.
- The largest pharmaceutical chains reportedly promote their own medicines in their stores to an unacceptable extent. They do not always follow doctors' prescriptions when selling medicines to the clients, and employees are instructed to sell and promote the medicines manufactured by respective companies.
- Aversi Rational and the company GMP play an important role in the development of the manufacturing sector in Georgia. They both hold GMP certifications for complying with European Good Manufacturing Practices from reputable private European consulting firms. The company GMP is currently in the process of receiving a GMP certification from an official government certifying body in France. There is no national GMP certifying agency in Georgia but the government plans to establish one in 2016. This will increase the safety and trustworthiness of Georgian medicines considerably.
- The Agency for State Regulation of Medical Activities responsible for examining the quality of medicines appears to lack the resources to perform its role effectively.
- Due to a loophole in the registration procedure, there is a possibility that counterfeits or “bad medicines” will enter the market.

- There seems to be a close relationship between the government, the ruling party and the big pharmaceutical companies.

Recommendations:

Promote Market Competition:

- *Effective Anti-Monopoly Regulation:* The newly established competition agency can play an important role in a comprehensive analysis of the pharmaceutical market. Further research over a longer period of time is important to understand the effects of the law and will provide grounds for appropriate action. The law defines a dominant position in the market as a situation where a company's market share is higher than 40%. Meanwhile, a market-share of 25% is defined as insignificantly limiting competition. Based on our findings, these margins should be the subject of further research and appropriate action. We recommend a comprehensive analysis of the pharmaceutical market and appropriate action to further stimulate competition through the newly-established competition agency.
- *Reference Pricing by the Market:* The insurance industry can play a role in balancing the prices through so-called "reference pricing" mechanisms. Reference pricing is based on limiting the pharmaceutical expenditure by introducing a limit on the cost of a pharmaceutical product that a patient has to pay. This limit can be defined by the difference between the average price, or the lowest price of an original brand of generic and the prescribed brand. The current situation however poses several problems to such policy. The overarching problem is that reference pricing is not yet institutionalized. First, only roughly 25% of the population is insured. Second, pharmaceutical companies Aversi and PSP also own insurance companies. There may not be enough incentives for these companies to engage in these voluntary activities.
- *Collection and Transparency of Statistical Data about Market Shares and Prices:* Geostat should collect and publish data about market shares and the prices of medicines by company, with reference to original brands and generics. This information is crucial for extended and comprehensive market analysis over a long period of time, which would provide an insight in the effects of policy and the development of the market.

Increase Affordability and Rational Use of Medicines

- *List of Essential Medicines and Promotion of Generics:* The high markups for lowest-price generics lead to low availability and affordability of medicines. Generics can play an important role in reducing the price and cost of pharmaceuticals, but fail to do so in the Georgian market. The World Health Organization has an updated list of essential medicines which can be used as a guide for the Georgian list. The promotion of generics—in combination with the regulation of their markup based on a list of essential medicines—would significantly increase the accessibility and affordability of products essential for public health.
- *Enforcement of Prescription Guidelines:* Doctors are offered financial and non-financial incentives introduced by the pharmaceutical industry to prescribe certain medicines. There are

currently around 170 guidelines approved by the government. However, these guidelines are not enforced and therefore lack any meaning, as no incentive exists to follow them. The guidelines could be enforced by physicians and the insurance industry, but this has not happened so far . Therefore the government should introduce incentives to encourage the adoption and application of these guidelines. Continuous monitoring is essential in order for the legislation to have an effect.

Improve procedures and the quality of medicines:

- *Traceability of Imported Medicines:* Stronger requirements for proper transportation and means to check the quality of transportation which can be based on the requirements of the European Medicines Agency..
- *Increased Resources for the Drug Agency:* The Agency for State Regulation of Medical Activities should have adequate resources in place to examine the quality for representative samples of medicine. There should be more transparency about the criteria and findings of the review, making it possible for the public to evaluate the agency's activities and have insight into the findings.

Introduction

This report examines the situation within the Georgian pharmaceutical sector, focusing primarily on the pharmaceutical market. The first part of the report deals with a description of the market's development and the current situation therein. It focuses on import, retail sales and manufacturing, and describes the situation and the practices of the largest companies within these sectors. Furthermore, it discusses the pros and cons of the amendments to the Law on Drugs and Pharmaceutical Regulation introduced in 2009, and the effects of these regulations on the market.

The next section of the report deals with the main problems that were mentioned frequently by key stakeholders in our interviews. The issues include traceability of medicines, problems that arise from the lack of a prescription policy, the lack of quality examination by the Agency for State Regulation of Medical Activities and a worrisome loophole in the registration procedures for medicines.

Research Methodology

The assessment of the market is based upon a bottom-up approach combining desk research, first-hand interviews and statistical data. In order to render the assessment as accurate as possible, information was verified through multiple sources.

Interviews: Two kinds of interviews were used: (1) Open in-depth interviews that contributed to our understanding of the market and made a deeper analysis of the situation possible, and (2) a closed questionnaire containing several hypotheses about the pharmaceutical market, of which we used the answers of 14 key stakeholders as reliable respondents.

Desk Research: Analysis of existing reports on the pharmaceutical sector in Georgia. Academic literature and media reports were used as additional sources.

Statistical Data: An analysis of existing statistical data. An important source has been the research of the Curatio International Foundation which analyzed the markups and prices of medicines over a period of three years.¹ The research was based upon a methodological approach of the World Health Organization and provides the most reliable data about price tendencies of medicines in Georgia over a longer period of time.²

Ownership Analysis: We have analyzed the ownership of the biggest pharmaceutical companies using the public registry of enterprises.

Indicators

The situation on the market is described using several indicators that are associated with competition or obstruction of competition, such as an oligopoly or a monopoly on the market.^{3 4}

-Market shares⁵

¹ Gotsadze T. (2011) *Price, Availability and Affordability of Medicines in Georgia 2009-2011*, Curatio Foundation International. And Ibidem.

² <http://www.curatiofoundation.org/?pg=29&cid=31&id=196>

³ Molnar M. et. al.,(2008) How large are competitive pressures in service markets? Estimation of markups for selected OECD countries, Organization for Economic Cooperation and Development.

⁴ Borg M. (2009) Measuring Market Competition in the EU; the Markup Approach, Bank of Valletta Review, No. 39.

- Development of the market
- Entry barriers (Licensing arrangements, access to scarce inputs, barriers to expansion, price characteristics)
- Regulatory arrangements
- Markups^{6 7}

Main Figures and Companies

The pharmaceutical market in Georgia grows at a rapid pace every year and appears to be a profitable market. While the turnover of retail trade was GEL 196.6 million in 2006, this increased to GEL 543.3 million in 2010.⁸ The turnover of wholesale of pharmaceutical products increased from GEL 502 million to GEL 896.5 million in 2006-2010, while the total production value increased from GEL 22.1 million to GEL 90.2 million in the same period of time.⁹

Between 2005 and 2010, the demand for pharmaceuticals grew at the rate of 17% per year.¹⁰ The average household in Georgia spent 34% of its disposable income on health care in 2010, compared to 15% in 2002.¹¹ In 2007, the average household spent 50% of their health expenditures on medical goods while in 2010 it spend 60% of their health expenditures on medical goods.¹² From 2007 to 2010, the expenditures on pharmaceuticals grew at the rate of 23.7% every year.¹³

Explanations for the large increase in expenditures on pharmaceuticals are often sought in the price increase for pharmaceuticals, which greatly exceed those for general goods and services in Georgia.¹⁴ According to the Health Utilization and Expenditure Survey of the World Bank, the main cause of increase has been the rising costs for outpatient drugs.¹⁵ Georgia currently spends 4% of its GDP on pharmaceuticals. This percentage is double that of the United States, a country known for its high expenditures on pharmaceuticals.¹⁶

There are 70 manufacturers in the Georgian pharmaceutical market; but two companies—Aversi Rational and GMP (PSP)—account for 90% of manufacturing.¹⁷ Aversi and PSP are also the largest companies in the import and distribution sector where they have a joint share of 48%. GPC and ABC

⁵ Ibidem footnote 4.

⁶ Ibidem footnote 3.

⁷ The Role of Economics in Cartel Detection, ESMT, website: http://www.esmt.org/fm/312/Role_of_Economics_in_Cartel_Detection_in_Europe.pdf.

⁸ Information provided by Geostat.

⁹ Information provided by Geostat.

¹⁰ Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011.

¹¹ Georgia – National Health Care Strategy 2011-2015; Affordable and Quality Health Care, Ministry of Labour, Health and Social Affairs of Georgia.

¹² Georgia Health Utilisation and Expenditure Study 2010, page 31

¹³ Ibidem footnote 11.

¹⁴ Ibidem footnote 11.

¹⁵ Georgia Health Utilisation and Expenditure Study 2010, Georgia Health and Social Projects Implementation Centre, MOLHSA National Statistics Office of Georgia, Geostat, Oxford Policy Management, Curatio International Foundation.

¹⁶ Expenditure on Pharmaceuticals Per Capita 2007, OECD ILibrary, website: http://www.oecd-ilibrary.org/sites/health_glance-2009-en/07/05/index.html?contentType=&itemId=/content/chapter/health_glance-2009-71-en

¹⁷ Based on the production value in USD. Invest in Georgia The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*.

Pharmacy are the largest companies after PSP and Aversi and jointly account for 23% of the import/distribution.

There are approximately 2,400 retail companies of which 46 have two or more outlets, and there are five pharmaceutical chains that have 30 or more outlets.¹⁸ The biggest retail chains are owned by the largest importers/distributors on the market: Aversi, PSP, GPC and ABC Pharmacy.

Aversi was established in 1994 and initially started as an importer and distributor. The company expanded its activities to the retail sector in 1998. In 2002, Aversi started to construct manufacturing sites and released its first medicines on the market under its Aversi Rational brand in 2005.¹⁹ Aversi Rational is only engaged in the last steps of the production process where they package pre-manufactured medical products.²⁰ Aversi is one of the largest taxpayers in Georgia and contributes tens of millions of GEL to the state budget annually.²¹ Aversi has seven clinics throughout Georgia and is currently constructing two new clinics. Under the hospital privatization plan, Aversi builds and manages hospitals bought from the government. Aversi also has its own insurance company Alpha, which has been providing social insurance funded by the government for large parts of the country.²² Aversi founder Paata Kurtanidze owns 67% of its shares, while the remaining 33,3% is owned by Nikoloz Kurtanidze.²³

PSP was founded in 1995 as an importer/distributor of medicines and expanded its activities to the retail market in 1999. PSP subsequently established its manufacturing brand GMP which produced its first medicine in 1999.²⁴ GMP is also engaged in the last steps of production and does formulation, such as making tablets from pre-manufactured active substances and packaging.²⁵ PSP owns a multi-profile hospital in Tbilisi, which was bought under a privatization program. Similar to Aversi, PSP owns an insurance company: The PSP group. PSP Pharma, and the PSP group are fully owned by PSP founder, MP Kakhaber Okriashvili.²⁶

GPC is the third largest pharmaceutical company in Georgia and also started as an importer/distributor in 1995. GPC entered the retail market around 1999 and has roughly 40 stores in Tbilisi and another 10 in the regions. GPC recently started a new franchise network under the name Red A.²⁷ However, it is unclear who exactly owns the company. The evidence we collected suggests that the largest share of GPC is owned by its founder David Kiladze.²⁸

ABC Pharmacy was established in 2000 as an importer/distributor of niche products. The company benefited from the expanded import opportunities created by the new legislation introduced in 2009. Its import shares rose from 4% to 12% between 2004 and 2012, and it is currently the fourth largest company on the market. In 2009, ABC opened its PharmaDepot stores which offered competitive prices

¹⁸ As noted in Invest in Georgia and based on our own data.

¹⁹ http://www.aversi.ge/main_racional.php?lang=eng&id=381&cat_id=1&type=3

²⁰ Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011

²¹ Ibidem footnote 20.

²² Information provided by the Ministry of Labour, Health and Social Affairs of Georgia.

²³ Based on information of the public registry for companies

²⁴ Website PSP: <http://psp.ge/?mid=45>

²⁵ Ibidem footnote 20.

²⁶ Based on information of the public registry for companies.

²⁷ Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011.

²⁸ Based on previous information of the public registry for companies. .

on prescription medicines, prompting other companies to lower the prices as well.²⁹ ABC Pharmacy has around 30 retail outlets of its PharmaDepot brand which are concentrated in the capital. The company aims to increase the number of its stores to 50 outlets throughout the Georgia by the end of 2012.³⁰ Recently, the company was awarded a USD 4 million loan by the European Bank for Reconstruction and Development which aims to boost competition within the pharmaceutical market.³¹ Enrico Beridze owns 85% of ABC Pharmacy, while Mikheil Abramidze holds the remaining 15% of the shares.³²

Politics and Pharmaceutical Companies

There appears to be a strong interrelation between the government and the largest pharmaceutical chains. The owner and founder of PSP: Kakhaber Okriashvili has been a Member of Parliament for the ruling United National Movement since April 2004. He has also been a member of the Committee on Health Care and Social Issues, and a member of the Committee on Sectors of Economy and Economic Policy.³³ TI Georgia's study of party financing showed that Aversi Pharma, PSP Pharma and GPC have been among the largest contributors to the electoral campaigns of the ruling party. Aversi Pharma donated GEL 200.000 between 2007 and 2010, and won public procurement contracts with a total value of GEL 823.997. PSP Pharma donated GEL 200.000 as well, and won public procurement contracts worth of GEL 141.044 . GPC spent GEL 175.000 in donations and won public procurement contracts worth of 61.847 between 2007-2010.³⁴

Pharmaceutical Market Before 2009

The current situation in the market can only be understood by examining its development and specific characteristics. The subsequent pages describe the market's development, the effects of new amendments made to the Law on Drugs and Pharmaceutical Regulation in 2009 and the current situation in the pharmaceutical market.

Development of the Market

The current market structure is the product of a chaotic and unstructured development that occurred after the collapse of the Soviet Union.³⁵ The centralized single market—where supply and demand were regulated by the government—was not replaced by a system or a policy with a strong vision for its development. The weak policy framework, along with the weak enforcement of existing rules in the years before the Rose Revolution, resulted in a disorganized and chaotic market.³⁶

With the emergence of the new market, immense opportunities for fresh entrepreneurs arose. Additionally, the new market also created multiple opportunities for newly-established importers by opening the doors for the importation of foreign pharmaceutical products. One of our respondents estimated that, in these first years, the amount of medical products on the Georgian market grew by 25% every year.³⁷ This increase—along with the opened market and the lack of regulation—created a

²⁹ Ibidem footnote 27.

³⁰ Website ABC Pharmacy: <http://www.abc-pharm.com/en/drugstores/PharmaDepot.html>

³¹ Website EBRD: <http://www.ebrd.com/pages/news/press/2011/110921.shtml>

³² Based on information of the public registry for companies.

³³ Members of Parliament, website: http://www.parliament.ge/index.php?lang_id=ENG&sec_id=2&cevri_id=1910

³⁴ Transparency International Georgia (2011) Political Finance Report.

³⁵ Anonymous respondent 15 December.

³⁶ Interview with Marina Beridze, Remember Hippocrates.

³⁷ Anonymous respondent 25 October.

situation where several companies could rapidly emerge as big players.³⁸ The big three companies played a positive role in terms of responding to the new opportunities in the 90's and ensuring that Georgian consumers could access imported products that were not available before. However, the lack of proper policy appears to have allowed them to abuse their position.

Barriers to Market Entry

During the last decade Aversj, PSP and GPC emerged as the key actors in the market. Their growth is due to an effective management strategy that allows them to generate profits that are then used for development of the company. The high amount of financial resources that they extracted from the import sector were used to expand their activities to other sectors of the market.³⁹ As the market was relatively new, these companies could rapidly establish themselves in all sectors of the market.

Their expansion in the import/distribution sector and establishment in the market has been aided by other practices as well. Interviews with key stakeholders and previous investigations seem to suggest that the three companies were able to emerge as the dominant actors in the market through exclusive access to the import of medicines, collusion, and the use of high fixed margins for other retailers.^{40 41} These practices have been dealt with as a result of the renewed legislation and have since lost some of their relevance. However they had a crucial influence on the development of the current situation in the market, which can only be understood in light of these practices. The description of this situation below is based on our interviews with several key stakeholders from the pharmaceutical market that told us the same story. Most of these statements were, however, questioned by Aversj.⁴²

Exclusive Contracts

An often-mentioned practice with relation to the Georgian pharmaceutical market—especially with reference to previous years—is the exclusive contracts between the biggest local importers and foreign suppliers.⁴³ Although exclusive contracts are not an unusual practice, they have contributed to the current situation in the market. Irakli Margvelashvili, Executive Director of the Association of Pharmaceutical Companies' Representatives in Georgia, mentioned that there used to be so called 'gentlemen's agreements' between foreign distributors, who were active in Georgia, and the big local importers.⁴⁴ This meant that one local importer had exclusive access to a medicine that was registered in Georgia and was therefore the only company that supplied the whole market with this product. Owners of smaller pharmaceutical companies told us that this made it very difficult for them to acquire the product directly from foreign suppliers registered in Georgia.⁴⁵ When they approached them, they were told that a distributor was already active in the market and they were therefore not interested in doing business with them.⁴⁶ Due to this situation, pharmaceutical companies depended on the local importers

³⁸ Interview with Marina Beridze, Remember Hippocrates.

³⁹ Eka Paataashvili Head of the Regulation Division of Healthcare Department 28 December.

⁴⁰ Interview Valeri Kvaratskhelia General Director People's Pharmacy, and Interview with Marina Beridze, Remember Hippocrates, and The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations* and Studio Monitor (2009) *Darksides of the Georgian Pharmacy*.

⁴¹ Ibidem footnote 40 and respondent that prefers to stay anonymous.

⁴² TI Georgia's correspondence with Aversj, 19 June 2012.

⁴³ Of the interview key stakeholders 6 have noticed the existence of these contracts Interview Valeri Kvaratskhelia General Director People's Pharmacy, and respondent who prefers to stay anonymous.

⁴⁴ Interview Irakli Margvelashvili; Executive Director Association of pharmaceutical companies representatives in Georgia.

⁴⁵ Interview Valeri Kvaratskhelia General Director People's Pharmacy, and respondent who prefers to stay anonymous.

⁴⁶ Interview with respondent that prefers to stay anonymous, and Studio Monitor (2009) *Darksides of the Georgian Pharmacy*.

that had exclusive access to the import of medicines. As there were just a few companies that had this exclusive access, the whole market relied on roughly five importers.

Two reasons have been mentioned why foreign distributors opted to sign these exclusive contracts. The first is the administrative burden. It was easier for a big supplier to sign a contract with one large importer that covered the whole territory of Georgia and already had contacts with the smaller pharmaceutical companies.⁴⁷ Another reason that has been mentioned is the fact that the local importer could offer to buy large quantities of a certain product from an international supplier without delay on the condition that the supplier would not sign a contract with another local importer. The advantage for the local importer was that it was the only company importing a product, while others had no access to the supplier.⁴⁸

Aversi has denied the existence of exclusive contracts in its communication with TI Georgia⁴⁹.

Limited Access to Quality Certificates

Another problem for the companies trying to import goods was the quality certificate that was required until 2009 and that very few companies had access to.

Eka Paataashvili; Head of the Regulation Division of the Health Care Departments, said:

“It was the case that a company that wanted to import pharmaceuticals on the Georgian market needed a quality certificate of a supplier which guaranteed the quality of a medicine. There were only a few companies that were able to have access to such documents. For this reason, only four or five companies were active on the pharmaceutical market.”⁵⁰

It is not totally clear why the other companies were not able to have access to these documents. It remains unclear whether the limited access was a result of a more professional strategy to obtain the necessary documents—such as the right knowledge and usage of the procedures—or the result of having crucial contacts within the government.⁵¹

Limited Access to the List of Registered Medicines

Another explanation for the limited access has been a dubious practice concerning the list of registered medicines in Georgia. This list was created by the government and only the registered medicines on this list could be imported into Georgia. A former employee of the drug agency told us that this list has long been disclosed for companies willing to import medicines and was only available to Aversi and PSP which acquired the list through alternative ways.⁵² When in 2004 the new Agency of Medicines came into force, the list was published and made accessible to everyone. The problem was that there were no legal obligations to publish the list. When in 2007 the Agency for State Regulation of Medical Activities was created, the list was once again taken out of publicity.⁵³

As a result of these practices, it was difficult for many pharmacies to import their own medical products. Many companies had difficulties getting the list of registered medicines that they could import. If they wanted to register a medicine themselves, it was very difficult to do, as only a few companies were

⁴⁷ Interview Eka Paataashvili Head of the Regulation Division of Healthcare Department 28 December.

⁴⁸ Ibidem footnote 44.

⁴⁹ TI Georgia's correspondence with Aversi, 19 June 2012.

⁵⁰ Interview Eka Paataashvili Head of the Regulation Division of Healthcare Department 28 December

⁵¹ Interview with Marina Beridze, Remember Hippocrates

⁵² Interview respondent who prefers to stay anonymous 23 October 2011.

⁵³ Interview respondent who prefers to stay anonymous 23 October 2011

able to have access to quality documents, for no clear reasons. An owner of a smaller pharmacy chain told us that he tried to set up an association between companies so that together they would have more influence on the market. His attempts failed as the other companies were not interested.⁵⁴ The reason that he gave for this was that they didn't want trouble with local importers who supplied them with their stock, or they did not see the advantage of such cooperation. The big pharmaceutical importers state not to be aware of such list.⁵⁵ However other (usually smaller) companies have emphasized the difficulties they faced when wanting to import and former employees of the agency told us about its existence.

Distribution and Collusion

Several of our respondents have stated that deliberate price setting between the three biggest distributor/retailers happened on a large scale for the medical products for which they had exclusive distributor contracts.⁵⁶ This has created a situation where the three big companies had access to all the products, while all other pharmacies were dependent upon them for their supplies.

The owner of People's Pharmacy—one of the smaller pharmaceutical chains—has stated that it is impossible to stock as much as they need without having to deal with the three importers. He stated that the companies still hold this exclusivity and, although they import their own goods, they are still dependent upon the three importers.⁵⁷

This mechanism has also been mentioned in a research article by Studio Monitor:

“Three main players (PSP, Aversi, GPC) in the Georgian pharmaceutical market have an agreement between each other that they will cooperate with different suppliers. If one of them works with Richter, the other two do not meddle. If you tell Richter that you are a new organization and you want to cooperate with them, they tell you: I already have a partner in Georgia and I do not need another,” – An owner of one of the small pharmacies says. Fearing problems, he did not disclose his name. Pharmacies like his have no chance of cooperating with big pharmaceutical producers. They are forced to buy medical products from local importers almost at a retail price.”⁵⁸

Collusion between companies can only be proved by hard evidence such as paper documents of agreements between companies, and we are not aware of the existence of such documents. PSP and Aversi have stated that there has never been any form of collusion between their companies but there rather was competition between them.⁵⁹ However we would like to note that many of our sources point towards collusion—especially in previous years—between Aversi, PSP and GPC on the import/distribution level in the form of price setting.⁶⁰

Profitable Margins

Several of our respondents, as well as previous inquiries, point out that the dependency upon the import of the so-called “exclusive pharmaceuticals” has been exploited by the three big importers by selling the medicines at exorbitant high prices to other outlets. The medicines that they exclusively

⁵⁴ Respondent prefers to stay anonymous

⁵⁵ TI Georgia's correspondence with Aversi, 19 June 2012.

⁵⁶ Interview Irakli Margvelashvili; Executive Director Association of Pharmaceutical Companies Representatives in Georgia, and Interview Valeri Kvaratskhelia General Director People's Pharmacy, and Monitor (2009) *Darkside of the Georgian Pharmacy and Respondents who prefer to stay anonymous.*

⁵⁷ Interview Valeri Kvaratskhelia General Director People's Pharmacy.

⁵⁸ Ibidem footnote 52, and, Studio Monitor (2009) *Darkside of the Georgian Pharmacy*

⁵⁹ TI Georgia's correspondence with Aversi, 19 June 2012; Interview Gocha Gogilashvili, General Director PSP.

⁶⁰ Standardized interviews.

imported where sold at a margin to other outlets not higher than 14% below the retail price. One of our respondents, who have been active for years on this market, stated about this:

“The big importers set up a chain of pharmacies, they were able to slowly but effectively kill small pharmacies by selling their shared drugs at high prices (only 10% below the retail price). It was therefore impossible for smaller companies to compete with them and to sustain their position in the market.”⁶¹

“It’s like this: one company imports drugs X and another imports drugs Y, they share these drugs with each other. They managed to create an oligopoly by sharing the import between their companies and selling the shared imported drugs to pharmacies at a fixed price. As they were the major importers and had exclusive contracts with manufacturers, they acquired a position in which pharmacies are dependent on their supply. No other importer is able to sign a contract with them. Through this control of the import market and the sharing of exclusive pharmaceuticals, every pharmacy is dependent on them if it wants to sell foreign drugs.”⁶²

Gocha Gogilashvili, General Director of PSP responded to this by saying that a fixed margin is a normal practice in the market and allows a company to make a profit on their distribution of the medicines that they don’t sell in their own pharmacies.⁶³

Legislative Amendments and Expansion of Import Opportunities

In 2009, the government adopted amendments to the Law on Drugs and Pharmaceutical Regulation aimed at increasing competition in the market.⁶⁴ The amendments expanded import opportunities for companies by removing barriers to the import of medicines. The new amendments dealt with the problems concerning the ability to import medicines described above, such as the lack of access to quality documents and the possibility to only import nationally registered medicines.

The import opportunities were expanded through the so-called “recognition policy” and by allowing parallel import of medicines. The recognition policy defines two types of “recognition”: (1) prior recognition by an accepted international partner or national recognition; (2) alternatively, brand name or generic pharmaceutical products can be registered in Georgia based upon their acceptance by a pre-approved intergovernmental pharmaceutical regulatory body or the regulatory body of a foreign country.⁶⁵ This list includes the European Medicines Agency (EMA) and the regulatory bodies of various European countries, as well as those of the United States of America, Japan, Australia and New Zealand. This means that products can be registered based on their prior approval by a foreign agency and do not need quality certificates of a producer.⁶⁶

Additionally, the new law allows parallel import that permits the entry of medical products into the market which are already registered by the initial importer, and therefore don’t require a new registration for a second importer on the Georgian market. Furthermore, to import a medicine, the importer should submit the approval of the provider, and information about the product and packaging

⁶¹ Interview with respondent who refers to stay anonymous on 3 October. 2011

⁶² Ibidem footnote 57.

⁶³ Interview Gocha Gogilashvili, General Director PSP.

⁶⁴ Georgia – National Health Care Strategy 2011-2015; Affordable and Quality Health Care, Ministry of Labour, Health and Social Affairs of Georgia.

⁶⁵ Ivestor.ge (2010) Importing Pharmaceutical Products into the Georgian Market: An Overview.

⁶⁶ Ibidem footnote 61.

which should be authorized in the country of origin, without having to be registered in Georgia.⁶⁷ The new amendments thus allow a company to go to Europe and look for the cheapest medicine produced by another manufacturer or packed differently which is not nationally registered in Georgia but is registered in a country recognized by the Georgian government. This significantly increases the possibilities for importing generics—as well as original brands—through different import channels.

All of our respondents see the new law as a positive stimulus for the market. It offers importers the possibility of selecting the cheapest version of a certain medicine in a particular country. More importantly, it offers the opportunity for companies to look for new medicines that were previously not allowed or very difficult to distribute in the Georgian market. Through the new import possibilities that the law offers, companies have more opportunities to import a medical product using new channels. The problems noted above—such as limited access to foreign distributors resulting from regulations—were removed by the new law.

The new import opportunities also made it possible for the established importers to import medicines directly from the European market, where they are often cheaper than in the CIS countries. Due to the expanded import opportunities and the easier access to European markets, the established importers now have access to these cheaper medicines.⁶⁸

Current Situation in Pharmaceutical Market

Import and Distribution

The market shares of companies are labeled as commercial private data, and are therefore inaccessible to the public. The estimates of import shares in this study are based on the amount of import in USD, as given in the Ministry of Healthcare's import data for 2010.⁶⁹ Important sources for the definition of the market shares used in this paper include earlier research papers of the Association of Young Financiers and Businessmen and an analysis of the pharmaceutical market for investors, supported by the Georgian government.⁷⁰ Furthermore, we verified our data using unofficial data provided to us by respondents.⁷¹

Different sources offer different estimation of market shares. Aversi, for example, estimates its market share to be around 20 percent.⁷² However, because of inaccessibility of the relevant information, the situation remains uncertain and market shares are open to debate.

Our data shows that Aversi and PSP have the highest shares in the import market followed by GPC and ABC Pharmacy. Together these companies account for almost three-fourths of imports.⁷³

⁶⁷ Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011.

⁶⁸ TI Georgia correspondence with Aversi, 19 June 2012.

⁶⁹ Website Ministry of Health, Pharmaceutical Activity, <http://moh.itdc.ge/>

⁷⁰ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*. Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011.

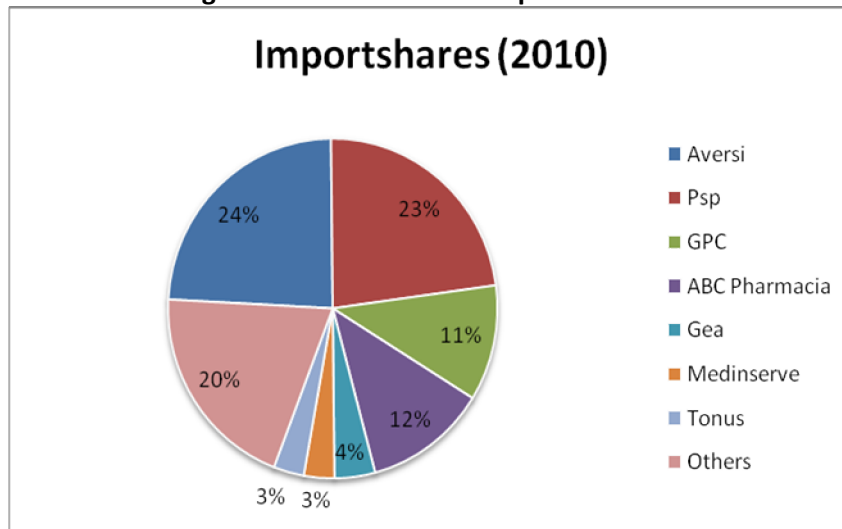
⁷¹ Information provided by respondents who prefer to stay anonymous.

⁷² Confidential data used as internal information of banks.

⁷³ TI Georgia correspondence with Aversi, 19 June 2012.

⁷³ Ibidem footnote 65.

Figure1 Pharmaceuticals Import Shares⁷⁴



It becomes apparent that ABC Pharmacy is growing at a rapid pace and is becoming one of the largest importers.⁷⁵ The share of ABC Pharmacy grew rapidly from 4% to 12% between 2004 and 2012, and can be explained by its effective use of the expanded import opportunities. It is the only company so far that has been able to grow this fast, while no other new company seems to be emerging. Most of our respondents believe that the increase in competition is linked to the presence of ABC Pharmacy and the reaction of the established companies to its emergence. The large shares confirm the high concentration of market power and support the claim, often mentioned in our interviews and previous research, that there is an oligopoly within in the market.⁷⁶

The Retail Sector

There are approximately 2,400 pharmaceutical retail outlets in Georgia.⁷⁷ These outlets are owned by 2,000 retail companies most of which only have one or two shops, while there are 46 companies that own more than two shops.⁷⁸ An investment guide for the Georgian pharmaceutical sector states that this is a very high number of pharmacies as there is approximately one pharmacy available for 1500 people.⁷⁹ The guide, prepared by Komsa International in cooperation with the government of Georgia, explains that this high number is the result of the high profit margins that are caused by a lack of competition in the sector and allow companies to open new shops without financial concerns.⁸⁰

⁷⁴ Ibidem footnote 65-66.

⁷⁵ Website ABC Pharmacy: <http://www.abc-pharm.com/en/about-us/history.html>

⁷⁶ Studio Monitor (2009) *Darkside of the Georgian Pharmacy*, and the survey used in this study.

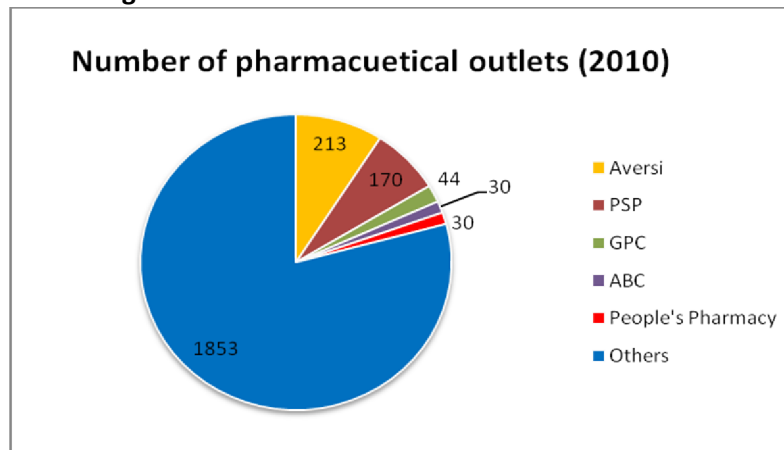
⁷⁷ Komsa International (2011) *Investment Guide; Opportunities in Georgia's Pharmaceutical Sector*, in cooperation with the government of Georgia, Dec. 2011

⁷⁸ Ibidem footnote 71

⁷⁹ Ibidem footnote 71

⁸⁰ Ibidem footnote 71

Figure 2: The Number of Pharmaceutical Outlets⁸¹



The largest retail chain is held by Aversi that claims on its website to have 213 pharmacies.⁸² The second biggest chain is PSP, with 170 pharmacies,⁸³ while GPC has 44 retail outlets.⁸⁴ ABC Pharmacy owns around 27 of its PharmaDepot shops.⁸⁵ Aversi and PSP are the only companies that have retail outlets in the capital as well as in the regions.

Being the largest distributors on the market, Aversi, PSP and GPC benefit from the small fragmented market of retail outlets that cannot import medicines themselves due to their small size. The owner of the smaller pharmacy chain, People's Pharmacy, stated that every pharmacy is dependent for a full stock on the imports of Aversi, PSP and GPC, even if it is importing some of the products itself.⁸⁶ The investment guide for the pharmaceutical market states that the large importers/distributors and retailers benefit from the existence of almost 2000 individually-owned outlets that are not able to import themselves.⁸⁷ The profit margin that Aversi, PSP and GPC use vis-a-vis the smaller retailers result in a situation where these retailers cannot offer competitive prices, which makes it very difficult for them to survive in the market and obstructs any possibility for their expansion.⁸⁸ At the same time Aversi, PSP and GPC are free to adjust the price of their products in their own stores.

The emergence of ABC Pharmacy in 2009 on the retail market caused a general price decrease, as the company was able to offer lower prices in its retail stores as a result of its high import shares, which allowed it to set prices independently. Nonetheless this positive development (the emergence of ABC Pharmacy) has not changed the system where almost 2000 pharmaceutical outlets depend for more than 60% for their stock on Aversi, PSP and GPC. The influence of these three companies on the retail

⁸¹ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*, and Komsa International (2011) *Investment Guide; Opportunities in Georgia's Pharmaceutical Sector*, in cooperation with the government of Georgia, Dec. 2011.

⁸² Aversi website: <http://www.aversi.ge/>.

⁸³ Interview Gocha Gogilashvili, General Director PSP.

⁸⁴ GPC Webstie: http://www.gpc.ge/index.php?option=com_content&task=view&id=192&task=view&Itemid=28&lang=ka

⁸⁵ <http://www.abc-pharm.com/en/drugstores/PharmaDepot.html>

⁸⁶ Interview Valeri Kvaratskhelia General Director People's Pharmacy.

⁸⁷ Komsa International (2011) *Investment Guide; Opportunities in Georgia's Pharmaceutical Sector*, in cooperation with the government of Georgia, Dec. 2011.

⁸⁸ Studio Monitor (2009) *Darkside of the Georgian pharmacy*.

level is caused by their dominance on the import/distribution level and the fragmented market that mainly consists of small pharmaceutical companies.

Dominance in Retail Market; the Story of Pharmacenter

The emergence of ABC Pharmacy and the launch of its Pharmadepo stores seem to have prompted a direct response of the other pharmacies. After Pharmadepo opened its doors and started an aggressive sales campaign that attracted many costumers, a new retailer called Pharmacenter became active on the market. The Pharmacenter stores also sold medicines at a reduced price with 20-25% discounts, similar to those of Pharmadepo. The Pharmacenter stores where always located around Pharmadepo stores and drew customers away.⁸⁹

Several respondents, as well as the earlier research by Association of Young Financiers and Businessmen, described the situation as an immediate response of the big companies aiming to obstruct the possible market expansion of a new actor.⁹⁰ We have tried to verify this allegation by looking at the data of the public registry for Georgian companies.

There is circumstantial evidence that confirms earlier allegations about Pharmacentre being linked to PSP. The registered director of Pharmacenter at the beginning of 2010 was Kakhaber Panchulidze, who was also registered as the director of PSP.⁹¹ Furthermore, the previous legal address of Pharmacenter was 1 Ingoroqva Street, which is currently the address of a PSP pharmacy.⁹² Although, we cannot say with certainty that Pharmacentre is a shadow company of PSP based on these findings, interviews we had with stakeholders, previous articles and the data of the public registry point to this.⁹³

Prices

The Curatio International Foundation recently published comprehensive statistical research about prices and markups of pharmaceuticals between 2009 and 2011.⁹⁴ This timeframe offers the opportunity to analyze the effect of the expanded import opportunities created by the changes in the legislation in 2009. The selection of the medicines is based on the criteria of the World Health Organization, and gives a representative picture of current tendencies in the market for this group of medicines.⁹⁵ The findings of this research have been questioned by Aversì.⁹⁶ However, we have found this research to be the only currently available data that covers a relatively long period of time and has a sound methodological basis.

Median Unit Price Change

Figure 3 shows that the median unit price of medicines decreased between 2009 and 2011, with a significant decrease in 2011, especially for original brands (OB). However, an analysis of the dataset on which this statistic is based shows that the price decrease only took place for 27% of the OB and 21% for

⁸⁹ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*.

⁹⁰ Ibidem footnote 83.

⁹¹ Business register, website: https://enreg.reestri.gov.ge/main.php?exit_url=https://public.reestri.gov.ge

⁹² Yellow pages

http://yell.ge/srch_adv.php?lan=2&name=&city_id=0&address=1+Ingorokva+&keywords=&phone=&Submit.x=26&Submit.y=1

⁹³ Ibidem footnote 85.

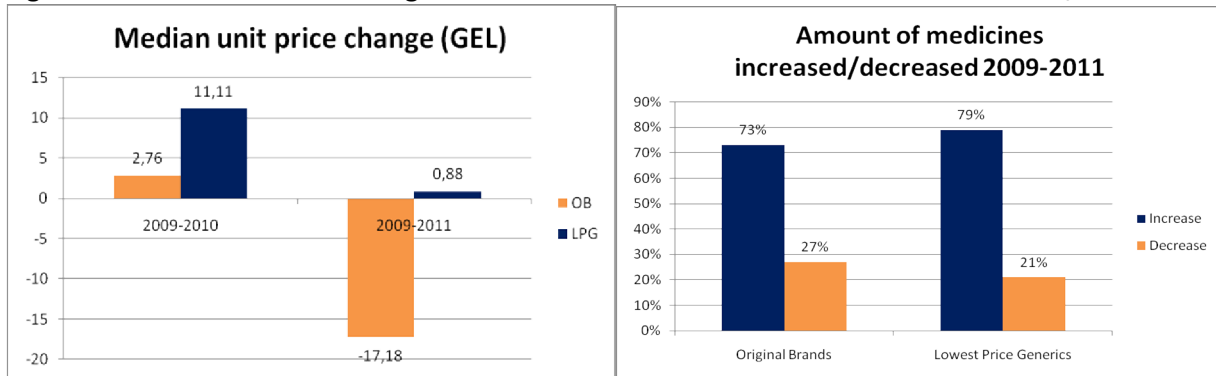
⁹⁴ Gotsadze T. (2011) *Price, Availability and affordability of medicines in Georgia 2009-2011*, Curatio Foundation International. http://www.curatiofoundation.org/upfiles/dfltcontent/197_2.pdf

⁹⁵ Ibidem footnote 88

⁹⁶ TI Georgia correspondence with Aversì, 19 June 2012.

the lowest price generics (LPG), while the rest of the medicines increased in price.⁹⁷ Based on these findings it can be stated that although the median and the average price went down, in fact three fourth of the medicines have gotten more expensive.

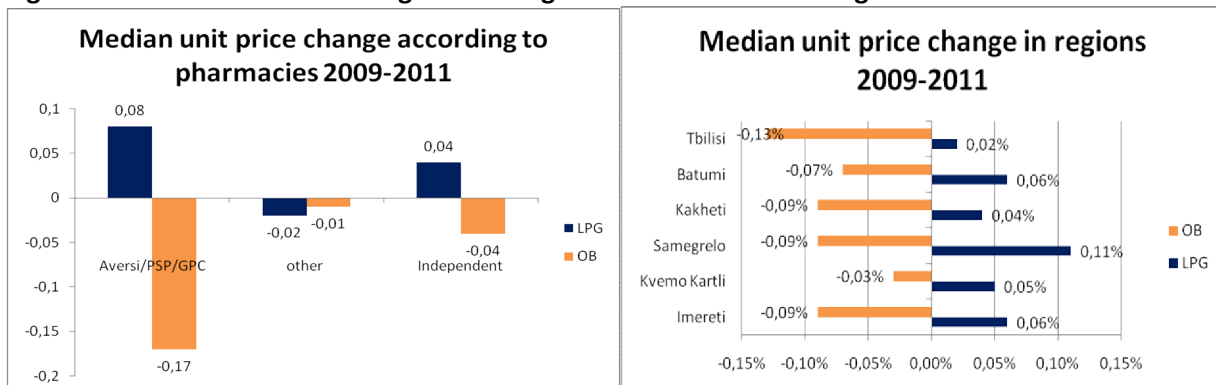
Figure 3. Median Unit Price Change in GEL and the Amount of Medicines that Increased/Decreased⁹⁸



The inconsistency between the general price decrease and the actual decrease—that only occurs for one fourth of medicines—needs further research. Two explanations were given by our respondents. The first, is that the major distributors might have purposely pushed the price of a group of medicines down in order to stimulate a positive image about the development of the market.⁹⁹ Another explanation given is that competition for some groups of medicines is more prominent, due to new contracts signed as a result of the expanded import opportunities.

The analysis of median price changes for OB and LPG according to different types of pharmacies shows that, while Aversi, PSP, and GPC have the highest decrease of OB, they have the highest increase of LPG. The Curatio International Foundation states that this decrease can be part of their short term strategy to push the new competitors out of the market.¹⁰⁰

Figure 4. Median Unit Price Change According to Pharmacies and in Regions¹⁰¹



⁹⁷ Gotsadze T. (2011) Rationalization of Pharmaceutical Expenditures in Georgia, Partnership for Social Initiatives.

⁹⁸ Ibidem footnote 88

⁹⁹ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*.

¹⁰⁰ Ibidem footnote 88

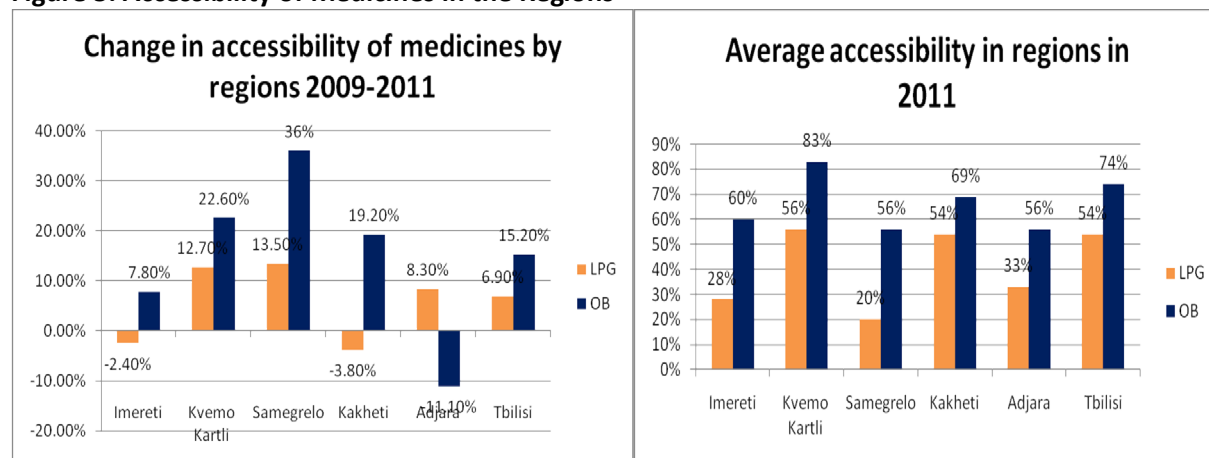
¹⁰¹ Gotsadze T. (2011) *Price, Availability and affordability of medicines in Georgia 2009-2011*, Curatio Foundation International.

http://www.curatiofoundation.org/upfiles/dfltcontent/197_2.pdf

The classification of 'Other' in this figure is based upon the other and smaller chains in the market that are not PSP, Aversi or GPC. The smaller companies or shops are categorized as being independent.

Figure 4 shows that the three biggest pharmaceutical chains have the highest decrease in median unit price for OB while having the highest increase for LPG. It also shows that there is a higher increase of the median unit price for LPG and a lower decrease for the OB in the regions. Several of our respondents have stated that there is a difference in competition between regions.¹⁰² However, the differences in our data are not significant enough to support this claim. Furthermore, the data suggests that the median unit price of OB and LPG between companies, as well as regions, has been quite constant over the last three years. This suggests that there has not been a real increase or decrease of competition but that the situation remained the same.

Figure 5. Accessibility of Medicines in the Regions¹⁰³



The accessibility of medicines varies significantly between regions. Although there has been a general increase of accessibility, the Curatio Foundation states it is still very low, especially for LPG.

Markups

The next figure shows that the general markup for original brands decreased significantly in 2011, which indicates an increase in competition. The markup change for LPG, however, is not of any significance as the markup for LPG remains extremely high, which indicates a lack of competition. The high markup for LPG could be explained by the fact Aversi and PSP produce and sell their own LPG themselves.

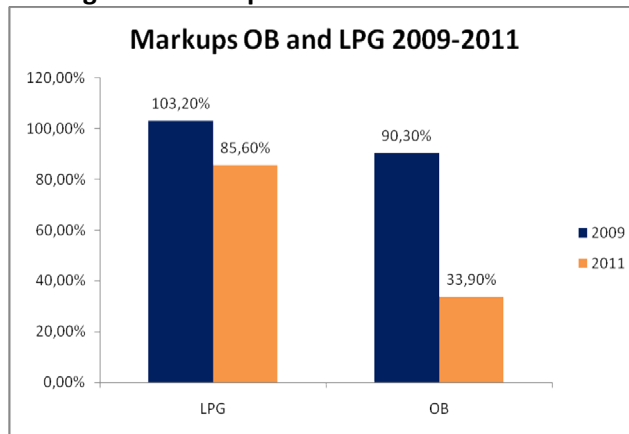
Similar to the median unit price change, the general markup decreased, but this decrease only accounted for 27% of the OB medicines and 21% of the LPG medicines, while the rest of the medicines increased in price.¹⁰⁴ This means that only one fourth of the medicines became cheaper.

¹⁰² Interview 27 October 2011 Devi Khechinashvili, Head of the Georgian Insurance Association.

¹⁰³ Ibidem footnote 94.

¹⁰⁴ GotsadzeT. (2011) Rationalization of Pharmaceutical Expenditures in Georgia, Partnership for Social Initiatives.

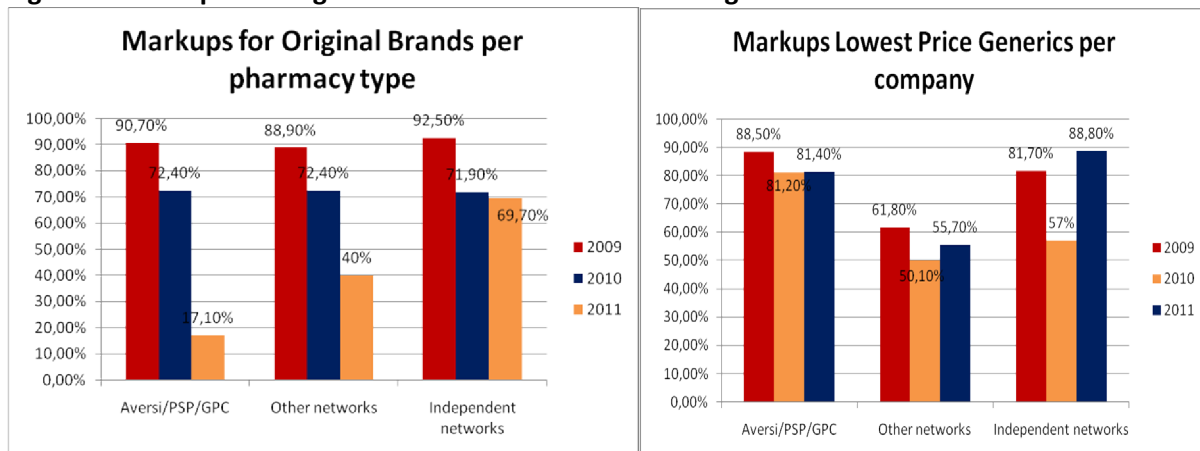
Figure 6 Markups OB and LPG 2009-2011¹⁰⁵



Markups According to Different Types of Pharmacies

The separate graph for the markup change for OB and LPG from 2009 to 2011 shows a clear difference between the two groups of pharmaceuticals.¹⁰⁶ Furthermore, it shows that a significant difference exists between the different groups of pharmacies. The different types of groups are based upon the following criteria: The first group includes the largest, well-established players that are importer/distributor, and retailer at the same time, consisting of Aversi, PSP and GPC. The group of other pharmacies refers to the newcomers or the smaller chains who import their own products to a certain extent and own retail chains as well. The last category of independent pharmacies refers to the single store pharmacies that are reliant upon the local importers/distributors and together make up the biggest share of pharmacies in Georgia. A considerable decrease in markups is most apparent in the first group (Aversi, PSP and GPC). It is not clear whether this decrease is a temporary strategy to push the other companies out of the market, or meant for the longer term.¹⁰⁷

Figure 7: Markups for Original Brands and for LPG According to the Pharmacies.¹⁰⁸



¹⁰⁵ Gotsadze T. (2011) *Price, Availability and Affordability of Medicines in Georgia 2009-2011*, Curatio Foundation International. http://www.curatiofoundation.org/upfiles/dfltcontent/197_2.pdf

¹⁰⁶ Ibidem footnote 98

¹⁰⁷ Ibidem footnote 98

¹⁰⁸ Gotsadze T. (2011) *Price, Availability and Affordability of Medicines in Georgia 2009-2011*, Curatio Foundation International.

The ability of the largest companies to perform this sudden price decrease is manifold, and may be linked to the benefits they get from other segments, benefits they already acquired, the renewed benefits of parallel import, the high quantities they stored and their control of the import/distribution. However, the general director of PSP said that the price decrease was mainly caused by their ability to sign better contracts due to the expanded import opportunities.¹⁰⁹ The sudden decrease seems to confirm claims made in previous research by Studio Monitor and the Association for young Financiers and Businessmen that the three are implementing a deliberate strategy to quickly push other pharmacy chains out of the market and obstruct their growth.¹¹⁰

Figure 8 Average pharmaceutical Markup Prices in Georgia vs other European Countries¹¹¹

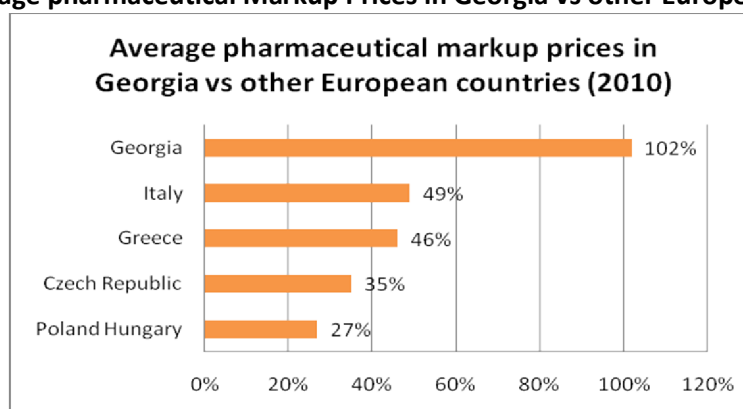


Figure 8 shows that while there has been a general decrease of markups in Georgia they are still significantly higher than they are in a number of European countries.

Manufacturing

The local manufacturing sector in Georgia consists of 70 producers, of which GMP and Aversi Rational represent a share of almost 90%.¹¹² Local manufacturing has been growing rapidly at a average rate of 46% per year from 2004 to 2010.¹¹³ The value of local production was GEL 90.2 million in 2010 while being GEL 22.1 million in 2006.¹¹⁴ The local sales of medicines produced in Georgia grow at a rapid rate of 38% per year. Of the products manufactured in Georgia, 60% is exported to other countries, and the top 3 export countries are Azerbaijan, Armenia, and Uzbekistan.¹¹⁵

¹⁰⁹ Interview Gocha Gogilashvili, General Director PSP.

¹¹⁰ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*.

¹¹¹ Ibidem footnote 101

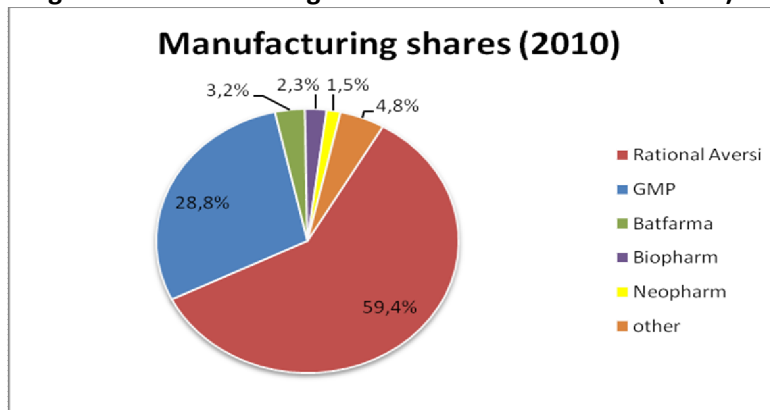
¹¹² Based on the production value in USD, the shares are confirmed by The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*, and Komsa International (2011) *Investment Guide; Opportunities in Georgia's Pharmaceutical Sector*, in cooperation with the government of Georgia, Dec. 2011.

¹¹³ Komsa International (2011) *Investment Guide; Opportunities in Georgia's Pharmaceutical Sector*, in cooperation with the government of Georgia, Dec. 2011.

¹¹⁴ Information provided by Geostat.

¹¹⁵ Ibidem footnote 106.

Figure 9: Manufacturing Shares of Local Production (2009)¹¹⁶



Shifting Profits

The difference between the change in OB and LPG noted above might partly be explained by the shifting of profits from OB to LPG that Aversi and PSP manufacture themselves.¹¹⁷ The total production value reached GEL 90.2 million in 2010, of which the main profits go to Aversi Rational and PSP which account for 90% of this production.¹¹⁸ Although the local sales of pharmaceuticals produced in Georgia account for only 10% of all the sold medicines in Georgia, this market is growing at a pace of 38% between 2005 and 2010.¹¹⁹ The markups that stayed consistently high between 2009 and 2011, along with the growing production values, suggest that the companies are gaining increasing profits from their locally-produced LPG that they can distribute, and sell directly in their own retail outlets.

Practices in Manufacturing

The biggest manufacturers Aversi Rational and GMP (PSP) reportedly engage in the last steps of the production process.¹²⁰ Aversi Rational only packages the imported bulk products and GMP does packaging as well as formulation, which involves processes such as making tablets from already produced active substances. None of these companies are engaged in the primary production of active substances.¹²¹

Aversi Rational and GMP both have certifications for complying with the internationally recognized quality standard for medicines: Good Manufacturing Practice (GMP). An investment guide for Georgia's pharmaceutical sector states that Aversi Rational and the company GMP both received the GMP certificates from a reputable private auditor rather than from government certifying agencies.¹²² The company GMP is currently in the process of obtaining GMP certification from an official government body in France, which will allow them to export their products to countries that recognize the EU-

¹¹⁶ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*. Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011, and The Financial :

¹¹⁷ Interview on 23 October and 6 February with respondents that prefer to stay anonymous.

¹¹⁸ Ibidem footnote 105.

¹¹⁹ Ibidem 105.

¹²⁰ Ibidem footnote 105.

¹²¹ Komsa International (2011) Investment Guide; Opportunities in Georgia's Pharmaceutical Sector, in cooperation with the government of Georgia, Dec. 2011, and The Financial :

http://www.finchannel.com/Main_News/Geo/102226_Doubts_over_Indian_Medicines_Sold_in_Georgia/

¹²² Ibidem footnote 114.

GMP.¹²³ These efforts show a rapid development of the manufacturing sector through the efforts of Aversi and GMP. While other manufacturers in Georgia also advertise their compliance with GMP guidelines, Aversi Rational and GMP are the only two companies that have these certifications.

There is currently no GMP-certifying agency in Georgia, but the government has expressed the ambition to have such agency established in 2016. Currently, the State Agency for Medical Activities does reviews and tests and certifies manufactured drugs, which includes some elements of the GMP, but these checks do not comply with all the GMP procedures and standards.¹²⁴ Pharmaceutical companies in Georgia should submit staffing plans, construction plans and technical plans to the agency to obtain an initial license. There are regulations and standards in place concerning pharmaceutical production which companies are expected to comply with, however provisions do not exist for annual registration or renewed license procedures. The agency reviews, tests and certifies individual drugs and conducts selective controls, but it does not issue GMP certificates for the production process itself. A government certified agency is of great importance to this rapidly developing sector and will increase safety, trustworthiness and the possibilities to export medicines.¹²⁵

Assessment of Competition in Pharmaceutical Market

The assessment of the market is summarized along the indicators for competition and barriers to competition used in this paper. These indicators and the subject dealt with are: Market shares, entry and expansion barriers, the development of the market and price and markup changes.

Market Shares

Aversi, PSP and GPC hold the largest shares in all sectors of the market. According to our data, Aversi and PSP control by far the largest shares in the import/distribution, retail and manufacturing sectors and thus create a “vertical monopoly”. They seem to be able to influence the behavior of other companies due to their dominance in all the sectors.

Entry and Expansion Barriers

The expanded import opportunities introduced by the 2009 amendments to the Law on Drugs and Pharmaceutical Regulation removed several entry and expansion barriers created by the previous law. The market structure indirectly creates barriers to expansion since a few companies hold large shares in all sectors, and are able to influence prices of most of the retail outlets through their position at the import/distribution level. Although it is not difficult to start a small retail outlet, it seems to be more difficult—not to say impossible—to expand a company. So far, only one company has been able to take advantage of the expanded import opportunities, but other companies seem to lack the resources to copy this strategy. The indirect evidence from the Pharmacentre story furthermore suggests that the dominant companies deliberately create barriers to the expansion of newcomers. Whether the sudden price decrease for OB is a short term competitive strategy deployed by the large actors to drive newcomers out of the market as stated by Curatio Foundation is not clear at this stage but their data could support this claim.

Development of the Market

The analysis of the market development shows that the previous regulatory system, as well as the market environment in general, benefited a few companies while obstructing others. This led to the

¹²³ Ibidem footnote 114.

¹²⁴ Ibidem footnote 114.

¹²⁵ Ibidem footnote 114.

dependency of all the other pharmacies upon the import and distribution of the big companies. Important factors for the establishment of the big importers/distributors have included exclusive access to import and fixed price setting. The fragmented retail market that primarily consists of small retail outlets also enforces the dominant position of the big players on the retail market, as they need local importers for their stock. Furthermore, only one company has so far been able to make efficient use of parallel import. This has created a system where Aversi PSP and GPC have been able to dominate the market on the import/distribution level, the retail level and the manufacturing level with very small chances for other companies to acquire a share.

Prices and Markups

Since 2009 (and especially in 2011), there has been a price decrease for medicines, which is likely the result of increased competition and expanded opportunities for companies to find the cheapest medicines. These markups suggest that the price decrease for OBs—which is the highest among Aversi, PSP and GPC—is compensated through the benefits they extract by increasing production of local LPG—whose value is rapidly increasing—and the high markups for these medicines.

The analysis of the dataset where 27% of the OB and only 21% of the LPG have actually decreased in price, shows that the general decrease in price and markups is not representative of all the medicines. Furthermore, the markups for Georgian medicines are still high compared to other European countries. Therefore, it is important to discern whether this decrease is a short-term strategy or a long term trend.

Policy, Regulation and Quality

Prescription Policy and Practices

A policy concerning the prescription of medicine does not currently exist in practice.¹²⁶ Several of our respondents stated that this lack of policy leads to several problems which result in wrong usage and over-consumption of pharmaceuticals. Furthermore, it creates an environment that does not limit the influence of the pharmaceutical industry upon the prescription practices of doctors.

Currently, an unrestricted availability of drugs in the Georgian market exists. Any drug can be sold without a prescription, with the exception of narcotics, antidotes, psychotropic drugs and other substances of intensive effect. People do not need to consult a doctor when they have a problem. They can instead go directly to the pharmacy to buy what they think or what the seller tells them they need. This leads to a situation where people in Georgia often do not consult a primary doctor.¹²⁷ The NGO “Remember Hippocrates” which focuses upon health care issues, has stated that this situation in primary health care makes the problem even more pressing as the information people receive is not based upon professional knowledge.¹²⁸ The World Health Organization states that unrestricted availability of medicines, along with a lack of skills and knowledge, are main causes of overuse, inappropriate self-

¹²⁶³ Interview with Marina Beridze, Remember Hippocrates.

¹²⁷ Ibidem footnote 121, and respondent that prefers to stay anonymous.

¹²⁸ Ibidem footnote 121.

medication and non-adherence to dosing regimes.¹²⁹ This can, in the end, lead to a population with antimicrobial resistance, adverse drug reactions, and a waste of resources.¹³⁰

Who Pays the for the Doctor's Holidays?

The Partnership for Social Initiatives (PSI) came to the conclusion that the prescription behavior of most doctors in Georgia is based upon incentives coming from the market, rather than upon price or quality of the medicines.¹³¹ A survey conducted among physicians showed that although 86% see the price of a medicine as an important factor for prescribing it, only 7% take the price into account when writing a prescription.¹³² It Furthermore states that although 60% of the doctors assess the quality of generics as good, only a marginal percentage of doctors actually prescribe them.¹³³ Several respondents confirmed this and stated that doctors are being paid based upon the amount of medicines they sell from a certain company. The PSI survey—in addition to the results of our own interviews—suggest that this practice might be happening on a large scale.

Doctor's Prescriptions Versus Pharmaceutical Sales

When a medicine is prescribed by a doctor, there is no guarantee the patient will go home with the prescribed medicine after visiting a pharmacy. Several of our respondents stated that the products a pharmacy sells to a customer are often different from the medicine which is prescribed by the doctor. This means that people might be offered a more expensive OB when prescribed a generic or vice versa. The main reason for this is that it is more profitable for a pharmacy to sell a medicine which is produced by one of its manufacturing companies or a medicine for which it has a special contract. However no pharmacy has ever been punished for this and there is no regulation in place that prohibits this practice. According to once source:

“Anecdotal evidence suggests that pharmacists are not restricted to change physician’s prescription by substituting prescribed medicine with an alternative, thus promoting a particular brand and/or locally produced medicines. Such behavior is not regulated by the legislation, however as it appears to be well established practice in the market, accepted by the customers.”¹³⁴

According to Joni Janashia, president of the Health, Pharmaceutical and Social Care Workers Independent Trade Union of Georgia, Aversi instructs its employees to sell its own manufactured medicines. He stated about having received messages from several employees that have been threatened with being fired if they would not sell enough medicines of Aversi.¹³⁵

Quality Checks

Many of our interviewees expressed concern about the lack of guarantees the government offers for the quality of medicines. This refers mainly to the quality check procedures and the resources allocated for this.

¹²⁹ Rational Use of Medicines, World Health Organization, Fact sheet No.338, Website: <http://www.who.int/mediacentre/factsheets/fs338/en/>

¹³⁰ Rational Use of Medicines, World Health Organization, Fact sheet No.338, Website: <http://www.who.int/mediacentre/factsheets/fs338/en/>

¹³¹ Gotsadze T. (2011) Rationalization of Pharmaceutical Expenditures in Georgia, Partnership for Social Initiatives.

¹³² Ibidem footnote 126.

¹³³ Ibidem footnote 126.

¹³⁴ Gotsadze T. (2011) Rationalization of Pharmaceutical Expenditures in Georgia, Partnership for Social Initiative.

¹³⁵ Interview Joni Janashia, President of Health, Pharmaceutical and Social Care Workers Independent Trade Union of Georgia.

Irakli Margvelashvili, executive director of the Association of Pharmaceutical Companies' Representatives in Georgia, stated that:

*“According to the information we have, the drug agency never found any counterfeit products, but how is this possible when there is a \$200-million market of fake medicines that occur particularly in low income countries such as Georgia? This should be checked and for that you need a good system: With technical expertise, financial resources and so on. But now you don't have this. This system currently does not exist in Georgia”*¹³⁶

The Agency for State Regulation of Medical Activities which operates under the Ministry of Labour, Health, Social Affairs and is responsible for checking the quality of medicines was assessed by most of our respondents as lacking both the expertise and the financial and technical resources to be effective.¹³⁷ Another problem is that both the information that the agency gathers and its practices are confidential and not accessible for the public. The government has restricted medicine regulation and does not, either directly or indirectly, accept any responsibility for the quality of medicines. While the process of quality checks is inaccessible for the public in Europe as well, the governments there have the full responsibility for quality assurance.¹³⁸

The practices and guidelines for checking the quality are often nonexistent or very unclear within the agency. An insider told us that the laboratory that was contracted to do the testing by the government could not do this, as it had not been supplied with any standards for the assessment of the medicines.¹³⁹

A Lack of Traceability and Increased Chances for Counterfeits

The simplification of the law and the possibilities for parallel import have raised concerns about the risks the policy creates for the quality of imported medicines, in the absence of regulatory safeguards. One of the problems in this respect is the lack of traceability of pharmaceuticals.¹⁴⁰

The current law does not require information about either the original producer of a medicine or information about the manner in which a product is transported. The person that imports a medicine into Georgia is only required to register the distributor he bought the medicine from. According to Irakli Margvelashvili, this creates a serious problem as most pharmaceutical products are often traded several times between several parties. Registering only the last distributor, obscures the original manufacturer of a product. Irakli Margvelashvili has stated that:

*“One of the main sources for parallel import are the Baltic countries. But the drugs are reaching the Baltic countries from various other countries. We only know it was imported from Baltic states but what happened before: Where it comes from, how it was transported, etc?”*¹⁴¹

The lack of traceability poses several problems with respect to the import of counterfeits and obstructs the possibility of finding the source of a medicine of a bad quality. For this reason, the European Medicine Agency (EMA) requires information about all manufacturers^{142 143} and distributors of a

¹³⁶ Interview Irakli Margvelashvili; Executive Director Association of Pharmaceutical Companies' Representatives in Georgia.

¹³⁷ Anonymous respondent former employee at the drug agency, and Interview Irakli Margvelashvili; Executive Director Association of Pharmaceutical Companies' Representatives in Georgia.

¹³⁸ Ibidem footnote 132.

¹³⁹ Interview 15 December, with respondent that prefers to stay anonymous.

¹⁴⁰ Interview Irakli Margvelashvili; Executive Director Association of Pharmaceutical Companies' Representatives in Georgia. George Ramishvili – Country Manager Georgia; Hoffman-La Roche Ltd.

¹⁴¹ Interview Irakli Margvelashvili; Executive Director Association of Pharmaceutical Companies' Representatives in Georgia.

¹⁴² Mail exchange with experts of the EMA.

medicine.¹⁴⁴ The relationship between the traceability of a product and counterfeits is still of great relevance in the EU. Recently the European Federation of Pharmaceutical Industry Associations (EFPIA) started a traceability program to find these counterfeits.¹⁴⁵

Guarantees for the Quality of Transportation

Several of our respondents point to another effect of the simplification which enables parallel import. According to Mr. Margvelashvili:

“The second point is that there might be special goods such as cold chain products, which require special handling. As a regular citizen you can simply take these medicines in the back of your car from a country and sell it here.”¹⁴⁶

Several medicines require transportation under specific conditions, such as a specific permanent temperature. However, there are no regulations in place that assure safe transportation. The opening of parallel import along with the lack of information about traceability or quality standards for importers, has increased the risks of improper transportation.

While every European country has strict guidelines for the traceability of medicines and secure transportation, these safeguards for the quality of medicines are absent in Georgia. Parallel import is believed to have had a positive impact on the market and prices for medicines. However, along with these opportunities, there should be policies in place guaranteeing good traceability and proper transportation of medicines.

A Loophole in the Registration Period for Imported Medicines

As part of the new law, the registration period has been simplified and shortened. The reason for this simplification was offered by the head of the Regulation Division of Healthcare Department, who said that the old procedure was unnecessary and costly, prompting the government to adopt a more flexible law.¹⁴⁷

There are currently two kinds of control. The first control is the administrative control which focuses on whether all the right documents are provided, such as permission of the producer and quality guarantees. The second control consists of selective laboratory checks that only have to be done for psychotropic and cardiovascular drugs.¹⁴⁸

According to Article 11, Paragraph 10 of the Law on Drugs, when the state regulatory agency turns down a request for the registration of a medicine, it has to inform the distributor within 10 days whether registration was denied because of incomplete documents, a lack of information, or other related problems. If the agency fails to notify the distributor about this within 10 days, the medicine is allowed to enter the market. An insider has told us that the agency does not have the human or the financial resources to perform this check for all the medicines within 10 days of receiving the relevant

¹⁴³ Community Register, reference documents, European Commission, Website:

http://ec.europa.eu/health/documents/community-register/index_en.htm

¹⁴⁴ Directive 2001/83 EC; on the Community Code relating to medical products for human use, European Parliament and Council, Website: http://ec.europa.eu/health/files/eudralex/vol1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf

¹⁴⁵ EFPIA starts traceability pilot program to combat drug counterfeiting, Euro pharma today, website:

<http://www.europharmatoday.com/2010/01/efpia-starts-traceability-pilot-program-to-combat-drug-counterfeiting-.html>

¹⁴⁶ Interview Irakli Margvelashvili; Executive Director Association of Pharmaceutical Companies' Representatives in Georgia.

¹⁴⁷ Interview Eka Paatashvili Head of the Regulation Division of Healthcare Department 28 December

¹⁴⁸ Ibidem footnote 142.

applications.¹⁴⁹ Many of our respondents highlighted this lack of resources, which has been illustrated very well by previous studies.¹⁵⁰ As a consequence of this short time frame and the lack of resources, a former employee told us that rejected medicines often enter the market because of the agency's late notification of the distributor.

As the agency does not publish information about the rejected medicines, it is absolutely unknown how many of these medicines are currently being sold on the market. However, the government states that the 10 days are more than enough to notify the company.¹⁵¹ The statements of our respondents tell a different story.¹⁵²

The new amendments to the Law on Drugs and Pharmaceutical Regulation have had a positive effect upon the market and should be retained. However, these changes pose new risks in terms of quality control due to the absence of necessary legislative safeguards. It is therefore necessary to find the right balance between the ease of import and quality safeguards.

Conclusion

The Georgian pharmaceutical market is rapidly developing and undergoing various changes in all its sectors. It is important that, in the process of development, greater attention is devoted to competition and quality safeguards than has been the case so far. While recent attempts to foster competition have affected the market positively, the situation can still be defined as an oligopoly and a vertical monopoly where two companies are dominant in all sectors. The new amendments to the Law on Drugs and Pharmaceutical Regulation that expanded import opportunities have been a good initial step, but have only changed the situation to a limited extent. While the median prices for a certain group of medicines has decreased, the median prices for the majority of medicines has not decreased. Furthermore, the general markup still significantly exceeds that of European countries, and the market continues to be dominated by a few major companies.

There is a lack of adequate quality safeguards, which stems from both the lack of legislative provisions and from the shortage of necessary resources for the Agency for State Regulation of Medical Activities. It is important to ensure that the public receives more comprehensive information about the agency's activities and how it conducts the assessment of medicines. This will make it possible for stakeholders to assess the agency's practices and to monitor its operation.

One of the most significant developments in the pharmaceutical market is the production of local generics in which Aversi and PSP play a leading role. This development has the potential to increase the accessibility of medicines once these generics are offered at a reasonable price. This is currently not the case as the markup for lowest price generics is close to 100%, and the companies appear to extract great profits from this sector. An alarming piece of information—in this respect—are the stories we heard about employees in Aversi and PSP stores allegedly being forced to sell the companies' own medicines, and doctors are allegedly paid by these companies to prescribe their medicines.

¹⁴⁹ Respondent prefers to stay anonymous.

¹⁵⁰ The Association of Young Financiers and Businessmen, (2011), *The Georgian Pharmaceutical Market Conclusions and Recommendations*.

¹⁵¹ Interview Eka Paatashvili Head of the Regulation Division of Healthcare Department 28 December.

¹⁵² Former employee of the drug agency that prefers to stay anonymous, and Interview with Marina Beridze, Remember Hippocrates.

The amendments to the Law on Drugs and Pharmaceutical Regulation have had a positive effect on the market and should be retained. However, the changes created some new risks in terms of quality control due to the lack of necessary regulatory safeguards. It is therefore essential to find the right balance between the ease of import and quality control.