



PHARMACEUTICAL MARKET IN GEORGIA

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Introduction

Transparency International Georgia periodically analyzes different large-scale markets, which have a significant impact on the economy of the country. In the past couple of years, TI Georgia has published reports on fuel market, postal service, pharmaceuticals and hospital sector, gambling business and others. The pharmaceutical business is one of the largest and most lucrative business in Georgia. TI Georgia first published a report on this sector in 2012.¹ We are now presenting our second report on this market.

This report analyzes the situation of the pharmaceutical market in Georgia during the period 2012-2016. Some of the data includes information from an earlier period. The report stresses on the company shares, import, production, turnover, amount of people employed in this sector, and on the export and import countries. The report includes an overview of the practices of the large companies and their ties with political parties. The report also discusses the amendments made in 2012-2016 to the Georgian Law on Drugs and Pharmaceutical Activity, the issues related to the quality of drugs, prices, the positive and negative sides of prescriptions and the problems of polypharmacy and pharmacovigilance.

The analysis of the market is based on the bottom-up approach, which is based on desk research, face-to-face interviews² and the collection and analysis of data. In order to provide complete and exact information, the information provided in the research has been verified through multiple sources.

¹ The Georgian Pharmaceutical Market, TI Georgia, 22 June 2012: goo.gl/dtHWN3

² The interviews were conducted with PSP, Aversi, ABC Pharmacy, LEPL State Regulation Agency for Medical Activities and Tina Turdziladze – Expert in Healthcare issues

Main Findings

TI Georgia published its first report on the pharmaceutical market in 2012. The report included an overview of the general trends, problems and solutions. The following findings are important from the previous report:

- The pharmaceutical market power is not distinctively concentrated. According to import statistics of 2015, approximately 70% of the market is distributed amongst five large companies. These are Ltd. PSP Pharma with 22.32%, Ltd. A-B-C Pharmacy with 14.91%, Ltd. Aversi-Pharma with 14.54%, JSC GPC with 10.20% and Ltd. Globalpharmi with 7.02%. Due to this, the pharmaceutical market can be characterized as a weak oligopoly. However, there are increased risks of diminishing competition and abuse of dominating positions with the recently announced merger of A-B-C Pharmacy and JSC GPC. Moreover, the positive sides of the merger should be noted, such as the unifying of resources, optimization of expenses and increase of effectiveness;
- Georgia still hasn't managed to adopt the international GMP standards. This negatively affects the export of drugs produced within the country and raises questions about the quality of drugs used within the country. The government planned to adopt the standards in 2016, but according to the new decision of the government, it has been postponed till 2018;
- The LEPL State Regulation Agency for Medical Activities, which is responsible for testing the quality of drugs, apparently does not have sufficient resources/budget for effectively fulfilling its purpose. Moreover, the current legislation does not allow for the effective and complete fulfillment of these functions;
- The rule for the "Recognition Regime" of pharmaceutical products creates moderate risks for the supply of low-grade drugs to the market;
- The positive sides for the prescription system is not high due to the existing administrative hurdles. Pharmaceutical networks are not always fined for issuing medication without prescription. The fines are not big enough to serve as a preventive measure for issuing drugs without prescription;
- Polypragmasy (the administration of many different remedies at the same time) and the non-existence of pharmacovigilance remain a problem in the country;
- The legislative amendments carried out in 2013-2016 generally concern the adoption of prescriptions (electronic prescriptions) and its related processes. In the same period, there the fines were made stricter for illegal pharmaceutical activities and for violation of rules of pharmaceutical activity. The fine for the violation of rules doubled;
- In 2014, especially after the month of April, the prices for all pharmaceutical products significantly increased. The peak in price surges was in the second quarter of 2015. The prices started to decline from November 2015 and by May 2016 the prices decreased for a certain category of drugs. The tendency of the price going down is still visible by December 2016;
- According to import statistics, Aversi-Rational and GMP play a significant role in the development of the pharmaceutical industry sector in Georgia. They hold a total of 97% of the market. As of now, 11,168 drugs are allowed on the market (including the form, dose and packaging of the drug), out of which 1,367 (a total of 12,25%) is produced in Georgia. 259 of the drugs are produced by Aversi-Rational, while 237 is produced by

GMP. Due to this, it is clear that there are producers in Georgia that produce pharmaceutical drugs from locally obtained raw materials;

- Individuals associated with the pharmaceutical companies donated a total of 415,000 GEL to the United National Movement in 2012. No such donations were observed after 2012.

Chapter I. The regulation of the pharmaceutical market

1. Legislative framework and the amendments

The legislative framework for Georgia's pharmaceutical market consists of the following main legislative acts:

- **Georgia's Law on Drugs and Pharmaceutical Activities**, which is effective since 1997 and establishes the legislative framework for the State to ensure the lawful practice of the circulation of pharmaceutical products;
- **Georgia's Law on the Licensing of Medical and Pharmaceutical Activities**, which regulates the processes related to the issuing of licensing for medical and pharmaceutical activities, defines the amendments, its scope and the updating and abolishing of rules, as well as defines the types of licensed activities and additional terms for licensing.

According to the Law on the Licensing of Medical and Pharmaceutical Activities, the licenses for Georgia's pharmaceutical activities are issued by the LEPL³ State Regulation Agency for Medical Activities that is part of the Ministry of Labor, Health and Social Affairs. The right of the Ministry and Agency to issue licenses is established by the law on the Issuing of Licenses and Permits for Business Activities.

According to Georgia's Law on the Licensing of Medical and Pharmaceutical Activities, the types of pharmaceutical activities eligible for licensing are:

- The production of medicinal products (including pharmaceutical products subject to special control) and sale (Group I Pharmacy);
- The sale of medicinal products (Group II Pharmacy);
- The sale (Group II Pharmacy) of medicinal products (except narcotics);
- The sale (Group III Pharmacy) of medicinal products (except for pharmaceutical products subject to special control);
- The retail sale of non-prescription medicinal products (Pharmacy branch)'
- The production of medicinal products and issuing to medical and preventative treatment networks, without retail sale (medical and preventive treatment pharmacy);
- The issuing to medical and preventative treatment networks, without retail sale (medical and preventive treatment pharmacy);
- The import, export, re-export and sale in wholesale prices (pharmaceutical base) of medicinal products (except for pharmaceutical products subject to special control);
- The import, export, re-export and sale (pharmaceutical base) of narcotics;
- The import, export, re-export and sale in wholesale prices (pharmaceutical base) of pharmaceutical products subject to special control (except for narcotics);
- The production of medicinal products (except for narcotics);
- The export and sale of produced medicinal products (except for narcotics);
- The import of medicinal products (except for narcotics) for own production (pharmaceutical production);
- The production of alternative or combined medicinal products for pharmaceutical products subject to special control, which does not belong to the list of narcotics;

³ Legal entity of public law

- The export and sale of produced products
- The import of drugs for own production (pharmaceutical production);
- The control of the quality of medicinal products (laboratory).

After 2010, there were amendments made to the Georgia's Law on Drugs and Pharmaceutical Activities in 2012, 2013 and 2015. The mostly significant changes were carried out in 2013-2015, which broadened the list of drugs subject to prescriptions (including electronic prescriptions). In the same period, amendments were made related to making the fines stricter for illegal pharmaceutical activities and violation of pharmaceutical rules. In many cases, the fine was doubled for the violation of rules. Moreover, a new article was added to the law, which envisaged a 500 GEL fine for the sale of certain category of drugs (Group I and II medications as defined by Article 11²) to minors.

Moreover, a sub-article was added to define substandard pharmaceutical products and therapeutic agents equated to pharmaceutical products under special control. According to amendments in 2015, a fine of GEL 500 and 1000 GEL in case of a repeat violation was established for the violation of the sanitary-hygienic norms in pharmacies and retailer outlets.

Below we will present a more detailed overview of the prescriptions, which constituted a significant portion of the legislation amendments in 2010-2015.

2. Oversight of the market

The government oversees the pharmaceutical market through two directions: (1) the protection of competition on the market and (2) the protection of security and effectiveness of products.

2.1. Protection of competition

According to the Law of Georgia on Competition, the LEPL Competition Agency was created with extended powers in April 14, 2014. The Agency had in 2012 replaced the Agency for Competition and State Procurements created through the order of the President of Georgia. TI Georgia actively participated in the formulation of these amendments. The six new models were based on the practices that are used in a number of countries, for example, such as Germany (Bundeskartellamt), France (Autorite de la Concurrence), Italy (Autorita Garante della Concorrenza e del Mercato), Poland (Office of Competition and Consumer Protection) and others)

Since its establishment, LEPL Competition Agency conducted a number of researches, including on the fuel market, but in spite of growing public interest has not conducted research on the pharmaceutical market. Notably, the pharmaceutical market attracts high public interest; there have been a number of publications on the dominant status of certain companies in this sector, of their collusion, price fixing and drug quality. The Competition Agency was addressed to study this sector but they turned it down on the basis that there is no reasonable doubt to do so.

In 2016, the Competition Agency conducted a research into the activities, namely parallel import, of the LEPL State Regulation Agency for Medical Activities. The working group involved in the research found that the LEPL State Regulation Agency for Medical Activities was breaching Article 10 (b) of the Law on Competition. The nature of the violation was that within the same terms and conditions it has registered a medicinal product Lorista to one importer, while denying it to another. The Competition Agency found this decision as a violation of law and so it demanded the State Regulation Agency for Medical Activities to take appropriate measures. As a result, the

State Regulation Agency for Medical Activities conducted a reevaluation of the documentation and reversed the decision of the Head of the Agency through the Order N02-1650 in 29 September, 2016. As a result of this Order, the interested person was denied to import the respective product with a different packaging-labelling.⁴

2.2. Protection of quality standards

LEPL State Regulation Agency for Medical Activities conducts oversight over the pharmaceutical market in terms of the protection of quality standards.

This Agency is a legal entity of public law under the control/system as of the Ministry of Labor, Healthcare and Social Affairs.

Stemming from its activities, the Agency is an oversight institution that:

- Studies the quality of medical service based on statements/complaints by a citizen;
- Conducts the monitoring of the terms of the licensing (in stationaries) and technical regulations (in ambulatories) in medical facilities;
- Conducts the inspection of the fulfillment of the state program for health security;
- Controls the process of medical-social expertise.

The Agency also:

- Issues licenses and permits for medical facilities;
- Supports the accreditation processes for medical facilities/schools after the acquisition of a diploma;
- Conducts tests and issues certificates to graduates of higher education schools;
- Participates in the formulation and implementation of consistent professional development for graduates with a diploma;
- Conducts respective registry keeping;
- Operates the functions of the Secretariat of the Board for Professional Development;
- The LEPL State Regulation Agency for Medical Activities also issues permits for authorized pharmacies, clinical trials, pharmaceutical production (medicinal products, except for narcotics), the import and export of medicinal products for pharmaceutical products subject to special control;
- Conducts the registration of pharmaceutical products (both local and foreign);
- Manages the flow of medicinal products and conducts control and oversight of pharmaceutical activities, as well as conducting relevant events;
- Conducts required registry.

The majority of medication used in Georgia are imported, and even a smaller portion is produced locally. According to Georgian legislation, permits are issued for the production of active substances and there are a number of such productions in Georgia. Active substances are produced in developing countries such as India, China and others. Its production may be related to such negative factors such as environmental pollution, therefore developing countries tend to avoid producing active substances on their own territory. In Georgia there is an import of both medications and active substances, which are then used to locally produce pharmaceutical products, such as medications. Notably, in Georgia primary and secondary packaging, which are technological stages of production, are considered as locally produced products.

⁴ <http://competition.ge/ge/page4.php?b=446>

All pharmaceutical products entering the country are checked at the border, whether or not the product is registered by the Ministry of Healthcare. If the product is not registered, then it is not allowed into the country. In 2009, the rule of registration of pharmaceutical products was made significantly easier. Since 2009, pharmaceutical products are allowed into the Georgian market through two regimes:

- Recognition Regime of state registration of a pharmaceutical product
- National regime of state registration of a pharmaceutical product

The grounds for using the “Recognition Regime” of state registration of a pharmaceutical product shall be the differentiation of a state body regulating pharmaceutical products in a foreign country or internationally in terms of reliability and granting a market authorization to only high quality pharmaceutical products in markets under the control of this body. Georgia unilaterally recognizes safety, efficacy, and quality requirements for granting market authorization to a pharmaceutical product in markets under the control of this body, set by a state body regulating pharmaceutical products in a foreign country or internationally. Georgia does not carry out a repeated expertise with regard to the above or similar requirements in order to determine the safety, quality and therapeutic efficacy of a pharmaceutical product.

The national regime registration is intended for pharmaceutical products that are not registered in countries with a high degree of trust. However, the legislation does not impose restrictions on this and the person interested with the registration makes the decision based on his commercial interests. In this case the Ministry of Healthcare’s list of required documentation is more detailed, and a medical-technical expertise is also required.

Representatives from the pharmaceutical business positively assess the “Recognition Regime” of state registration of a pharmaceutical product (simplified registration of pharmaceutical products approved in countries with high degree of trust).

According to most of the respondents, the adoption of this regime saved a lot of time and financial resources, as well as decreased the price for medications. However, a small portion of representatives from this sector consider the registration rules as too simplified, which has resulted in risks of having low-grade medications entering the country’s market. For example, if the producer, which is responsible for the quality of the product, decides to abolish the registration, then according to Georgian legislation a distributor can still make a primary registration of the product by providing a small set of documentation. This case can happen if someone in a country with a high degree of trust makes a mistake and does not receive the request for abolishing of registration. Moreover, it is possible for the producer to abolish the registration once the product has already been registered in Georgia. Getting information on this is difficult for us since the registration happens beyond the scope of the licensor and the producer in the “Recognition Regime.” This creates a risk of import of low-grade products in the country. The Agency for Medical Regulation notes that such cases haven’t yet been observed, however they admit there are risks and that the registration rules should be amended. According to them, falsified and substandard medication may still find its way to the market in a strictly regulated environment, so the current liberal rules and terms do not provide a complete and exhaustive analysis of the security and effectiveness of the quality of medication.

Several representatives of the pharmaceutical business that the problem is not in the rules for registration, but in the lack of coordination within the State Regulation Agency for Medical

Activities. According to them, the exchange of best practices should occur between our regulation agency and the regulation agencies of countries with a high degree of trust.

Medication can be assessed by several parameters. These are: safety of the medicine, effectiveness of the medicine and the quality of the medicine. The quality of the medicine implies the commonality of the drug. During the production of the medicine, the standards for its requirements are set out. However, this does not have a direct effect on the effectiveness of the medicine; it may be standard, but not effective. The clinical trials assess the effectiveness and safety of the medicine. A bioequivalent trial is required to assess whether a medicine is innovative or generic (repeatedly manufactured pharmaceutical product). A bioequivalent trial is one of the methods of checking the effectiveness of drugs, which is the basis for the test of its bioavailability. After the medicine has entered the country, individual pharmaceutical companies are responsible for its quality. The State Regulation Agency periodically and randomly checks the quality of medicine, however respondents have stated that the inspectors only look at the packaging and are less orientated at checking the quality.

The State Regulation Agency for Medical Activities makes a response to this statement by noting that they are acting within their capacity as defined by the law to control the issuing of permits and the terms of technical-hygienic-sanitary at pharmacies (specialized retail outlets) and retail outlets, as well as the assessment of the traceability. The Law on Drugs and Pharmaceutical Activities gives the regulation agency the right to only perform random control of pharmaceutical product sellers based on risk assessment. During the process of control of the distribution network of the pharmaceutical product, the Regulation Agency buys a sample of the medicine and assesses whether the product meets the requirements as defined by the law for the packaging-labelling, shelf life, right of entry into Georgian market, distribution rights, etc. In case of falsification or high risk of counterfeiting and spoilage (the Minister shall approve risk criteria), the Regulation Agency buys and studies the sample of the product, and if needed, the mechanism of laboratory control is used, which is carried out based on the Order of the Government and the funds allocated.

According to one of the respondents, the program for the random testing of quality of medicine has the less budget in the whole Healthcare sector. GEL 3,298 thousand is allocated (2,530 thousand of which is for salaries) in 2016 for the program of medical activity regulation, while 7,260 thousand (3,100 thousand for salaries) is allocated to the program of disease control and epidemiological security. The budgets for the aforementioned programs are one of the least funded in the healthcare sector. Moreover, only GEL 15,000 is allocated for the buying of samples of medicine and GEL 147,000 for checking quality with laboratory tests, which we also think is a small amount of funding. We should also note that laboratory control is permitted only in 10% of the bought samples of medication, in other cases it should be checked only visually.

We can therefore conclude that the resources allocated to the State Agency and the existing legislation are not sufficient for the exhaustive and complete assessment of quality of medicine in the country.

When we talk about quality, the main challenge is the nonexistence of Good Manufacturing Practice (GMP) and international inspectors in the country. Georgia selectively recognizes the international, regional and national set of standards of the GMP, however the protection of international GMP standards is not and cannot be obligatory, because the international GMP inspector, which checks and provides the certificates of quality, does not exist in Georgia. The possession of this certificate proves that the production of the product is in line with the international GMP standards. Currently the State Regulation Agency for Medical Activities makes

a parallel assessment of compliance with GMP standards when checking and certifying medicine during the national regime registration, but these are not in compliance with all the procedures and standards of the GMP.

According to Order N349 of the Government, the pharmaceutical producers have the right to voluntarily implement the change to the standards defined by the international, regional or national GMP. Private companies have the right to invite international GMP experts to obtain certificates. As of today, the permit of running a pharmaceutical production is issued as defined by the law and the LEPL State Regulation Agency for Medical Activities is responsible for the control and oversight. As a result, today the biggest producers, GM Pharmaceuticals and Aversi-National are forced to individually hire GMP, test products and receive respective certification, which is connected with additional financial and time resources. However, it should be noted that there are many countries where these certificates are not sufficient and compliance to international GMP standards is required.

The discussion to transition to international GMP standards and establishment of inspectors has been going on for years. The Georgian government planned to change to the new standard by 2016, but it has been postponed until 1 January of 2018 according to Order N349. To have international GMP inspection in the country, it is required to have only several GMP inspectors, which will be involved in the international inspection framework and be subject to retraining once in every two years.

Therefore, the existence of international inspectors in the country is significant for the increase of quality of pharmaceutical products available to the users and the increase of export of production of medicine produced in Georgia. International inspectors strengthens the security and reliability of medicine within the country, as well as on foreign markets and thus results in the growth of exports. Since the transition to the new standards was planned in 2016 but was delayed, it is still questionable whether the new announced date of transition will be met in 2018.

As far as prescriptions are concerned, which can be discussed as one of the leverages for supporting the quality of medicine, their positive effects are not very high. Prescriptions may bring about positive effects when administered properly. According to our respondents, prescription may decrease the risks and negative effects of self-medication and improper application of medicine. The negative side is the nonexistence of a well-managed system for the monitoring of prescriptions.

According to our respondents, only a number of pharmacy networks do not sell pharmaceutical products without a prescription, while others ignore and violate the rule. They also note that this is a problem for companies that are honest and abide by the law. The companies that violate the rule are not frequently fined, since the State Regulation Agency does not have sufficient inspectors to monitor their activities. The respondents state that the amount of inspectors is not enough for them to frequently monitor the pharmacies and as a result not many pharmacies are fined. Moreover, the fine is GEL 500 (in case of a repeat offense – GEL 1000) and this amount does not serve as a preventive measure. The pharmacy may also appeal the fine to a court, and since this process stretches on for 7-8 months, the pharmacies are not against paying the 500-1000 fine once or twice every year. According to the pharmacies that do not give out medicine without prescription, their sales have significantly decreased.

The State Regulation Agency for Medical Activities states that it is incorrect to say that not all pharmaceutical networks are fined when selling medicine without prescription. To support their proof, they bring the statistics of violations: in 2014, the Regulation Agency detected 250

administrative violations (82 related to the sale of Group II pharmaceutical products⁵, in 2015 – 398 instances (218 related to the sale of Group II pharmaceuticals) and in 2016 – 467 instances (160 related to the sale of Group II pharmaceuticals).

According to the State Regulation Agency, an administrative violation protocol is drafted is always drafted and presented to the respective court. The Agency also notes that the legislation does not envisage the temporary freeze/termination of activities of the functioning institution in case of repeat violations; therefore, the State Regulation Agency has no capacity to act beyond the drafting of an administrative violation protocol.

According to several respondents, the critical position towards the prescription system stems from the interests of the main players on the market, which have the resources to have a prescription issuing service in parallel to running a pharmacy. By this they are trying to close down competing small businesses that do not have the financial resources to afford a doctor and prescription issuing service. According to the respondents, the first violates the law openly, while the second violates it allusively, but in reality both of them are in violation.

Due to this, we believe that the monitoring of prescriptions and its administration should be improved.

the second group shall include pharmaceutical products, whose inappropriate use may cause considerable damage to human health and life, and/or which may not be administered according to the patient information leaflet only, without a physician's prescription, and which are dispensed on prescription (the Minister shall determine the procedure for writing a prescription for a pharmaceutical product falling under the second group);

The successful use of prescriptions can decrease the practice of polypragmasy (the administration of many different remedies at the same time). If electronic prescriptions (which are implemented throughout the country but are not obligatory) are made obligatory or are implemented on a large scale, then instances of polypragmasy may be detected through the analysis of the accumulated information in a single database. If electronic prescriptions are made obligatory, all pharmacy companies should have access to a computer, which is a significant problem in the regions. According to the respondents, the single database for electronic prescriptions and a change towards an effective system should be carried out immediately.

According to one of the heads of a pharmaceutical company, the lack of unified protocols, guidelines and standards is the main reason causing polypragmasy. This issue will always be a problem if the Ministry of Healthcare does not set guidelines, approved standards, protocols and rules of administration of medicine after diagnosis. One doctor will say that he should have prescribed two drugs, while another will say that three drugs were required. In developed countries, there are associations for doctors of all specializations, for example Allergists Association, Surgical Association, Endocrinological Association, etc. These associations formulate standards as to how to make a diagnosis. The associations should prepare and present to the Ministry of Healthcare for approval the list of tests to run for diagnosis of all diseases and the list of medicine required for treatment. These guidelines, as we have noted, exist in developed countries and Georgian associations, in an effort to save financial resources, can only translate

⁵ The second group includes pharmaceutical products, whose inappropriate use may cause considerable damage to human health and life, and/or which may not be administered according to the patient information leaflet only, without a physician's prescription, and which are dispensed on prescription (the Minister shall determine the procedure for writing a prescription for a pharmaceutical product falling under the second group); the requirement to issue Group II drugs by prescription was defined by law on January 1 2014.

them. According to our respondents, the problem of polypragmasy will remain until the aforementioned protocols and unified standards are created in all spheres of medicine.

Moreover, the transition to obligatory electronic prescription system and generally to a unified database approach can have a positive impact on pharmacovigilance's so called adverse effects notification department.

The State Regulation Agency notes that according to the Law on Drugs and Pharmaceutical Activities, doctors from curative-prophylactic networks, specialists from medical facilities and agencies from the Ministry of Labor, Health and Social Affairs participate in the monitoring of the adverse effects of drugs. The State Regulation Agency for Medical Activities coordinates the monitoring system and analyzes the information. The Agency states that according to Article 26 (4) of the Law on Drugs and Pharmaceutical Activities "subjects of the circulation and use of therapeutic agents shall be obliged to provide the Drug Agency with information on all cases of side effects of a therapeutic agent and other particularities of the interaction of the therapeutic agent, which are not indicated in its patient information leaflet." The existing legislation requires that an interested person should present information of the last 5 years on the adverse effects of the drug in case of a new renewed registration. Moreover, the Agency permanently receives information on the adverse effects from pharmaceutical products undergoing clinical trials, as well as products allowed for sale. In 2016, the Agency received up to 300 notifications. The staff of the Agency are also involved in international trainings and seminars related to pharmacovigilance. Information published by international organizations is regularly processed and official notifications are received and responded to in a duly manner (in certain cases, the Agency suspends/terminates the registration, provides the customs department with the specific serial numbers or withdraws the pharmaceutical product from the market). The Agency is also involved in the international management for adverse effects of drugs. Pharmacy networks are asked to display information in a visible manner for the patients to address in case of adverse effects the pharmacist, who in turn is obliged to notify the Agency.

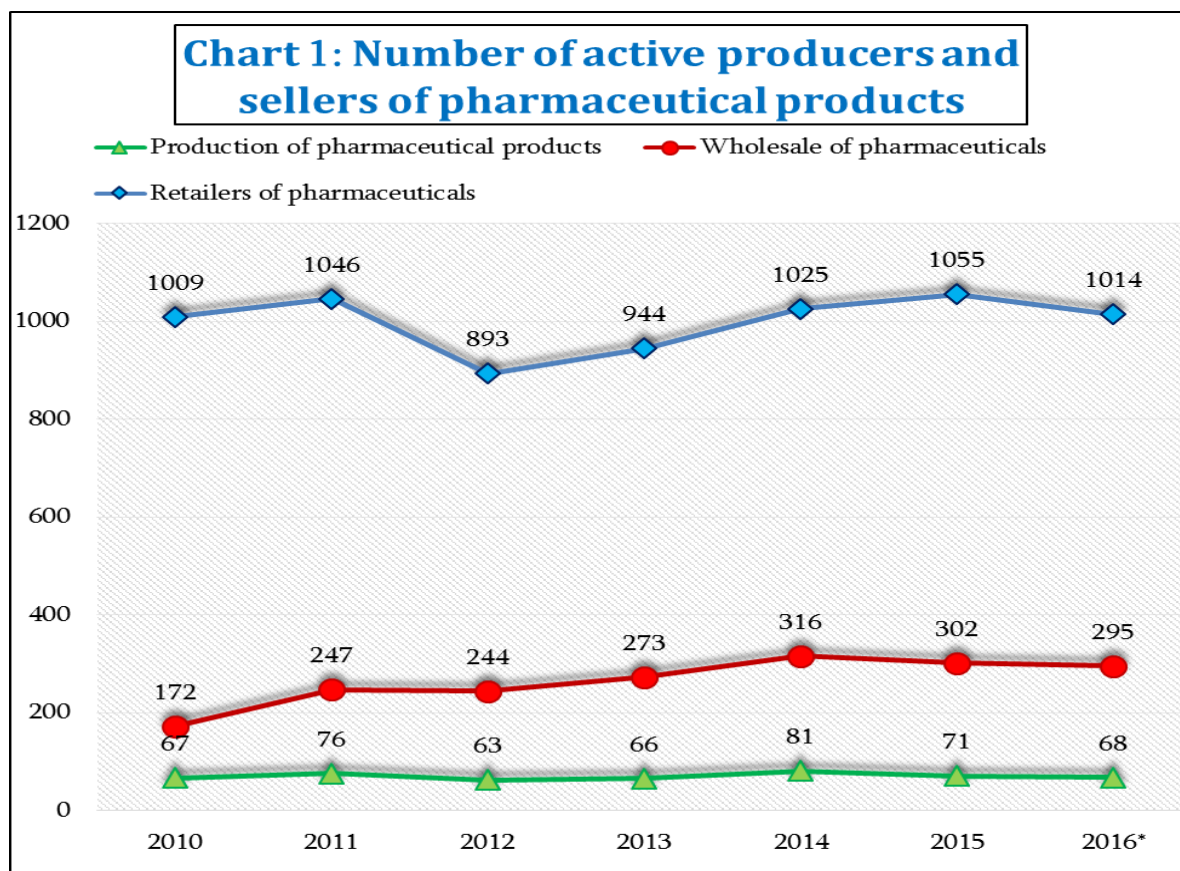
In spite of this, pharmaceutical company representatives state that as of today, the management of the pharmacovigilance system is not effective.

To improve the existing system, the State Regulation Agency for Medical Activities suggest that the law should be amended and that it must include an obligation to provide a monitoring plan for the adverse effects and assign a contact point, who will responsible for presenting a report on it in case the pharmaceutical product needs to undergo a new registration.

Chapter II. Characteristics of the pharmaceutical market

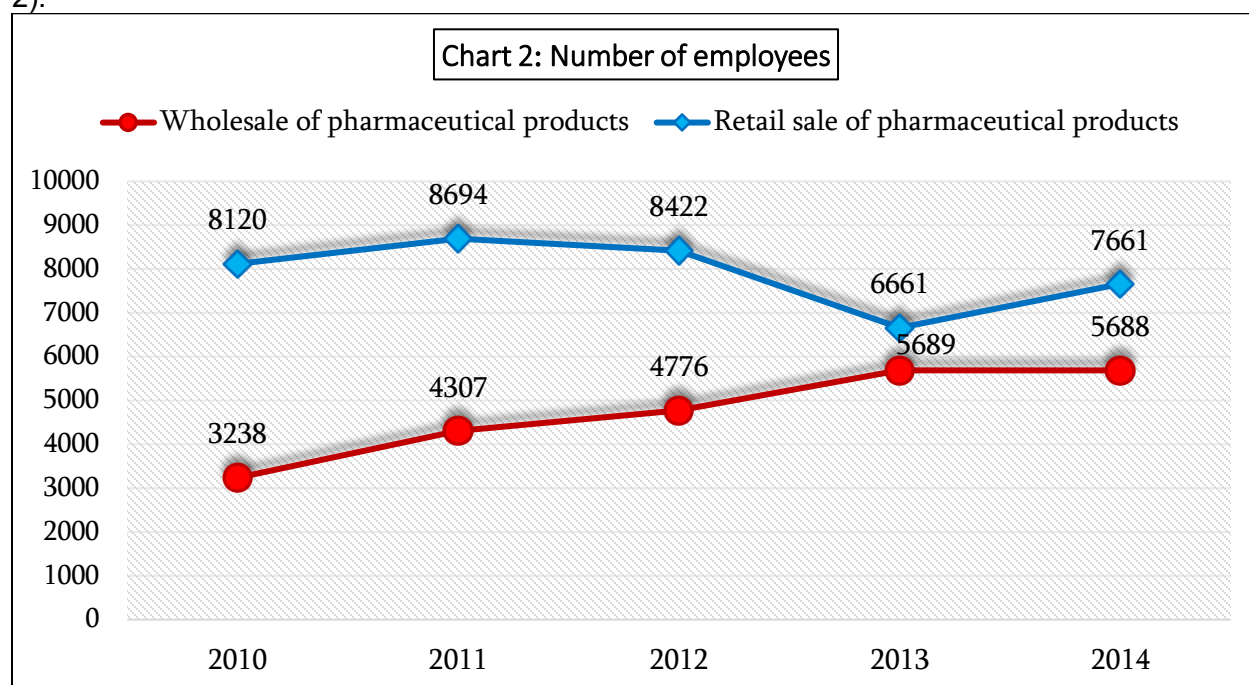
1. Structure of the market

The amount of wholesaler and retailers and producers of pharmaceutical products has shown a changing tendency from 2010 until 2015; the amount has both increased and decreased over the year, however the range of change has been insignificant either way. The amount of wholesaler and retailers and producers of pharmaceutical products increased insignificantly in 2015 from 2010 (by 4 and 46, respectively). As a result, 71 producers of pharmaceutical products and 1,055 retailers were active in 2015. As far as wholesaler producers are concerned, its numbers increased more significantly from 2010 (increased by 130 and totaled 302). (See chart 1). We should not that these statistics do not include the amount of pharmacies. The statistics show us the number of legal persons and individual entrepreneurs who are active as wholesalers and retailers.



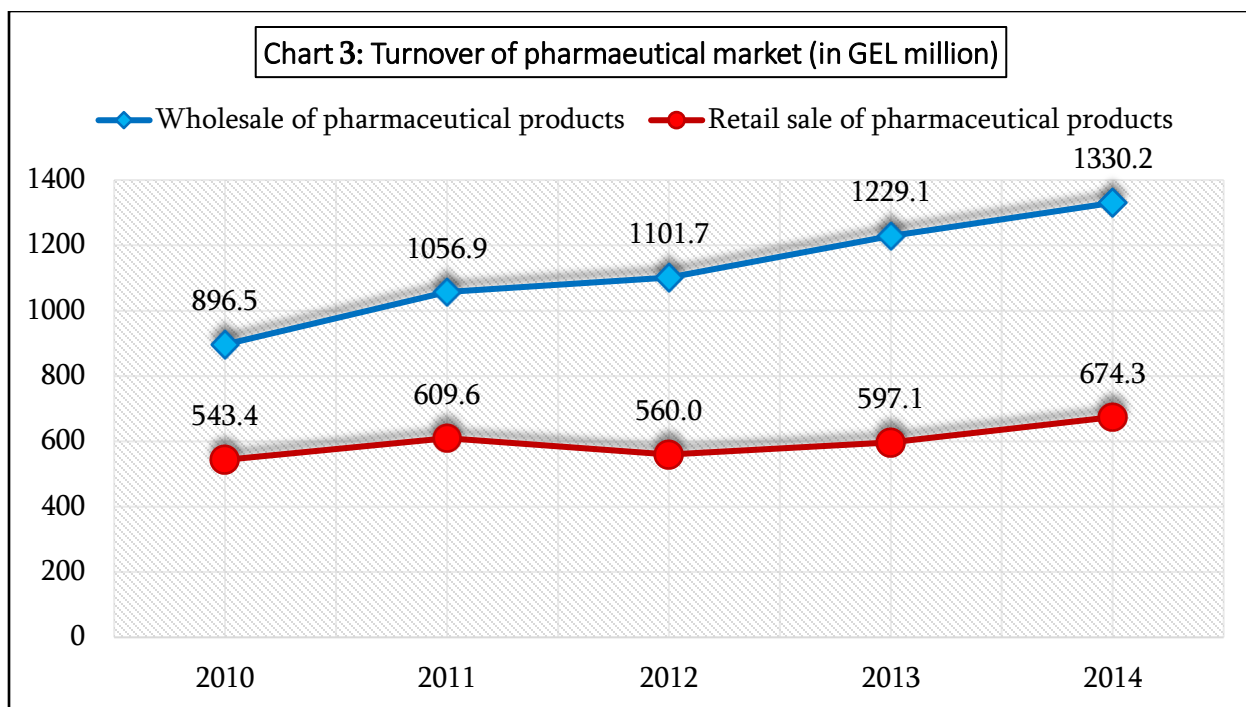
Source: National Statistics Office of Georgia

The pharmaceutical business is one of the largest private employers in the country. In 2014, 13,349 persons were employed in the retailer and wholesaler sectors. There was a fluctuating tendency in the number of employed persons in the pharmaceutical product retailer sector throughout 2010-2014; the numbers decreased and increased, and in 2014 the number decreased by 459. As far as the retail sector is concerned, there has been a tendency of increase; the number of employed persons grew by 245 to a total of 5,688 in 2014 compared to 2010. As far as the difference between these two types of businesses are concerned, the number of employed persons per type has been getting even and in 2014 the number of employer persons in retail exceeded the number of employed persons in the wholesale only by 1.3 times. (See chart 2).



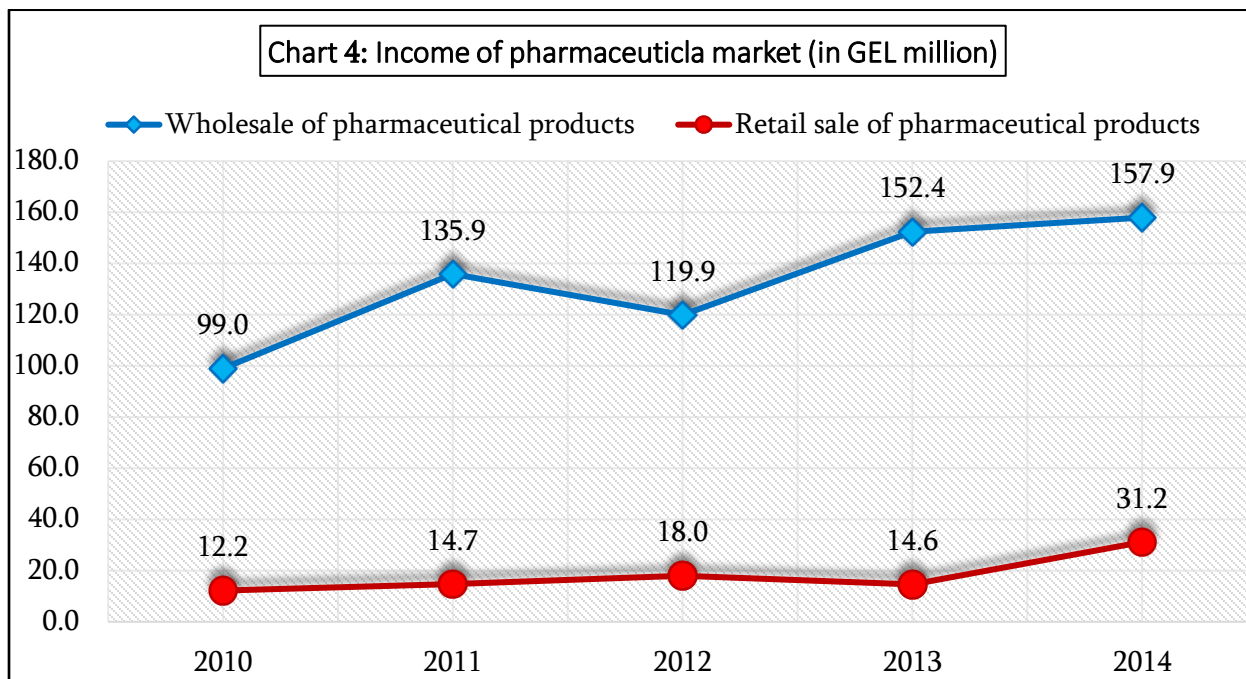
Source: National Statistics Office of Georgia

The annual turnover of wholesalers and retailers of pharmaceutical products amounted to a near total of 2 billion Lari in 2014 (latest data). More specifically, there has been a tendency of increase of annual turnover for the wholesalers; compared to 2010, the turnover increased by 533 million lari in 2014. As far as the turnovers of retailers are concerned, the tendency has been fluctuating but has in overall been increasing and in 2014, compared to 2010, increased by 130 million lari. (See chart 3).



Source: National Statistics Office of Georgia

The net income of companies involved in pharmaceutical business in 2014 (latest data) amounted to a near total of 190 million lari. More specifically, there has been a tendency of increase for the net income of wholesalers and compared to 2010, the amount increased by 58 million lari in 2014. As far as retailers are concerned, the tendency was fluctuating and it grew by 9 million lari in 2014 compared to 2010. (See chart 4).

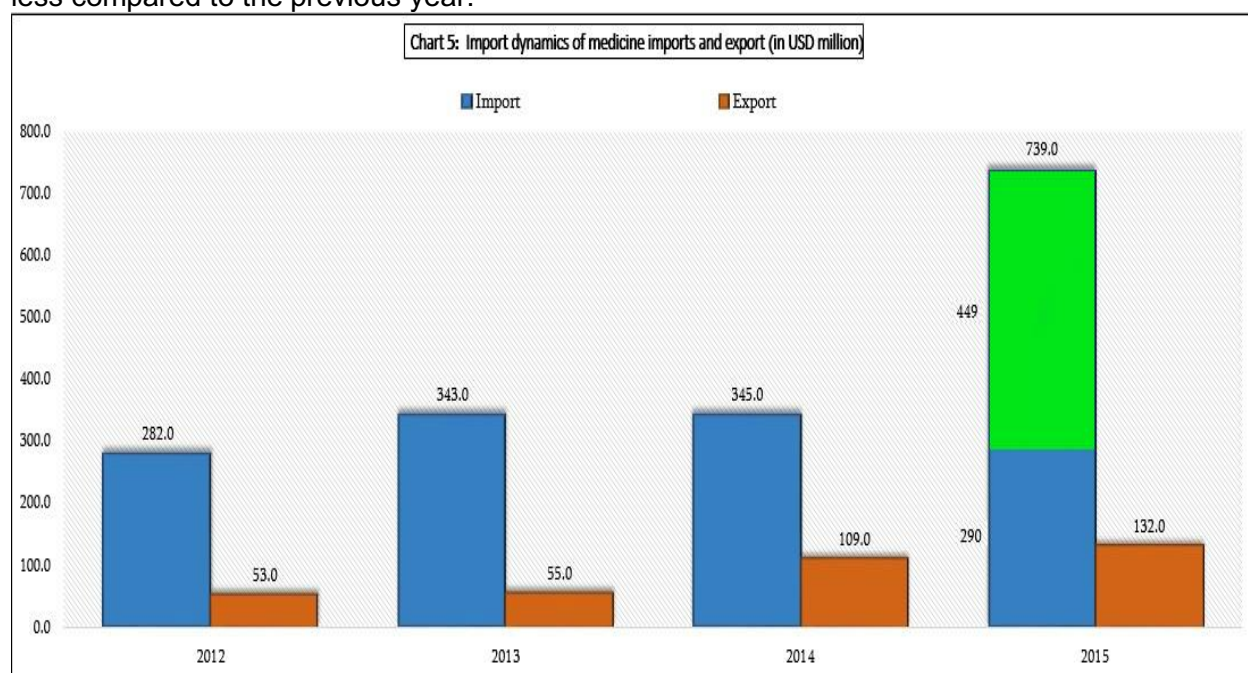


Source: National Statistics Office of Georgia

It is clear from the analysis of the data (charts 1,2,3 and 4), that the net income per year for wholesaler producers is on average five times more than in retail producers, despite the fact that the number of producers and number of employed persons in retail producers are on average twice as much as in the wholesaler producers. It is also clear that the four activities outlined above show a tendency towards growth. Therefore we can assume that this market is actively developing.

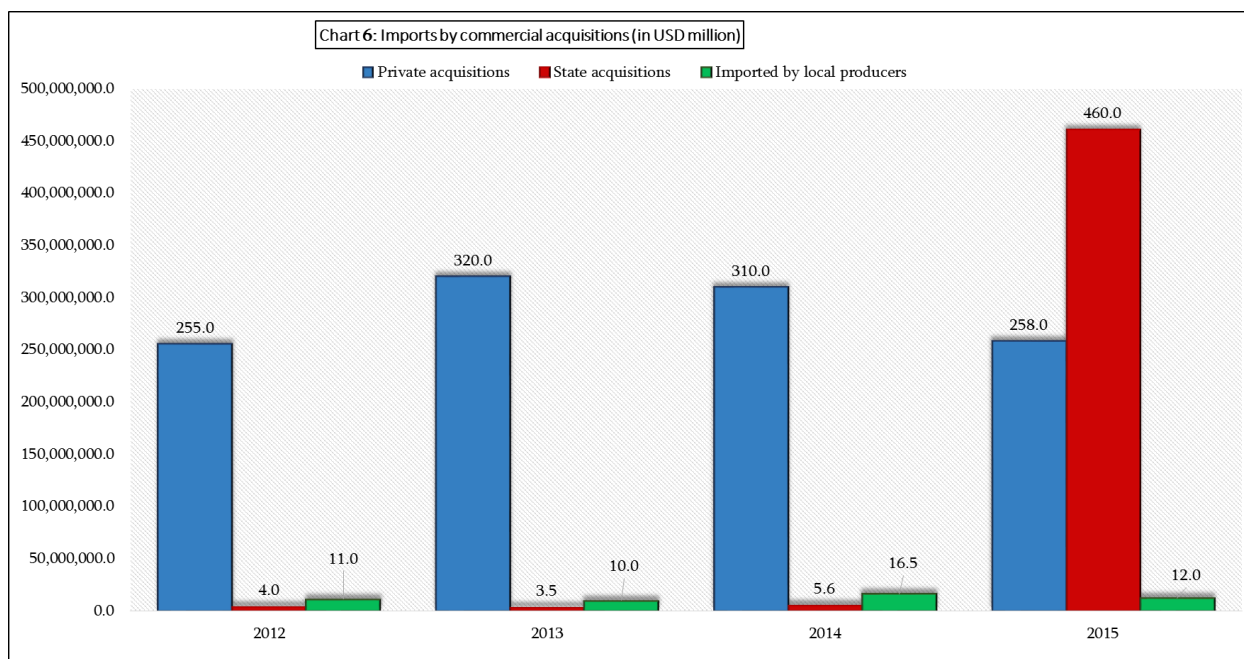
1.2 Indicators of export and import

There has been a tendency of growth for the import and export of drugs in 2012-2015. The indicators for import significantly exceed (nearly by five times) the export annually. In 2015, the indicators for import grew by 114.1% compared to 2014 and totaled 739 million lari (see chart 5). The main reason behind this is the import of free medication for C hepatitis (449 million lari was counted towards the imports, despite being provided free of charge). If we calculate the import costs without these medications, then the import totals to 290 million lari, which makes it 16% less compared to the previous year.



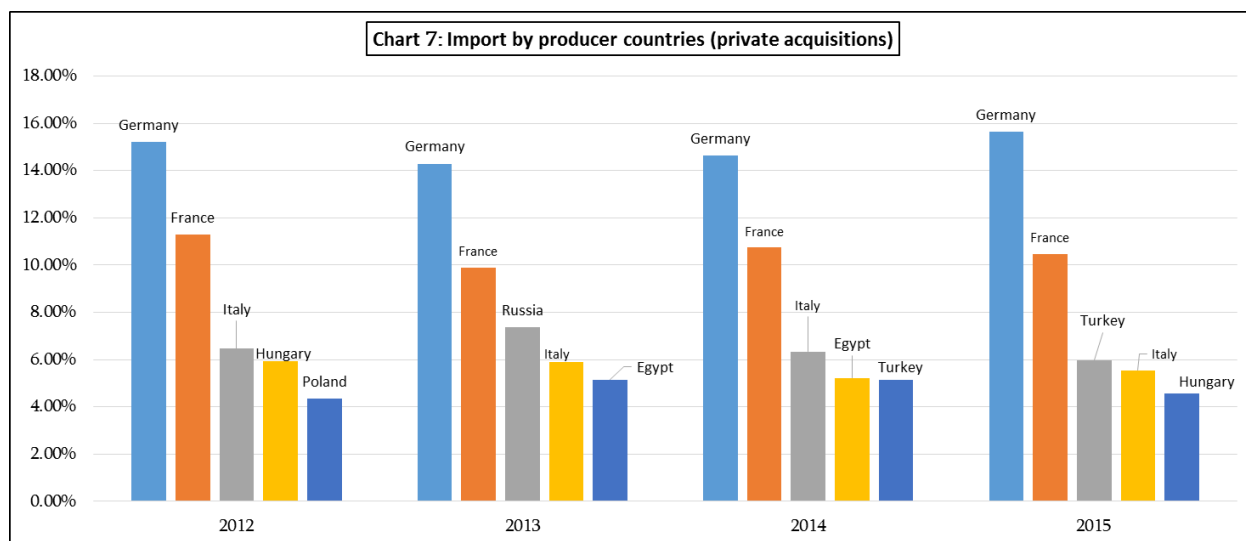
Source: Ministry of Labor, Healthcare and Social Affairs; <http://pharmacy.moh.gov.ge/Default.aspx>

It is also interesting to analyze the commercial import procurements by private, state procurements and local producers. In 2012-2014, the share of private procurements in commercial procurements varied between 93%-96%. In 2015, that figure dropped to 35% due to the rise of state procurements share to 63%. The latter's growth was conditioned by the purchase of free medication for Hepatitis C. Notably, the state procurements constituted only 1.5%-2.0% in 2012-2014. The share of local producers in imported drugs was 1.7%-5.0% in 2012-2015. (See chart 6).



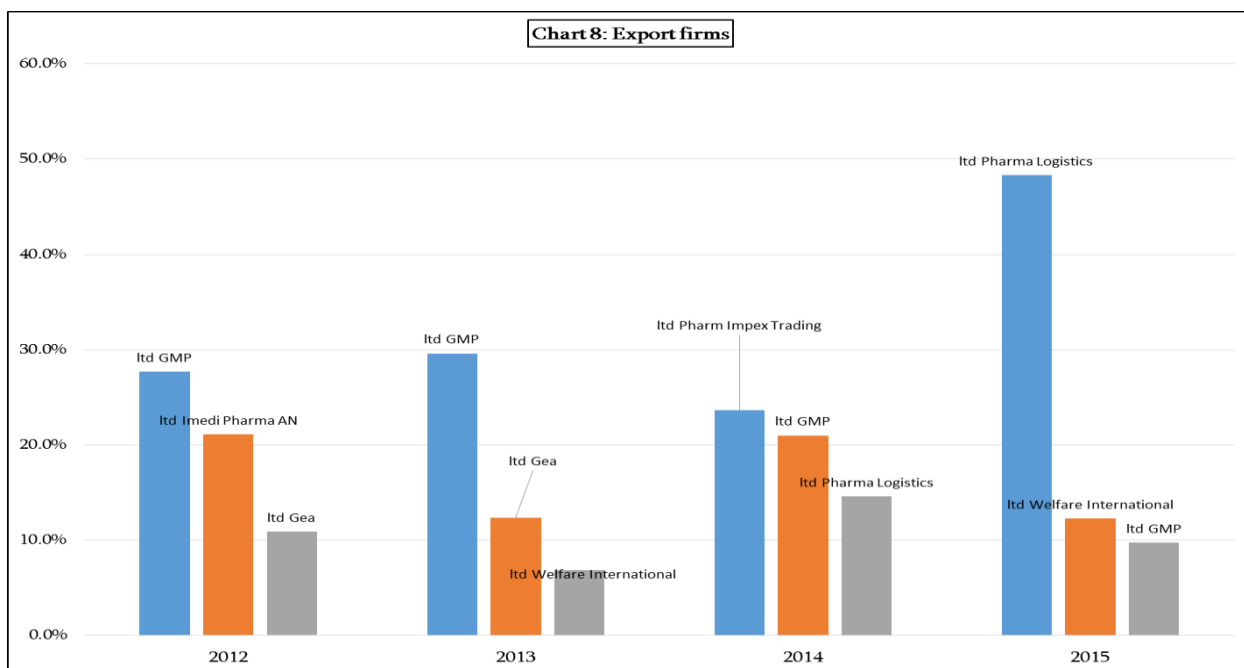
Source: Ministry of Labor, Healthcare and Social Affairs; <http://pharmacy.moh.gov.ge/Default.aspx>

In 2012-2015, drugs were imported (arranged by producer countries) from the following countries: the most from Germany, then from France, and Russia, Italy and Turkey respectively (See chart 7).



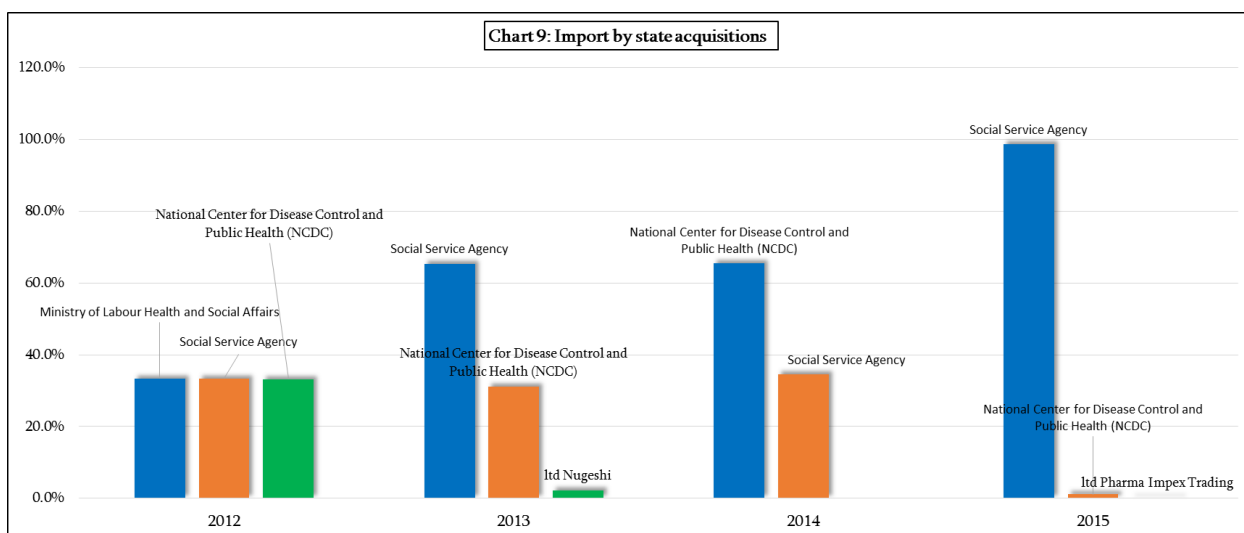
Source: Ministry of Labor, Healthcare and Social Affairs; <http://pharmacy.moh.gov.ge/Default.aspx>

As far as export of drugs is concerned, which compared to imports is five times less, the largest exporter in 2012-2015 is Ltd. GM Pharmaceuticals, Ltd Pharm Impex and Ltd Pharma Logistics. Notably, the last two companies are involved in the reexporting of drugs. (See chart 8).



Source: Ministry of Labor, Healthcare and Social Affairs; <http://pharmacy.moh.gov.ge/Default.aspx>

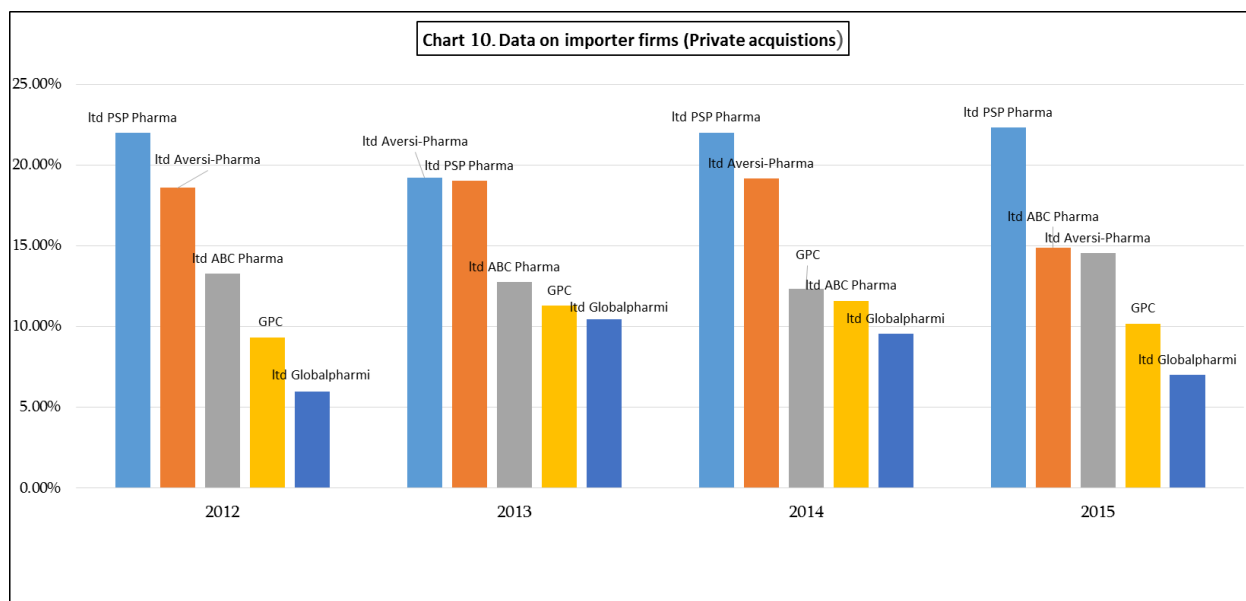
In 2015 LEPL Social Service Agency is on the first place with USD 454 million (98.6%) by state procurement imports, the second is LEPL National Center for Disease Control and Public Health with USD 5 million (1.2%), and the third is Ltd Pharm Impex Trading with USD 874 thousand (0.2%) (See Chart 9).



Source: Ministry of Labor, Healthcare and Social Affairs; <http://pharmacy.moh.gov.ge/Default.aspx>

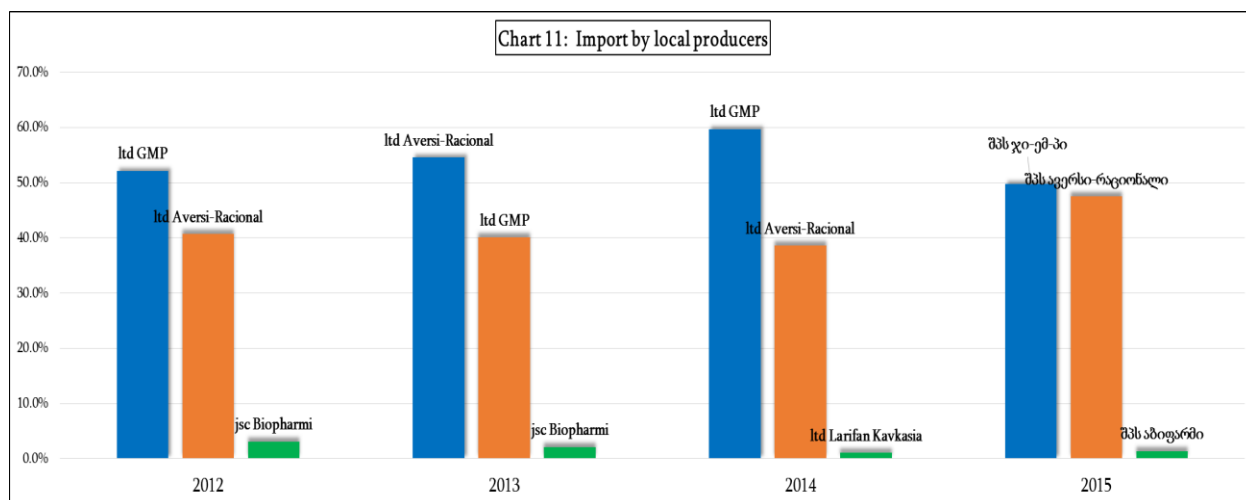
As far as import companies are concerned, in 2015 Ltd PSP Pharma is on the first place with USD 58 million (22.32% of the whole import). This company is annually the largest importer, except in 2013, when Ltd Aversi-Pharma was in the lead with USD 62 million (19.25% of the whole import). According to 2015 data, Ltd. ABC Pharmacia is on the second place after Ltd. PSP Pharma, with USD 39 million (14.91% of the whole import), Ltd. Aversi-Pharma is on the third place with USD

38 million, joint stock company GPC is on the fourth place with USD 26 million (10.2%), and Ltd. GlobalPharmi is on the fifth place with USD 18 million (7.02%). (See chart 10).



Source: Ministry of Labor, Healthcare and Social Affairs: <http://pharmacy.moh.gov.ge/Default.aspx>

While the share of imports by local producers is insignificant, it is still interesting to see the companies involved in them. In 2012-2015, the first was PSP's business Ltd. GM Pharmaceuticals, except for in 2013 when Ltd Aversi-Rational was first with 54.6%. In the following years, the first and second place is divided between Ltd. Aversi Rational and Ltd GM Pharmaceuticals (See chart 11).



Source: Ministry of Labor, Healthcare and Social Affairs: <http://pharmacy.moh.gov.ge/Default.aspx>

2. Main players on the market

We can talk about the main players on the pharmaceutical market based on the import statistics. As it has already been mentioned, these are the five largest importing companies of drugs according to 2015 data:

- Ltd. PSP Pharma – 22.32% of the total imports
- Ltd. ABC Pharmacia – 14.91%
- Ltd. Aversi Pharma – 14.54%
- Joint stock company GPC – 10.20%
- Ltd. GlobalPharmi – 7.02%

The shares of other companies do not exceed 3% individually, to a total of 31% in overall. When analyzing the large players on the market, TI Georgia looks at the connections between political parties and business companies in order to detect risks of corruption. More specifically, we look whether they have donated money to the political parties. In 2012, the pharmaceutical companies stood out in this regard. If we take five leading companies, four out of their shareholders and nine persons related to the business are connected with the United National Movement, having donated a total of GEL 415,000. After 2012, these persons have not donated to any political party.

To detect risks of corruption, we also check the participation of these companies in state procurements. Namely, we focus on the value of the contracts secured without a tender through the simplified procurements. There has been no interesting tendency in this regard in 2010-2016. The procurement contracts obtained by companies took place through a tender, and the direct contracting did not constitute a significant sum.

2.1. PSP

Ltd. PSP Pharma is one of the companies of PSP Group, there a number of other companies part of this company. PSP has operated in Georgia for already 20 years, and their founders are MPs from four convocations Kakhaber Okriashvili⁶, who has cooperated with the ruling party in 2014, and Gocha Gogilashvili. Initially the distributing company Implementation Centre PSP was created, and today it operates the distribution of over 10,000 drugs and curative cosmetics produced by 1000 pharmaceutical factories, imports hygienic products and distributes them throughout Georgia. Since 2000, PSP's pharmaceutical factory GMP produced the first drug. The factory produces over 150 different drugs and exports products to over 11 countries worldwide.⁷

Since 2010, PSP Insurance has worked on the insurance segment and has insured up to 70,000 persons from 100 companies; in 2011, PSP opened a 150-bed clinic in Ortachala.⁸

Ltd. PSP Pharma's director is Gocha Gogilashvili. The owner and holder of 100% of shares is Kakhaber Okriashvili, while the manager of the shares is Vaja Okriashvili.

Ltd. Pharmacy's director is Kakhaber Fanchulidze. The owners are Vaja Okriashvili (50%) and Tengiz Jamelashvili (50%).

Joint Stock Company PSP Insurance's director is Vladimer Bejashvili. The head of the supervisory board is Gocha Gogilashvili, his deputy is Vaja Okriashvili. Mamuka Bregvadze is the member of the supervisory board.

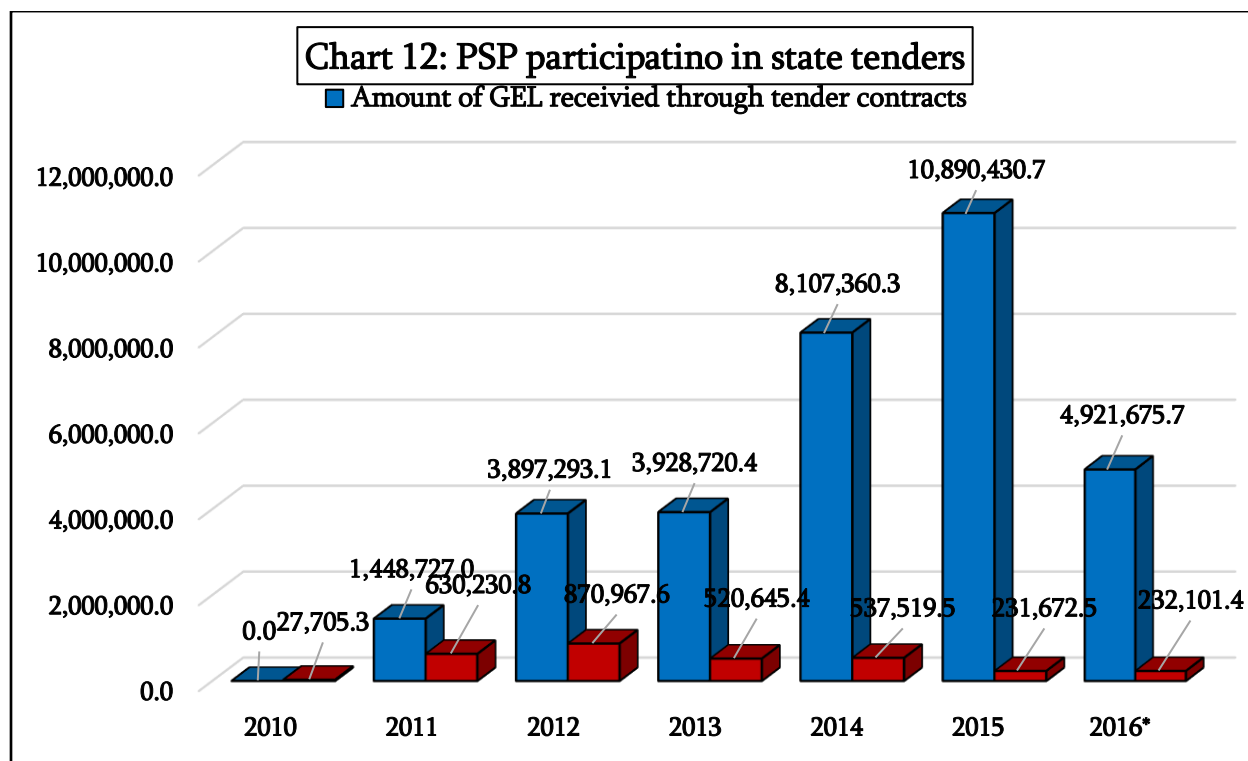
⁶ <http://parliament.ge/ge/mp/2115>

⁷ <http://psp.ge/new/pages/page/1>

⁸ Ibid.

From the aforementioned persons, only Vaja Okriashvili is amongst the list of donators to political parties. He has donated GEL 60,000 to the United National Movement in 25 July 2012.

As far as PSP's participation in state procurements is concerned, Ltd. PSP Pharma and PSP Pharmacy, throughout the period 2010 – June 2016, have secured 706 tenders. The total income from this tenders amounted to a near total of GEL 33 million. In the same period these companies secured 1,332 contracts through the simplified procedure, which amounted to nearly GEL 3 million. (See chart 12)



Source: Tender monitoring: <http://tendermonitor.ge/ka>

2016* - Data from first five months

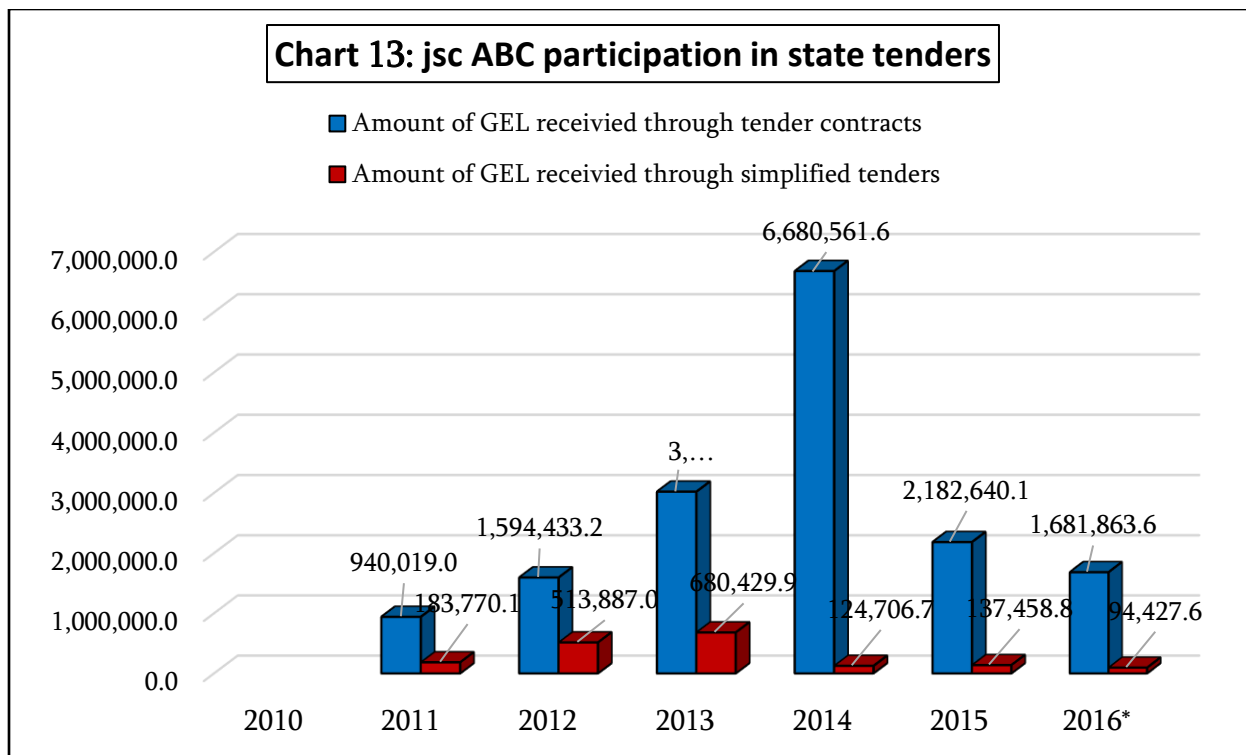
2.2. Joint stock company ABC Pharmacy

Joint stock company ABC Pharmacy was founded in Georgia in 1999, as the marketing representative of Bristol Myers Squibb. In parallel to other activities throughout the years, the company founded the pharmaceutical network Pharmadepo in 2009.⁹

Joint stock Company ABC Pharmacy's executive director is Mikhel Abramidze. The general director is Enriko Beridze. These persons are not amongst the list of donators to political parties.

ABC Pharmacy actively participated in state procurements. Throughout the period 2011 – June 2016 the company secured 188 tenders; the amount secured amounted to a near total of GEL 16 million. In the same period, ABC Pharmacy secured 803 tenders throughout the simplified procedure, the total of which amounted to nearly GEL 2 million (see Chart 13).

⁹ <http://abc-pharm.com/ge/about-us/history.html>



Source: Tender Monitoring <http://tendermonitor.ge/ka>

2016* - Data from first five months

2.3. Aversi

Pharmaceutical company Aversi was founded in 1994 by Paata Kurtanidze. Aversi is represented by 107 pharmacies in Tbilisi, and 126 pharmacies in the regions. Paata Kurtanidze also owns several other companies. Aversi began building the construction of the Aversi-Rational factory in 2002. The first drug was produced and up for sale in 2005. Currently Aversi-Rational produces 141 different drugs under 240 positions. Aversi's founder Paata Kurtanidze founded the insurance company Alfa in 2009 and the charity organization Aversi in 2010. In 2011, Aversi bought the Institute of Surgery and transformed it into a medical establishment.¹⁰

The general director of Ltd. Aversi-Pharma is Irakli Phurtseladze. The owners are Paata Kurtanidze (67%) and Nikoloz Kurtanide (33%).

The general director of Ltd. Aversi Rational is Malkhaz Kurtanidze. The owners are Paata Kurtanidze (60%), Nikoloz Kurtanidze (25%) and Malkhaz Kurtanidze (15%).

The general director of Ltd. Aversi-Clinic is Dimitri Jorbenadze. The holder of 100% shares and owner is Ltd. Aversi-Pharma.

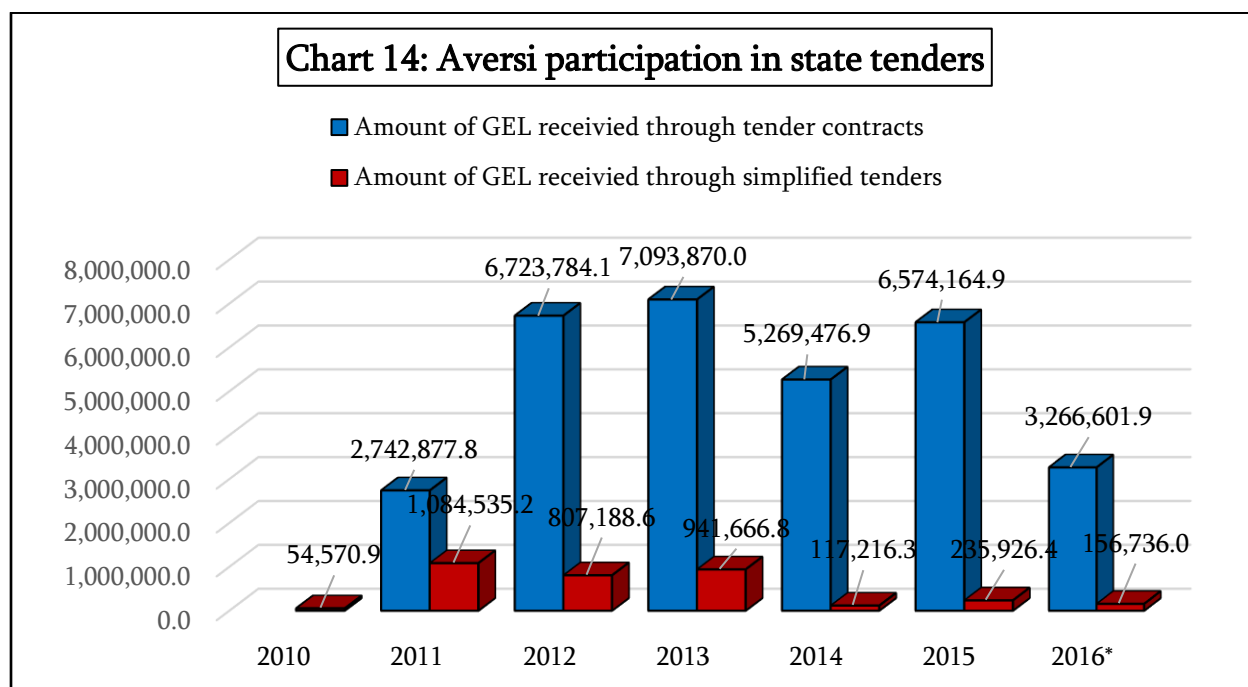
¹⁰ <http://www.aversi.ge/ka/301/Cvens-Sesaxe>

The members of the supervisory board of joint stock company Insurance Company Alfa are Irakli Phurtseladze, Giorgi Gvetadze and Aleksandre Janashia. The general director is Maka Sologhashvili.

The persons mentioned above are amongst the list of donators to political parties. Namely, in 2012 the following persons have donated a total of GEL 215,000 to the United National Movement:

- Irakli Phurseladze – Donated GEL 50,000 to the United National Movement on 4 September 2012;
- Paata Kurtanidze – Donated GEL 60,000 to the United National Movement on 29 August 2012;
- Malkhaz Kurtanidze – Donated GEL 60,000 to the United National Movement on 4 September 2012;
- Dimitri Jorbenadze – Donated GEL 40,000 to the United National Movement on 31 August 2012;
- Aleksandre Janashia – Donated GEL 5,000 to the United National Movement on 30 August 2012.

As far as for Aversi's participation in state procurement, Aversi GeoPharma (which merged with ltd. Aversi-Pharma in the beginning of 2016), ltd. Aversi-Clinic and ltd. Aversi-Pharma have secured a total of 852 tenders throughout the time period 2011 – June 2016. The total income from these tenders was GEL 32 million. In the same time period, Aversi secured 2,600 contracts through the simplified procedure, the total of which constituted GEL 3.4 million (See chart 14).



Source: Tender Monitoring: <http://tendermonitor.ge/ka>

2016* - Data from first five months

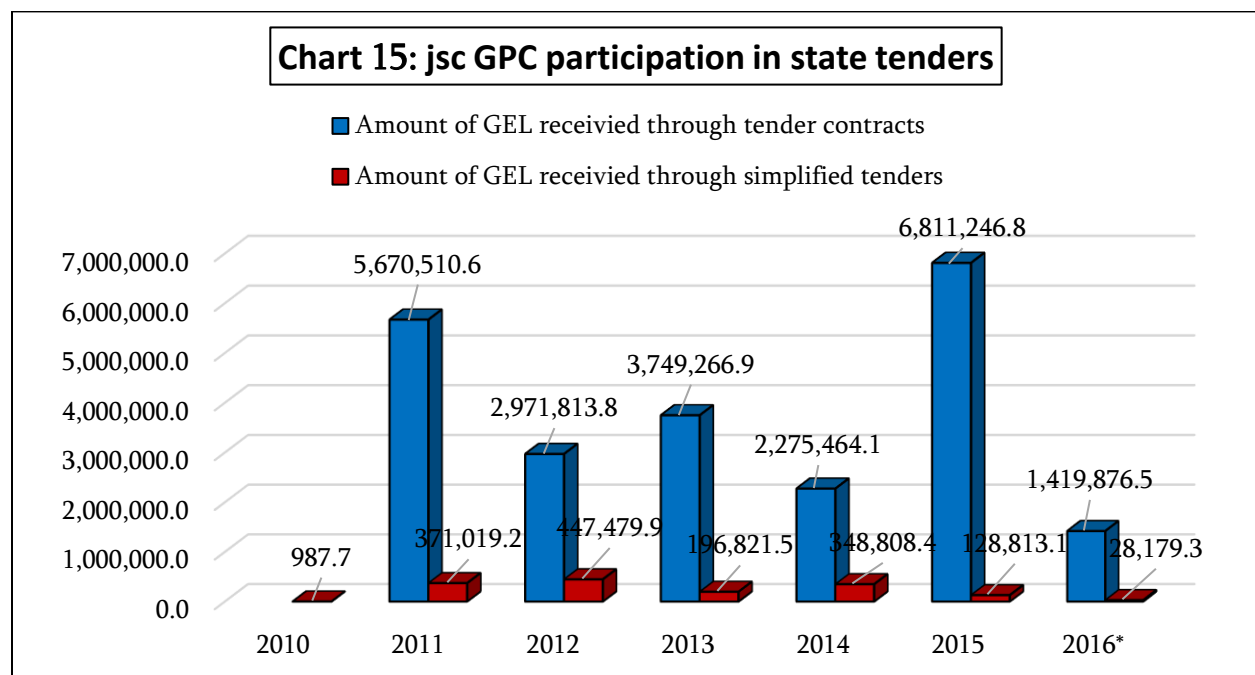
2.4. Joint stock company GPC

Joint stock company GPC began the development of its pharmaceutical network in 1998. The head of the supervisory board of the company is Giorgi Arveladze. The deputy chairperson is Irakli Gogia and Nikoloz Gamkrelidze is a member. The general director of the company is Davit Kiladze.

The following persons are amongst the donators to the political parties:

- Irakli Gogua - Donated GEL 60,000 to the United National Movement on 25 July 2012.
- Davit Kiladze – Donated GEL 30,000 to the United National Movement on 2 July 2012.

As far as for GPC's participation in state procurements, the company secured a total of 223 tenders throughout the time period 2011 – June 2016. The total income from these tenders was around GEL 23 million. In the same time period, GPC secured 650 contracts through the simplified procedure, the total amount of which constituted nearly GEL 1.5 million. (See chart 15)



Source: Tender Monitoring <http://tendermonitor.ge/ka>

2016* - Data from first five months

2.5. Ltd. GlobalPharmi

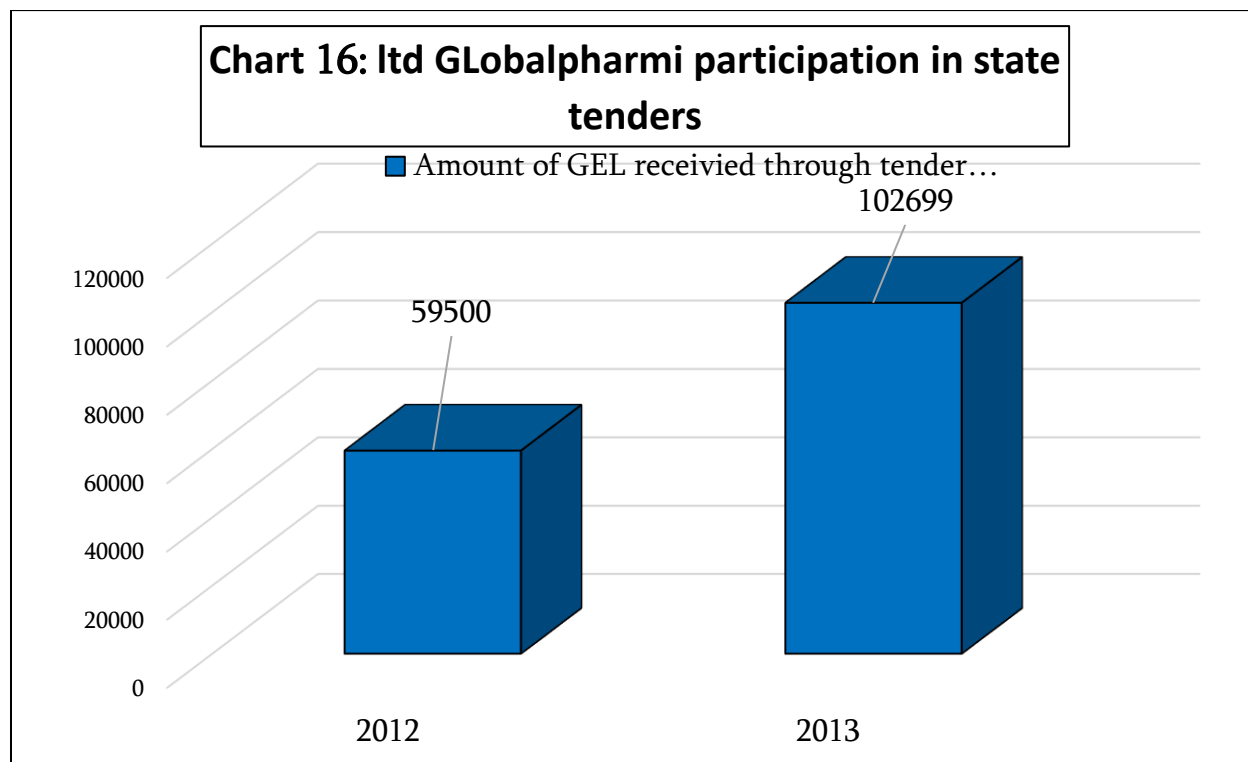
Pharmaceutical company GlobalPharmi was founded in 2005. Currently the company conducts the distribution of drugs on the Georgian market, and cooperates with pharmacies and pharmaceutical bases. Globalpharmi conducts the imports of drugs from companies such as World Medicine and World Medicine Ophthalmics, the representation of which was founded in 2005, Rotapharm, the representation of which was founded in 2008, and Dr. Sertus, the representation of which was founded on 17 July 2013.¹¹

¹¹ <http://globalpharm.ge/georgian/company>

The holder of 100% of shares and general director of Ltd. Globalpharmi is Anton Obolashvili. The director is Giorgi Gvinadze and the commercial director is Robert Eloidze.

From the persons mentioned above only Robert Eloidze is amongst the donators to political parties. He donated GEL 50,000 to the United National Movement on 27 July 2012.

As far as for Globalpharmi's participation in state procurements, the company secured 3 tenders in 2012-2012, the total of which amounted to GEL 162,000. The company has not secured any tender through the simplified procedure (see chart 16).



Source: Tender Monitoring: <http://tendermonitor.ge/ka>

From the data above it is clear that the pharmaceutical market (according to private procurements) in Georgia has five main players, which control around 70% of the total market.

As for the distribution of the market by producers (based on import statistics), there are two main players on the market – Ltd. PSP and Ltd. Aversi, which hold 97% of the market. We should note again that these shares are only based on the import statistics. Currently 11,168 drugs are allowed onto the market (bearing in mind the form, dosage and packaging of the drug), out of which 1,367 is produced in Georgia (this constituted 12,25% of all of the drugs available on the market. 259 of the products produced in Georgia are made by Aversi-Rational, while 237 is produced by GM Pharmaceuticals. By this it is clear that some of the Georgian producers produce drugs with raw materials obtained in Georgia, which constitutes nearly 60% of all the Georgian pharmaceutical products.¹²

Based on the latest data, the pharmaceutical market is best described as a weak oligopoly, as 70% of the market is in the hands of five companies. According to latest information, ABC Pharmaci, which has had a dominant position on the market (second place after PSP) in 2015, is planning to merge with GPC. A new corporation Georgian Pharmacy was created (GEPHA) that

¹² Information provided by the LEPL State Regulation Agency for Medical Activities

will manage the merging of Pharmadepo and GPC. As it is known, the decision of the State Competition Agency is required, which will be known in about a month.¹³

The Agency, according to Georgian legislation, may give the green light to the merger or prohibit it:

A) If agency finds out that the planned concentration falls within the scope of the Law, but it does not significantly restrict effective competition on the goods/service market of the country or on its significant part, shall take a decision on declaring such concentration compatible with normal effective competitive environment;

B) Agency shall issue a decision on prohibition of concentration, if it finds out that the planned concentration falls within the scope of the Law and it restricts competition significantly on service or goods market of Georgia (or on its significant part) and which have effect of acquiring or strengthening dominant position.

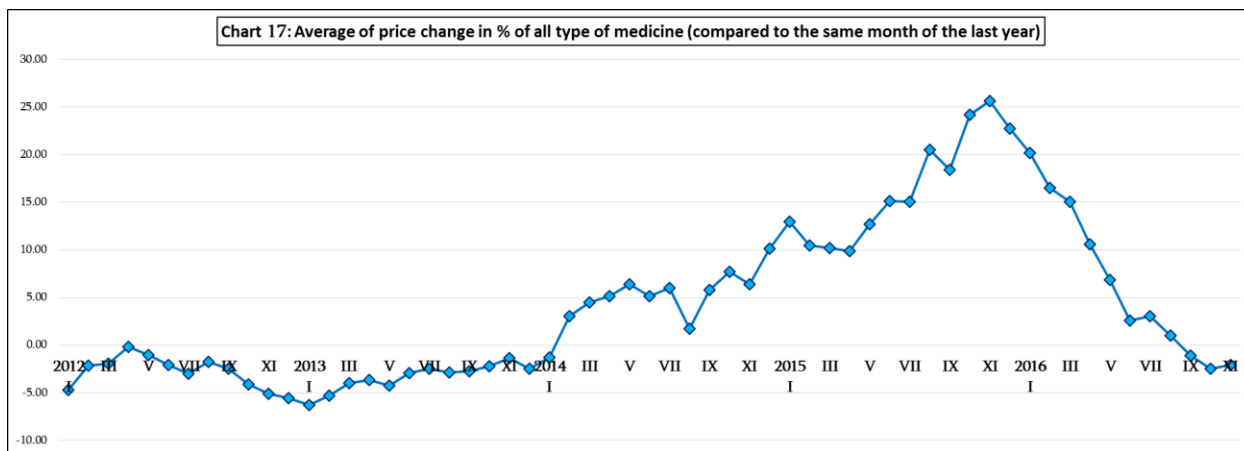
With the mentioned concentration, GEPHA will hold 25% of the market (based on import statistics), and as a result will hold the dominant position on the market and decrease the number of main players on the market from five to four. This concentration may have both negative and positive sides. The negative side is that holding 25% of the market will create more risks of abusing the dominant position. The positive side is that the merger will support the consolidation of resources and as a result funds will be optimized and the effectiveness of the company will increase in all directions.

3. Drug prices

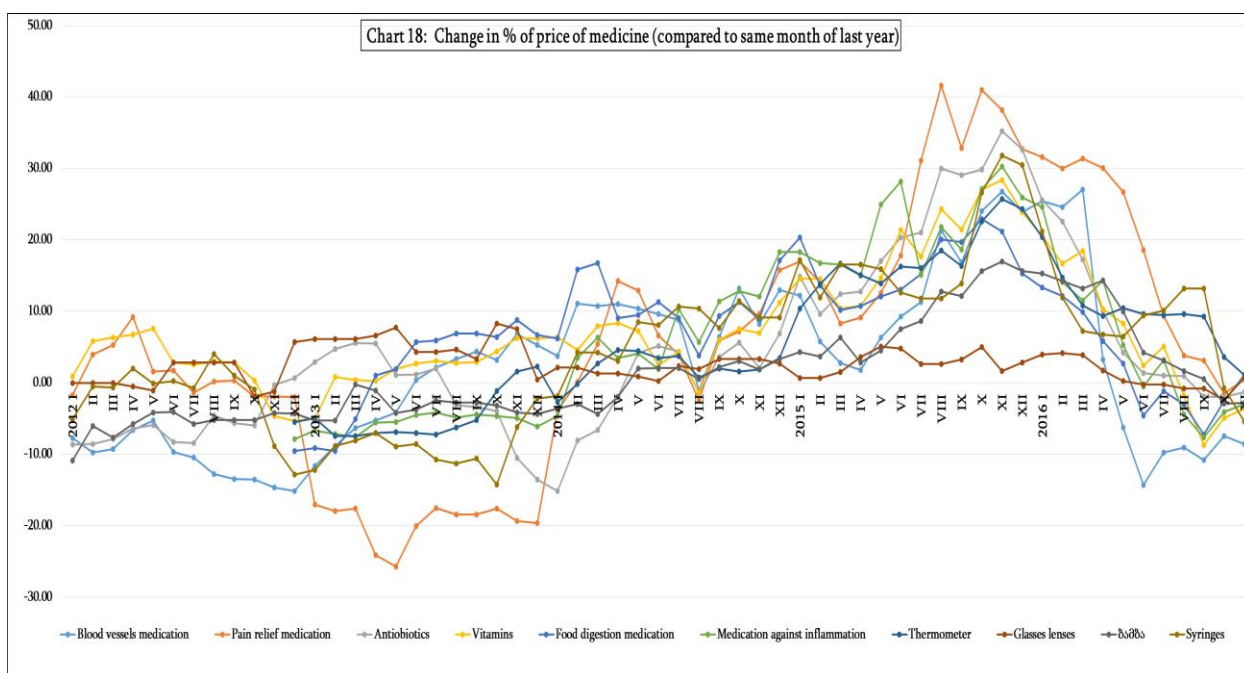
The tendency in the change in prices for drugs (comparison of month from the previous year with the same month of the subsequent year) can be summarized as following: the prices for certain category of drugs increased from 2012 until 2014 and prices for some categories decreased. In overall, if we look at all categories of drugs, there have been no significant changes in the price. In 2014, especially the period after April, the price for all drugs saw a drastic increase in price, reaching a peak of 25% in the second quarter of 2015. The drastic rise in prices began in parallel to the depreciation of the Georgian lari, namely eight months prior. The pharmaceutical companies blame the State Regulation Agency's restriction on parallel imports, an accusation that the Agency denies. From November 2015, the rise in prices of drugs saw a decline and by May 2016 the prices for certain category of drugs have already decreased. The tendency of the price going down can be observed on nearly all pharmaceutical products in December 2016 (see Chart 17 and 18). If the Georgia lari keeps on depreciating, this will naturally have a negative effect on the prices of drugs and will stimulate a further rise in prices. However, it is to be noted that according to statistics¹⁴ of November 2016, the annual inflation is only 0.2%.

¹³ <https://goo.gl/POZvxa>

¹⁴ <https://goo.gl/pLX7yb>



Source: National Statistics Office of Georgia: <http://geostat.ge/?action=price&ppid=1&lang=geo>



Source: National Statistics Office of Georgia

Recommendations

TI Georgia finds the following steps are required to be made to address the problems presented in the report and to decrease risks:

- The Competition Agency should pay attention to supporting competition on the pharmaceutical market. Based on import statistics, no single company holds a dominant position on the market, but with the recently announced merger of ABC Pharmacy and GPC, the share of the market for the new corporation GEPHA will be 25%;
- One of the biggest challenges of the pharmaceutical markets is that Georgia still hasn't managed to adopt to international GMP standards. The government planned to adopt the standards in 2016, but according to the new decision of the government, it has been postponed till 2018. Due to this, no one knows for certain if the decision won't be postponed again in 2018. This negatively affects the export of drugs produced within the country and raises questions about the quality of drugs used within the country. The creation of respective GMP inspectors requires the training of several international GMP specialists, which requires only 2 years and respective funding. The existence of these inspectors is essential for the pharmaceutical market and the economy of Georgia in general;
- The LEPL State Regulation Agency for Medical Activities, which is responsible for testing the quality of drugs, apparently does not have sufficient resources/budget for effectively fulfilling its purpose. Moreover, the current legislation does not allow for the effective and complete fulfillment of these functions. The laboratory testing of drugs is restricted by the law, it is allowed only in 10% of drugs. The others can be inspected only visually. We think that the budget for the program of testing of drugs, namely for the acquisition and laboratory testing of drugs, should be increased and amendments should be made to the law;
- It is worth noting the positive sides of the amendments made to the rule of registration of pharmaceutical products in 2009. However, in the case of recognition registration, there are still some risks of bringing in low-grade products into the market. To address this problem, the Georgian Regulation Agencies and Regulation Agencies of countries with high level of trust should strengthen their cooperation, and/or the rules for registration should be changed again;
- It is important to address the problems in the administration of prescriptions and improve the monitoring system. We think that the inspectors should randomly and more frequently check the activities of the pharmacies. Also, the fines for violations should increase;
- Polypragmasy and the lack of pharmacovigilance is an issue. It can be addressed by increasing the scale of electronic prescription system and making it obligatory, as well as creating a single base for electronic prescriptions. A single database will support data analysis, processing and easy identification of problems, as well as providing solutions. Moreover, a significant problem is the lack of unified protocols, guidelines and standards

on how to provide diagnosis and how to administer treatment. Associations should exist for doctors of all specializations. The associations should prepare and present to the Ministry of Healthcare for approval the list of tests to run for diagnosis of all diseases and the list of medicine required for treatment. These guidelines, notably, already exist in developed countries and Georgian associations, in an effort to save financial resources, can simply translate them. To address the issue of pharmacovigilance, a monitoring plan for the adverse effects should be presented during registration and a contact point should be assigned, who will responsible for presenting a report in case the pharmaceutical product needs to be registered anew.