

Corruption in the Pharmaceutical Industry

Ketevan Baramidze

In accordance with financial data, among 36 countries that manufacture pharmaceuticals, in 2003 the Georgian pharmaceutical market held mostly by following countries: Austria, Great Britain, Germany, Russia, France, Switzerland, Hungary, Slovenia and Denmark. In other words, according to results of the analysis undertaken by the State Pharmaceutical Agency, the largest part of the pharmaceutical market in Georgia is represented by production in the countries with superior quality. However, according to the volume of imported drugs, in reality the situation is completely different and rather disturbing, as the great bulk of pharmaceuticals in Georgian market is imported from countries which do not produce very high quality pharmaceuticals, namely Poland, Bulgaria, Turkey, Ukraine, Russia and India.

Therefore, it is obvious how a realistic picture could be distorted if research is directed in the wrong way. For this reason at the beginning of our work we developed a research methodology implying: a) examination of regulations of the pharmaceutical sector in order to reveal factors conducive to corruption; b) the pharmaceutical market analysis considering total monetary, retail prices, quantity of pharmaceuticals, and assortment; c) identification of mechanisms of corruption based on the analysis and collation of results.

Results of the study

The analysis of standard acts regulating the pharmaceutical sector of Georgia revealed that the legislative basis is inadequate and contains many factors conducive to corruption. Areas that require improvement, include:

- Standard acts do not provide a definition of the concept “small-scale retail trade”, thus allowing drugstores to manipulate prices to hide corrupt dealings;
- The standard act does not regulate relationships between pharmaceutical wholesale and retail trade networks, thus enabling them to monopolize the pharmaceutical market through corrupt deals;
- The standard act does not regulate the rule for the operation of the pharmaceutical register; therefore, inaccurate data included into the register from whatever point of view represent a factor conducive to corruption in the export/import process;
- Rules for storage of medications in pharmaceutical organizations have not been developed. Therefore, the result of the inspection depends on the inspector’s disposition and attitude;
- Standard acts do not regulate procedures for revoking or suspending an enterprise’s registration. This gives the inspector a chance to judge discovered medications “with cancelled registration” according to his/her own disposition and attitude;
- Pharmaceutical industrial standards are not developed. Therefore, results of the inspection of a pharmaceutical organization depends on the inspector’s disposition and attitude;
- Rules for requisitioning and destruction of falsified, outdated, spoilt and unregistered pharmaceuticals are not developed. This allows for the opportunity to retain such medications in the pharmaceutical network and besides, provides basis for numerous corrupt deals;
- The methodology for the collection of information on adverse drug reactions is not developed. Cases of adverse reactions are not registered anywhere. This allows for

the opportunity for corruption by preventing competent opinions on drug reactions from being publicized;

- Prescriptions are actually not practiced in Georgia (excluding prescriptions for type one and two narcotic and psychotropic drugs); this is a potential for corrupt deals during drugstore inspections;
- Drugstores within the medical/clinical organizational network have no right to retail trade of pharmaceuticals, though private drugstores opened through corrupt deals have the right to operate retail trade on the territories of the same clinical institutions. This provides possibilities for corrupt deals and for the interpretation of law in different ways;
- There are no regulations for trading basic medicinal components. As a result, according to existing law, substances such as acetone, sulfuric acid, ethylic ether, and chloric acid are included into the list of controlled substances. In fact, their use is widespread in different industries: sulfuric acid, for example, is used in all car maintenance service centers. Pharmaceutical manufacturers and other enterprises are not even aware of this ban, which allow bureaucrats to manipulate business owners during inspections;
- The standard act does not define a procedure for labeling specific medicines as “generics.” Such information could be given extremely quickly (in less than one hour), but in the case of corrupt dealing it might be prolonged until an interested person accomplishes selling without loses;
- The list of licensing documentations of a pharmaceutical institution includes “a passport of a pharmaceutical institution,” which is currently not regulated for pharmaceutical industries and cannot be submitted; therefore, this meaningless list is a factor conducive to corruption;
- Legal documents for the assessment of materials and the technical requirements for enterprises are not developed. Their unavailability does not allow commission to evaluate enterprises, thus making it impossible for the licensing system to play a role of a quality management, although it provides basis for corrupt deals;
- Rules for the preparation, production, purchase, storage, registration, distribution (selling), standardization, transportation/shipping and destruction of pharmaceuticals are not developed. Decision-making during the inspection of pharmaceutical enterprises depends on the inspector’s mood, while in case of drafting a protocol of administrative violations, on the judge’s mood;
- The low qualification of the standard act which bans the opening and operation of private drugstores on the territories of medical facilities allows its bypassing. Therefore, private drugstores which engage in retail trade function on the territories of clinical institutions (e.g. #1 Clinical Hospital, National Center of Oncology, etc.). They were able to open through various corrupt deals. For example, a portion of a clinic’s territory is excluded from the clinic’s balance sheet, and that “missing” territory is purchased by the drugstore owner.
- Due to Decree #141/n “On Regulation of Quality Assurance of Pharmaceuticals” (chapter II, item 10 of the addendum #2) dated 3 May 2002, a very important group of pharmaceuticals is excluded without any justification from the obligatory controlling regimen (Health Ministerial Decree #191/n). This change is actually the result of a seriously corrupt deal;

The above problems have lead to a situation where, only three enterprises operate in Georgia’s pharmaceutical market: Aversi Pharma, PSP and GPC. These companies actively collude and have agreed to control mutually the main wholesale and retail trade network, thus

hindering healthy competition. If these circumstances are not changed, there these companies could see the power over the market expand by great lengths, resulting in a classical form of market oligopoly with corresponding private price controls on pharmaceutical products, which would raise prices for consumers. In addition to affecting prices for domestic customers, there are two other important consequences. First, the three companies' dominant position, control of wholesale and retail prices, and actual exclusivity of import, provides a supportive environment for the existence of low quality and falsified production on the market. Second, the dominant distributors are mainly oriented toward the sale of imported products (though similar medicines produced locally is available at more affordable prices). Moreover, two of the dominant economic agents have their own industrial entities. The combination of these circumstances has prevented the development of a significant local pharmaceutical industry.

In light of these problems, we developed 18 recommendations. These recommendations aim to decrease corruption existing in the pharmaceutical sector, if not eradicate it completely.

1. A concept "small-scale wholesale trade" should be defined and mechanisms of relationships of pharmaceutical wholesale and retail trade networks should be regulated in order to avoid control of the pharmaceutical market by means of corrupt deals;
2. Regulations for maintaining a national drug catalog should be developed. This would exclude inaccurate data from being included in the catalog which is one of the most important factors conducive to corruption in export/import;
3. Regulations for drug storage, registration, cancellation, and suspension procedures should be developed so that such decisions would be decided within a legal framework and not be based on inspectors' attitude and disposition towards a business owner;
4. Regulations for seizing falsified, outdated, spoiled and unregistered drugs should be developed. This would decrease the volume of such drugs in the pharmaceutical network and reduce the possibilities of corrupt deals;
5. Procedures and the methodology for collecting information on a drug's adverse reactions should be developed to exclude the possibility of corruption related to prevent authorities from giving false statements regarding drug reactions;
6. A rule concerning the trade of legal medicinal components should be developed, as well as a procedure for assigning of an "analogue" status;
7. Rules for preparation, production, purchase, storage, registration, distribution (selling), standardization, transportation/shipping and destruction should be developed in order to prevent situations when during the inspection of pharmaceutical institution decision depends on the mood of the inspector, while during the drafting of administrative violation protocol – on the mood of the judge;
8. The standard act prohibiting the opening and operation of private pharmacies on the grounds of health institutions should be perfected in order to avoid the possibility of bypassing this act;
9. A standard document should regulate the non-register labeling of a drug (moreover, the formulation of the law "On Drugs and Pharmaceutical Activities," article 11, item 3 states: "An application submitted on the issue of registration of a pharmaceutical includes information on the producer or the international unlicensed name and trade name with registration right, substance, synonyms, form of a drug, dose, full composition, conditions of distribution, rules of use, terms and conditions of storage, and packaging;" this formulation does not include labeling for drugs registered since 1

- January 2003, which requires instructions in Georgian), or to label in Georgian language only;
10. Rights and responsibilities of foreign companies' representative offices in Georgia should be defined for the following purpose: If the producer fails to provide documented confirmation of the exclusive distribution right to specific drugs of a specific pharmaceutical base, then all pharmaceutical bases must enjoy equal rights. In this case any company wishing to distribute medicines may purchase drugs directly from the producer rather than from intermediary pharmaceutical trade companies. We believe that such a solution would reduce the likelihood of supplying low quality drugs to the pharmaceutical network resulting from suspicious intermediary deals;
 11. A standard document should be developed defining the necessity of a serial control of drugs;
 12. Regulations should be developed in the shortest possible time period to provide the framework to assess the material and technical basis of pharmaceutical enterprises;
 13. Regulations for new drug development and implementation should be developed;
 14. Regulations for compiling and approving regulatory documents (NS, NTD) for pharmaceuticals should be developed. Revision of existing regulatory documents should be initiated in order to approximate them to European and other pharmacopeias;
 15. A legal basis for regulating operations of pharmaceutical enterprises should be developed;
 16. Amendments to the law of Georgia "On Licensing of Medical and Pharmaceutical Activities" should be drafted in order to improve licensing requirements and to turn the licensing system into a guarantor of the quality of pharmaceuticals;
 17. A rule should be developed for the reprocessing or disposal of spoiled or advertised series of pharmaceuticals in pharmaceutical enterprises;
 18. A competent expert commission should be established after the above-mentioned documents are developed, approved and put into effect. The commission would undertake monitoring (not control) of the current situation of pharmaceutical enterprises and prepare recommendations for the following stages of transition to good entrepreneurial practice.