The Challenge of Counterfeit Drugs in the Republic of Armenia

Master of Public Health Integrating Experience Project

Problem Solving Framework

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Executive Summary

Counterfeit drugs are a major global public health problem. They comprise 10% of all drugs worldwide and their revenue reaches approximately 96 billion U.S. dollars yearly. The problem is more critical in less developed countries where the counterfeit drug percentage in the market is 10 times higher than in more developed ones.

Counterfeit drugs annually kill one million people, and no country has ensured safety from such drugs. According the World Health Organization's (WHO) estimations, the percentage of counterfeit drugs in circulation in Armenia can be up to 20% of the market. However, during 2001-2012, the Drugs and Medical Technology Expertise Scientific Center detected only 16 cases in the country; a number inconsistent with WHO estimates. These data suggest that governmental oversight of the pharmaceutical market is ineffective in detecting counterfeit drugs.

The factors that facilitate drug counterfeiting in the Republic of Armenia are weak drug legislation and regulation, increasingly sophisticated criminal operations, high prices for legitimate drugs, and limited public unawareness.

Potential intervention strategies include: regulating drug prices, international cooperation, cooperating with local manufacturers, increasing public awareness, developing drug legislation and punishments and controlling the supply chain. The criteria for assessing the pros and cons of the mentioned strategies include intervention effectiveness, intervention feasibility, intervention cost, intervention sustainability and political acceptability. The assessment suggested that control of the supply chain emerges as the most effective in the given situation to provide quality medications to consumers.

A three-step monitoring and evaluation strategy will be implemented to see the effectiveness of the chosen strategy, which includes baseline data collection, ongoing monitoring, and finally the outcome evaluation. The output related indicators will include the number of people trained to work in the new facility, development of the work plan and protocols for the storage activites, the proportion of drug shipments tested, the proportion of drugs appropriately labeled and the proportion of drugs sold in appropriate packages. In addition, outcome measures will include collecting baseline and follow-up data on the percentage of counterfeit drugs out of 5000 randomly collected drug samples from the market.

Statement of Problem and Its Magnitude

A large number of pharmaceutical drugs are used to treat mental or physical disorders; consequently, pharmaceutical drugs play a central role in the medical sphere. According to the Law on Drugs of the Republic of Armenia(RA) the definition of pharmaceutical drug is "Any biologically active measured-out preparation, originated from one or several substances and subsidiary ingredients, consisting of standard components, produced under fixed brand names, in adequate dosage, form and design; intended for human and animal treatment, diagnostics, prevention, anesthesia, contraception, with the aim of effecting the organism functions".[1]

Armenia has adopted the World Health Organization (WHO) definition of counterfeit drugs as "One which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging".[1,2] The WHO classifies counterfeit drugs into six categories: counterfeit drugs without active ingredients (32.1% of counterfeits), with wrong amount of active ingredients(20.2%), with wrong ingredients,(21.4%), with fake packaging (15.6%), with high level of contaminants (8.5%), and copies of original (1%).[2]

In many cases, counterfeit drugs do not contain active ingredients, or they contain wrong ones. From time to time, they contain the wrong amount of active ingredients and this is why the rehabilitation process for most of the patients lasts longer than it is supposed to be, as well as it may cause dangerous side effects to health.[2] Counterfeit drugs constitute about 10% of all drugs worldwide and cause up to one million deaths yearly throughout the world.[3,4] For example,

650000 counterfeit capsules for diet were found in Taiwan, which contained ingredients causing cancer and the ingredients have not been used in production since 2001.[3]

Every product in the pharmaceutical market can be counterfeited independent of its price.[5] In developed countries such as the USA, Canada, Japan and most of the European Union (EU) countries, which have highly developed regulatory systems and market control, the counterfeit drugs' total value is approximately 1% of the total market value. In some countries in Africa, Asia and Latin America about 30% of medicine can be counterfeit.[2] Most countries in the world have the risk of having counterfeit drugs in the country's pharmaceutical market circulation and therefore, the challenge of counterfeit drugs is a global public health problem.[2]

The major reasons why counterfeiters fake drugs are the high prices and the limited availability in a given market. The latter will stimulate them to sell counterfeit drugs to gain tremendous profits.[2] The pharmaceutical market is developing year-by-year, and the total revenue of the global pharmaceutical market has significantly increased during the last decade. In 2003, the total revenue of the world pharmaceutical market was 502.2 billion U.S. dollars, however, by the end of 2012 it had reached 962.1 billion U.S. dollars.[6,7] Taking into consideration the fact that the total revenue of pharmaceutical market of the world reached 962 billion dollars in 2012, we may estimate the total revenue of counterfeit drugs to be almost 96 billion dollars annually.[2]

Furthermore, the counterfeiters do not spend any financial resources for researching, creating, and patenting new drugs, while the drug manufacturing companies spend billions of U.S. dollars yearly for a limited time monopoly for their new drugs. The counterfeiters also sell their falsified products like the original ones at monopoly prices, making tremendous profits and simultaneously damaging the profits of the patent owner.[2]

Situation in Armenia

The approximate number of companies that import drugs into the Republic of Armenia (RA) is 60 - 65. About 20-25 wholesalers regularly import drugs into Armenia.[8] The import leaders, Natali Pharm and Alfa Pharm, have their own pharmacy chains containing 64 and 120 pharmacies respectively located throughout Armenia.[8,9] The total number of pharmacies in the RA reaches approximately 1700, of which nearly 1000 are located in Yerevan.[2,8,10] In Armenia, the number of registered drugs is approximately 4600 while in the Russian Federation and in the U.S. the number of registered drugs is 14000 and 18000, respectively.[11]

In many post-Soviet Union countries, the proportion of illicit medicines may comprise 20% or more of the pharmaceutical market value[12] in developing countries, this proportion is estimated to be about 10%.[2] Since the RA is a developing post-Soviet Union country, the counterfeit drugs could be in the range of 10-20% of the pharmaceutical market of the country.

Drugs produced in Armenia form only 5% of the whole circulation of drugs in the market. The current number of drug manufacturing companies in Armenia is 18, while in 2009 the number of manufacturers was 12.[8] The annual production of domestic products in this sphere has a similar annual growth as the imports; thus, the proportion of domestic products in the pharmaceutical market remains unchanged.[8]

The import of pharmaceutical products of the RA increased significantly during 2006-2014. In 2006, the amount of drugs imported cost over 33 million U.S. dollars, while in 2014 it was 95 million U.S. dollars.[13] The import of drugs has increased almost by 200% during the last 8 years.[11]

The current strategies that prevent pharmaceutical market from counterfeit drugs in Armenia are:[8,14]

1. Testing at entry: when a drug crosses the RA's borders, it goes to the customs storage. The customs service then sends exemplars of the drugs to the Drugs and Medical Technology Expertise Scientific Center (DMTESC). Only after the positive conclusion of the DMTESC the Ministry of Health permits the drug to enter the market.
2. Market monitoring: the Ministry of Health via its State Health Inspectorate fights against counterfeit drugs in the pharmaceutical market through administrative proceedings and inspections. The State Health Inspectorate realizes the examination of drugs to detect the drug, which might be counterfeit. The State Health Inspectorate transfers the detected drug to the DMTESC, which is authorized to confirm whether the drug is counterfeit or not after having examined it in the laboratory through the appropriate testing.

During 2014-2015, approximately 150 cases of drugs had negative conclusion from the DMTESC and therefore, the Ministry of Health did not permit those drugs to enter the country; during 2009-2010 the number of cases rejected entrance to Armenia was 125.[11] These drugs could potentially be counterfeit and the testing at entry prevented their presence in the market.

The DMTESC identified 16 counterfeit drugs in the RA during 2001-2012 (Table 1): 14 out of these drugs had wrong packaging, 4 were without active ingredients, 2 were with wrong amount of active ingredients, and 6 were with wrong active ingredients.[11] Since March 2014, the State Health Inspectorate's mandate has been to identify counterfeit drugs. During this time-period, the enhanced administrative inspections by the Department of "Control on Drugs and

Drug Manufacturing" of the State Health Inspectorate found one counterfeit, 53 out of date and 62 unregistered drugs in pharmacies in Armenia.[8]

Objectives

This paper examines the current situation in the pharmaceutical market in Armenia, finding the gaps that allow counterfeit drugs to circulate and identifying strategies to fix the gaps to ensure only high quality medicine reaches consumers in Armenia. The strategies should be evaluated according to intervention effectiveness, intervention feasibility, intervention cost, intervention sustainability and political acceptability criteria.

Key determinants

Various factors promote drug counterfeiting. Many factors are common across nations; some are unique to specific countries or regions.[2] Six factors drive drug counterfeiting in Armenia: weak drug legislation and regulation, technology development and criminal experience, high prices of drugs, demand versus supply, prescriptions by doctors, lack of public awareness, drugs that are sold without packaging, and internet market.

Weak Drug Legislation and Regulation

Strong drug legislation and regulation should cover the issues of safety of drugs, good quality and effectiveness of drugs.[2] The Armenian law on drugs suggests that every consumer in the RA has the right to receive high quality pharmaceutical service in affordable price and on time.[1] However, because of weak drug legislation and regulation in Armenia this right of consumers is not always fulfilled.

The only regulations of counterfeit drugs is the 280th act of the Criminal Code of the RA; it suggests punishments for counterfeit drug manufacturing and circulation. The Criminal Code

of the RA was adopted in April 2003 and the counterfeit drug provisions did not change in the last 12 years making it easier to find gaps and circumvent the regulations. According to the 280th act:[15]

- Private medical or pharmaceutical practice without an appropriate license that negligently causes damage to human health is punished with a fine in the amount of 300minimal salaries or correctional labor for up to 2 years or imprisonment for up to 3 years.
- Manufacturing or sale of false drugs is punished with imprisonment for up to 3 years.
- Negligently causing human death is punished with imprisonment for 5 years.

In the Republic of Armenia, illegal private medical or pharmaceutical practice, manufacturing or trade of false drugs are crimes against public health.[16] Manufacturing of counterfeit drugs get more sophisticated with time and, therefore, the appropriate institutions should continuously develop and strengthen the existing regulations.[17]

For example, one of the gaps that has not been fixed in the existing laws is the ambiguity/poor definitions in the law that allow offenses that are truly counterfeit drugs to be classified under the less severe unregistered category. According to the Criminal Code and Administrative Offences of the RA, certain counterfeit drugs can be categorized as unregistered drugs, thus, punishment for their sale is less severe than the punishment for the sale of counterfeit drugs. Moreover, in case if counterfeiters change the packaging and write the amount of ingredients that are in the counterfeit drug, the Ministry of Health cannot prove that the drug is counterfeit and the pharmacy should pay the penalty for selling unregistered drugs.

During the last two years the bill related to selling expired, non-registered and counterfeit drugs has not been adopted as a law, therefore no amendments were made to the law on

Licensing.[18]According to the bill, in case if a pharmacy is selling expired, unregistered or counterfeit drugs, the license of the pharmacy should be suspended or terminated.[19] The adoption of this law could prevent the appearance of counterfeit drugs in pharmacies.

As drugs are special product, the conditions for import of them should be completely different from the ones meant for other products. The borders of Armenia are open to every product including drugs that are imported from the union countries: Russia, Belarus, Kazakhstan and Kyrgyzstan. The Agreement which was signed between 5 countries became effective January 1, 2015.[20] Drugs that are imported from these countries, therefore, are not checked for quality or monitored and cataloged as are direct imports.[14] These countries also suffer from counterfeiting. Therefore, the total value, the quality, and the quantity of the drugs in circulation is unknown, making detection of counterfeits more difficult.

Good Manufacturing Practice

The Ministry of Health faces great challenges cooperating with local drug manufacturers to assure safety, quality and effectiveness of the products. Good Manufacturing Practice (GMP) deals with all the processes of production including the initial materials, environment and equipment, also training and personal hygiene of staff. Its aim is to reduce the level of risk designed to minimize the risks of any product of pharmaceutical market, which cannot be eliminated by testing. The mentioned procedures are important for each kind of process which will cause better quality of the already prepared product.[21] Only two companies of 18 in the pharmaceutical market of the country produce drugs under the GMP standards.[11] As a result of absence of the proper conditions for drug production that is all necessary materials, equipment, etc. the amount of ingredients for the drugs might be wrongly selected, thus increasing the risk of producing substandard drugs, which is classified as a counterfeit drug. Putting it differently, the

absence of GMP standards is considered to be a threat for proper drug production. Moreover, maintaining the GMP standards is a method, which enables to make sure that the products are under a constant control of the quality of the product.[21] For meeting the GMP standards, each of the domestic drug producing companies should follow a certain timeline. As it was mentioned earlier only 2 out of 18 drug producing companies do follow the mentioned standards. Another 3 companies in that list followed the standards in earlier periods of their drug production; however, because of poor inspections in that companies nowadays they do not follow their duties related to the standards any longer. They continue producing drugs which enter the market. Producing drugs without following GMP standards is a serious threat for the market, since the risk of producing counterfeit drug in companies which do not follow GMP is much higher (GMP ensures the hygienic and proper conditions for drug production). To lessen this risk it is of high importance to make all the companies follow the GMP standards; thus, ensuring the safety and proper origin of the drug.[11,22]

Technology Development, Criminal Experience

The technology development allows the counterfeiters to get counterfeit packages as similar to the original one as possible. In many "copy" cases of counterfeit drugs, even the original drug manufacturer cannot differentiate from the original one. Furthermore, counterfeiters become more and more organized and find new gaps in supply chains to insert their products into circulation.[13]

High Prices of Legitimate Drugs

High prices of legitimate drugs can motivate counterfeiters to supply counterfeit drugs cheaper than the original ones. It is a great opportunity for the counterfeiters to have tremendous profits, because minimal expenses are made to counterfeit drugs.[10] If a counterfeiter invests

1,000 US dollars into the business, then the profit that they can get might be up to 400 times greater than the investment, a far greater return with far less risk than selling heroin where the same investment returns only 20-fold.[4] Studying the drug market of the RA, the first thing that makes the prices of the drugs high is tremendous amount of imported drugs, which includes additional expenses such as transportation cost. All these drugs are bought paying foreign currency.[14] The other reason of high prices of drugs particularly in the RA is the unstable Armenian currency, which is a major problem in the given situation of imports and the high rate of devaluation of the Armenian currency leading to higher prices.[14] Another factor that makes the price higher is the value added tax (VAT). VAT of 20%, is applied to all drugs without exception.[23]

When starting the producing process of a new drug, the drug companies have the patent rights to be a monopolist in the market for a five-year period.[24] New drugs are more expensive because the company has patent protections and it can gain very high profits. The monopoly price, in its turn, is very high because the company is the only supplier in the market and is authorized to establish the high prices of the product. After the five-year term of monopoly, the company usually pays to the other drug producing companies for delaying their production and continue to maintain its monopoly.[25] However, when other companies start producing the same drug in five years under names different from the original, the drug that was initially produced by the monopolist company becomes more expensive and the patients who are used to buying the known brand-name drug even then are ready to pay a higher price. In this case competition does not decrease the prices of the drugs.[26] Counterfeiters do not use new technologies or high price ingredients, which increases the counterfeiters' profit margin.[4]

Demand versus Supply

In situations, when the demand of the drug exceeds the supply of the same drug, the counterfeiters can fill the gap in supply with falsified drugs. In cases, when the drug importing company stops the import of a certain drug for some reason, there is no supply of that exact drug in the market and patients are ready to buy the drug wherever it is possible; this situation makes it easier for counterfeiters to thrive.[2]

Prescriptions by Doctors

One of the main factors that weaken the regulatory system is having unregistered drugs in pharmacies. Doctors recommend the patients to use drugs, which are not registered by the Drugs and Medical Technology Expertise Scientific Centre in Armenia. Therefore, there is demand for certain unregistered drugs in the market, which, in its turn, can lead to the supply of unregistered drugs or counterfeit unregistered drugs. The doctors prescribe unregistered drugs first of all for their effectiveness, because the doctors are responsible for the wellbeing and the minimum time for the treatment of their patients.[27] The second reason why the doctors can prescribe unregistered drugs is the financial interest that they pursue from the sale.[28] All the doctors that prescribe drugs have the list of the registered drugs in the RA; therefore, the unawareness of the doctors is not the reason for the unregistered drug prescription.[28,29]

Lack of Public Awareness about Counterfeit Drugs

Consumers lack appropriate knowledge to differentiate counterfeit drugs from the genuine ones. The RA had no organized social campaigns to raise the awareness of the population about counterfeit drugs and their health consequences during the last decades.[8] Everyone needs to identify counterfeit products from the genuine ones, thus, the campaigns for

raising the awareness of the public regarding the issue are organized to reduce the use of counterfeit drugs. A study demonstrated that a successful campaign could make sure that about 90% of people understand the dangerous consequences of counterfeit products and try to avoid any doubtful purchase.[30]

Selling Drugs without Packaging

In the RA, drugs are sold without packages, mainly in small plastic bags without any notes about the drug, instruction or the pharmacy name. Many countries of the world apply the practice of selling drugs in special packages, which have the name of the drug, the name of the pharmacy and contact information, the name of the doctor and the instruction on use.[31] However, in the RA this practice is not applied and thus, one of the most important problems typical for the RA is selling drugs without packages.[8] In many cases, the consumer does not have enough money to buy the whole package of drugs and asks the pharmacist to sell several tablets from the package and sometimes the package is already open and not full.[8] The counterfeiting of the tablets or the blister packs is very easy, because they do not include any security marks.[8] The counterfeit tablets or blisters can appear in the opened packages and replace the genuine ones.

Import of the ingredients for drug production

The import of ingredients for drug manufacturing is another challenge for the country to ensure the domestic production from inappropriate ingredients. Ingredients imported form countries with weak regulatory systems are more likely to be of poor quality. Thus, using poor quality ingredients might result in having substandard drugs.[17]

Developing Internet Market

The internet gives opportunity to the drug counterfeiters to distribute their drugs for the people who order drugs via internet. The field cannot be controlled easily, and everyday opening pharmacies, that look like licensed ones sell the prescription drugs without any license.[13,17] The difficulty regulating such pharmacies makes the market open for substandard and counterfeit drugs. In many cases, the owners of the websites do not know what products they sell. They buy them from certain companies without any quality assurance and sell them.[17]

According to the law on services and trade of the RA, the drugs should be sold in separate facilities. The law prohibits the online sale of drugs which means that in the RA the risk of the sale of counterfeit drugs decreases.[32] The internet pharmacies are not popular in the RA and the State Health Inspectorate never detected cases of the internet pharmacies that sells their product in Armenia.[8]

Current and Proposed Prevention/Intervention Strategies

The above-listed key determinants provide insights into appropriate solutions. Possible solutions are discussed according to each factor.

Labeling of Drugs

The Republic of Armenia has recently adopted a new law, which refers to labeling drug packages. According to the law, drugs are classified as products that must be labeled the same way as any other product in the list and cannot be sold without labels. The law has come into force starting April 1, 2015 and aims at controlling the circulation of drugs to prevent unregistered and counterfeit drugs from the market.[33] The labels of both drugs and other

products in the list are visually the same.[14] Presenting the amount of imported drugs the companies get labels from the Ministry of Finance.[14]

We propose to strengthen the labeling of pharmaceutical products using different labels so that customers can distinguish between labels of drugs and other products.

Drugs from the EEU

Imports from the Eurasian Economic Union countries have created new problems in this context since it is impossible to control the amount of imported drugs from these countries. The new bill about the quantity imported to Armenia from the Eurasian Economic Union countries is in process. According to the draft bill, the importers should inform the customs service about the imported amount by the 10th day of the next month of import.[34] The purpose of the law is to have statistical data about products imported from the union countries.[34] The importer only needs some documental evidence to demonstrate that the purchased products are from the union countries. If this bill gets adopted, it will be easier to import counterfeit drugs.

In the given situation, we propose to revise the draft bill to make sure the drugs coming from the EEU countries will undergo all the procedures as drugs that are imported from other countries. Drugs should be separated from the other products that enter Armenia from the EEU countries, as they can influence human health.

New Law on Drugs

Modifying the law on Drugs could facilitate the regulation of the pharmaceutical market. The ongoing updating of the Law on Drugs has the potential to make the fight against counterfeiting more effective.[8] The fight against counterfeit drugs with the help of the new law on drugs is designed to make the punishments on circulation of counterfeit and unregistered

drugs stricter, more careful and consistent monitoring of the drugs will be held. The draft bill pays attention to enforcement mechanisms and provides more contemporary regulatory and legislative system in the country. Now the bill is already in the National Assembly and should undergo some changes before being adopted as a law.[35]

We propose to exclude the first chapter, 3rd article, 48 point about the parallel import from the bill in order to strengthen the fight against counterfeiting. The parallel import law implies that in case of its enactment importers can purchase registered drugs not only from the official representatives of drug companies situated in that country, but also from the ones all over the world.[35] Figure 1 is introduced below to provide a more visual representation of the current situation. After the bill comes into force, the supply chain will get more "hands" within which will only raise the risk of advent of counterfeit drugs into the market.[1,3,35] Figure 2 illustrates the portrait of the supply chain in case parallel import is enacted.

We propose the new draft Law on Drugs to include a point about prescriptions of unregistered drugs. The law should imply that the doctors who prescribe such drugs must take civil responsibility.

The new draft Law on Drugs should also include a solution for the problem of selling drugs without packages in the RA referring to methods that are being successfully implemented in other countries.[31] Drugs that are imported into Armenia and distributed to the pharmacies are already packaged in small quantities, in average up to 10-20 tablets in each package.[8,11] In this case, the new Law on Drugs should ban the sale of drugs without packages; if the pharmaceutical product comes in big quantities and the pharmacy decides to sell smaller amounts, they should put the drugs in a special package that would show the name of the product, the dose, expiration date, and the name of the pharmacy. In case of breaking this law the pharmacies will take

responsibility. This law will make the realization of the counterfeit drugs by the pharmacies through the open packages almost impossible. The Control on Drugs and Drug Manufacturing department of the State Health Inspectorate will be the body to control the implementation of the law and will realize continuous monitoring of the pharmacies throughout the country.

Stronger regulation of pharmaceutical market could be facilitated through implementation of the revised new Law on Drugs that will provide additional strategies for control mechanisms. At the same time, the increase of fines and imprisonment for the violation of drug legislation and regulation may result in reduced motivation to counterfeit drugs in the market.[3]

Cooperation with Local Manufacturers

Another way to fight against counterfeiters is to encourage cooperation with local manufacturers. When the major part of the pharmaceutical market is imported, the government cannot ensure the quality and the safety of transportation through the long supply chains.[17] To avoid such risks, the imports should be decreased and the domestic production of drugs should be expanded. To compare with the U.S., the domestic production there is approximately 60%, while in the RA it is 5% of the pharmaceutical market.[8,17] The government of the RA should cooperate with the local manufacturers in terms of domestic production increase in the pharmaceutical market of the RA. Since there is no change in the percentage of the domestic production, a governmental intervention should be implemented. In terms of intervention, the government could subsidize local manufacturers to let them launch production of highly demanded drugs that are currently imported into the country.

Regulation of Drug Prices in the RA Market

The pharmaceutical market in the RA is competitive. Government does not control the prices of drugs suggested by importers, manufacturers or retailers.[14] High demand and unregulated prices of drugs prove to be excellent motivation for counterfeiters to continue their activities.[2] A possible way to address this problem is to prompt the government to undertake steps which will control the maximum prices of drugs.[10] Moreover, the exemption of drugs from the value added tax (VAT) would decrease the prices of drugs in the market. The VAT law would need to be amended to exclude drugs from the list of products subject for the VAT.

Improve Public Awareness about Counterfeit Drugs

Social campaigns could be organized from time to time to inform people about the dangerous effects that counterfeit drugs may have and to provide appropriate information that would help to differentiate between genuine and counterfeit drugs.[13,29, 35] TV, radio and social network announcements should be chosen to inform the public about the problem. People also will become familiar with regulations, which protect them from counterfeit drugs in the market. While prescribing any drug for the patients, the doctors should provide information about the drug prescribed as well as the dangerous effects of the counterfeit drug. This way the doctors could help the patients improve their knowledge about the counterfeit and genuine drugs.

Control of Supply Chain

The RA purchases drugs from local official representatives rather than from main manufacturers, because the minimum quantity that a manufacturer is willing to sell is too big compared with the demand in a small country like Armenia.[14] Therefore, controlling the supply chain from the manufacturers to the borders of the RA is difficult, and it is very important for the

RA to check drugs entering its territory before allowing them to enter the pharmaceutical market. However, a solution for this issue would be concentrating more on the checking procedures of the drugs while they are entering the borders of the country. The checking body will be the custom storage since all the drugs that enter the country should pass through the customs.

The custom storages do not have appropriate conditions for drug keeping. The maximum required time for the Ministry of Health for a positive conclusion of the drug imports is seven days.[11,14] Drug is a specific product and needs to be kept in appropriate conditions and when keeping the drug in inappropriate conditions for seven days, the risk that it can lose its effectiveness and even become dangerous is high.[11] The solution of this problem will be building of new custom storage with appropriate conditions for drug keeping.

Since not all drugs of the market are imported, the regulations should be implemented in the direction of controlling the domestic production entering the market. Domestic drug production forms little part of the pharmaceutical market, thus the custom storage will also check the drugs that are produced in the RA according to the same criteria as the imported drugs.

The last circle of the supply chain is the pharmacies which supply the drugs directly to the consumers. Many gaps in the supply chains lead the unregistered or counterfeit drugs to the consumer.[17] The State Health Inspectorate found 62 unregistered drugs in the pharmacies during one-year period;[8] this suggests that suppliers find ways to bring unregistered drugs to pharmacies illegally. Similarly, the probability is high that the counterfeit ones can also appear there. Therefore, we propose to strengthen the control of the supply chain in the country using the new laws and regulations for reduction of risks of counterfeit drugs entrance to the market. The State Health Inspectorate of Ministry of Health will be the authorized body to regulate the internal supply chains to detect the cases which is banned by the law.

Policy and Priority settings

All the suggested strategies were evaluated against the following criteria: intervention effectiveness, intervention feasibility, intervention cost, intervention sustainability and political acceptability. Table 2 illustrates the advantages and disadvantages of each strategy. Strategy effectiveness is classified from the lowest to the highest.

Regulation of Drug Prices

The pharmaceutical market in the RA is believed to be rather competitive, since the government does not regulate the drug prices.[11] However, the process of implementing such regulations and reformulating the whole structure of the pharmaceutical market might not be the best strategy to apply as it might take too long.[14] On the other hand, establishing maximum prices on drugs might create disincentives for importers and drug manufacturers. As a result, domestic production, which already has a comparatively low market share, might dramatically decrease. The decrease in local supply could lead to situations when the demand surpasses supply making customers to buy products without even considering its genuineness.

Eliminating VAT for drugs could help to reduce prices by 20%. However, given the current state budget situation this will not be politically feasible.

Labeling of Drugs

Additional human and financial resources are need to develop new method of labeling for pharmaceutical products. The process of designing of the new labels to make them different from other products could take about three months. However, the new labels will decrease the possibility of false labeling of drugs by pharmacies or counterfeiters, as it would be very easy for consumers to see if the labeling was not appropriate.

Cooperation with EEU Countries

Considering the fact that drugs are special products, they should be separated from the other products and should also be checked by the Ministry of Health. This checking will assure that the drugs coming from EEU countries enter the pharmaceutical market after being checked by appropriate authorities. This could minimize the potential for importing counterfeit drugs to Armenia from the EEU countries. However, this process would need more human and financial resources to implement the checking process for the drugs coming from the EEU countries in addition to other countries.

Cooperation with Local Manufacturers

Cooperating with local manufacturers the government could possibly increase the percentage of domestic pharmaceutical products in the market and ease the regulatory activities since it is much easier to control domestic production than import through the long supply chains.[17] Legal drug manufacturers are eager to eliminate counterfeit drugs from the country and support the authorized members of the government in this fight. However, establishing such cooperation with local manufacturers is expected to be highly to be a longer term goal.

Improved Public Awareness about Counterfeit Drugs

Improving public awareness about counterfeit drugs could decrease the risks of purchasing and using counterfeit drugs.[13] Social advertisement and campaigns will require financial and media resources; to evaluate the effectiveness of the campaign additional research will be needed. In case the public is aware of counterfeit drugs, it will be easier to detect them, however it will not ensure that the amount of counterfeit drugs will significantly decrease in the market.

Stronger Drug Legislation and Regulation

Making drug legislation and regulations much stronger in Armenia is a very important strategy. However, the changes and adoption of the new Law on Drugs will not be implemented immediately, since the process is highly time-intensive. The process of enforcement of the new laws takes time. About 2-6 months are necessary for developing a new bill for a draft law for circulation among the legislators. After the new bill is ready, it goes to the National Assembly for further discussions and changes which takes approximately one month. After the approval of the new law, it usually comes into force in a few months to give time to the stakeholders take the necessary steps to be in compliance with the law.[14]

Custom Storage Building as a Filter for Supply Chains

To implement the above listed strategies, building a special storage place is necessary and will require long time and hard work. The custom storage will be a filter for the drugs entering the pharmaceutical market and will exclude counterfeit drugs from them. After the building of the storage, the entrance to the market will be regulated at multiple levels, which will result in safety of pharmaceutical market. With the building of the custom storage, the need to regulate long supply chains becomes unnecessary and the purchase directly from the manufacturers will not be a required point for the imports. The custom storage will be a filter for the domestic production and will prevent counterfeit drugs from entering the pharmaceutical market of the country. Beside these points, the custom storage with the appropriate conditions of drug keeping will be the best place for the drugs to be stored while the checking procedures are in process. Significant financial resources are necessary to accomplish the project, the implementation of which will ensure that each drug entering the market is genuine. A large number of specialists is also needed and they should be trained for working in the storage. The absence of this practice is

a major difficulty for implementing this idea, since there might be numerous unexpected circumstances not addressed before.

New regulations of the pharmaceutical market will exclude all the suspicious cases that were not detected by the custom storage and will be the additional checking circle for the drugs that can appear in the pharmacies. The State Health Inspectorate should also control the drugs not to be sold without packages. The personnel of the State Health Inspectorate has very little to control all the markets and it is impossible to exclude all the cases that can occur in pharmacies. However, the increase in number of the personnel and continuously actions will reduce the cases of doubtful drugs appearance in the drugstores and also reduction will be in case of selling without packages. Filtered internal supply chains and regulated pharmacies will be the last circle of the safe pharmaceutical market.

Specific Recommendations

Taking into consideration all the above mentioned problems and the fact that 95% of the drugs in circulation are imported, the priority strategy targets controlling the drugs as they are imported into the country through control of supply chain. To strengthen control of the supply chain of drugs in Armenia, the following specific steps should be taken:

- Build separate customs storage to process imported drugs
- Regulate drugs imported from Eurasian Economic Union countries the same was as drug imports from other countries
- Mandate testing of a randomly selected sample from every imported drug shipment
- The same mandatory testing should be implemented for the locally produced drugs before they enter the market

- Implement differential labeling of drugs
- Ban the sale of drugs without packaging.

The implementation of the strategy Control of supply chain will ensure the advent of appropriate quality of drugs into the country. Table 3 presents the Gantt chart of the 30-month implementation plan.

Research: Research should be conducted to correctly estimate the capacity of the newly built storage. It is of a great importance to be aware of the approximate amount of drugs coming into Armenia in order to develop an appropriate storage. The research is estimated to be conducted in three-month period.

Financial investments: When the research is finished, the government will be expected to determine the amount of money necessary to build the storage and provide financial investment to start the construction. Three months will be needed to receive appropriate financial investments.

Building of the storage: The next step is to build a new storage. For this, a competition will be announced and the most appropriate building company with the best building conditions will be chosen to accomplish the construction in an appropriate period. As it was discussed above, the conditions of the storage are very important for the appropriate preservation of drugs. Therefore, the best storage in terms of safe conditions among the offered ones will be chosen. The set of the given procedures will last 21 months.

Special labels for drugs: In parallel with the construction of the storage, the Ministry of Finance should create special labels for drugs, so that consumers could differentiate them from labels of other products. The procedure will approximately last six months.

Training of the personnel: During the last three months of the storage construction, the personnel trainings should launch. The DMTESC will be responsible for training the storage personnel. The trainings will last six months.

Appropriate equipment: Along with the training of the personnel, appropriate equipment should be purchased and installed. Appropriate conditions for the drug storage are of a strong necessity. Additionally, there should be appropriate equipment to ensure safe preservation of drugs under special temperature, hygienic condition and other factors. Continuous technology development will facilitate such processes as keeping equipment under better condition, labeling and other processes for further control of imported drugs.

Implementation and evaluation

The main obstacle on the way to implementing the strategy will probably be lack of financial resources. The personnel will be trained in parallel with the construction of the storage facilities, which will be expected to correspond to all standards for drug storages. The strategy cannot be implemented unless it is under the governmental control and appropriate financial resources are allocated.

The storage place should have its own laboratories for the examination of the drugs and special conditions for drug keeping. The personnel should be well trained. A special working plan should be developed to have effective outcomes in terms of ensuring the proper conditions of drugs entering the market are maintained. The protocols of the storage will be the best way to control and monitor the working process of the institute.

After the start of the custom storage activities, a certain amount of drugs entering the custom storage should be checked to make sure that the entire part of drugs is genuine. All the

drug packages that are ready to enter the market after the checking procedures should be labeled by the custom storage to ensure the genuineness of the product. The labeled packages that enter the market should be sold in the pharmacies without opening them and in full packaging. This should be regulated by the State Health Inspectorate.

The regular work of the custom storage will regulate the drug entrance to the market avoiding the counterfeit and suspicious cases eliminating them from the future circulation. Custom storage cooperation with the State Health Inspectorate will result in safe pharmaceutical market in the country.

A Monitoring and evaluation of the implemented strategy should be conducted to see the effectiveness of the chosen strategy. The first step will be creating continuos monitoring and evaluation plan for output related indicators which include the number of people trained to work in the new facility, development of the work plan and protocols for the storage activites, and the proportion of drug shipments tested. The continuous monitoring/surveillance system should collect regular information on the proportion of drugs appropriately labeled and the proportion of drugs sold in appropriate packages. In addition to monitoring related activities, we will look at outcome measures, which will include collecting baseline data on the percentage of counterfeit drugs out of 5000 randomly collected drugs from the market. This testing will be repeated one year after opening the Custom storage and then repeated approximately every three years. These steps of the evaluation will give a full picture of strengths and weaknesses of the storage activities. Contionous monitoring will result in improvements in the storage activities which will ease the way to reach our goals.

Conclusion

No country is protected from the risk of facing counterfeit drugs in the market. The problem exists in the Republic of Armenia and the suggested strategies are believed to reduce the risk of encountering such drugs in the market. The field requires continuous efforts and control tools against the counterfeiters because the latter develop their schemes and technologies.

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Table 1: Counterfeit drugs found in Armenia during 2001-2012[11]

	Report date	Trade name and dosage form on label	INN/Approved Name/ Composition On Label	Active ingredient status	Batch number	Evidence
1	2001	Erythromycin tablets 25mg N10	Erythromycin	Absent	4042001	Bad quality packaging and labeling. Analysis showed absence of the active ingredient.
2	2001	Kefzol 1g powder for injection	Cefazolin	Correct And Correct Amount	AR 283Y1	Absence of the protective sign of the original manufacturer's name. The original medicine's manufacturer confirmed the fact of the falsification.
3	2001	Kefzol 1g powder for injection	Cefazolin	Incorrect Amount 0.1 G	035lpa	Different immediate packaging label. Analysis showed that active ingredient was below standard-0,1g.
4	2001	Cefazolin 1g powder for injection	Cefazolin	Different	3403200	Analysis showed that instead of the active ingredient- Cefazolin product contained benzyl-penicillin.
5	2002	No-Spa tablets 40mg N100	Drotaverine Hydrochloride	Absent	2191201	Unusual color and printing of the outer and immediate packaging label, bad quality package leaflet. Analysis showed absence of the active ingredient.
6	2003	Cavinton tablets 5mg N50	Vinpocetine	Absent	T12003A	Different outer packaging, unusual packingthe pack contained two different colored blister. Analysis showed absence of the active ingredient.
7	2003	Orungal capsules 100mg N15	Itraconazole	Correct And Correct Amount	00HR232	Different color of the immediate packaging label. The original medicine's manufacturer confirmed the fact of the falsification.
8	2004	Claritine tablets 10mg N10	Loratadine	Incorrect Amount- 5 Mg	01E12575	Different printing of the packaging label, absence of the firm logo. Analysis showed that active ingredient was below standard- 5mg.

9	2004	Aspirin Cardio tablets 100mg N20	Acetylsalicylic Acid	Correct And Correct Amount	027	Different printing of the outer packaging label. The original medicine's manufacturer confirmed the fact of the falsification.
10	2004	Suprastin tablets 25mg N20	Chloro-Pyramine	Absent	18844	Different immediate and outer packaging label. Analysis showed absence of the active ingredient
11	2005	Nizoral tablet 200mg N10	Ketoconazole	Correct And Correct Amount		Absence of the outer packaging. Different color of the immediate packaging label. The original medicine's manufacturer confirmed the fact of the falsification.
12	2006	Zinacef 750mg powder for injection	Cefuroxime	Different	4116	Absence of the outer packaging. Different immediate packaging. Analysis showed that instead of the active ingredient cefuroxime product contained ampicillin.
13	2006	Zinacef 750mg powder for injection	Cefuroxime	Different	4130	Absence of the outer packaging. Different immediate packaging. Analysis showed that instead of the active ingredient cefuroxime product contained ampicillin.
14	2007	Xenical 120mg capsules	Orlistat	Absent	B 2395	Absence of the outer packaging, different color of the immediate packaging label. Analysis showed that product contained simple powder instead of the granulated one and absence of the active ingredient.
15	2008	Xenical 120mg capsules	Orlistat	Absent	B 2306	Absence of the outer packaging, different color of the immediate packaging label. Analysis showed that product contained simple powder instead of the granulated one and absence of the active ingredient.
16	2009	Augmentin 1g+200mg powder for injection	Amoxycilline, Clavulanic Acid	Different	002720	Absence of the outer packaging. Different immediate packaging. Analysis showed that instead of the active ingredients product contained ampicillin 1.396mg

Table 2: Intervention strategies

Eligibility criteria	Labeling of drugs	Cooperation with EEU countries	Cooperation with local manufacturers	Developed drug legislation and regulation	Regulation of drug prices	Increase of public awareness	Custom storage building
Intervention effectiveness	++	++	++	+++	+	++	++++
Intervention feasibility	++++	+++	++	+++	++	++++	+++
Intervention cost	++	+++	++++	+	+	+++	++++
Intervention sustainability	+++	+++	+++	++++	+++	++	+++
Political acceptability	++++	++++	+++	++++	++	+++	++++
Priority setting	+++	+++	++	+++	+	++	++++
Advantages	-Eliminate false labeled drugs -Safer drugs in the pharmacies	-Checked drugs from the EEU countries -Less imported counterfeit drugs in the country	-Decrease in imports of drugs -Developing domestic drug manufacturing -Easy regulated market	-Developed regulations in the market -Decrease of willingness of counterfeiters	-Maintain maximum drug prices fixed -Decrease the motivation of counterfeiters	-Less cases of buying counterfeit drugs -More people for detecting counterfeit cases	-Regulated entrance to the market -Safe drugs in the market -Safe market

Disadvantages	-Additional human and financial resources -Additional time	-Additional human and financial resources	-A lot of financial resources needed -A lot of time for organizing the new production	-A lot of time needed for establishing laws -A lot of time needed for the law to go into the force	-The whole structure of the market should be changed -The risks to be succeed is very high	-Is not mandatory -Low engagement	-A lot of funds needed -The new personnel needed -A lot of time needed to manage all
Priority rating	Low		Low	Medium	Very low	Low	High

Coding: **Very low +**

Low ++

Medium +++

High ++++

Table 3: Gantt chart for implementation strategy

Implementation activities	3 months	1	2	3	4	5	6	7	8	9	10
Research for making evidence based decisions regarding the customs storage											
Financial investment											
Developing special labels											
Building the storage											
Training of personnel											
Required appropriate equipment											

Figure 1: Current supply channels in the RA

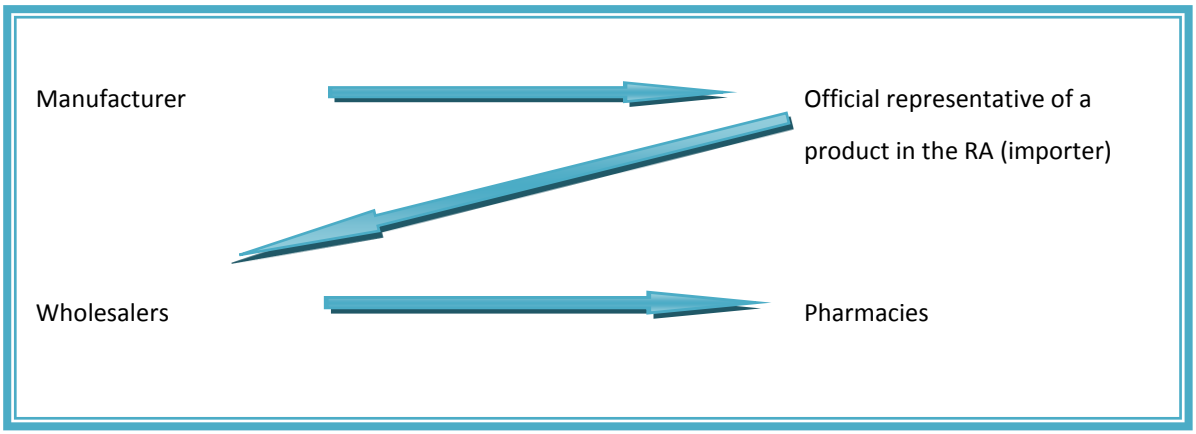

Figure 2: The supply channels if the bill on parallel import adopted