Health threat from counterfeit drugs and strategies for its prevention in Armenia.

Master of Public Health Thesis Project Utilizing Problem Solving Framework

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Executive Summary.

The World Health Organization (WHO) has identified counterfeiting drugs as a problem in 1985 at the Nairobi Conference of Experts on the Rational Use of Drugs. The number of reports of fake drugs over the last 10 years has been increasing. Moreover, circulation of counterfeit drugs is 2.5 times higher in developing countries than in developed ones.

Drug counterfeiting is a criminal activity, because it poses significant public health risk; it continues to create a threat to health by causing injury and even death in many countries. The problem of counterfeit drugs is a worldwide problem, and it has also touched Armenia. From 1996 to 2002, about 60 counterfeit drugs of different country manufacturers were identified in Armenia.

There are several factors contributing to drug counterfeiting in Armenia, such as growing pharmaceutical industry, poor pharmaceutical regulation, high drug prices, value added tax, prescription of drugs without registration, and lack of public awareness.

The objective of this paper is to suggest preventive measures against drug counterfeiting in Armenia to minimize the health threat of fake drugs to the population. Among possible strategies the priority is given to the one that is more feasible, has long-term effectiveness and fewer limitations; consumer education is recognized as the most appropriate policy to minimize the threat of drug counterfeiting and assure that patients receive safe and effective medications.

The evaluation of the proposed intervention will be based on assessment of people's knowledge concerning drug counterfeiting and the number of reports to the Drug Regulatory Authority (DRA) about counterfeit drugs.

Statement.

### *The problem and its magnitude*

The counterfeiting of commercial products has existed since ancient times [1]. An old written document from IV B.C. indicates the dangers of counterfeit drugs; and in I A. C., ancient documents gave evidence that Greek physician Dioskorides discovered fake drugs and gave recommendations on how to identify them [1, 2, 3].

Counterfeiting drugs has been identified as a problem by the World Health Organization (WHO) in 1985 at the Nairobi Conference of Experts on the Rational Use of Drugs [1, 4]. There are several definitions of counterfeit drugs [4]. According to the Black law dictionary counterfeiting is "to copy or imitate, without authority or right, and with a view to deceive or defraud, by passing the copy or thing forged for that which is original or genuine" [4]. The United States Federal Food, Drug and Cosmetics Act's definition of a counterfeit drug is: "a drug which, or the container or labeling of which, without authorization, bears the trademark, the trade name, or other identifying mark, imprint, of device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor, other than, the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor" [5].

The WHO definition is most commonly used; according to it "counterfeit medicine is 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 correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging" [1, 2, 4, 5].

The WHO reports the following statistics about counterfeit drugs in 2000/2001: 43% products without active ingredients, 21% low content of active ingredient, 24% poor quality drugs (substandard), 2% wrong ingredients, and 7% wrong source (see figure 1, 2) [5].

Figure 1: Types of counterfeit drugs reported between January 2000 and

      December 2001 (WHO, 2001)
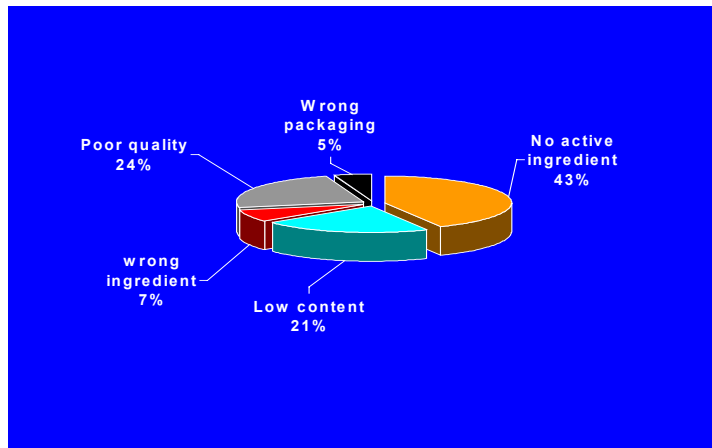
Figure 2: Therapeutic Classes of drugs reported as counterfeit

      between January 2000 and December 2001 (WHO, 2001)
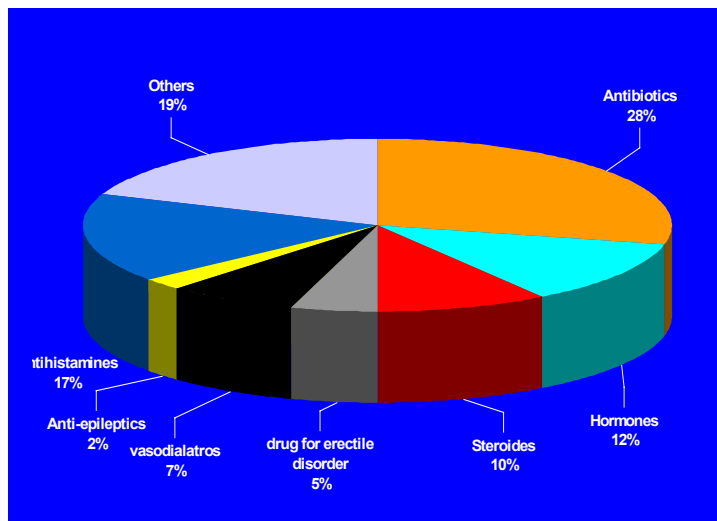
Substandard drugs, or poor quality drugs, which do not meet quality specifications, should be differentiated from counterfeit drugs (appendix 1) [2, 5]. Substandard drugs could be considered counterfeit if they are produced intentionally or deliberately [5]. Such drugs containing improper quantities of ingredients can cause allergies or resistance to the medicine (antibiotics) and can be dangerous for patients because of possible interaction with other drugs [6, 7]. Drugs with wrong ingredients are even more dangerous because they are often contaminated by toxic substances, which can cause death [6].

The more frequent counterfeited drug forms are tablets and capsules [8]. Both generic (well-known) and original drugs are subjects for counterfeiting, but more often, expensive and high consumption drugs are forged [5].

This happens more often in countries with poor drug regulation [5]. Different countries have different types of drug counterfeiting, for example, in African and Asian low-income countries, antibiotics, anti-TB drugs, antiprotozoals (anti-malaria), and pain suppressants are more often counterfeited; and in high income countries like the United States of America (US) and the western European countries, the majority of reported counterfeit drugs are immunosupressors, cardiac drugs, so called lifestyle drugs, such as Viagra, and hormones and steroids (such as, Human Growth Hormone used for body-building) [5, 6, 9, 10]. Information about 771 cases of counterfeit drugs was received worldwide by the WHO from 1982 to 1998, from which 52% were antibiotics, 7% corticosteroids, 8% drugs for the alimentary tract, and 33% others [1, 2, 4, 11]. According to the WHO report, from 1999 to 2000, 46 cases of counterfeiting were detected in 20 various countries, of which 60% were from developing countries [9].

Circulation of counterfeit drugs is 2.5 times higher in developing countries than in developed ones [12]. The number of reports of fake drugs over the last 10 years has been increasing [12].

Unregulated development of the pharmaceutical industry in the recent past has led to different problems, including drug counterfeiting [1]. The real scope of the problem is not known because drug counterfeiting is a criminal activity and is hard to reveal and control [5]. Less than 5% of the 191 WHO Member States are providing information on counterfeit drugs [5]. Therefore, the WHO statistics on counterfeit drugs do not completely reflect the real situation [5]. According to the WHO, 10% of the world commodity circulation consists of counterfeit drugs, and the commodity circulation of the world pharmaceutical market amounts 350 billion US dollars [2, 8, 13, 14, 15]. These statistics show how profitable drug counterfeiting could be.

A survey in Southeast Asia found that the range of the counterfeit malaria drug artesunate varied from 11% in Thailand to 64% in Vietnam; almost 38% of the samples contained no active ingredients [6, 16]. Thirty malaria deaths in Cambodia in May 2000 could be linked to inadequate treatment due to counterfeit drugs [6, 16]. The deaths of more than 500 people in 1937 in Haiti, mostly children, were caused by taking fake paracetamol containing diethylene glycol, used as anti-freeze toxic chemical [1, 3, 8]. About 2,500 people died in Niger from using counterfeit meningitis vaccine [6, 8]. Counterfeit inhalers against asthma were detected in the Philippines in 1995 [6]. Recently, the WHO found anti-malarial drugs, which had no active substance, contraceptives that consisted of wheat flour, and Neomycin eye drops containing only water [6, 8]. In the US, 17 people died in 1999 as a result of using the counterfeit antibiotic gentamycin sulfate, produced by an unknown manufacturer [17]. In 2002, seven people were arrested and 5 pharmaceutical companies were closed in the US because of their involvement in manufacturing the counterfeit Viagra and doing illegal business via the Internet [6]. The state regulatory authority of Florida has observed that the incidence of counterfeit and diverted drugs increased from no cases in the 1990's to more than 50 in 1999 [13].

Drug counterfeiting in Russia has increased 10 times since 1998 and accounts for about

7% of the whole market; this results in 100 million US dollars loss by pharmaceutical

companies annually [6]. In 2000, approximately 150 cases of counterfeit drugs were detected

and recorded in Russia [18]. About 80% of counterfeit drugs confiscated by the Bureau of

Food and Drugs (BFD) of the Philippines were not registered, among them 20% were

substandard and 80% were imported drugs [7].

Drug counterfeiting is an authentic problem for the world and for Armenia as well.

From 1996 to 2002, about 60 counterfeit and not registered drugs of different country

manufacturers were identified in Armenia (appendix 2) [19]. As figure 3 shows, the main

sources of drug counterfeiting were Russia, India, Armenia, and unknown country

manufacturers.

Figure 3 Counterfeit and not registered drugs by country of origin detected in Armenia

from 1996 to 2002.
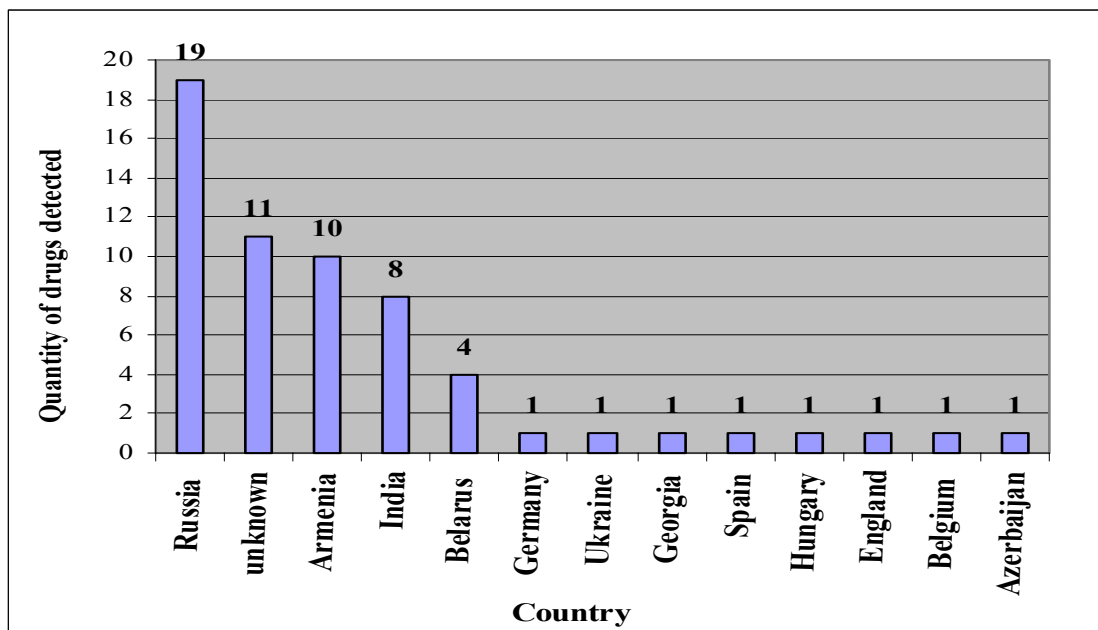
There were different types of drug counterfeiting identified in Armenia in 1996-2002

(Figure 4). Out of 60 detected cases, 25 were not registered in the Republic of Armenia, and

35 were counterfeited: 9 did not have active ingredients, 4 contained low active ingredients, 2 contained wrong ingredients, 10 were wrongly packed, and 10 were of poor quality (Figure 4) [19].

**Figure 4 Types of drug counterfeiting identified in Armenia from 1996 to 2002**
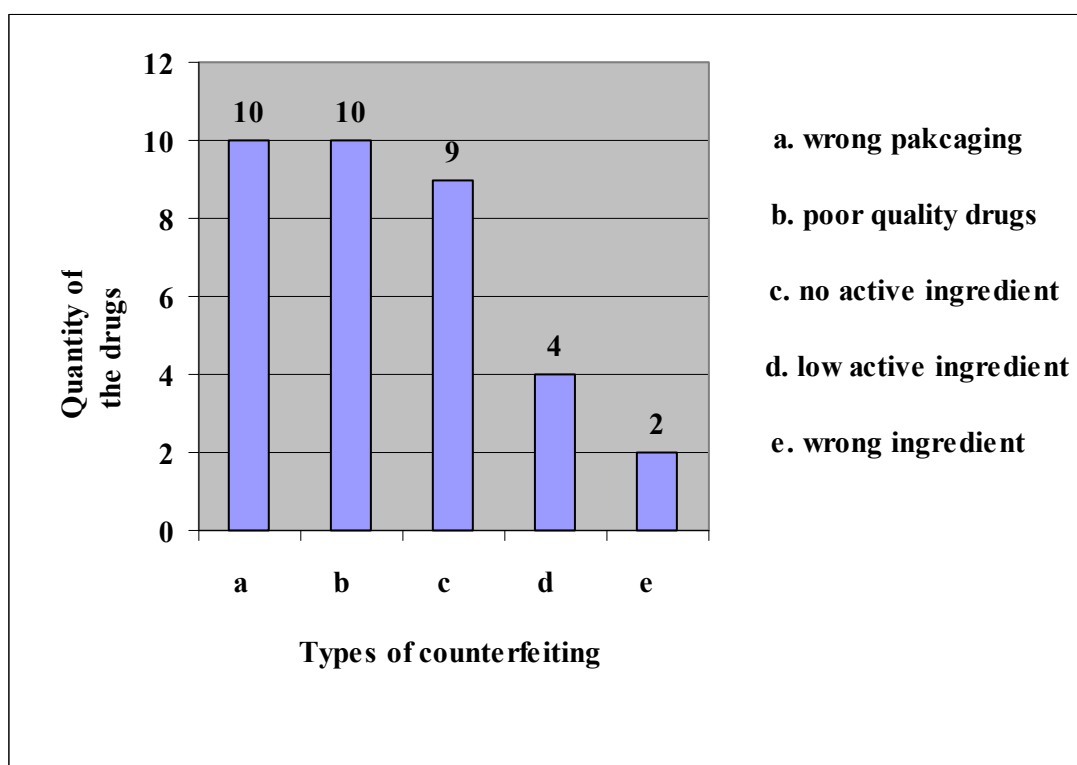
Among detected counterfeits there are different therapeutic classes of drugs including antibiotics, antiseptics, antipyretics, analgesics, and sedative drugs (appendix 2) [19]. Samples of detection of counterfeit drugs by Drug and Medical Technology agency of Armenia (ADMTA) are the following: 400 packs of the fake drug poliglucin and reopoliglucin were detected and banned, which prevented a lot of people from suffering; in 1996 during examination of gentamycin importation into Armenia, it was found that the ampoules contained sterile water instead of the active ingredient; and in 2001, the drug cefazolin natrium was identified, which contained benzyl penicillin instead of cefazolin [19, 23] (for more information see appendix 2).

Impact of the problem

Drug counterfeiting has not only human impact, but also economic impact [8, 13, 15]. It results in tremendous profit for counterfeiters and tens of billions of dollars of commercial loss every year [8, 13, 15]. The counterfeit drug trade is a type of grey economy along with prostitution, narcotics, terrorism and arms trade [6]. "The counterfeiting industry is like the Mafia: the rewards are big. Either the patient dies or doesn't know he/she has taken a counterfeit drug" said Maureen Kirkman, head of scientific and regulatory affairs at the Pharmaceutical Manufacturers' Association [20]. The International Federation of Pharmaceutical Manufacturers Associations (IFMA) estimates are high; annual worldwide drug sales account for about 327 billion US dollars, of which 2% (6 billion US dollars) is accounted by counterfeit drugs [21]. But some well-known pharmaceutical companies' estimate of counterfeiters' annual profit is much higher and reaches about 19 billion US dollars [21]. And the WHO estimates are even higher; commodity circulation of the world pharmaceutical market accounts for 350 billion US dollars, of which 10% (35 billion US dollars) consists of counterfeit drugs [2, 8, 13, 14, 15].

According to data from the department of export and import of the ADMTA, the annual drug sales have an increased in Armenia since 1997 (Figure 5) [22].

Figure 5. Drug import in Armenia from 1997 to 2002
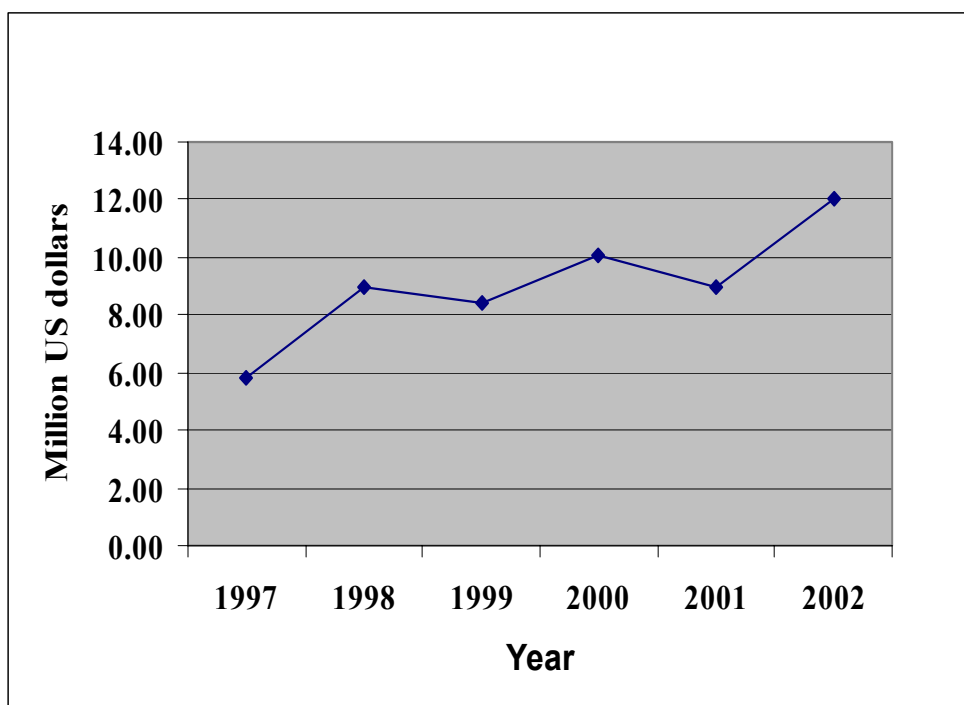
They were about 5.8mln US dollars in 1997, and 12mln US dollars in 2002 [22]. On the one hand, saturation of the pharmaceutical market provides enhancement of public health, but on the other hand it stimulates such a negative phenomenon as drug counterfeiting [23]. Unfortunately, there are no annual data about the quantity of counterfeit drugs in Armenia to calculate the counterfeiters' profit.

Counterfeiting is in fact a big business, which may result not only in a huge loss of revenue to the pharmaceutical industry, but also in financial loss to people with low and middle socio-economic status, who often have to spend all their money for one of the family members' treatment [21, 24].

Drug counterfeiting is a criminal activity, because it poses significant public health risk; it continues to create a threat to health by causing injury and even death in many countries [13, 25, 26,]. "The evil of fake drugs is worse than malaria, HIV/AIDS and armed robbery put together, whereas AIDS can be avoided, malaria can be prevented, and armed robbers can kill a few at a time, fake drugs kill thousands" says the Director of the National Agency for Food and Drug Administration (NAFDAC) of Nigeria [6].

According to the FDA (Food and Drug Administration), counterfeit drugs exported from different countries to the US can not be controlled completely which means that these drugs can reach even the President. [6, 17].

Even when the drug contains the proper amount of active ingredient it may still be harmful, because along with the proper composition, the drug should be produced under Good the Manufacturing Practice (GMP) requirements, ensuring its quality and safety [15].

Key determinants

There are several factors contributing to drug counterfeiting. Some contributing factors are common and some of them are different for different countries, depending on the socioeconomic status of that country. The main contributing factors to drug counterfeiting in Armenia are the following:

a) Growing pharmaceutical industry

In the last years the number of pharmaceutical factories has increased in Armenia. Some manufacturers do not register the whole spectrum of their pharmaceutical products in Armenia, but this drugs could be found in Armenian drug stores. Moreover, not all pharmaceutical factories produce drugs under the Good Manufacturing Practice (GMP) requirements. And finally, new high technology equipment is entering Armenia as a result of the growth in the pharmaceutical sector, and the establishment of joint (Armenian-foreign) pharmaceutical companies could be used for perfect imitation of genuine drugs.

b) Poor pharmaceutical regulation

There is disagreement between the Drug Law of the Republic of Armenia (RA) and the Criminal Code of the RA. The Drug Low does not contain a definition of counterfeit drugs and consequently punitive sanctions against people who sell, distribute and produce counterfeit drugs are not cited [27]. But the Criminal Code of the Republic of Armenia, which went into force on April 2003, describes punitive sanctions against counterfeit drug manufacturers and sellers [28]. In Armenia, penalty fees for drug counterfeiting are a maximum of about 500 US dollars and imprisonment of a maximum 3 years [28]. But punitive sanctions against distribution and sale of drugs without registration are absent. Drugs that are not registered may be more easy counterfeited, because they do not pass quality control during the registration process that assures a quality, safety and efficacy of the drug [29].

c) Demand versus supply

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In situations when demand for some drugs is high and there is a short of supply for different reasons (e.g., delayed shipment, absence of registration in the RA, or drugs under "reregistration" process), counterfeit drugs could easy enter the pharmaceutical market.

d) High drug prices

Currently, drug prices are not regulated in the Republic of Armenia; they are set according to free market laws. That is why drug prices are high, and there is significant variation in drug prices. This stimulates the introduction of cheap counterfeit drugs into the market.

e) Value added tax (VAT)

Since January 1, 2001, drug sales have been taxable in Armenia [30]. This value added tax contributes to higher prices. As a result, illegal drug imports have increased about three times, especially from neighboring countries, and counterfeit drug circulation has become more intensive [31]. According to experts, illegal drug imports account for about 40-50% of the overall drug market in Armenia [31].

f) Prescription of drugs without registration

In Armenia, it is a common practice among physicians to prescribe unregistered drugs. This practice artificially creates demand for specific drugs. This encourages the illegal import of counterfeit drugs into the country.

g) Ineffective cooperation between the National Drug Regulation authorities, police, customs and the court system, complicates the process of detecting counterfeit drugs (1, 2, 3, 4).

h) Lack of public awareness

The general population does not have enough information concerning the problem of counterfeit drugs. Often, because of financial difficulties, they try to find cheap drugs and buy them from illegal sources, such as street markets.

Objectives

The objective of this paper is to develop/implement preventive measures against drug counterfeiting in Armenia in order to minimize the health threat of fake drugs to the Armenian population, and to provide safe and effective medications.

The implementation of new strategies and strengthening of existing measures can be a tool against drug counterfeiting. A problem-solving framework is used for developing a program proposal.

The plan of action is prepared by taking into consideration the current situation in the country, the magnitude of the problem, infrastructure, manpower, finance and other resources needed [2]. The plan of action is organized step by step and includes all those concerned such as government, pharmaceutical companies, drug distributors, physicians, pharmacists, customs, consumers, and nongovernmental organizations.

The evaluation of the proposed intervention will be based on assessment of people's knowledge concerning drug counterfeiting and number of reports to the DRA about counterfeit drugs.

Prevention/intervention strategies.

The problem of counterfeiting is a problem of low-income as well as high-income countries [1]. Many low income countries started to fight the problem by establishing drug regulatory authorities and strengthening legislation. For example, implementation of the counterfeit drug legislation in Nigeria has demonstrated successful results; the quantity of counterfeit drugs has begun to decrease [32]. In order to control drug counterfeiting in Brazil, some changes were made in health regulatory mechanisms to strengthen the licensing of pharmaceutical products' distribution [32]. The Brazil government has also established small taxes for producers and distributors of the most expensive and well selling non-generic

drugs [32]. Russia has introduced "Modifications to the Federal Law on Medicines," which now includes the definition of counterfeit drugs and focuses on sanctions against any activity concerning counterfeiting drugs [32]. Very strong actions against drug counterfeiting have been taken in the Republic of Philippines. "Public act No 8203, which shall be known as the Special Law on Counterfeit Drugs," adopted by the Congress of Philippines, provides penalties, such as different administrative sanctions, penalty fees, and even imprisonment, against counterfeit drug manufacturers, distributors and sellers [34]. Counterfeiting drugs, having been mostly a problem of low income countries, is now occurring in developed countries as well [35]. According to Lewis Kontnik, a consultant of a specialized anti-counterfeiting firm and FDA associate commissioner for regulatory affairs, counterfeit drugs already penetrate into the US and it is necessary to take actions against their dissemination [35, 36]. Some legislative measures for this problem are already taken [35, 36].

Some measures to fight the problem are currently being implemented in Armenia [2, 23]. In the Republic of Armenia, drug regulation and policy are provided by the Drug Regulatory Authority (DRA), the Ministry of Health of the Republic of Armenia (MOH) and the ADMTA. Provisions of drug regulation and policy mainly include State Drug Registration, state licensing of medical activities (including drug manufacturing), drug import/export control, drug quality control through Quality Control Laboratory, control of the internal pharmaceutical market, drug side effects monitoring, and postgraduate education of pharmacists [2].

In 1999, the ADMTA, in collaboration with the WHO, organized seminars for physicians and pharmacists dedicated to drug counterfeiting [23].

The Government of the Republic of Armenia adopted punitive sanctions against counterfeit drug manufacturers and sellers in April 2003 [28]. An appropriate amendment was made in the Criminal Code of the Republic of Armenia:

"Article 280. Illegal private medical or pharmaceutical activities, counterfeit drug

manufacturing and distribution

1.   Private medical or pharmaceutical activity without special permission (license), if it

accidentally harms people's health is:

Punished by penalty fees at a maximum of three hundred times the minimal salary, or

corrective labor for a maximum of two years, or imprisonment, for a maximum of three years.

2.   Manufacturing of counterfeit drugs and distribution:

penalized by imprisonment- fort a maximum of three years.

3.   The same products, which accidentally cause death of people:

penalized by imprisonment for a maximum of five years" [28].

Additional options for intervention/prevention.

   1) Strengthening of national DRA

   The power and responsibilities of the DRA should be defined in the law. It is necessary to

provide inspections of pharmaceutical factories for insuring the GMP. With the growth of

the pharmaceutical market and the increasing number of distributor companies and

pharmacies, it is necessary to provide more frequent inspections of distribution centers and

drug stores. For this purpose, it is necessary to have qualified and trained staff.

   2) Amendments into legislation

   It is necessary to bring into agreement the Drug Law and Criminal Code. For this purpose

the definition of counterfeit drugs and punitive actions should be added to the Drug Law. For

strengthening the legislation, there should be punitive measures for distribution and sale of

drugs without registration in the RA. Punitive measures should also be developed for

physicians prescribing drugs not registered in the RA. In view of the fact that counterfeiting

is a criminal activity, along with penalty fees and imprisonment, extreme measures, such as

disqualification from business activity, canceling licenses of pharmacists or physicians can be

considered.

3) Developing measures for drug price regulation

Such measures could include controlling and monitoring drug prices, especially for the

drugs on the essential list;

4) Amendments in the VAT law

VAT on drugs should be repealed. This will lead to drug prices decrease, and therefore to

decrease of cheap counterfeit drug entrance by illegal ways.

5) Co-operation with the public

It will be helpful to encourage consumers to report any cases of suspicious drugs to the

DRA. A special report form could be used for reporting, which could be based on the

modified WHO report form. It will include information on the reporting person (if the parson

would like to provide it; otherwise it could be anonymous report), the place of detection and

some descriptive data on the detected counterfeit drug (for more details see appendix 3).

6) Providing consumer education and organizing information campaigns.

Materials for public education should include brief information about the problem of

counterfeiting in the world and in Armenia. Updated versions of the complete list of detected

counterfeit drugs in the RA should be available for consumers to help them to be more

attentive while buying these drugs. People should be taught how to avoid the purchase of

counterfeit drugs; a list of recommendations should be developed based on worldwide

practice. Main points of such recommendations are:

a) Buy drugs only in licensed drug stores,

b) Avoid purchase of drugs from unreliable sources, such as street markets, telephone

     and internet traders, and other illegal sources,

c) Before buying the drug inspect the package; do not buy drugs with damaged or dirty packaging, because those drugs may be stored improperly,

d) Do not buy drugs if the name of manufacturer, the expiration day, and batch number are not mentioned on the packaging ,

c) Avoid buying drugs not registered in RA, because they have not passed quality control, (Information on registered drugs could be obtained from the DRA)

d) Do not buy drugs passed their expiration date,

e) Do not buy cheap drugs,

f) If some drug seems suspicious, ask for such documentation as quality certificate, import permission given by the DRA, proforma-invoice of shipment, or registration certificate in the RA,

g) If you have used a particular drug before, always carefully check the similarity of packaging, looking at the design, logo, color, and text. Also, pay attention to the shape of the drug, its color and words embossed on it [2, 37, 38, 39].

All education materials should be prepared with the help of experts from the DRA. For the educational intervention several ways could be used:

a) Publishing information in regular journals and news-papers;

b) Publishing and distributing recommendation booklets in hospitals, policlinics and pharmacies;

c) Informing the public through TV and radio;

d) Constructing free internet web-site containing appropriate information on counterfeit drugs for consumers. It is possible to have on this site a list of State registered drugs, and a picture of their colored packaging.

Policy and Priority Setting

Table I. Intervention Strategies

Eligibility criteria	Strengthening national DRA	Amendments to legislation	Drug-price regulation	Amendments to the VAT law	Co-operation with public	Consumer education
Intervention effectiveness	+++	+++	++	++	++	+++
Intervention feasibility	++	+	++	++	++++	++++
Intervention cost	+++	+++	++	++++	+	+++
Intervention sustainability	++++	++++	++	++	++	+++
Political acceptability	+++	++	+	+	+++	++++
Priority Setting	+++	+++	+	++	++	++++
Advantages	-increasing drug regulation and policy -control over different chains of drug supply and distribution	-increasing drug regulation and policy	- drug price regulation -drug price variation decrease, and consequently decrease in drug counterfeiting	-drug price decrease, and consequently decreasing drug counterfeiting	-revealing illegal drug circulation -detection of places of counterfeit drug sale/distribution	-Increase of population awareness -Involving large number of people -Sharing of information among different layers of society
Disadvantages	-long period of time needed for comprehensive functioning of DRA	-suggestion of law amendments and their adoption is a long lasting process -time needed for the new law to be working	-difficult to implement free market conditions	- low political acceptability	-lack of public willingness because of national culture	-Time consuming -Needs staff and funds
Priority rating	Medium	Medium	Low	Low	Medium/low	High

*Coding:
+ very low
++ low
+++ medium
++++ high

Table I provides information of the listed implementation strategies in accordance with eligibility criteria. Each strategy is scored within criterion, and based on that a priority rating is given to each strategy.

1. Implementation of the drug price regulation strategy will allow drug price variation in Armenia to decrease. Also, this strategy may help control drug prices by establishing some maximum level. This strategy will decrease incentives for counterfeit drug import by illegal means. But legislative measures, needed for drug price regulation, are a long-lasting processes, and besides it will be difficult to implement them under free market conditions. That is why this strategy has a low priority rating.

2. After VAT on drugs came into force in Armenia, drug prices increased, and the illegal import of counterfeit drugs became more frequent, especially the so called "suitcase trade," the shipment of thousands of fake drugs by one person in his/her personal baggage [23]. By making amendments to the VAT law, or repealing it may decrease drug prices and therefore reduce counterfeit drug flow into the country. But this strategy is considered less feasible because of low political acceptability. The VAT on drugs stimulates money inflow into the state budget, and repeal of the VAT will have a negative effect on the state budget.

3. Cooperation with public intervention has medium/low feasibility. This strategy will make it possible to detect places of counterfeit drug sale, and distribution, and will also help reveal chains of illegal drug circulation. But taking into account a national characteristic of people in Armenia, they will be unwilling to report the name of person or distributor companies or drug stores to the DRA or other regulatory body. Thus, this strategy has low feasibility and priority.

4. The implementation of the strategy concerning amendments into legislation will increase drug regulation and policy. Thus, it will help to have control over counterfeit drugs. But the legislation about drug control/regulation should be regularly examined and

amendments should be done when it is necessary [1]. The adoption of new amendments is a long-lasting process and time is needed to make a new law work. A medium priority rating is given to this strategy.

5. Strengthening national DRA is a good strategy for drug regulation and control over the different chains of drug supply and distribution.

In Armenia, drug regulation is currently provided by shared responsibilities of the MOH and the ADMTA, which was established in 1992. The structure of the ADMTA resembles more the DRA because it includes appropriate departments, Drug Quality Laboratory and staff of experts. It should be mentioned that the power and responsibilities of the ADMTA are not correctly stated in the law. That is why it is not clear whether the ADMTA could be considered as a DRA or not. On the other hand, the final permission on drug export/import given by the MOH is based on the expert's conclusion and analysis results of the Drug Quality Control Laboratory of the ADMTA. Such discrepancy is an obstacle in the way of drug regulation and control in the RA.

In order to have a strong national DRA, it is necessary, as recommended by the WHO, first of all to clarify in the legislation the responsibilities of the DRA and then to coordinate responsibilities of drug control within the only agency [1, 8].

But long period of time is needed for comprehensive functioning of the DRA and making amendments into the law. Therefore, a medium priority is given to this strategy.

6. Priority should be given to the strategy, which is more feasible, has long-term effectiveness and fewer limitations. Based on the selection criteria, consumer's educational intervention is the most appropriate policy. This intervention will be less time consuming and more feasible compared with strengthening of the DRA and legislation changes. Besides, it will cover large number of people, with different socio-economic status. Moreover, this strategy will provide at least protection of people from using visually

suspicious drugs (wrongly packed) and drugs not registered in the RA. Among 60 counterfeit

drugs detected in the RA, 25 were not registered and 10 wrongly packed; this means once

informed many people could be protected from some counterfeits identified in Armenia.

Each of the above mentioned strategies has its positive and negative sides. A combination

of proposed strategies should be used to successfully combat counterfeiting. However, they

cannot be implemented all at once. Step by step implementation of strategies (from high to

low priority) is more feasible and appropriate.

Specific recommendations

Providing consumer education and organizing information campaigns is a strategy, which

is recommended to be implemented at first stage. This strategy should increase public

awareness concerning the problem of counterfeit drugs. Furthermore, it should spread the

information among different layers of society. Some specific recommendation could be

made for this strategy:

1. It is necessary to start consumer's education and information campaigns continuously.

Drug counterfeiting is a problem which can not disappeare at once. That is why people

should be periodically reminded about existence of that problem and preventive measures.

2. Educational materials should be regularly updated. New information, including

preventive measures from all over the world concerning drug counterfeiting issue should be

available to the consumers.

3. The list of counterfeit drugs detected in Armenia should be updated periodically and

publicly accessible. Consumers should have complete information about circulating

counterfeit drugs in the market in order to be careful and more attentive wile baying

medicines.

4. Consumers should be informed about holograms or simple visible signs or any other changes of drug packaging in order to be able to recognize original drug from the fake one.

Implementation and Evaluation

During implementation of the proposed strategy some barriers can be identified. Since it is educational program and should be continuously provided, the role of financing is very important. Lack of financial resources may be the obstacle for program implementation. Furthermore, drug counterfeiting is a profitable industry, and such barrier as conflict of interests with business makers may also occur during the program implementation.

The evaluation of proposed intervention will be done through assessment of the:

1) People's knowledge concerning drug counterfeiting. It could be done with the help of a questionnaire after 6 months of intervention. The questionnaire should contain general questions concerning the problem and recommendations on how to avoid purchasing counterfeit drugs.

2) Number of public reports to the DRA about counterfeit drugs from the public. The data about counterfeit drug reports could be obtained from Administrative Department of the DRA. And it could be done at 6 months after the program implementation and continued by annual monitoring of the reports.

Conclusion

Drug counterfeiting is a worldwide problem. There is no country, which can be secure from the existence of counterfeit drugs on its pharmaceutical market. This problem has also touched Armenia. Existing prevention/intervention strategies in Armenia along with implementation of additional proposed ones will assure safe and effective medications to the people of Armenia.

Different authorities within the country, the customs, the police, the court system, and governmental and nongovernmental organizations could achieve success in anti-counterfeiting campaign by enhancing their collaboration.

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Appendices

Appendix 1

Table 1: Differences of counterfeit and substandard drugs.

Counterfeit drugs	Substandard drugs
Manufacturer (true identity/source) unknown	Produced by known (legitimate) manufacturer
Manufacturer involved in a criminal activity	Arise due to poor manufacturing process
All counterfeit drugs are substandard	Not all substandard drugs are counterfeit

Table 2: Similarity of counterfeit and substandard drugs.

1	Both of them result from poor regulation of manufacturing, import, marketing and sale of drugs
2	Both of them can be harmful to health
3	Both of them undermine confidence in physicians, pharmacists, drug manufacturers, distributors and drug regulatory authorities.
4	Both of them can delay treatment and make illness worse. In case of antibiotics-antimicrobial resistance can develop.
5	Both of them can cause economic damage
6	Contributing factors are similar for both of them

Appendix 2

The list of counterfeit and not registered in the Republic of Armenia drugs detected from 1996 to 2002.

N	drug name	drug dosage and form	manufacturer	country	points do not corresponding to specifications by points/or not registered in the RA	date of analysis	source
1	Haemodes	500ml solution for infusion	"Biochemic" Saransk	Russia	genuineness, description	08.03.1996	drug store
2	Rheopolyglucin	400ml solution for infuson	"Biochemic" Saransk	Russia	genuineness, description	08.03.1996	drug store
3	Gentamycin	80mg/2ml vials	Eric Johnson Laboratories	India	genuineness, pH and quantitative composition	10.07.1996	drug store
4	Sea buckthorn oil	30ml vial	"Sadovod"	Russia	genuineness, quantitative determination and microbiological purity	19.03.1996	drug store
5	Kefzol	1g	Lilly S.A. Alcobendas	Spain	quantitative determination	28.04.1998	drug store
6	Valeriane tincture	30ml vial	Borisovsky zavod	Belarus	Quantitative determination, dry remains, labeling	28.04.1998	drug store
7	Solutio camphorae spirituosae	10 % 30ml vial	unknown	Russia	labeling	08.09.1999	n/a
8	Tinctura Leonuri	30ml vial	Borisovsky zavod	Belarus	labeling	08.10.1999	drug store
9	Diclox - Diclofenac	75mg/3ml solution for injection 5x3ml ampoules	B.M. pharmaceutical	India	Packaging are identicals to the drug Duclofen manufactured by Roma Pharma Ltd and Tison Pharmaceuticals	25.02.1999	drug store

N	drug name	drug dosage and form	manufacturer	country	points do not corresponding to specifications by points/or not registered in the RA	date of analysis	source
10	Zinc ointment	10% 10g	unknown	unknown	labeling	n/a	drug store
11	Solution iodi sprirituosa 5%	5% alcohol solution, 30ml	unknown	unknown	Quantitative composition	11.10.1999	drug store
12	Solution iodi sprirituosa 5%	5% 30ml vial	unknown	unknown	Quantitative determination	08.09.1999	drug store
13	Solution iodi sprirituosa 5%	5% small vial	unknown	unknown	Quantitative determination	08.09.1999	drug store
14	Solutio Ammonii 10%	10% solution	unknown	unknown	Quantitative composition	08.10.1999	n/a
15	Viride nitentis 2% alcohol solution	vials	unknown	unknown	Quantitative determination	08.09.1999	n/a
16	Benzyl benzoate	25% emulsion	unknown	unknown	Quantitative determination	08.10.1999	drug store
17	Tinctura Leonuri	30ml vial	unknown	unknown	dry remains	08.10.1999	drug store
18	Baralgin	tablets	Marvel Medilinx	India	not registered in the RA in that time	19.03.1999	n/a

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N	drug name	drug dosage and form	manufacturer	country	points do not corresponding to specifications by points/or not registered in the RA	date of analysis	source
19	Acidum C	homeopathic drug	unknown	Russia	not registered in RA in1999 wrong composition indicated on packaging	11.06.1999	procurator's office
20	Medny vsadnik	homeopathic drug	unknown	Russia	not registered in RA in that time, absence of composition , manufacturer and country on the packaging; absence of active ingredients, except water, alcohol and signs	11.06.1999	drug store
21	Valeriane Tincture	n/a	Pharmco	unknown	description	19.03.1999	procurator's office
22	Diclofenac	75mg/3ml ampoules	AGIO-Pharmaceutica	India	not registered in the RA at that time	19.03.1999	drug store
23	Erythromycin	0,25g tablets	Phitopharm	unknown	disintegration	15.06.1999	n/a
24	Tinctura Leonuri	30ml vial	Borisovsky zavod	Belarus	labeling	n/a	drug store
25	Pasta Teimurovi	30g pasta	Phitopharm	absent	labeling	n/a	drug store
26	Pasta Teimurovi	30g pasta	"Azerchem"	Azerbaijan	labeling	n/a	drug store
27	Baralgin	solution for injection, ampoules	Natalia	India	quantitative composition (below 50%)	n/a	drug store

N	drug name	drug dosage and form	manufacturer	country	points do not corresponding to specifications by points/or not registered in the RA	date of analysis	source
28	Sea buckthorn oil	30ml vial	"Altay-Service"	Russia	genuineness quantitative composition (below 50%)	14.01.2000	drug store
29	Erythromy cin	0,25g tablets	"Moschimpharmpre paraty"	Russia	genuineness (not has antimicrobial activity)	26.11.2001	drug store
30	Cefazolin	1g , vial	Belmedpreparaty	Belarus	genuineness (not contain active ingredient)	19.04.2001	citizen complain
31	Erythromy cin	0,25g tablets	JSC "Sintez"	Russia	genuineness (not has antimicrobial activity)	26.11.2001	drug sellers at the trade markets of Yerevan
32	Senadexin	tablets	Tbilchimpharm	Georgia	labeling, desintegration	05.11.2001	n/a
33	Cefazolin sodium	1g powder in vial	CJSC "Bryntsalov A"	Russia	genuineness (contains benzyl penicillin sodium instead of cefazolin sodium)	05.11.2001	drug store
34	No-spa	Tablets N100	Chinouin	Hungary	genuineness	10.10.2002	drug store
35	Ringer	Solution for infusion 400ml glass bottle	Likvor Pharmaceutical	Armenia	Contains 96% ethyl alcohol, impurities	18.07.2002	8th medical center
36	Orungal	100mg capsules N15	Janssen Pharmaceuticals	Belgium	labeling, packaging	25.11.2002	drug store
37	Capoten	25mg tablets N40	Bristol Myers Squibb	England	labeling, packaging	n/a	drug store
38	Baralgin	tablets N10	Jackson laboratoria	India	description	n/a	n/a
39	Cuprum baralgin	tablets N10	G.C.M. Laboratoria	India	description	n/a	n/a

N	drug name	drug dosage and form	manufacturer	country	points do not corresponding to specifications by points/or not registered in the RA	date of analysis	source
40	Tincture eucalypti	25ml solution	"Ivanovski pharmzavod"	Rossia	not registered in the RA at that time	n/a	n/a
41	Lidaza	ampoules N5	"Immunopreparat"	Russia	not registered in the RA at that time	n/a	custom
42	Interferon	ampoules N10	Biomed	Russia	not registered in the RA at that time	n/a	custom
43	Bifidumbacterinum siccum	vials N10	"Konpo"	Russia	not registered in the RA at that time	n/a	custom
44	Taufon	eye drops, 4% 5ml	"Yug"	Russia	does not registered in the RA at that time		custom
45	Kanamycin sulfate	1g , vial N1	"Sintez"	Russia	not registered in the RA at that time	n/a	drug store
46	Ampicillin sodium	0,5g, vial N1	JBF industrie ltd	India	not registered in the RA at that time	b/a	drug store
47	Oletetrin	125000 IU, N25 tablets	Biosintes	Russia	not registered in the RA at that time	n/a	drug store
48	Sulfadimezin	Tablets 0,5g N10	"Irbitskiy zavod"	Russia	not registered in the RA at that time	n/a	drug store
49	Cicloferon	2ml ampoules	Polisan	Russia	not registered in the RA at that time	n/a	drug store
50	Mesaton	1% /1ml ampoules N10	"Goskombiomed"	Ukraine	not registered in the RA at that time	n/a	n./a
51	Cedax	400mg capsules N20	Schering	Germany	not registered in the RA at that time	n/a	n/a
52	Solutio Rivanoli	0,1% 100ml	"Pharmko"	Armenia	Quantitative determination; does not registered in the RA at that time	09.06.2000	procurot's office

N	drug name	drug dosage and form	manufacturer	country	points do not corresponding to specifications by points/or not registered in the RA	date of analysis	source
53	Formidron	50ml solution	"Pharmko"	Armenia	Quantitative determination; does not registered in the RA at that time	09.06.2000	procurot's office
54	Solutio Furacillini	100ml	"Pharmko"	Armenia	Quantitative determination; not registered in the RA at that time	09.06.2000	procurot's office
55	Glycerini	35g	"Pharmko"	Armenia	Dentisity ; not registered in the RA at that time	09.06.2000	procurot's office
56	Tinctura Calendulae	30ml	"Pharmko"	Armenia	Quantitative determination; not registered in the RA at that time	09.06.2000	procurot's office
57	Solutio Hydrogenii peroxydi	30%, 50g	"Pharmko"	Armenia	Quantitative determination; not registered in the RA at that time	09.06.2000	procurot's office
58	Solution Calcii chloridi	5% 100ml	"Pharmko"	Armenia	Quantitative determination; not registered in the RA at that time	09.06.2000	procurot's office
59	Solutio Ammonii	30ml	"Pharmko"	Armenia	Quantitative determination; not registered in the RA at that time	09.06.2000	procurot's office
60	Solution iodi sprirituosa 5%	5% solution 30ml	"Pharmko"	Armenia	Quantitative determination; not registered in the RA at that time	09.06.2000	procurot's office

Appendix 3.

Counterfeit drug reporting form

Report No._____

Date of reporting_____

Reporting person information:	
anonymous	
name	
address	
Detection date	
Place of detection (check all that apply)	
Drug store	
Market place	
Distribution warehouse	
other	
The origin of the drug:	
Locally produced	
Produced by foreign companies	
Other (specify)	
Description of suspected drug (why it was considered as counterfeit-wrong packaging, absence of manufacturer name, different shape or color of the drug, absence of treatment effect and etc.)	
Any other information relevant to case	