THE ROLE OF THE JUDICIAL AUTHORITY IN ORDER TO STOP THE SPREAD OF COUNTERFEIT MEDICAL PRODUCTS AND THE JUDICIAL PROSECUTION AGAINST THE COUNTERFEITERS

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INTRODUCTION

In 2006, it was realized the Diagnosis and Measurement of the Illegal Market of Medicines in Lima and Callao. We found that between 2002 and 2005 there were 3,123 effective action, including 123 control operations.

By these operations were interposed 1,476 establishments and seized 4'291,292 units of pharmaceutical and related products. The seizure included counterfeit medicaments, in a bad state of conservation, with the date expired and those stolen from public institutions.

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INTRODUCTION

As for the **judiciary aspect**, we have until July 15, 2007, from 324 reports lodged to the Judiciary Power, 160 were resolved (49%), leaving 214 still to be resolved (35.5%) and 50 were closed (15.5%). Such a balance, with slight variations continues with similar percentages.

About the resolved causes, we understand that counterfeiters think, as they no purge jail or not to receive severe enough penalties, they would choose to continue their illegal activities

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SANITARY OBSERVATIONS IN THE PERUVIAN LEGISLATION

It presents 6 observations:

1. COUNTERFEITS PRODUCTS
2. Products with the date “expired”.
3. Products which were stolen from the public institutions (MINSA, ESSALUD FOSPOLI, FOSPEME).
4. Products with the label adulterated or erased.
5. Products without the sanitary record.
6. Products with unknown origin.

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THE ILLEGAL TRADE OF THE COUNTERFEIT MEDICINES

Counterfeit medicines and their effects in the pharmacies:

The illegal trade has gained space on the shelves of pharmacies.

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ORIGIN OF THE ILLEGAL TRADE OF MEDICAMENTS

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LEGAL DISPOSITIONS

MAIN LAWS

The Political Constitution of Peru

The General Law of Health

The regulations of pharmaceutical products

The regulations of pharmaceutical establishments

- The last two regulations are in process of modification

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LEGAL DISPOSITIONS

R.M. Nº 1240-2004-MINSA – The National Policy of medicines.

R.M. Nº 047-2006-PCM – Technical Group – CONTRAFALME

This norm was proclaimed by the Ministers Council

Law Nº 29316 which modifies, incorporates and regulates diverse dispositions, including the General Law of Health in order to implement the agreement of free Trade signed between Peru and USA.

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THE GENERAL LAW OF HEALTH

The General Law of Health

The modification of the General Law of Health about the pharmaceutical establishments:

Since january 14, 2009 those have to get a previous sanitary authorization for working.

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THE GENERAL LAW OF HEALTH

The changes of the sanitary records of the pharmaceutical products with the new law.

Since the same modification, the medical products have a previous evaluation in order to get the sanitary record.

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ADMINISTRATIVE DISPOSITIONS

Administrative Rules: About products and establishments

Sanitary Measures: Immobilization, confiscation, temporary closing and definitive closing.

Sanctions: Fines.

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LEGAL FRAMEWORK OF PERU

The Criminal Code of Peru:

For these type of crimes it had to the collective health as juridical protected good and is an interest of the state to protect it from the danger that imports the utilization of harmful medicines.

Article 286º

Article 287º

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LEGAL FRAMEWORK ON WHICH DEVELOPS PERUVIAN JUDGES

The Criminal Code of Peru

Article 288º

Article 294º

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LEGAL FRAMEWORK ON WHICH DEVELOPS PERUVIAN JUDGES

It must be mentioned , that the article 288º was modified in 2005 by the Law Nº 28513.

Previously, it regulates only the trade or the trafic of harmful products.

It introduces, the medicinal substances with date “expired”.

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LEGAL FRAMEWORK ON WHICH IT DEVELOPS PERUVIAN JUDGES

The need to change these laws:

- They no mean an individual type of crime for the counterfeit medicines.
- The penalty should be higher.

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LEGAL FRAMEWORK ON WHICH IT DEVELOPS PERUVIAN JUDGES

- However, judges with those rules, dictate sentences, giving validity to the results of the raids which execute "DIGEMID" in coordination with the Public Ministry and the National Police of Peru - DIRINCRI-SIMFA.

- The desirable thing is that the judges have legal dispositions more drastics in order to send to jail to the counterfeiters.

PENALTIES AND LEGISLATION: DEVELOPMENT OF THE ACTIONS, PLANS, DISSUASIVE SANCTIONS, AND THE RULES ABOUT THE INSTRUMENTS FOR ACTION TO STOP THE COUNTERFEITERS

Replacing text of the articles 286º, 287º, 288º y 294º of the Criminal Code:

The changes are very important in order to dissuade those who wants to incurre on these criminal acts.

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The advantages of those modifications:

- The medical products will be separated of the harmful food and they will have their own address.
- The punishment will be aggravated for the health professional perpetrators

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

The new text changes 3 articles:

The articles 286 º, 287 º and 288 º limit them to the sanction to punish the pollution and altering the food for human consume and substances or goods from public use, as well as the trade or illegal traffic of food for public use.

By the article 294 º, it changes the term of medical susbstances to the pharmaceutical and related products.

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The new text incorpore 2 articles

Article 294-A: It punishes the pollution, counterfeit or alteration of expiration date of pharmaceutical or related products; or who imports, trades, stores, transports, or distributes in such conditions, as well as who imports or trades pharmaceutical or related products with due dates which guarantees their good condition. And it aggravates the penalty if the counterfeiter is owner, technical director or pharmaceutical regent.

Article 294-B: The penalties are stronger if the crime caused serious injuries or the death.

PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

With an independented criminal type of medical products by the Article 294 º-A, the criminal penalty will be established in prison not less than 4 or not more than 8 years, an also it is increased the penalty until 10 years for the cases when the counterfeiter is the Owner, Technical Director or Regent.

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

And the modification will add the fine penalty which goes from 180 to 365 fine days; as well as the penalty of disqualification for:

(1) the practice a profession or commission done by the agent,

(2) inability to obtain a job or a public commission

(3) and inability to practice by their own or through other persons a profession, business or industry about medical products.

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PROPOSED AMENDMENT TO CHAPTER OF PERUVIAN PENAL CODE CONCERNING CRIMES AGAINST PUBLIC HEALTH

In 2008, these draft amendments, were approved by the Committees of Health and Justice of the Peruvian Congress; however, despite being placed on the agenda of the assembly it was not evaluated.

We hope that in this new legislature, we have a greater political commitment of the legislative and executive powers, for its approval.

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THANK YOU