# PROPOSAL FOR THE EXECUTING UNIT

In order to implement the actions to prevent and fight against drug counterfeiting, an executing unit with a flexible structure is proposed as part of the national health authority.

## 1. Scope of responsibility

The responsibility of the unit should be defined as the monitoring and control of the quality and safety of the drugs available in the country.

A program should be implemented that includes inspection of the various links that form the chain of steps that comprise the marketing of the drugs. Its purpose should be preventing illegitimate introduction of drugs to the market and acting to combat it when it does occur, guaranteeing to the consumer pharmaceutical products that are properly authorized by the health authority.

Toward that objective a program for inspections should be developed in order to confirm the legitimacy of the medicinal products marketed and the sales documentation that guarantees their origins and destinations as they move through the various links that comprise the marketing chain.

The universe of action of the program, whose scope should extend to the national level, will be formed by all those establishments empowered to engage in the marketing of drugs.

## 2. Functional structure

**Proposed model:**

- General Coordination performed by a pharmacist
- A group of pharmacist inspectors, charged with carrying out the inspections
- Intelligence personnel devoted to the tasks of logistical support for the investigation
- Administrative personnel
- Legal Advisory Services provided by a lawyer.

## 3. Information system

3.1 Data base

For the purpose of optimizing the tasks of the program, data bases containing information related to their development should be available and should be updated regularly.

Some types of such data bases are proposed below:

- Authorized establishments in the drug trade (such as drug distributors, drugstores, and pharmacies). The following can be specified: type of establishment, address, technical person responsible, and owners.
- Inspected establishments and the results of that inspection, which can be based on the list of authorized establishments described above, complemented with a description of the results obtained in the inspections.
- Establishments where irregularities were detected, with the pertinent results or conclusions.
- Authorized manufacturers.
- Pharmaceutical products prohibited by the health authority.
- Pharmaceutical products drawn as samples in the inspections.
- Denunciations received in the program.
- Follow-up on the denunciations processed in the judiciary.
- Counterfeit drugs detected in the country.
- Counterfeit drugs reported to WHO.
- Procedures carried out in collaboration with the judiciary.
- Final result or conclusion.

3.2 Communication mechanisms

Mechanisms for network communication should be established among those involved in communication of risk and for the joint management of information for the investigation.

## 4. Tools used for preventing and fighting counterfeiting

- The work methodology will be based on visual inspection, sampling of drugs, and investigation of documentation at the different points in the marketing chain.

- In the presence of presumably counterfeit drugs during the inspection, some units will be sampled, while preventively avoiding use and marketing of the remainder until the legitimacy of the product is confirmed.

- The sampled units can be transferred to the official control laboratory, where the respective quality controls will be exercised, subject to recognition of the legitimacy of the titular signature in the registry.

- In situations that involve counterfeit drugs the following procedures can be carried out: denunciation before the judiciary and preparation of the

administrative act prohibiting use and marketing of the product lot involved throughout the country.

- For execution and follow-up in cases of drug counterfeiting an interdisciplinary team working jointly with the judiciary, the national security agency, and other organs that the authority considers necessary should be formed, so that all are continually connected and informed and can act. In this regard, the formation of a prosecuting commission (judicial authority) to prosecute and monitor the denounced cases of counterfeiting is suggested.
- Regular reports containing the results obtained in the inspections will be prepared and sent to the jurisdictional health authorities, so that they receive the correct information and can act in the area of their competence.
- Presentation of denunciations can be promoted by making the different ways of doing that known (telephone, fax, in person, and national drug surveillance network).
- The population can be informed of those products detected as counterfeit through the official communications media (through publication in the official bulletin, for example), as well as through other bulletins, publications, and the web pages of the national health agency, professional schools, consumer protection organizations, or others considered pertinent.
- Through the program, information on drug counterfeiting can be provided to different provincial or regional entities and pharmaceutical organizations and other countries.
- During the course of the inspections the professionals can be offered the opportunity to relieve their doubts, while at the same time being instructing in the critical points about drug marketing with the objective of avoiding the introduction of counterfeit products into the market (by requiring qualification of suppliers and legal purchase vouchers, for example).
- Report of counterfeit drugs to WHO. All cases should be reported to WHO in order to facilitate worldwide exchange of information on drug counterfeiting.

## 5. Evaluation, analysis, and impact of the counterfeit products found

The information obtained in the inspections should be processed at program headquarters to allow preparation of a record of the results obtained and development of the statistics and indicators that reflect the different situations observed, for use in follow-up and evaluation. These will be used to evaluate the impact of the counterfeit drugs found and to implement actions responding to the situations detected.

As has been mentioned in previous paragraphs, those situations that involve counterfeit drugs will be denounced before the judiciary and reported to the jurisdictional health authority, and marketing and use of the product lots involved will be prohibited throughout the country.

## 6. Continuing training and education

The inspectors of the program should be trained and receive updating regularly in different subjects of interest in the area, basically in techniques of investigation, negotiation, communication, labeling of containers, packaging, and marketing documentation. A proposal for regional training is presented in Annex 3.

## 7. Manual of procedures

The program should have written procedures for the activities for which it is responsible, such as the following:

- Inspection procedures;
- Preparation of reports to the jurisdictional health authority;
- Verification of the legitimacy of the products sampled in inspections, in the titular laboratory of the registry;
- Reporting of cases of drug counterfeiting to WHO;
- Entry and exit of records;
- Receipt of denunciations;
- Presentation of denunciations before the judiciary.
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These will be updated whenever required and will be available to the personnel.

## 8. Interactions

The program should interact on a regular basis with different entities, such as the following:

8.1 Provincial or regional health authority

- Inspections will be coordinated by the national health authority and can be carried out jointly with the jurisdictional health authority, in accordance with the institutional characteristics of each country;
- Situations of presumed drug counterfeiting should be denounced to the program;
- Drugs should be sent to the program for the purpose of confirming their legitimacy;
- The program will submit reports of the results of the inspections to the jurisdictional health authority;
- On a regular basis, information concerning the prohibition will be sent to the agencies dealing with counterfeit drugs at the national level.

8.2 Pharmaceutical organizations

- They should report situations of presumption of drug counterfeiting to the program;
- They can send drugs to the program in order to confirm their legitimacy;
- They will send information concerning the prohibition to the agencies dealing with counterfeit drugs at the national level on a regular basis;
- They can have strategies to bring together and mobilize pharmacists and other health professionals for the purpose of cooperating with the initiative.

8.3 Pharmaceutical industry

- Determination of legitimacy will be carried out in the titular registry laboratories with respect to the various products collected in the inspections or denounced by different agencies;
- The laboratories will report to the program on new innovations in product packaging, changes in presentations, *recall* of products, and other like matters;
- Its members should report situations in which drug counterfeiting is suspected to the program immediately;
- Its members should collaborate with the initiatives of the health authority in this matter.

8.4 Prosecutors and the judiciary

- Cases of drug counterfeiting will be denounced to the judiciary (commission of prosecutors created for the purpose);
- Program inspectors can be made available to the judiciary for participation as "*suitable personnel*" in different procedures related to drug counterfeiting.

8.5 Municipal organizations

- Joint inspections can be implemented in those establishments empowered by the municipal entity only.

8.6 Consumer protection agencies

- Denunciations concerning drug counterfeiting will be received in different ways, such as by telephone or fax or in person, and a system for disseminating that information will be set up.

8.7 Other sectors of the Ministry of Health

- Unit responsible for development and implementation of the national drug policy;
- Unit responsible for pharmaceutical services in the health system–to guarantee access to safe drugs of quality.

8.8 Universities

- Inclusion of quality, safety, and rational use of drugs among the subjects included in the training of health professionals;
- Cooperation in the production and dissemination of knowledge of the subject (in the areas of identification technologies, safety mechanisms, and research on improvement of work processes, for example).

8.9 Finance/customs

- Joint inspections in establishments in accordance with the institutional characteristics of each country;
- Cooperation in the control of the products in the chain (in exchange of information and training, for example);
- Indentification of illegitimate products and prevention of their entry into the country.

8.10 International cooperation

Among health authorities of the countries and PAHO/WHO:

- Action to strengthen cooperation with regard to the subject in the integrated subregional blocs: the Andean Pact, MERCOSUR, NAFTA, and the Central American Common Market;
- Exchange of information, experiences, and results related to preventing and fighting counterfeiting with the other health authorities of the Region of the Americas;
- Submitting reports of counterfeit drugs to WHO.
- Conducting workshops and seminars with other authorities in the region and informing the other countries of the events to be carried out and their results.