



**PAN AMERICAN NETWORK ON DRUG REGULATORY
HARMONIZATION**

**WORKING GROUP FOR PREVENTION AND
COMBAT OF COUNTERFEITING OF MEDICINES**

November, 2008

**PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION
(PANDRH)**

**WORK PLAN PROPOSAL OF THE WORKGROUP FOR PREVENTION AND
COMBAT OF COUNTERFEITING OF MEDICINES (WG/PCCM)**

1. Introduction and Background

The First Pan-American Conference for Drug Regulatory Harmonization took place in 1997, with participation by health authorities and associations representing the pharmaceutical laboratories and professional bodies.

In 1999, at the Second Pan-American Conference for Drug Regulatory Harmonization, the work group "Counterfeit Medicines" was created, coordinated by Brazil (National Agency for Sanitary Vigilance).

The first Work Group meeting was conducted in December 2001, during which a survey for the diagnosis of the situation of counterfeit medicines in the country was introduced. Said survey was presented at the Third Pan-American Conference for Drug Regulatory Harmonization, which took place in April 2002 and where a work plan was approved for the Work Group.

The Mission and Objectives of the Work Group were developed during the second Work Group meeting held in Mexico City in August 2003.

Mission: *"To promote, facilitate and motivate the implementation of proactive strategies to prevent and combat counterfeiting of medicines and thus contribute to improving health care in the countries of the Americas."*

Objectives: *"To develop policies and strategies for implementation by the countries, to develop criteria and standards for adoption in national legislations and to optimize the processes of inspection/investigation; to develop and promote the implementation of educative and practical training programs and to promote the exchange of information."*

The WG/PCCM, in pursuance of its Work Plan, addressed the formulation of proposals on the development of policies and strategies for implementation by the countries, the development and promotion of educational and practical training programs for optimization of inspection/investigation processes, and the promotion of the exchange of information.

At the third meeting held in Sao Paulo in August 2004, the WG reviewed the commitments and discussed, among other things, the proposed regional health authorities' course.

At the Fourth Pan-American Conference for Drug Regulatory Harmonization, held in the Dominican Republic in March 2005, some recommendations were established and some documents submitted by the WG/PCCM were approved, including: Critical Path, Executorial Unit, Indicators, and Educational Program.

The fourth meeting of the Work Group was held in November 2006, in Buenos Aires. This time a new Work Plan was established for 2007 and 2008. One of the definitions was that due to the evolution of knowledge, practices and reality, the educational program presented at the Fourth Conference should be updated. Argentina and Brazil jointly developed a new program, based on the national experiences of the two countries and also of MERCOSUR, which conducted a seminar in Montevideo in September 2007. Besides, international benchmarks were used by WHO for the construction of the contents of the event.

The pilot program of the Workshops for discussion of tools and generation of proposals for prevention and combat of counterfeiting of medicines was held in Panama, from August 5 through 8, 2008.

Through electronic media the WG formulated the proposals for the Fifth Pan-American Conference for Drug Regulatory Harmonization presented in this document.

2. WG/PCCM Proposals for the V Pan American Conference for Drug Regulatory Harmonization

The WG/PCCM proposes some priority actions for development in the coming period, based on a review of the WG Work Plan developed in the last meeting, held in 2006 in Buenos Aires, and taking into consideration the evolution of discussions in the international scope, mainly with the work developed by WHO, which often are the same ones proposed by the WG.

2.1 Priority activities for development by the WG/PCCM and timelines for implementation

1. Effectively establishing a network of national and regional focal points, according to the communications structure proposed in topic 3.2.
Period: until 2009.
2. Conducting Workshops for discussion of tools and generation of proposals for prevention and combat of counterfeiting of medicines, according to the proposal submitted in topic 3.3.
Period: ongoing activity, according to formal requests from countries.
3. Preparing a guide for identifying irregular drugs in the market, as a document of assistance for the establishment of national procedures for the identification of irregular drugs and also to serve as a reference for implementing proactive programs to identify counterfeit or irregular products.
Period: until 2009.
4. Revising and updating the documents of Critical Path and Operational Unit to serve as basic document for countries and for the Workgroups, since they are general documents.
Period: until 2010.
5. Introducing the issues of Traceability and e-Commerce (Internet) of Products in the discussions, considering their relationship and developing the discussion of Good Distribution Practices.

Period: ongoing activity.

6. Developing of online raining based on the course developed by ANMAT.
Period: Until 2010.



MODEL OF FOCAL POINTS NETWORK TO COMBAT MEDICINES COUNTERFEITING

A document prepared by ANVISA / Brazil, based on the documents presented at the WG/CMC of the PARF Network (presented by Colombia at the WG IV Meeting - Buenos Aires, Nov. 2006) and the document present at the II General Meeting of IMPACT (Lisbon, Dec. 2007)

**PAN-AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION
(PANDRH)
WORKSHOPS FOR DISCUSSION OF TOOLS AND GENERATION OF
PROPOSALS FOR PREVENTION AND COMBAT OF COUNTERFEITING OF
MEDICINES**

**WORKGROUP FOR PREVENTION AND COMBAT OF COUNTERFEITING OF
MEDICINES**

In line with WHO recommendations, the responsibility for combating medicines counterfeiting should be shared by all the actors involved, for example, Health authorities, Police, Prosecutor's Office, the Industry and others that directly or indirectly have responsibilities for the protection of public health. In addition, the effectiveness of the actions is also related to the awareness and the articulation of these actors.

In view of this, at the Fourth Meeting of the Workgroup in November 2006 in Buenos Aires, it was agreed that Argentina and Brazil would jointly develop the program with the participation of the actors mentioned above, based on national experiences of the two countries and also of MERCOSUR, which conducted a seminar in Montevideo in September 2007.

Brazil and Argentina will develop the program with the objective of stimulating awareness, participation, interactivity and integration of the participants. In this sense, it was decided that this is not a training activity but rather an exchange of experiences among participants, from awareness activities, presentation of tools and an assessment of local reality, as a basis for the generation of effective proposals to combat the problem.

In this sense, it was also decided that the Workshop should be carried out in a single country, to allow greater number of participants of each institution, so as to broaden the effectiveness of the proposals established.

General Objective

To establish effective guidelines to improve prevention and combating of counterfeit medicines in the country.

Specific Objectives

- To create awareness in the various actors operating in the country of the importance of the problem, strengthening the work links, coordination, cooperation and communication among the participating institutions;
- To contextualize the participants in relation to data and international initiatives on the subject;
- To present the various tools and experiences developed for the prevention and combating counterfeit medicines;

- To get to know the existing structure in the country for the prevention and combating counterfeit medicines;
- To seek the commitment of participants to continuity of activities, setting strategies for the development of inter-institutional action plans.

Audience and academic load

The Workshop is directed to representatives of health, police, prosecutor's office and justice authorities, and representatives of pharmaceutical and academic monitoring, with a total of 50 participants. The proposed academic load is 30 hours.

3.3.4 Methodology and teaching strategies

The Workshop was developed to be as interactive as possible, using tools to encourage participation by all. Therefore, it is possible to divide the Workshop in the following elements:

- Creation of awareness of the participants with the presentation of the international initiatives and statistics and comparative videos between regular and clandestine manufacture of drugs;
- Presentation of local reality under the terms of the various institutions involved;
- Presentation of international references and initiatives to prevent and combat the problem;
- Group Activity practices recognition of counterfeit medicines and case studies that will group participants, one from each sector, to discuss and propose a solution to the case presented based on the local reality and the information presented;
- Construction of a work schedule with identification of the main weaknesses, actions, persons responsible and timeframe for fulfilling the tasks.

The pilot program

At the request of Panama, the pilot event was conducted in Panama City, from August 5th through the 8th, 2008. 46 participants intervened, all invited sectors were present. The speakers were from Brazil and Argentina. PAHO presented the structure of the PANDRH and the work conducted in the Workgroup. In addition, Peru submitted its expertise on communication strategies and education to society. As a practical outcome, a plan of action to identify those responsible and dates was established. The monitoring of the actions undertaken will be done by the workgroup, which will also help with whatever may be necessary. In a final evaluation meeting, the need was observed by the organizers for small changes in some talks, so that the workshop is more didactic and objective. These changes will be covered in the next event. The program and evaluation form used in Panama are presented in Attachment 1.

ATTACHMENT 1

Workshops for discussion of tools and generation of proposals for prevention and combat of counterfeiting of medicines.

Workgroup for Prevention and Combat of Counterfeiting of Medicines

August 5th to 8th, 2008, Panama City, Panama

Tuesday, August 05

- | | |
|---------------|---|
| 08:00 - 08:30 | Accreditation |
| 08:30 - 09:00 | Opening
Representatives of National and International Authorities |
| 09:00 - 09:30 | Lecture
PANDRH – PAHO Network – Regional strategies for prevention and combat of counterfeiting of medicines.
<i>José Luis Castro</i> – PAHO Representative |
| 09:30 - 10:30 | Plenary meeting
Presentation and participants' expectations.
Presentation of the course and its objectives.
<i>María José Sánchez and Tiago Lanius Rauber</i> |
| 10:30 - 10:45 | Break |
| 10:45 - 11:15 | Lecture
IMPACT/PAHO – Illegal pharmaceutical products: a growing global program.
<i>María José Sánchez</i> |
| 11:15 - 12:30 | Lecture
Medicine chain sanitary control: the importance of medicine registry and good manufacturing, distribution and transportation practices.
The original and the counterfeit.
<i>Domingos Sávio da Silva Júnior</i> |
| 12:30 - 14:00 | Lunch |
| 14:00 - 14:40 | Lecture
Counterfeit medicine: Concept and identification.
<i>Maximiliano Derecho</i> |
| 14:40 - 14:50 | Discussion and Comments |
| 14:50 - 15:10 | Lecture
The Private Sector: Industry's Vision. |
| 15:10 - 15:40 | Break |

15:40 - 17:00 Round Table

15:40 - 16:00 Operational structure, action strategies and account of the experiences of the health authority.

16:00 - 16:20 Operational structure, action strategies and account of the experiences of the health authority.

16:20 - 16:40 Operational structure, action strategies and account of the experiences of the customs authority.

16:40 - 17:00 Operational structure, action strategies and account of the experiences of the judicial authority.

Moderators: Maximiliano Derecho y Maristela Figueiredo de Almeida

17:00 - 17:30 Discussion and questions

Wednesday, August 06

08:30 - 10:30 Lecture
Critical Path and Operational Unit.
María José Sánchez

10:30 - 11:00 Break

11:00 - 12:30 Lecture
Essential components to be considered in national legislations against medicine counterfeiting.
Maristela Figueiredo de Almeida

12:30 - 14:00 Lunch

14:00 - 15:00 Group work
Identification of counterfeited medicines.
Coordinator: María José Sánchez

15:00 - 15:30 Break

15:30 - 16:45 Lecture
Guidelines to be considered by the health authorities in face of suspicion of counterfeiting.
Maximiliano Derecho

16:45 - 18:00 Lecture
Guide for research of counterfeited medical products and other pharmaceutical offenses.
Maristela Figueiredo de Almeida

18:00 - 18:15 Summary of the day
Moderators: María José Sánchez y Maristela Figueiredo de Almeida

Thursday, August 07

- 08:30 - 10:30** **Group work** – Case studies
Facilitators: María José Sánchez, Tiago Lanius Rauber, Maximiliano Derecho, Maristela Figueiredo de Almeida and Domingos Sávio da Silva Jr.
- 10:30 - 11:00** **Break**
- 11:00 - 12:30** **Group work** - Case studies (continuation)
- 12:30 - 14:00** **Lunch**
- 14:00 - 15:30** **Plenary meeting**
Presentation of conclusions from case studies.
María José Sánchez y Tiago Lanius Rauber
- 15:30 - 16:00** **Break**
- 16:00 - 16:30** **Lecture**
Information systems and access to sources of information.
Tiago Lanius Rauber
- 16:30 - 17:00** **Lecture**
Action planning and evaluation of results: the use of indicators.
Tiago Lanius Rauber
- 17:00 - 18:00** **Lecture**
Technology for prevention and combat of counterfeiting of medicines.
Tiago Lanius Rauber
- 18:00 - 18:15** **Summary of the day**
Moderators: Maximiliano Derecho and Tiago Lanius Rauber

Friday, August 08

- 08:30 - 09:30** **Lecture**
Inter-institutional and international cooperation and communication mechanisms.
María José Sánchez
- 09:30 - 10:10** **Lecture**
Strategies for education of society.
Elizabeth Carmelino García
- 10:10 - 10:30** **Break**
- 10:30 - 12:30** **Plenary meeting**
Preparation of effective proposals for prevention and combat of counterfeiting of medicines. Summary of elements constituting the work plan.
Moderators: María José Sánchez and Tiago Lanius Rauber

Rapporteur: Camilla Horta Gomes

- 12:30 - 14:00** **Lunch**
- 14:00 - 14:30** **Drafting of conclusions**
- 14:30 -** **Presentations of conclusions and Closing**



History

Medicines counterfeiting and pharmaceutical crime in general are swift phenomena that directly affect public health and that require a multidisciplinary, multisectorial and cross border perspective. The basic principles of a suitable approach are the cooperation and responsibility among several interested parties at national and international level.

Said cooperation can be created *ad hoc* for isolated cases, but in order to guarantee effectiveness and a sustained action, this cooperation should be structured within a network with defined functions and procedures. Inside the networks, a Model of Focal Points Network to Combat Medicines Counterfeiting (MFPNCCM) should cooperate to address the objectives established in advance.

The purpose thus of the networks based on MFPNCCM is to rationalize the effective cooperation between the interested parties at national level, and when necessary, at international level, in order to take the necessary and urgent measures to protect public health and intervene suspicious offer / confirmation of medicines counterfeiting cases.

A model of a FPNCCM based network is presented in this document. Said model is the conceptual basis to establish or to strengthen regional cooperation and systems base on PFCF networks.

Purpose

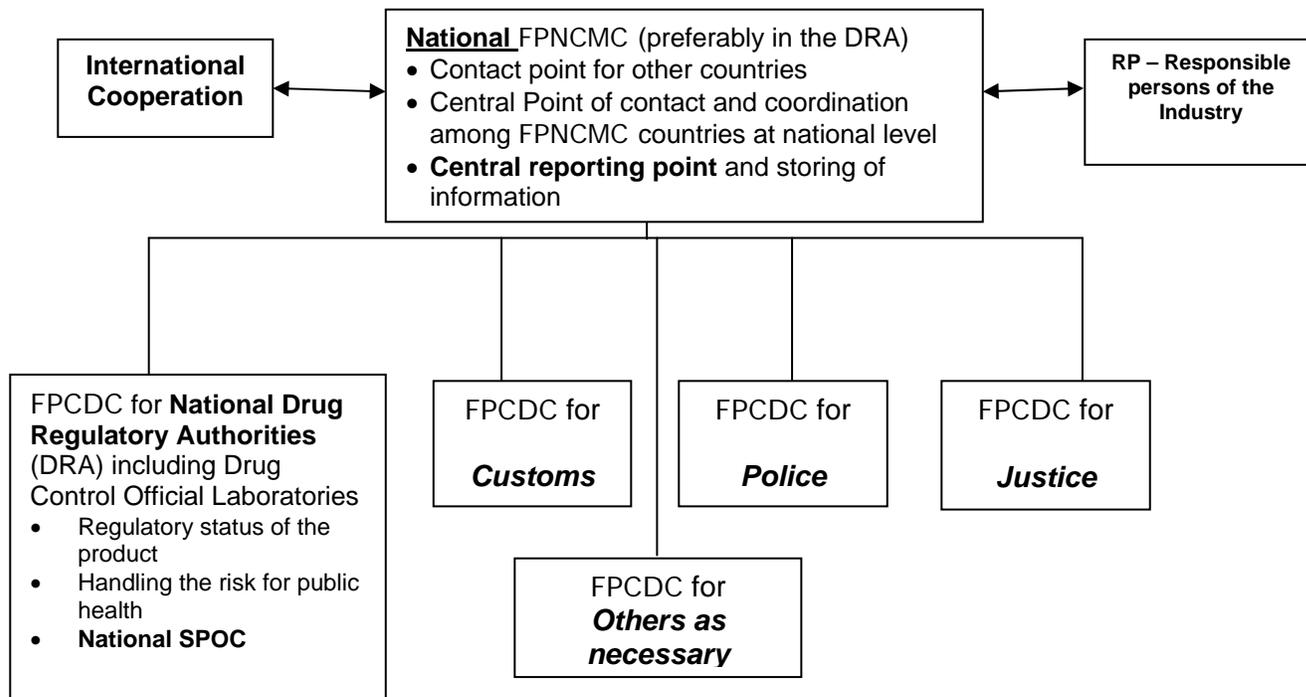
This model should be the basis for:

- Establishing the concept of a MFPNCCM system at national and international level;



- The countries to confirm the existence of networks or to establish new MFPNCCM system at regional and global levels.

Structure of the network at national level (according to the legislation of each country):



The MFPNCCM and a system are intrinsically involved with each other. A national network should be created by and among the main relevant national authorities for handling pharmaceutical crime. For the majority of the countries, the official authorities are the DRA, Police, Customs and Justice. Depending on the specific national situations, each one of them can correspond to different specific institutions and definitions.

The proposal is that the national MFPNCCM be within the DRA, however some countries do not have a structured DRA and it may be necessary to choose another institution as the national MFPNCCM.



The DRA covers all the technical and administrative functions pertaining to pharmaceutical regulation and control, which also includes quality control laboratories.

Objectives of a national network

1. Ad hoc and regular meetings should be organized and a secretariat should be established. All the information should be collected and stored in a secure database at MFPNCCM and system level. The network can use a Rapid Alert Form if necessary. The network will have to create national procedures to handle suspicious cases of medicines counterfeiting and other signs of crime (for example, theft of products, post offices and Internet) and to develop training opportunities.
2. The network will be based on informal or official agreements between the institutions that participate and with external interested parties, such as the pharmaceutical industry and health practitioners.
3. The network is responsible for preparing an annual report that should reflect all the data gathered in relation to pharmaceutical crime, the recognition of new trends in pharmaceutical crime, the initiatives adopted to improve legislation, education programs established for the different network partners and awareness raising programs in different interested parties.
4. The network should update actively its references at international level and establish procedures for cooperation, exchange of information, data collection and handling.



5. The interested parties should notify any sign or suspicion to the Central Reporting Point, which in turn shall inform the network if necessary.

MFPNCCM profile and operation within the network

Designation and operation of the focal point shall depend on the organic structure and coordination mechanisms of each government. Each government shall have a single National Focal Point and its alternate, identified by the relevant Ministry or Department in which the National Focal Point is located, preferably the Health Authority.

The MFPNCCM represents the institution as a contact point inside the network. But the functions of this focal point, according to the complexity of the activities in country, can be developed by national teams. In this case, the team shall be of a multidisciplinary nature, preferably including a biochemist and /or a Pharmacist.

All the MFPNCCM's should have the following responsibilities, tasks and objectives:

1. To be the MFPNCCM system information channel of the region. The MFPNCCM administers information received and sent– and if necessary– reports a case to other national MFPNCCM based on the need of knowledge.
2. The MFPNCCM manages the information flow according to the applicable legislation on data protection. Confidential information, such as name of patients and/or notifications, etc., should be handled with specific procedures, and not be included in databases.
3. The MFPNCCM develops and applies a procedure model to manage counterfeiting and pharmaceutical crime cases within its authority.



4. The ARN's MFPNCCM coordinates risk management of pharmaceutical crime suspicions. Suspicious cases should be identified, analyzed, evaluated and handled with. Risk management should be continuously reviewed and improved. In any case, protecting public health is a priority.
5. The Operational MFPNCCM takes the initiative in the investigation when appropriate.
6. The MFPNCCM shall have the right to create A Pharmaceutical Crime Unit that consists of one operations section and one intelligence section.
7. The MFPNCCM has authority to provide detailed information to other MFPNCCMs in the areas of international and national network. As to the information flow, it is important to differentiate between the information (analyzed and interpreted data) and evidence (pertinent information for criminal proceedings which can also be used in courts). Information can only be exchanged among MFPNCCMs and between the countries taking into account privacy laws and legal procedures. However, no legal procedure shall impede the swift exchange of information in live threatening situations.
8. When sending information to other MFPNCCMs, each MFPNCCM should make sure that this information can be used in an adequate and effective manner, in order to take the appropriate actions.
9. To suggest intersectorial coordination activities and mechanisms to disseminate inside the country information on the activities being performed in the area of medicines counterfeiting.
10. To prepare, participate and promote, with the support of the authorities involved, an integral diagnose on medicines counterfeiting in country, which should include qualitative and quantitative information and be updated on a regular basis, this in order to define action fronts and priorities thereof.



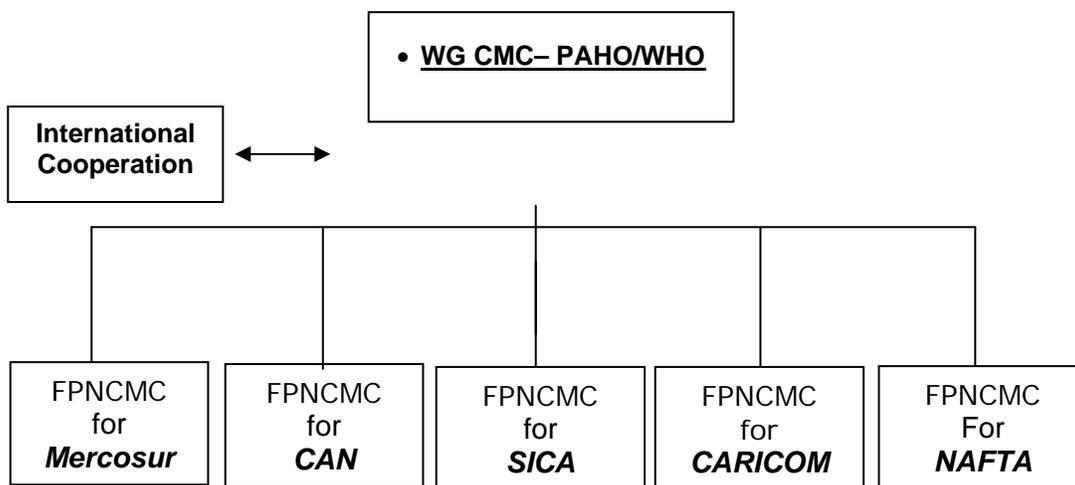
11. To be up to date on prevention of and combating of medicines counterfeiting and action plans of the different institutions involved at national level.
12. To maintain the international MFPNCCMC system on the actions developed and the progress made in the national programs and action plans to prevent and to combat medicines counterfeiting.
13. To maintain in contact with the MFPNCCMC system of participating countries, with the PAHO and other international organizations to promote and to foster combat of medicines counterfeiting.
14. To channel or coordinate at national level the activities pertaining to the Working Group to Combat Medicines Counterfeiting (WG/CMC) of the PARF Network, including educational activities.
15. To channel, follow up and forward the remarks on WG/CMC's documents or proposals, and to use the impact indicators developed by the Network.
16. To participate and to promote the relation with the pharmaceutical industry, consumers, suppliers, especially pharmaceutical practitioners, and other parties interested in matters related with the prevention of and combating of medicines counterfeiting.
17. To facilitate the creation of contact and networks between the actors of the country that combats medicines counterfeiting.
18. To publish on a regular basis the results of actions, alerts and other type of information, that can form a risk for Public health.

It is important for the National MFPNCCMC to have access to the following knowledge:



1. The MFPNCCM should have extensive knowledge of the drugs.
2. The MFPNCCM should have experience in the application of sanctions (*enforcement*) to pharmaceutical crime (including field investigation of pharmaceutical crime).
3. The MFPNCCM should have good knowledge of drug legislation
4. The PFCF should have basic knowledge of criminal law, investigation and criminal procedures (for example, handling of evidence).

Network structure at sub-regional level



All sub-regional MFPNCCM should have the following responsibilities, tasks and objectives:

1. To be the MFPNCCM System information channel of the sub-region, the remaining sub-regions and with the PAHO. The sub-regional MFPNCCM manages information received and sent based on the need of knowledge.



2. To be up to date on prevention of and combat of medicines counterfeiting programs and action plans of the different entities involved at regional level and of the countries in the sub-region.
3. To exchange information with the MFPNCCM system of the other sub-regions on the actions developed and the progress made in the sub-regional programs and action plans to prevent and combat medicines counterfeiting.
4. To maintain contact with the MFPNCCM of the participating governments of the sub region, with PAHO and with other international organizations to promote and foster the combating of medicines counterfeiting.
5. To channel or coordinate at sub-regional level the activities pertaining to the Working Group to Combat Medicines counterfeiting (WG/CMC) of the PARF Network, including educational activities.
6. To channel, follow up and forward the remarks on the WG/CMC's documents and proposals.
7. To promote, with the support of the institutions involved, an integral diagnose on medicines counterfeiting in the sub-region, which should include qualitative and quantitative information and be updated on a regular basis in order to define action fronts and the priorities thereof.
8. To cooperate with regular updating of the MFPNCCM s list in the sub-region.

Reporting procedure for MFPNCCM

The procedure model on the way to manage medicines counterfeiting at national level has been described in the "Orientating the management of medicines counterfeiting – structure and procedure model for cooperation": diagram, see exhibit 1.



At international level, the national MFPNCCM can use a Rapid Alert Form to inform other national MFPNCCM on pharmaceutical crimes.

Implementing and maintaining the network

For the effective implementation and maintenance of the communication network through the MFPNCCM at national and sub-regional levels, it is recommended:

1. that the PAHO, through its national representatives sends a document to all health authorities in the countries of the region, informing them on the need to create a MFPNCCM system to structure the communication mechanisms to combat medicines counterfeiting among the countries of the region and the indication of the national MFPNCCM and its alternate;
2. That the PAHO sends a document to the five groups of countries (sub-regions), informing them on the need to create the MFPNCCM system to structure communications mechanisms to combat medicines counterfeiting and the need of indicating a PFCF of the sub-region and its alternate;
3. that via the sub-regional MFPNCCM the relation of the national MFPNCCM of the countries that constitute the sub-regions is kept updated;
4. that the official meetings schedule be communicated through the sub-regional MFPNCCM, where the relation of the national MFPNCCM of the countries that constituted the sub-regions will be updated;
5. As a maintenance measure of the network activity, that the working group documents, dissemination of WG/CMC activities and also of the countries with respect to the subject matter, the information coming from international events, news and confirmed cases of medicines counterfeiting in the region be communicated to all the MFPNCCM on a regular basis.



6. That the exchange of experiences be stimulated between the sub-regional MFPNCCMs, through the coordination of the WG/CMC and the PAHO.



Exhibit 1 – Information flow model for action in cases of suspicion of medicines counterfeiting

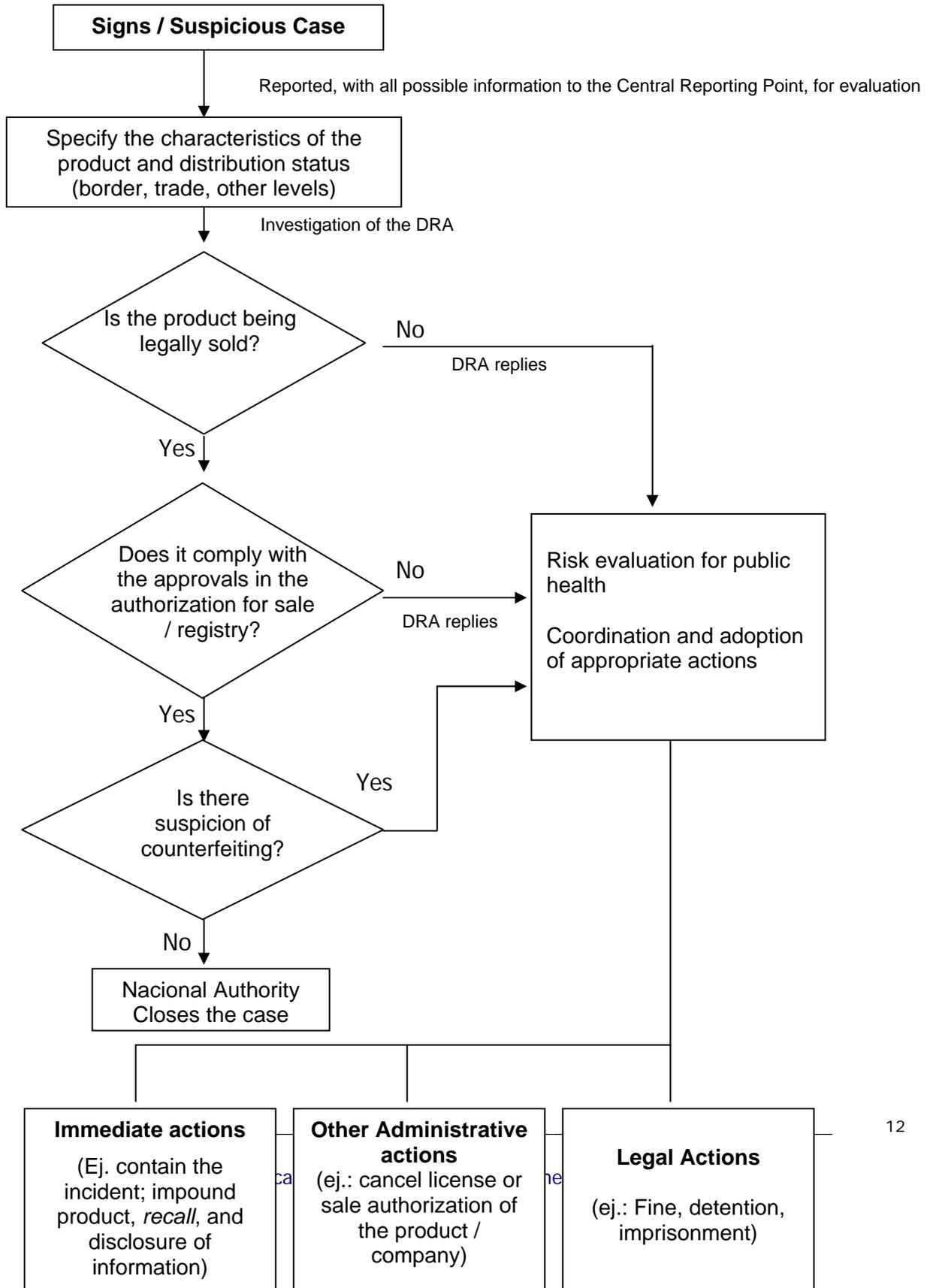




Exhibit 2 - Definitions

Pharmaceutical crime: any crime involving counterfeiting, adulteration, handling, manufacturing / distributing and possessing of unlicensed drugs, or of medical products in an illegal way, deviation, trafficking, sale and illegal activities through Internet.

Drug Control Official Laboratories: national drug control laboratories. They can be preferably organized in an international network; they are important partners and can participate on a regular basis or *ad hoc*.

Person responsible or MFPNCCM for the industry (PR): the pharmaceutical industry is part of the network, but does not have enforcement authority. Personnel of the pharmaceutical industry are an important part in this case and are involved in an *ad hoc* basis. Each company should offer a PR or MFPNCCM.

Central Reporting Point: located in the MFPNCCM's unit, where all the information on pharmaceutical crime is centralized and that disseminates information to the network's partners based on the need of knowledge. Information / signs of the interested parties (such as pharmacists, patients) should be channeled via the appropriate channels in a fast and efficient way to the MFPNCCM national chains.

National MFPNCCM: works as contact point within the international network and preferably, is part of the National Drug Regulatory Authority (DRA).

Sub Regional MFPNCCM: works as a contact point within the international network, for the countries that constituted a sub-region.



Focal Points to Combat Medicines counterfeiting - MFPNCCMC: an institution responsible for the operational management of a sign in its own area of responsibility and of exchange of information.

Network: formal or informal cooperation between the MFPNCCMC at national level.

Networks (Networking): Activities, among the members of a network, including operational management and exchange of information in relation to pharmaceutical crime.

Sign: Indication of a problem with drugs or medical products that can be considered pharmaceutical crime.