PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH)

MODEL FOR A FOCAL POINT NETWORK TO COMBAT COUNTERFEIT MEDICINES

WORKING GROUP TO PREVENT AND COMBAT COUNTERFEIT MEDICINES (WG/CCD)

History

Medicine counterfeiting[1] directly jeopardizes public health. It obliges health authorities to make every effort possible to prevent and combat a practice that compromises the safety of the entire population.

In the national arena, the fight against counterfeit medicines is a complex task and represents a shared responsibility involving important government agencies, pharmaceutical manufacturers and distributors, health professionals, consumers, and the general public. Governments must create an environment that allows all stakeholders to participate. Cooperation and collaboration between government agencies—such as health authorities, customs, law enforcement, and the courts—are also essential to achieve success in this area.

In this regard, strengthening the regulatory capacity of the health authorities to deal with the health-related aspects of this issue is a task both essential and necessary for health leadership. Health authorities must be empowered to do their part to prevent and fight counterfeit medicines

Furthermore, medicine counterfeiting has taken on international dimensions. The variety of counterfeit products has also increased due to the growth of online medicine sales, which encompasses a broad range of pharmaceuticals. Although no data are available to accurately assess the magnitude of the problem, it is well known that it affects developed and developing countries alike. The problem is more pronounced in countries where the manufacture, importation, distribution, supply, and sale of pharmaceutical products are less regulated and where compliance is minimal. As a result, there is a need to promote cooperation among countries, as well as subregional and regional cooperation, to deal with the problem. Such a process will strengthen both the role and capacities of the health sector.

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[1] *Translator's note: For* the purposes of this document, the terms **medicine**, **medicine**, **pharmaceutical product**, and **pharmaceutical** are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic, or therapeutic use, as stated on page 10 of the WHO document *Counterfeit MEDICINES: Guidelines for the development of measures to combat counterfeit MEDICINES*. Department of Essential Medicinesand Other Medicines, World Health Organization, Geneva, 1999. Available online (accessed 27 May 2011) at http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf.

In this regard, the PANDRH network, at its Fifth Conference held in 2008 in Buenos Aires, approved a document for the implementation of a Network of Focal Points of Combat Counterfeit Medicinesin the Americas. Activities have been developed in PAHO/PANDRH's area of expertise based on the guidelines approved.

At that time, the network approved a network-type structure to involve all actors responsible for fighting crime in the form of medicine counterfeiting, such as customs, law enforcement, and judicial authorities, among others. Furthermore, a recommendation was made to the WG/CCD to prepare a model proposal for a network of focal points to combat counterfeit MEDICINES, dealing with operational aspects and implementation issues.

In later discussions in an international context, especially within the World Health Organization (WHO), progress was made with the notion that efforts to combat counterfeit medicinesshould focus on the medicines' health-related aspects, thus bolstering the need for empowerment and capacity-building of health authorities in such processes. In this sense, with a view to strengthening the perspective of protecting and promoting public health to better deal with preventing and combatting medicine counterfeiting in the Americas, the WG/CCD understands that, in developing such a network, the key role and competencies of PAHO/WHO and the health authorities in this issue must be taken into account. At the national level, when necessary, the latter will act as a linchpin to bring in other actors to help confront the problem. Thus, although the network should work to stimulate interinstitutional collaboration at the national level, its implementation is the responsibility of each country.

In that sense, the present document represents an update of the original proposal endorsed by PANDRH. As such, it bolsters the main focus of work to promote and protect public health.

General Objective

Enhance communication and effective collaboration among the states that are party to this initiative by empowering health authorities, with the goal of protecting the public from counterfeit pharmaceuticals.

Specific Objectives

- Establish effective communication channels among health authorities in PAHO/WHO member countries, through the exchange of information, resources, and experiences, in order to promote and develop activities to prevent and combat counterfeit MEDICINES.

- Share information on actions taken and progress made in programs and national action plans to prevent and combat counterfeit medicines.

- Promote and collaborate in the implementation of activities at both national and regional levels to prevent and combat counterfeit MEDICINES, including joint training activities.

- Report any cases of counterfeit medicines to the countries that ultimately could be affected by the risks associated with the pharmaceutical products in question, so that appropriate sanitary measures can be adopted.

Proposed Topics for Discussion by the Network of Focal Points to Combat Counterfeit Medicines(FPCCD)

The FPCCD Network should be both active and dynamic. Below is a list of topics that it should address:

1- Discussion and information exchange on national procedures for investigating cases of medicine counterfeiting

2- Development of convergent national procedures to prevent and combat counterfeit pharmaceuticals, including contacting the countries in order to manage confirmed cases of medicine counterfeiting, in accordance with what was stated in the previous section

3- Discussion of documents that the WG/CCD is putting together

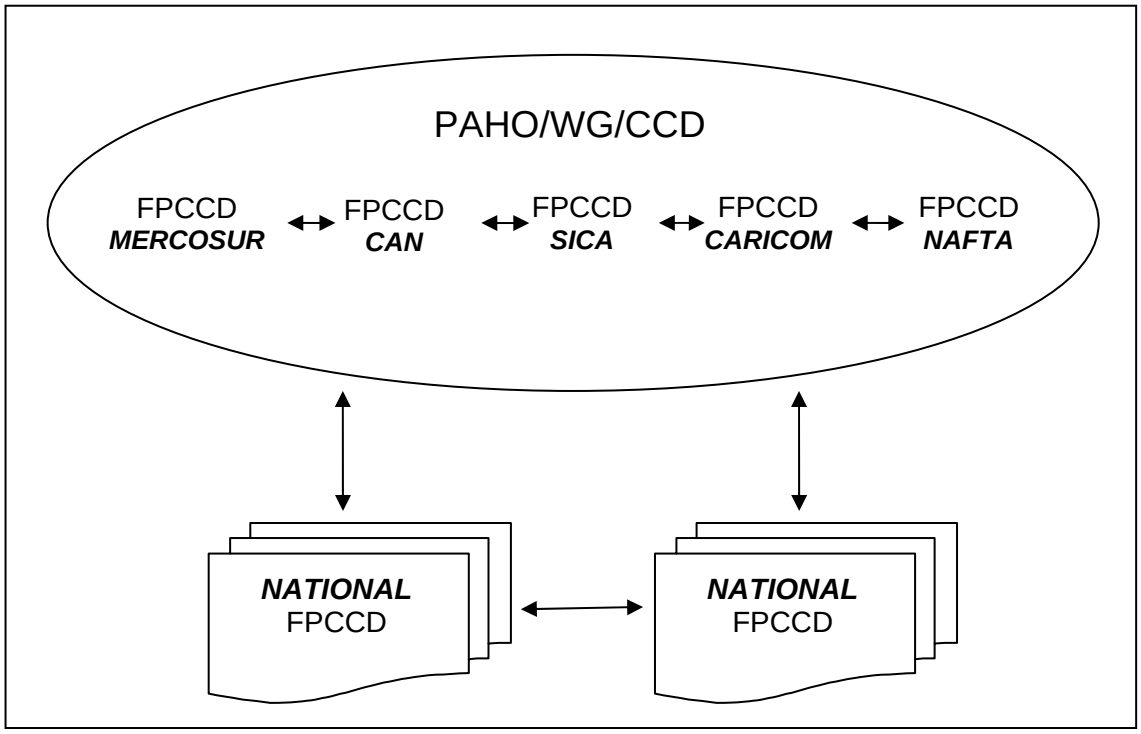
4- Sharing of national experiences on the following:

- Updates in national legislation
- Training programs
- Public education activities
- Development of a national stakeholders network to involve other sectors, in accordance with the reality of each country
- Implementation of systems, mechanisms, and technologies for pharmaceutical tracking
- Information systems and resources used to investigate cases involving counterfeit pharmaceuticals
- Programs for the identification of counterfeit medicines on the market
- Bilateral or multilateral collaboration proposals

Structure and Operation of the Network of Focal Points to Combat Counterfeit MEDICINES

The FPCCD network should consist of experts appointed by the health authorities of PAHO/WHO member countries, as well as alternates for each of them. The national focal point should act within the ministry of health or the national medicine regulatory agency (NDRA). Together with the WG/CCD, it it is the responsibility of the countries to keep the focal points, their alternates, and media contacts updated whenever any changes occur.

Naturally, WG/CCD members and their alternates will work in tandem with the focal points from their respective country, as well as with the subregional focal points for those subregions that are represented (see the diagram below).



Coordination of the FPCCD network will be the responsibility of the WG/CCD, which should delegate network facilitation to a subregional focal point who is a member of the WG/CCD and to that person's alternate, in

accordance with the work plans developed by the group. The facilitator and his/her alternate should be redesignated every two years by mutual consensus of the PANDRH/WG/CCD members.

Communication within the FPCCD network will basically be done via e-mail, with copies consistently sent to the facilitator and her/his alternate. Likewise, virtual meetings will be held by *videoconference* to take up topics and discuss them, as well as to exchange of information and experiences. Other communication mechanisms can be adopted if the countries consider find it necessary, such as setting up a website.

The Network should submit a report semiannually, or if necessary at more frequent intervals, by means of a virtual meeting of the WG/CCD, to contain the following:

a) a summary of all communication on cases occurring and measures adopted by the countries during that period
b) a brief account of the activities carried out and progress made at both national and regional level
c) any difficulties and threats that have been identified
d) a proposed work plan for evaluation by the WG/CCD
e) any requests for collaboration or information

The following are the responsibilities of the facilitator and his/her alternate:

1. Promote the implementation of the *Work Plan for the Network.*
2. Promote discussions and stimulate the participation of all focal points.
3. Collaborate with the countries by managing all incoming and outgoing information, and whenever necessary by communicating information on medicine counterfeiting cases to those countries that ultimately could be affected by the health risk represented by the counterfeit medicines. In cases involving the communication of information originating from a country, prior authorization from

the focal point or health authority of that country will be required before the information can be released.

4. Organize virtual meetings of the network within set time frames.
5. Prepare and submit a report on network activities for the WG/CCD virtual meeting, based on accounts from the subregional FPCCDs.

Responsibilities of the National Focal Point and Her / His Alternate

1. Act to funnel information on the country throughout the FPCCD network.
2. Communicate all cases of medicine counterfeiting to those countries that ultimately could be affected by the health risk represented by the counterfeit medicine, with copy to the facilitator and his/her alternate.
3. Handle all incoming and outgoing information, bearing in mind the advisability of reporting to other national institutions whenever necessary.
4. Manage information in accordance with applicable legislation for protection of information. Confidential data, such as the names of patients and/or informants, etc., should be handled using specific procedures and should not be disseminated.
5. Coordinate and promote the implementation of proposed network activities within the country.
6. Channel, monitor, and send observations on documents or proposals submitted by the WG/CCD.
7. Keep up to date on programs to prevent and combat counterfeit medicines, as well as on action plans of the different entities involved at the national level.
8. Report to the Network on actions carried out and progress made in programs and national action plans to prevent and combat counterfeit pharmaceuticals.

9. Facilitate the creation of channels of communication between the health authority and those actors within the country that also intervene in the fight against counterfeit MEDICINES.

Profile of the National Focal Point and Her/His Alternate

The national focal point and his/her alternate will be knowledgeable in the following areas:

1. Health surveillance practices as they apply to pharmaceutical products
2. Control and detection of counterfeit products
3. Legislation and regulatory guidelines applicable to pharmaceutical products

Responsibilities of the Subregional Focal Point and His/Her Alternate

1. Act to funnel information from the subregion throughout the FPCCD network.
2. Promote the implementation of the work plan of the network within the subregion.
3. Disseminate the work of the network within the subregion.
4. Promote discussions and stimulate the participation of all subregional focal points.
5. Prepare and submit to the facilitator a semiannual report on the activities of the Network in the subregion.
6. Keep up to date on programs to prevent and combat medicine counterfeiting, as well as on action plans of the different entities involved at the subregional level.

Implementation and Maintenance of the FPCCD Network

The WG/CCD should do the following:

1. Prepare a work plan for the establishment and implementation of the network, designating the facilitator and her/his alternate and defining the topics that will be addressed during the first phase.
2. Include within the initial work plan details on how the communications procedure will be set up and provide a form for case reporting.
3. Update and evaluate the work plan.

PAHO/WHO, through its national representation offices, will be responsible for reporting to the health authorities on the implementation of the network as well as on its objectives and structure, and for requesting the designation of the national FPCCD and her/his alternate.