

WORKING GROUP TO COMBAT DRUG COUNTERFEITING (WG/CDC)

REGIONAL TRAINING PROGRAM

In the design of the proposal for the course and the formulation of its objectives the following were taken into account: the problems noted in the Analysis of the Prevention of and Fight against Drug Counterfeiting in the Americas, held in 2001 by ANVISA and PAHO/WHO; the strategies and plan of action developed during the seminar of the technical group held in Rio de Janeiro in December 2001 and approved at the III Pan American Conference on Drug Regulatory Harmonization; and also the strategies devised at the meeting of the technical group held in Mexico in August 2003.

1. General Objective

The general objective of the course is to train human resources for the prevention of and fight against drug counterfeiting and fraud in the countries of the Americas.

2. Specific objectives

- Contribution to the implementation and strengthening of organizational and operational structures to prevent and fight counterfeiting and drug fraud in the regulatory agencies of the countries of the region;
- Training of the focal points to prevent and fight counterfeiting, fraud, and other problems with drug quality and to act as multipliers in their countries;
- Formalization of the constitution of the Pan American network for preventing and combating counterfeiting and drug fraud, and identification of strategies for its strengthening and for mechanisms of cooperation among countries.

3. Target Population and academic length

The course is directed toward the representatives of the regulatory health authorities of the countries (the possibility of two participants per country, in the largest countries, is considered), who will act in the future as focal points responsible for giving the course in their own countries (in collaboration with PAHO/WHO, a university, or other organizations) and representatives of the manufacturers' associations (ALIFAR and FIFARMA).

The proposed course length is 40 hours (32 hours of training in preventing and fighting counterfeiting and eight hours of pedagogical training).

4. Teaching methodologies and strategies

Different methodological approaches are proposed with the objective of placing special importance on active learning, with emphasis on the student as an agent of his or her own learning which is understood as a continuous process that lasts for one's whole life. That those present in the course have the important mission of acting as multipliers in their countries of origin is also considered.

The objectives are organized under three approaches:

1. Formal structuring of the health regulatory authority for preventing and fighting counterfeiting and drug fraud and some aspects of the management;
2. Training for realization of specific actions, with a view to the harmonization and standardization of procedures in the area; and,
3. Strengthening of the network of focal points in the countries, through communication and cooperation.

5. Budget

The WG/CDC estimated an operational budget of US\$ 108,600.00 for two training workshops at sub-regional level and for an estimated of 59 to 60 participants representing all countries in the sub-region. This budget covers all operational cost (travel, per-diem, documents, and local expenses to support the training activities).

6. Preliminary program

	Day 1	Day 2	Day 3	Day 4	Day 5
8:00	Presentation of the course	Plenary 1: Presentation of the course	Conference 3: Operating unit proposal	Plenary 5: Presentations by the groups	Conference 7: Information and reporting system
8:30	Expectations of the participants	Plenary 2: Expectations of the participants		Plenary 5: Continuation	
9:30	Group A: The learning process (formation of multipliers)	Plenary 3: Presentations of experiences of the subregions	9:00–Group 2: Strategies for harmonization of the concept of counterfeit drug		9:00–Conference 8: Mechanisms of interinstitutional and international cooperation
10:00	Coffee	Coffee	10:40 Coffee	Coffee	Coffee
10:15	Group A: Continuation	Plenary 3: Continuation	Group 2: Continuation	Conference 5: Access to sources of information	Conference 9: Planning, evaluation, and management tools
11:00	Group A: Continuation	Plenary 3: Continuation	Plenary 4: Presentations by the groups	Conference 6: Techniques for identifying counterfeit drugs	Conference 9: Continuation
12:00	Meal	Meal	Meal	Meal	Meal
13:30–15:00	Groups B: Learning and communication (training of multipliers)	Groups 1: Concept of health risk and role of drug regulation	Round table 2: Experiences in investigation and measures adopted	Group 4: Identification and differentiation of counterfeit drugs	Groups 5: Plan of action
15:00–16:00	Group B: Continuation	Round table 1: Experiences in preventive measures	Conference 4: Proposal for guidelines for investigation and measures adopted	Group 4: Continuation	Group 5: Continuation
16:00	Coffee	Coffee	Coffee	Coffee	Coffee
16:15–17:30	Group B: Continuation until 16:30	Conference 1: Proposals for strengthening the regulatory framework and the concept of a counterfeit drug	Groups 3: Problems with counterfeiting	Group 5: Communication and negotiation	Plenary 8: Presentations by the groups
17:30–18:30		Conference 2: Proposal for guidelines for inspection	Group 3: Continuation	Plenary 6: Negotiating table and film short	Plenary 9: Evaluation and closing ceremony
18:00	Opening ceremony		Film short or dynamics of integration		
19:00	The situation relating to preventing and fighting against drug counterfeiting in the world				
19:40	The situation relating to preventing and fighting against drug counterfeiting in the Americas				