



## Working Group to Combat Drug Counterfeiting (WG/CDC)

### PROPOSAL OF NATIONAL PROGRAMS FOR PREVENTION OF DRUG COUNTERFEITING AND AN ACTION PLAN (ROAD MAP)

All countries should prepare national programs for preventing and fighting against drug counterfeiting, with action plans whose objective is to improve the regulatory capacity to guarantee quality, legitimacy, and safety of the drugs available in the country.

#### 1. Objective

Development of specific policies and strategies for implementation by countries.

#### 2. Activities

Development of an action plan (road map) for the evaluation of products, in order to identify counterfeiting.

#### 3. Background

The problem of counterfeit drugs is an important issue for almost all regulatory agencies of the world and the Pan American Network for Drug Regulatory Harmonization has established a working group to address it. Using the WHO definition as its basis, the Working Group met to consider the harmonized definition of counterfeit drugs. This definition is as follows:

*“ A counterfeit medicine is one that is manufactured deliberately and fraudulently with respect to its identity and origins. It may contain products with the correct ingredients, or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging” .*

Prevention and combat against counterfeit drugs are needed and a mechanism for cooperation, collaboration and participation among the several national and international regulatory agencies is a prerequisite for any objective prevention. It is essential that regulatory agencies be proactive in monitoring counterfeit drugs within their own territory or region, as well as maintain cohesive coordination and dissemination of information. In order to monitor proactively, a process of evaluation of the products is needed. In designing the evaluation process, a road map has been developed for consideration by committee members.

#### 4. Risk management road map for the determination and monitoring of counterfeit products

##### 4.1 Risk identification

- Collection of information through intelligence gathering.
- Identification of any obstacles and their determination.
- Defining the trigger events in counterfeiting.

##### 4.2 Risk estimation

- Defining the probable effect on consumers and other stakeholders.

- Estimation of the risk of counterfeit products prior to any intervention.
- Estimation of risk and damage control.

#### **4.3 Strategy and work plan**

- Design a strategy to address the issue.
- Review the strategy.
- Develop an action plan.

#### **4.4 Implementation and control of follow-up**

- Intelligence scanning.
- Execution of strategy.
- Evaluation of impact and preparation for unforeseen issues.

#### **4.5 Risk communication**

It is important that a proper mechanism to communicate the risk associated with counterfeit products be established. More specifically, risk communication is an action of conveying and transmitting significant information related to risk, as well as the decision and action aimed at managing and controlling such risk. All stakeholders, including consumers and other government agencies, should be part of this exercise. It is sometimes very difficult for consumers to understand the probability of the risk associated with counterfeit products. Emphasis on education and training is needed to develop greater awareness of such products.

#### **4.6 Infrastructure**

So that each regulatory agency involved in the monitoring and surveillance of counterfeit medicines can be proactive, it is suggested that it establish an appropriate unit responsible for the evaluation, monitoring, and coordination of products. Timely identification and dissemination of information, along with appropriate compliance and enforcement, are needed to fight counterfeiting successfully.

#### **4.7 Intra- and intersectoral and international cooperation**

So that the actions result in actual problem-solving, formal mechanisms for cooperation must be established.

#### **4.8 To strength pharmacovigilance national programs**

