



Working Group to Combat Drug Counterfeiting (WG/CDC)

Background

Between 1982 and 1997 WHO received confidential reports about counterfeit drugs found in at least 28 member countries; the majority of the cases were neither confirmed nor validated. In the analysis of 751 cases of drugs reported, 25% came from industrialized countries and 65% from developing countries, while for 10% information on the source was not available.

During this period two resolutions were issued by the World Health Assembly: the first in 1988 in which the Member States were urged to establish programs for prevention and detection of imports, exports, and smuggling of counterfeit drugs,¹ and the second in 1994 in which it was recommended that the Member States make efforts to assure the quality of the available drugs and to combat the use of counterfeit drugs.²

In 1995 WHO developed a program on drug counterfeiting in which 30 experts from drug regulatory authorities, international and nongovernmental organizations, and other involved institutions participated. The objective was to have a forum for review of the prevalence and type of drug counterfeiting and progress in the resolution of the problem, and to discuss the establishment of a network in order to strengthen the initiative against counterfeiting and the development of a manual to assist the governments in the implementation of preventive actions.

In November 1997 an international workshop on drug counterfeiting was held. It recommended that WHO continue its function of observer for the purpose of collecting and analyzing reports and monitoring the situation in the Member States, and also requested information on the cases reported.

Some of the countries involved have in recent years exerted efforts to combat the counterfeiting of drugs through passing more rigorous legislation, strengthening existing legislation, and establishing agreements for cooperation; Some of those countries are Colombia, Argentina, Brazil, Paraguay and Venezuela

The workshop requested, as a starting point in the prevention of counterfeiting, that the countries establish strong, effective national systems for drug regulation, including aspects related to authorization of drug marketing, authorization of producing laboratories, and development of inspection programs.

In addition, it was recommended that at the national level there be close collaboration among drug regulatory authorities, consumers, police authorities, professional organizations, the pharmaceutical industry, and other related institutions.

The International Conference of Drug Regulatory Authorities (ICDRA), promoted by WHO, has from 1992 to the present incorporated in the agendas of its meetings the problem of drug counterfeiting. At the XI Meeting held in Spain in 2004, pre-conference activity was devoted to the subject of drug counterfeiting; a proposal was discussed-- "Combating Counterfeit Drugs: a Concept Paper for an International Framework Convention and Related Strategies", which is being circulated globally to obtain comments from interested parties. The subject was also discussed at ICDRA and it

¹ WHA41.16 of the World Health Assembly.

² WHA47.13 of the World Health Assembly.

was recommended that the countries: a) adopt the guidelines for the development of measures to combat drug counterfeiting proposed by WHO as a way of solving the problem; b) increase international cooperation with respect to the issue; and c) engage in information exchange among distributors, drug regulatory authorities, nongovernmental organizations involved in the subject, legal agencies, industries, and other relevant international organizations. It was requested that WHO, in collaboration with distributors, develop a document for an international drug counterfeiting convention prior to the next meeting of ICDRA.³

In the Americas, during the II Pan American Conference on Drug Regulatory Harmonization (1999) a panel discussion was held on drug counterfeiting during which the WHO guidelines to combat drug counterfeiting were presented and it was concluded that: a) counterfeiting is a problem that exists in varying degrees in most of the countries of the region and in some countries strong measures have been taken to reduce the problem; b) the guidelines for the development of the fight against counterfeit drugs, recently published by WHO, is a good tool that can be used by the countries; c) most of the countries lack up-to-date legislation that would make it possible to address this crime and enforce exemplary penalties; d) addressing the problem requires that the health authorities coordinate their actions with the police and judicial authorities and with producers and distributors, and uncontrolled proliferation of distribution channels and pharmacies in some countries can affect the existence of this crime. In addition, it was recommended that a) the countries review and modernize their legislation and identify mechanisms to enforce penalties; b) the executive committee of the network propose strategies for dissemination and promotion of the exchange of information regarding counterfeit products among countries; and c) the development of integrated control systems in the regulatory area and other, related areas (judiciary, police, and intellectual property protection, among others) be promoted.⁴

In December 2001 the I Meeting of the Working Group on the Prevention of and Fight against Drug Counterfeiting was convened. There was a presentation on research which had been conducted from May to August 2001 to determine the situation of drug counterfeiting in the countries of the region and which yielded information on 15 countries (60%). In addition, the work plan of the group was developed.⁵

At the III Pan American Conference on Drug Regulatory Harmonization in April 2002, the Working Group on the Fight against Drug Counterfeiting (WG/CDC) presented an analysis of the situation of the fight against drug counterfeiting in the Americas and the Caribbean, the proposal of a definition of counterfeit drug, and an action plan for the fight against drug counterfeiting. The conference approved the report and the proposals submitted and recommended: a) that the definition of counterfeit drug be expanded to include the concept of fraudulent drug; b) that in the absence of good practices of distribution and dispensing a study on their implementation be prepared; c) that the influence that the absence of pharmaceutical professionals in drug dispensaries has on drug counterfeiting be evaluated; d) that the drug surveillance systems be strengthened as instruments for detecting counterfeit products when reports of therapeutic failures are received; e) that emphasis be placed on the involvement of consumer associations in programs to educate the public; f) that analysis of risk factors be incorporated into the actions in the prevention of and fight

³ *Report on XI ICDRA. Spain, February 2004.*

⁴ *Report on the II Pan American Conference on Drug Regulatory Harmonization. Washington, D.C., November 1999.*

⁵ *Report of the I Meeting of the Working Group on the Prevention of and Fight against Drug Counterfeiting. Brazil, December 2001.*

against counterfeiting, and g) that an expeditious system to alert the countries of detection of counterfeiting problems be developed.⁶

In accordance with its work plan, the WG/FDC devoted itself to the formulation of proposals for development of policies and strategies for implementation by the countries; the development and promotion of programs for training aimed at optimization of inspection and investigation; and, to the promotion of the exchange of information.⁷

Indeed, the WG/CDC:

- a) Developed a road map proposal--so that the focal points in drug counterfeiting (as approved by the III Conference) can evaluate the implementation cycle. This road map includes a component of international and interinstitutional cooperation and inter-country collaboration;
- b) Prepared a proposal of executive structure that serves as reference to the regulatory authorities in their efforts of restructuring in order to be able to better address the problem of drug counterfeiting;
- c) Addressed the development, promotion, and implementation of educational programs, including remote methodologies using technologies such as the Internet, web sites, CD-ROM, and video conferences; and
- d) It was recognized that the exchange of information is basic to the struggle against counterfeiting and that this exchange is weak in the Americas, which means that the Regulatory National Authorities (RNA) should be motivated to disseminate information on the basis of what was provided by WHO. The WG/CDM considers that it is necessary to promote the countries to disseminate information to the WHO database. The WG recognized that this objective was recommended in the III Conference and that was not fulfilled, and decided to reincorporate it in the next work plan.⁸

⁶ *III Pan American Conference on Drug Regulatory Harmonization. Report. Washington April 2002*

⁷ *Report of the Second Meeting of the Working Group on the Fight against Drug Counterfeiting. Mexico, August 2003.*

⁸ *Report of the Third Meeting of the Working Group on the Fight against Drug Counterfeiting. August 2004.*