

# ORGANIZATION OF AMERICAN STATES



INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

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**FINAL REPORT**

**EXPERT GROUP ON CHEMICALS**

**August 13 – 15, 2001**

**Washington, D.C.**

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(PHARMACEUTICAL PRODUCTS)  
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## **I. BACKGROUND**

During the Twenty-eighth Regular Session of CICAD held in Port of Spain, Trinidad, October 24-26, 2000, the Delegation of Colombia introduced its Government's proposal for development of an information system for control of the raw materials, ingredients and precursors used to manufacture controlled medicines (documents CICAD/doc.1084/00 and 1096/00). The Commission decided to ask the Expert Group on Chemicals to examine the issue of the control of pharmaceutical products, and make recommendations thereon to the Commission.

## **II. PROCEEDINGS**

### **A. PARTICIPANTS**

#### **1. MEMBER STATES OF CICAD**

Experts from the following member states participated in this meeting: Argentina, Belize, Brazil, Chile, Colombia, Costa Rica, Ecuador, Guatemala, Jamaica, Mexico, Peru, Dominican Republic, St. Kitts and Nevis, Trinidad and Tobago, United States, Uruguay, and Venezuela. (Directory of Experts, Annex I).

#### **2. INTERNATIONAL ORGANIZATIONS**

The International Narcotics Control Board (INCB) also participated in this meeting.

### **B. SESSIONS AND ORGANIZATION OF THE MEETING**

#### **1. OPENING SESSION**

The opening session took place at 9:30 a.m. on August 13, 2001 in the Padilha Vidal Room in the General Secretariat Building of the OAS. Mr. David Beall, Executive Secretary of CICAD, Mrs. Maria Cristina Chirolla, Director of the National Fund for Narcotics of Colombia and Chairman of the Expert Group and Ambassador Humberto de la Calle, Permanent Representative of Colombia before the OAS, offered opening remarks during the ceremony.

#### **2. WORKING SESSIONS**

The Group of Experts on Chemicals met during five working sessions to analyse the control of pharmaceutical products in accordance with the Calendar of Activities. Doctor Carmen Selva of the INCB presented an overview of the

international framework for the control of pharmaceutical products. Dr. Selva also discussed the elements of a national system that should be in place to control these drugs. Mr. Wayne Michaels of the US Drug Enforcement Administration (DEA) made a presentation of current trends in the diversion and abuse of pharmaceutical products and the emerging role of the Internet in this process.

Each of the participating countries made a presentation on their national system for the control of pharmaceutical products. The Chair of the Expert Group presented a summary of the questionnaires on "The Framework For The Control Of Pharmaceutical Substances at the Hemispheric Level", further to information presented by the countries. According to the work methodology adopted, the Experts divided into two groups to identify the major problems existing at the national and international levels regarding the control of pharmaceutical products. The Plenary reviewed the work of the two groups and formulated conclusions and recommendations that will be presented to the Commission at its next Regular Session.

### **3. CLOSING SESSION**

The Expert Group concluded its work at 12:30 on August 15. The Chair of the Group closed the meeting.

## **III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS**

Although members of the Expert Group agreed that there is a growing problem of abuse and diversion of controlled pharmaceuticals, they acknowledged that the countries do not have sufficient information to enable them to assess the true scope of the problem. They also recognized that systems for regulation, control, and prevention that enable this phenomenon to be addressed must be developed at national and hemispheric levels.

Taking the questionnaires, the national presentations and discussions held in the working groups as starting points, the Experts identified some problems of common concern to the participating countries.

### **PROBLEMS:**

1. Legislation that is inadequate and out of date
2. Inadequate application of existing legislation
3. Deficiencies of national control systems
4. Differences in the application of control systems at the international level
5. Lack of timely and efficient information systems at both the national and international levels

6. Need for training of control officials and health professionals involved in prescribing and dispensing pharmaceutical products
7. Insufficient financial resources to ensure effective control in the areas of law enforcement, health and Customs, among others.

Based on the problems identified, the Experts made a number of recommendations for CICAD and the member states.

### **RECOMMENDATIONS TO CICAD IN ITS THIRTIETH REGULAR SESSION:**

1. To create, within the CICAD framework, an expert group on pharmaceutical products to further the study of the problems of pharmaceutical abuse and diversion and to develop and implement a work plan based on the decisions and mandates defined by the Commission.
2. Once established, the Group of Experts concerning Pharmaceutical Products should develop a reference guide of elements that should be included in a national administrative and regulatory control system for pharmaceutical substances. This reference guide should promote implementation of the provisions of the international Conventions.
3. Once established, the Group of Experts concerning Pharmaceutical Products should develop a plan of action to address the deficiencies and problems identified in the control systems in place in the countries to ensure the effective implementation of the provisions on international trade of the international conventions on drugs. To the extent possible, the information provided by countries to the Group of Experts as well as the results of the Multilateral Evaluation Mechanism (MEM) should be considered.
4. Once established, the Group of Experts concerning Pharmaceutical Products should prepare a reference guide for health professionals concerning their role in the prevention and the detection of abuse of these drugs and their diversion to illicit channels.
5. Once established, the Group of Experts concerning Pharmaceutical Products should examine existing automated information systems for the control of pharmaceuticals such as the National Data System (NDS) developed by the United Nations and the Chemical Control Software developed by Peru and made available through CICAD and make recommendations to the Commission on which system is best suited for countries to consider as a common or standard system for the Hemisphere.
6. Once established, in light of the reference guide developed pursuant to Recommendation 2 and the plan of action developed pursuant to Recommendation 3, the Group of Experts concerning Pharmaceutical Products should consider the development of model regulations on pharmaceuticals,

which include the provisions contained in the international conventions on drug control and trends in the phenomenon. Among other things, such regulations might include provisions on transport, smuggling, lists of substances, sale by means of the Internet, drug surveillance, licensing, permits, ports of entry/import and exit/export, advertising, statistics and trends, research and the design of minimum standards for elements of a prescription.

7. Once established, the Group of Experts on Pharmaceutical Products should collaborate with the Multilateral Evaluation Mechanism (MEM), as requested.
8. To request the Executive Secretariat to publish on the CICAD web page:
  - A list of pharmaceutical products controlled by countries in addition to those included in the international Conventions and the nature of the controls that are applied
  - The authorized ports of entry/import and exit/export
  - A directory of the competent authorities responsible for the control of pharmaceutical products.
9. To request assistance from the Inter-American Observatory on Drugs of CICAD in preparing an assessment of the scope and nature of the abuse of pharmaceutical products and to evaluate its future trends with a view to strengthening regulatory and prevention mechanisms.
10. To request the Group of Experts on Demand Reduction to develop, based on a study of the research into pharmaceutical abuse, prevention programs, including ways to prevent self-medication.

## **RECOMMENDATIONS TO THE COUNTRIES:**

To ensure rational use of controlled pharmaceuticals and prevent their diversion to illicit channels, countries should:

1. Bring legislation up-to-date with respect to, *inter alia*, new types of abuse, marketing via the Internet, and smuggling through the use of international couriers, among others. This updating should take account of the provisions of the model regulations.
2. Update lists of controlled substances to introduce controls for other substances that may be abused and diverted to illicit channels.
3. Strengthen the application of administrative and penal sanctions regarding offences related to the diversion or inappropriate use of pharmaceutical products.

4. To allocate sufficient resource for the proper operation of existing control systems, where possible, establishing a fee structure for licenses and other administrative procedures related to pharmaceutical products.
5. With the support of CICAD, create an integrated national information system that will permit all of the organizations involved in the control of pharmaceutical products to have efficient and timely access to information for decision making purposes. The system should include information concerning the national use of pharmaceutical products, based on epidemiological profiles and consumption data, for use in estimating licit annual needs.
6. Through the national drug commission or other governing body for drug policy, strengthen the inter-agency coordination by police, administrative entities, Customs and health level, among others, in order to overcome the deficiencies in the national control system for pharmaceutical products.
7. With the support of UNDCP, CICAD, PAHO/WHO, train officials of the various entities responsible for the control of pharmaceutical products.

#### **IV. OTHER ISSUES**

Within its discussions the Group of Experts expressed its concern over the increasing problem of the illicit manufacture, distribution and consumption of synthetic drugs and other psychotropic substances. The Group submits that this issue requires greater and more sustained examination and consideration by groups of experts of the Commission.