ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

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FORTY SECOND REGULAR SESSION
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Santa Marta, Colombia

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FINAL REPORT

GROUP OF EXPERTS ON PHARMACEUTICAL PRODUCTS

September 19 – 20, 2007
Mexico City, Mexico

ORGANIZATION OF AMERICAN STATES

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GROUP OF EXPERTS ON
PHARMACEUTICAL PRODUCTS
September 19-20, 2007
Mexico City, Mexico

OEA/Ser.L/XIV.4
CICAD/doc.3/07
October 10, 2007
Original: English

FINAL REPORT

(Preliminary Version)

I. BACKGROUND

II. PROCEEDINGS

A. PARTICIPANTS

MEMBER STATES OF CICAD

Fifty-eight experts from the following 20 member states participated in this meeting: Antigua and Barbuda, Argentina, Bahamas, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Jamaica, Mexico, Panama, Peru, Suriname, Trinidad and Tobago, United States, and Venezuela.

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

The opening session for the meeting of this Group of Experts took place in the José María Morelos y Pavón room of the Ministry of Foreign Affairs Building in Mexico City on September 19, 2007. Dr. Eduardo Jaramillo, of the Health Ministry welcomed the participants to the meeting and offered some preliminary remarks.

2. WORKING SESSIONS

A. Presentations

The Group of Experts on Pharmaceutical Products met in four working sessions during which the following presentations were delivered:

Counterfeit medicines trade (Brazil)

- Mr. Klebber Pessoa of the Health Ministry of Brazil delivered a video presentation to the Group which showed the different methods and techniques employed in the illicit production of counterfeit drugs. Mr. Pessoa went on to highlight the growing problem of this illicit trade in Brazil and the region.

Counterfeit drugs monitoring and control (Bahamas)

- Mr. Marvin Smith of the Health Ministry of the Bahamas presented the guide for health professionals concerning counterfeit drugs, which highlights the magnitude of the problem, describes what practical steps the regulatory authorities can take to counter this problem and suggests ways to reduce the production and distribution of such falsified drugs. The Guide also includes several annexes with various suggested formats such as Checklists for Procurement Entities, Drug Regulatory Authorities, Reporting Procedures for Health Professionals, among others. The delegations of Argentina, Bolivia, Brazil, Canada, Colombia, Costa Rica, Chile, Dominican Republic, Ecuador, Mexico, Panama, and Peru commented on their respective situations and experiences with this problem and offered ideas on how to improve the Guide. After considering the document, the Group decided to submit it to a sub-group for further review and analysis.

Investigation of the diversion and distribution of Ketamine (Dominican Republic)

- Mrs. Arelis Cruzado of the National Drug Commission of the Dominican Republic delivered a presentation on an investigation that the National Police had conducted regarding the illicit trafficking Ketamine. This case involved a group that had established an operation involving a number of different businesses around the country. Through this network, the group had been able to successfully divert and sell the Ketamine. The presentation described the operation and investigation that finally ended the illegal activities of this group.

Mrs. Cruzado underlined the complexity of the investigation and the critical role that inter-institutional cooperation among many agencies inside the Dominican Republic played in the dismantling of this organization and the successful conclusion of the case.

Ephedrine and Pseudoephedrine control (Mexico)

- Mr. Víctor Manuel Luna of Mexico presented the Guide for the Rational Use and Control of Products Containing Ephedrine and Pseudoephedrine, which describes and recommends a regulatory strategy for precursors of this type based on five basic guidelines: strengthening the law to control the sale and use of these substances; implementing policies to protect against health risks; preventing diversion through effective inspection mechanisms on the import, export, and distribution, as well as the manufacture and sale of medications containing these precursors; maintaining a close relationship with the pharmaceutical industry; and ensuring that the legal supply of pharmaceutical products containing these substances coincides with the real needs according with the epidemiological studies. The delegations of Bahamas, Brazil, Canada, Colombia, Costa Rica, Peru, and the United States put forth a number of changes and additions to make the Guide more “functional” and the delegation of Mexico agreed to incorporate those suggestions and submit a revised version of the Guide to the Secretariat for its review and posting on the OAS web page.

Diversion investigation training (United States)

- Mrs. Lena Watkins of the Justice Department of the United States presented the Training Program for Diversion Investigation of Pharmaceutical Products, which is a model curriculum for countries to consider in their efforts to enhance the investigative capabilities of their personnel and counter the illicit diversion of such products. The presentation centered around general and administrative procedures, inspections and investigations in general, legislative and regulatory schemes, investigation techniques of business operations (manufacturing, distribution, retail), and practical exercises, including field trips and staged visits. The training curriculum also covers drug pharmacology, identification of controlled substances, pharmaceutical intelligence on tracking the most commonly abused controlled substances, and illicit internet pharmacy investigation. The delegations of Bahamas, Brazil, Costa Rica, Mexico and Panama requested an opportunity to further enhance and improve the document based on their experiences. Therefore, the Group decided to submit the matter to a sub-group for further review and completion.

B. Working Groups

Guide on Counterfeit drugs investigations and control

After giving preliminary consideration to this Guide in the plenary, participants in this working group led by the delegation of the Bahamas, decided to make two documents out of the Guide - taking into account the length and nature of the document. The first document would be for “internal” use between the countries, as an operational tool to conduct international investigations and the sharing of intelligence information, which would include country synopsizes on their respective situations. This project will be coordinated by the delegation of the Bahamas, contacting other group members via the internet with emphasis on operational confidentiality. The second document will be an abbreviated version of the original based on the comments and suggestions received, and will be revised as such and finalized by the delegation of the Bahamas for presentation at the next meeting of the Group.

Pharmaceutical diversion investigations training

During the last meeting of this Group, this issue had been the subject of considerable discussion. Based on that discussion, the delegation of the United States agreed to prepare a guide related to diversion investigations. The working group was led by the delegation of the United States, which presented the document entitled “Diversion Investigation Training Curriculum” for further revision and completion. During the course of an active exchange on the issue, participants offered comments and suggestions to enrich the draft guide. The finalized version of this draft guide is attached and is offered for the consideration and approval of the Commission.

C. Other issues

In addition to the foregoing, the Group identified the emerging problem of the illicit trafficking and use of veterinarian products, with especial emphasis on Ketamine, as a key issue of concern related to the control of pharmaceutical products to be included in the agenda of the next meeting of the Group.

3. PLAN OF ACTION

Further to the discussions in plenary and in the working groups, the Group of experts has prepared the following plan of action from which the assigned products will be presented when the Group next meets:

Guide for health professionals concerning counterfeit drugs (Bahamas)

4. CLOSING SESSION

The Group of Experts concluded its work at 17:00 on September 20. Dr. Jaramillo thanked the members of the Group for their important contributions to the success of the meeting. He further stressed that the diversion of pharmaceutical products impacts all member states, underlining the need for increased international cooperation by all to deal with this problem.

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS FORTY-SECOND REGULAR SESSION:

The Group of Experts on Pharmaceutical Products recommends that the Commission:

1. Consider and accept the guide or documents and direct the Executive Secretariat to post them to the CICAD web page:

    - **“Diversion Investigation Training Curriculum”**

2. Consider and accept the plan of action proposed by the Group of Experts and direct that the Group meets in 2008 to consider the issues in the plan as well as other new trends or threats identified in the area of control of pharmaceutical products.

ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

MEETING OF THE GROUP OF EXPERTS
CONCERNING PHARMACEUTICAL PRODUCTS
September 19-21, 2007
Mexico City, Mexico

SCHEDULE OF ACTIVITIES

Wednesday, September 21

13h00 – 14h00 **Registration**

14h00 – 14h30 **Introduction and Review**

- **Background**
- **Objectives and CICAD Commission expectations**
- **Schedule of work**
- **Proposed work methodology**
- **Status report on Recommendations**
- **Other issues**

14h30 – 15h00 **Roundtable introductions and identification of issues of concern**

15h00 – 15h15 **Break**

15h15 – 16h00 **Guide for health professionals concerning counterfeit drugs (Bahamas / Brazil)**

16h00 – 16h45 **Guide for the rational use and control (administrative/regulatory) of products containing ephedrine or pseudoephedrine (including natural products) (Colombia / Mexico)**

16h45 – 17h40 **Training Curriculum in the Control of Pharmaceutical Products (United States)**

Thursday, September 22

09h00 – 09h30 **Presentation by Mexico**

09h30 – 12h30 **Discussion by Working Group**

12h30 – 14h00 **Lunch**

14h00 – 17h00 **Working group discussions (con't)**

Friday, September 23

09h00 – 09h30 **Presentation by Mexico**

09h30 – 10h45 **Working Group Presentations**

10h45 – 11h00 **Break**

11h00 – 12h30 **Conclusions, issues, commitments and recommendations for action by the Expert Group**
Working group discussions (con't)

12:30 – 13h00 **Closing**

13h00 – 14h30 **Lunch**

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DIVERSION INVESTIGATION TRAINING

DIVERSION INVESTIGATION TRAINING

I. General and Administrative Matters

A. Administrative Overview

Overview of the government office(s) responsible for pharmaceutical and chemical investigations (*1 Hour)*

B. Investigatory Tools

1. Databases, Applications and Other Research Tools

a. Computer / Database Overview

Training on how to navigate within the regulatory office computer / database system(s) to obtain information to support investigations, including how to query information in the history file and master records maintained by the regulatory agency; overview on updating registrant records (*6 Hours)*

b. Controlled Substances Tracking Database

Instruction about the system used to track the flow of controlled substances∗ from manufacturer through distributor to pharmacy
(*6 Hours)*

c. Chemicals Database

Introduction to the chemicals database and instruction on how to navigate within the system to obtain import and export data concerning handlers of regulated chemicals (*2 Hours)*

d. Other Government and Privately Owned Databases

∗ The phrase "controlled substances" refers to narcotic drugs and psychotropic substances addressed by the UN Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, and by the UN Convention on Psychotropic Substances, 1971, and to any other drugs and substances subsequently placed under international control in accordance with the provisions of those conventions.

Helpful databases maintained by other government offices and private entities to which investigators have access (*4 Hours)*

e. Internet Search

Use of the Internet in furtherance of domestic and international trafficking investigations *(4 Hours)*

f. EXCEL

Fundamentals of the EXCEL spread sheet application *(4 Hours)*

2. Inspections and Investigations – General

a. Administrative Inspections in General

The administrative inspection process (*4 Hours)*

b. Regulatory Actions

Regulatory actions that may be taken against a registrant who has violated the national laws or regulations (*2 Hours)*

c. Report Writing Principles

Policies regarding the preparation of Reports of Investigation; training on how to write Reports of Investigation concerning Pre-Registration Investigations, In-Depth/Cyclic Investigations and Complaint Investigations involving registrants *(4 Hours)*

d. Proceedings against Registrants

Reasons to initiate proceedings to deny an application for registration to handle controlled substances or regulated chemicals or to revoke a registration (*4 Hours)*

II. Legislative and Regulatory Scheme

A. National Controlled Substances Laws and Regulations

Provisions of the national controlled substances law that investigators can expect to use against persons who divert pharmaceutical controlled substances and regulated chemicals; introduction to the compendium of national controlled substances regulations and information on how to use it as a reference (*12 Hours)*

B. The Quota System

Production quotas for controlled substances (and regulated chemicals, if applicable), as outlined by the pertinent national laws and regulations
(*2 Hours)*

C. Requirements for Registrants

1. Security

Required physical security controls for controlled substances handled by registrants as outlined in the applicable national laws and regulations
(*6 Hours)*

2. Inventories, Records, and Reports

In-depth instruction on the records and inventories required to be kept, and reports to be made, by all registrants (*4 Hours)*

3. Chemical Records and Reports

Records and reports required of registrants who are authorized to handle regulated chemicals (*2 Hours)*

4. Import/Export

Regulatory requirements pertaining to the import, export and transshipment of controlled substances and regulated chemicals
(*2 Hours)*

III. Drug and Chemical Overview

A. Controlled Substances

1. **Drug Pharmacology and Identification**

Psychological and physical effects of scheduled controlled substances and information about identifying controlled substances (*8 Hours)*

2. Pharmaceutical Trends

Pharmaceutical intelligence pertaining to the most commonly abused controlled substances in the country (*2 Hours)*

B. Chemicals

1. Diverted Chemicals

Chemicals used in the illicit manufacture of controlled substances, including precursor and essential chemicals that are manufactured in, imported to, or transit the national territory, or which are smuggled into or through the country *(3 Hours)*

2. Chemical Control Program

An overview of the Chemical Control Program, including domestic and import/export aspects *(2 Hours)*

3. Methods of Diversion

Common methods of diversion by individuals and businesses registered to handle controlled substances (*4 Hours)*

IV. Procedures and Policies – Pharmaceuticals

A. Registration

Procedures governing the registration of manufacturers, distributors, dispensers, importers and exporters of controlled substances pursuant to the national drug law and regulations (*4 Hours)*

B. Pre-Registration Investigation

The legal authority for conducting pre-registration investigations; the purpose of conducting such investigations; reasons for the potential denial of the registration; practical methods and investigative techniques which can be utilized in conducting this type of investigation; identification of information needed to write the Report of Investigation to document the investigation
(*4 Hours)*

C. Annual Investigation

Statutory authority for conducting such investigations; purpose of the investigation; reasons for the potential denial of registration; practical methods and investigative techniques to use in conducting this type of investigation; identification of information needed to write the Report of Investigation to document the investigation
(2 *Hours)*

V. Procedures and Policies – Chemicals

A. Registration

Procedures governing the registration of regulated chemicals handlers pursuant to the national drug law and regulations
(2 *Hours)*

B. Chemical Pre-Registration

How to conduct a chemical pre-registration investigation, including the legal authority for conducting such investigations; the purpose of conducting such investigations; reasons for the potential denial of the registration; practical methods and investigative techniques to utilize in conducting this type of investigation; identification of information needed in writing the Report of Investigation to document the investigation
(*2 Hours)*

C. Scheduled Investigations

How to conduct chemical scheduled investigations, including the legal authority for conducting such investigations; the purpose of conducting such investigations; reasons for the potential denial of the registration; practical methods and investigative techniques to utilize in conducting this type of investigation; identification of

information needed in writing the Report of Investigation to document the investigation (2 *Hours)*

VI. Business Operations and Investigation Techniques

A. Manufacturing Operations

The operations of a registered drug manufacturer, including record keeping requirements; types of records generally found; security requirements; completion of computation charts for the raw material, granulation and tableting stages; preparing for management discussion; and reporting the investigation (*17 Hours)*

B. Distributor Operations

The dynamics of how a drug or chemical distributor operates, including record keeping requirements; types of records generally found; security requirements; completion of computation charts for the records required to be maintained by registrants who are operating as distributors; preparing for management discussion; and reporting the investigation (*16 Hours)*

C. Retail Pharmacy Operations

The operations of a registered retail pharmacy, including record keeping requirements; types of records generally found; security requirements; completion of computation charts for the accountability audit; preparing for management discussion; and reporting the investigation (*16 Hours)*

D. Pain Management / Addiction

Characteristics of legitimate and illegitimate prescribing of narcotics for pain management and characteristics of addicts who are illegally seeking narcotics (*4 Hours)*

E. Narcotic Treatment Programs

Regulations and policies concerning Narcotic Treatment Programs (*2 Hours)*

F. Auditing Techniques

Techniques for auditing of persons and/or businesses authorized to handle controlled substances; systems of weights and measures to be used to conduct accountability audits *(4 Hours)*

G. Illicit Internet Pharmacy Investigation

Introduction to and survey of techniques involved in investigating illicit Internet pharmacies, including international aspects of investigations
(*24 Hours)*

H. Domestic Chemical Investigations

Basics of investigating a chemical registrant to determine if it is in compliance with applicable laws and regulations for security, record-keeping, reporting and other requirements *(2 Hours)*

I. International Chemical Investigations

Methods used to obtain information regarding the importing and exporting of regulated chemicals to determine suspicious shipments; procedures relative to chemical programs and operations in an overseas environment, including the investigation of illicit Internet operations (*2 Hours)*

VII. Practical Exercises

Practical exercises, including field trips and staged visits, designed to present real-life scenarios that challenge students with realistic and increasingly complex situations and to reinforce and apply the principles and techniques learned in the classroom. These exercises will afford students the opportunity to tour facilities and ask questions to employees about security and other pertinent questions about the firms' operations.

- Trip to a Pharmaceutical Manufacturer – *5 Hours*
- Trip to a Chemical Manufacturer – *5 Hours*
- Trip to a Distributor Operation – *4 Hours*
- Trip to a Retail Pharmacy/ Survey – *4 Hours*
- Pharmacy Audit – *4 Hours*
- Authorized Search of a Doctor's Office – *4 Hours*
- Conducting a Pre-Registration Investigation – *4 Hours*

- Conducting a Distributor Audit – *4 Hours*
- Conducting a Manufacturer Audit – *8 Hours*
- Undercover Investigation at a Doctor's Office – *4 Hours*

**Total Number of Instructional Hours* - __237__