ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

THIRTY SECOND REGULAR SESSION
2-5 December, 2002
Mexico City, Mexico D.F.

OEA/Ser.L/XIV.2.32
CICAD/doc.1204/02
27 November 2002
Original: Spanish

FINAL REPORT
OF THE EXPERTS GROUP
CONCERNING PHARMACEUTICAL PRODUCTS

(22-24 October, 2002, Washington, D.C.)

EXPERT GROUP CONCERNING
PHARMACEUTICAL PRODUCTS
October 22-24, 2002
Washington, D.C.

OEA/Ser.L/XIV.4
CICAD/doc.9/02
27 November 2002
Original: Spanish

FINAL REPORT

(Preliminary Version)

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.

CICAD's Expert Group on Chemicals met from August 13-15, 2001 and recommended the establishment of the Group of Experts concerning Pharmaceutical Products. The Commission adopted the recommendation to create the new Expert Group during the Thirtieth Regular Session of CICAD, celebrated in Caracas, Venezuela in November 2001.

II. PROCEEDINGS

A. PARTICIPANTS

1. MEMBER STATES OF CICAD

Experts from the following member states participated in this meeting: Antigua and Barbuda, Argentina, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Guatemala, Guyana, Mexico, Peru, St. Kitts and Nevis, United States, and Venezuela. (Directory of Experts, Annex VI).

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

The opening session took place at 9:30 a.m. on October 22, 2002 in the Padilha Vidal Room in the General Secretariat Building of the OAS. Mr. David Beall, Executive Secretary of CICAD, Ms. Martha Ballesteros, 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 Pharmaceutical Products met during five working sessions to analyse measures to improve control over diversion and abuse of pharmaceutical products. Mr. Ziggie Malyniwsky presented a diagnostic on the status of pharmaceutical control in the hemisphere. The diagnostic, which was based on

countries' replies to the Multilateral Evaluation Mechanism questionnaires, identified general weaknesses in existing systems and common impediments to implementing pharmaceutical controls.

The Expert Group on Pharmaceutical Products then reviewed the report prepared by the Expert Group on Chemicals Substances, during its meeting at CICAD headquarters from August 13-15, 2001. They agreed that the problems identified and the proposed Recommendations in the mentioned report are still valid and as such the Group assumed them as a point of reference for this first meeting. These problems include:

1. Legislation that is inadequate and out of date
2. Inadequate application of existing legislation and deficiencies of national control systems
3. Incompatibility in the application of control systems at the international level
4. Lack of timely and efficient information systems at both the national and international levels
5. Need for training of control officials and health professionals involved in prescribing and dispensing pharmaceutical products
6. Insufficient financial resources to ensure effective control in the areas of law enforcement, health and Customs, among others.

In reviewing the recommendations put forth by the Expert Group on Chemical Substances in their report, the Expert Group on Pharmaceutical Products agreed that these recommendations were relevant since they constituted an appropriate means for addressing the above-mentioned problems. As such, they adopted these recommendations and propose to address them in the work plan or plan of action. (See Annex I – Final Report of the Expert Group on Chemical Substances.)

During the plenary session that followed the Experts focused on the following three activities:

- review of the draft reference guide of elements of a system for the control of pharmaceutical products, prepared by the Chair
- Identification of problems and issues
- Development of a plan of action or work plan

Recommendation number two, originally proposed by the Expert Group on Chemical Substances, is concerned with the development of a guide of elements that should be included in a national administrative and regulatory control system for pharmaceutical substances. In fulfillment of this recommendation, the Chair presented a draft for the consideration of the Group. The Experts agreed that it was a well-drafted and comprehensive document that would serve as an excellent point of departure for further discussion and amplification.

Using this draft and an outline format that was developed during the meeting, the Group began its work on the guide. Limited time made it impossible to complete the work. As such, the Group agreed that the experts from Mexico and the United States would coordinate the further development of the document with input from the other Experts for finalization at second meeting proposed for the first quarter of 2003.

The Chair also tabled a guide for health professionals regarding their roles in the identification of diversion and abuse of pharmaceutical products. The already full agenda did not allow for any discussion of this draft guide. The Group agreed that during the time between the conclusion of this meeting and the proposed second meeting, the Experts from Venezuela and Chile would coordinate the further development of this guide with input from the rest of the group (see Annex V).

The Group also recognized the important role that the pharmaceutical industry and other related parts of the private sector could play in the control of pharmaceutical products. Effective controls and cooperation between all parties could also be enhanced through a better understanding of needs, limitations and restrictions faced by all parties. The Group therefore proposed the development of a guide for industry that would be coordinated by experts from Colombia and Brazil (see Annex V).

Upon analyzing the current situation in the region, the Group acknowledged the differences in control over pharmaceutical products that exist from country to country. This includes the products that are controlled. The international conventions define a minimum level of control including what substances must be covered by these controls. In some instances, due to particular circumstances, countries include other pharmaceutical products that are not listed in the conventions. As an aide to member states, the Group recommended that Executive Secretariat prepare a section in the CICAD web page listing these additional products (see Annex V). The Group also proposed that the Executive Secretary post the list of authorized ports through which pharmaceutical products could enter or leave a country.

The Group of Experts asked the Executive Secretariat to transmit this recommendation to all the Member States and ask the countries to send the list of additional substances and authorized ports no later than November 30, 2002.

The Group developed a Work Plan for completing the foregoing activities that can be found in Annex V.

In addition to the foregoing, the Group identified a series of problems and issues that it should address. There was insufficient time during the current meeting to discuss these issues or to develop a work plan that would define how the Group proposed to address them. The preliminary Plan of Action defining the issues is contained in Annex IV. The Plan contains actions to be pursued by the Group and by the Executive Secretariat as well. The Group proposed that it could undertake a further elaboration of the issues and the development of a work plan during a meeting proposed for the first quarter of 2003.

3. CLOSING SESSION

The Expert Group concluded its work at 1:30 on October 24. Mr. David Beall and Ms. Martha Ballesteros, the Chair of the Group, closed the meeting.

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

Members of the Expert Group agreed that there is a growing problem of abuse and diversion of controlled pharmaceuticals. 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.

Based on the discussions that took place during the plenary sessions, the Experts formulated the following recommendations:

1. Proceed with the implementation of the work plan defined in Annex V and the activities proposed.

2. Convene a second meeting of the Group to take place in the first quarter of 2003 to:

    - finalize the activities and documents proposed by the attached work plan

    - define a plan of action to address the problems and recommendations proposed by the Group of Experts on Chemical Substances as well as other issues that the Group may identify in the future.

Annex I

EXPERT GROUP ON CHEMICALS
(PHARMACEUTICAL PRODUCTS)
August 13 – 15, 2001
Washington, D.C.

OEA/Ser.L/XIV.4
CICAD/doc.6/01 rev.1
4 October 2001
Original: Spanish

FINAL REPORT

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 considerer 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.

Annex II

Outline for the Control of Pharmaceutical Products Containing Narcotics and Psychoactive Substances (with the recommendations of the Chair from October 24, 2002)

Fundamental Principles

- Signatories to International Conventions [1]must implement the controls and fulfill the responsibilities of these agreements
- There is a need to balance control over pharmaceutical products and the prevention of their diversion while ensuring their availability for medical purposes
- National controls need to respond to the unique problems of diversion and abuse identified in each country, with consideration to the context and the constraints that exist
- International cooperation is essential to developing effective strategies for the control of pharmaceutical products
- Effective control of pharmaceutical products depends on the application of a range of activities and measures from legislation and regulations to monitoring and the implementation of corrective actions.
- The final disposal of unusable, expired and confiscated pharmaceutical products and substances must be regulated and carried out in a secure manner that guarantees the protection of the environment and avoids diversion

I. Legislative foundation and regulatory framework

Principles:

- Legislation and regulations must:
  - Provide the authority to regulate the use and distribution of all controlled substances
  - Identify the government components responsible for control and regulation
  - Identify who has the authority to conduct transactions in controlled substances (manufacture, sale, e.g.)
  - Identify what substances are to be controlled and provide the means to amend or add substances as required
  - Create regulatory and criminal offenses (further definition from Canada)
  - Provide for administrative or civil penalties when there are violations of the regulations
  - Provide for criminal or penal sanctions related to illegal activities such as diversion of pharmaceutical products

Measures:

- Promote, inside national legislation, efforts to typify crimes when the above-mentioned pharmaceutical products are used for purposes other than medical or scientific purposes or for the illicit manufacture of synthetic drugs.
- The organization, management or financing, public incitement or induction, participation, harboring, association, accessory after the fact, association, collusion, attempt, facilitation and advice to commit illegal activities in which pharmaceutical products are involved should be considered in the criminal law of each country.
- Provide for civil or administrative penalties, consisting of ***reprimands; fines; confiscation; suspension or cancellation of registration permits and licenses; and temporary or***

[1] (list conventions)

definitive shutdown of the establishment, when any conduct contrary to the good use of pharmaceutical products is apparent.

II. Coordination and the Exchange of Information

Principles:

- effective domestic control depends on competent authority
- the competent authority cannot operate unilaterally but rather must work in collaboration with other national agencies and health professional regulatory authorities
- There should be an ongoing exchange of information between agencies (nationally and internationally) involved in the control of pharmaceutical products.
- There should be an active exchange of information between the national control agencies and the pharmaceutical industry (importers, exporters, manufacturers etc)

Measures:

- Creation of mechanisms and tools whereby companies that produce, manufacture, prepare, transform, destroy, store, import, export, market, distribute, dispense, transport or carry out any other type of transaction can inform rapidly and efficiently the competent authorities about any irregular movements of these pharmaceutical products, as well as any losses or disappearance.
- Promote the exchange of information as a necessary element for studies on the consumption of pharmaceutical products in the hemisphere: the impact of this sector on the economy and the establishment of patterns that show the use of these products to meet the epidemiological needs of the population.
- The companies that produce, manufacture, prepare, transform, destroy, store, import, export, market, distribute or dispense pharmaceutical products should submit reports about each one of these procedures to the central authority in charge of controlling and overseeing them. The periodicity of these reports shall be determined on the basis of the needs of the records required by the central authority to submit reports to the International Narcotics Control Board (INCB).

III. Import/Export

Principles:

- Quantities of pharmaceutical products (raw form or substances) should be consistent with national needs
- Imports and exports should only take place between authorized persons, companies and institutions
- Promote cooperation, nationally and internationally, between competent (coordinating) authorities, police and Customs
- Control measures should apply to all phases of the movement or shipment of pharmaceutical products from the originator, transshipment points (as goods in international transit) to the final destination

Measures:

- establish a mechanism to assess national needs
- all importers and exports should be licensed/registered (Conventions)
- register of companies (automated/manual)
- criteria for licensing/registration (verification of applicant)
- conditions/responsibilities once licensed
- mechanisms for import or export permits
- security requirements/responsibilities
- record requirements

- pre-export notifications
- accountability for transactions
- Determine efficient mechanisms to meet the requirement of ***notice prior*** to export of pharmaceutical products, bearing in mind the provisions of International Conventions on Narcotic Drugs and Psychotropic Substances and against illicit traffic in narcotic drugs.
- Imports by those legally authorized to import will take place within the limits of the total ***Estimates*** requested and authorized by the central authority, bearing in mind the prior study of needs, substantiated by data of an epidemiological nature.
- All the requirements (import licenses) by the customs systems of each country for the import of pharmaceutical products and any special regulatory framework must be met.
- The central authority may request additional requisites for releasing merchandise and shall provide for the procedures deemed necessary to improve the control and supervision of imports.
- The central authority in charge of controlling and overseeing pharmaceutical products should keep an up-to-date record of the establishments that are legally authorized to manage them.
- The export of pharmaceutical products by those who are legally authorized to do so will take place in keeping with international conventions on narcotic drugs and psychotropic substances.
- According to international conventions, if the importing country requires an Export Certificate, the exporter shall request it from the central authority in charge of control and shall attach thereto the corresponding certificate of the importing country.
- Once the export is approved by the government agency in charge of controlling exports, the exporter shall request the central authority for the control of pharmaceutical products to schedule a visit from one of its delegates to witness the weighing and packaging of the products to be exported. An official record of the procedure that was carried out should be drawn up for this proceeding.
- Request the registration and/or authorization of the national central institutions in charge of control and surveillance, so that the interested parties can import/export, manufacture, and distribute pharmaceutical products.

IV. Manufacture

Principles:

- Pharmaceutical products should be prepared under Best Manufacturing Practices
- Manufactures must have in place appropriate records to ensure accountability and avoid diversion
- Manufacturers should be able to distinguish between quantities of pharmaceutical products intended for domestic consumption and those for export
- Standards or requirements should be defined that companies must meet to be licensed to manufacture pharmaceutical products and continue to be licensed

Measures:

- Request the registration and/or authorization of the national central institutions in charge of control and surveillance, so that the interested parties can manufacture and distribute pharmaceutical products**.**
- For the manufacture of drugs by duly authorized companies or laboratories, the raw materials will have to be purchased through the mechanism provided for this purpose by the central authority. Regarding this, they should inform the date and time of the transformation, for the purpose of having the authority accompany the process, thus exercising greater control over the raw materials that are used for the manufacture of pharmaceutical products.
- The destruction or disposal of pharmaceutical products should be undertaken with consideration to appropriate records
- When issuing requirements for licenses, registrations, records, authorizations or other similar, international and national regulations on the control of chemical substances and pharmaceutical

products or the existence of convictions for infringing national laws on the illicit trafficking of narcotic drugs and psychotropic substances must be taken into account and observed.

- For those who manufacture drugs subject to special control, they must at least be required to observe Good Manufacturing Practices, secure Sanitary Registration approval, and a special distinctive feature for the packaging of the pharmaceutical product.
- Establish the use of computerized systems to keep a record of the processes of pharmaceutical products and provide for the mandatory presentation of reports on production, manufacturing, ~~import, export,~~ distribution, storage, dispensing, transformation, destruction and use, complying with national standards for these purposes and also in line with the reports that each State has to submit to INCB.
- All the procedures should be set forth in the respective registry books or similar publications.
- The central authority in charge of controlling and overseeing pharmaceutical products should keep an up-to-date record of the establishments that are legally authorized to manage them.
- Set forth the requisites that national industry has to meet to produce controlled substances and to manufacture pharmaceutical products.
- Any establishment legally authorized to manufacture, distribute, manage or sell pharmaceutical products should have safe and suitable means of storage, in keeping with Good Storage Practices.

V. Distribution

Principles:

- ~~Distribution~~ The sale of pharmaceutical products should be regulated through all the stages of the process from the authorized distributor to the final user
- Exercise control over pharmaceutical products in transit and corresponding notification to the point of destination

Measures:

- The distribution of pharmaceutical products by those legally authorized to sell them shall be made directly to the interested party and only upon presentation of a physician's prescription, and their sale through the mail, Internet or any other similar means shall be forbidden.
- Any legally authorized pharmaceutical establishment, in order to sell controlled drugs, shall keep a record of the movements of these drugs and shall report them to the central authority.
- Any establishment legally authorized to manufacture, distribute, manage or sell pharmaceutical products should have safe and suitable means of storage, in keeping with Good Storage Practices.
- In case of theft or loss of pharmaceutical products, the respective report should be made to the competent authority, and the central authority in charge of controlling these products should also be informed of the above.
- The central authority in charge of controlling and overseeing pharmaceutical products should keep an up-to-date record of the establishments that are legally authorized to manage them.
- Formulate requisites for dispensing in pharmacies and distributing pharmaceutical products by retail and wholesale distributors.
- The distribution of pharmaceutical products by those legally authorized to sell them to pharmacies, drug stores, hospitals, etc., will be carried out directly with the interested party and the competent authority will be directly informed. ~~shall be made directly to the interested party and only upon presentation of a physician's prescription, and their sale through the mail, Internet or any other similar means shall be forbidden~~.

VI. Monitoring/Investigation

Principles:

Measures:

- Establish a surveillance system consisting of monitoring the treatment of patients who use controlled drugs
- Identify the chemical substances subject to special control and the pharmaceutical products containing them, mentioned by the Guide, with their names and respective numerical codes appearing in the Harmonized Commodity Description and Coding System of the World Customs Organization (WCO).
- Promote the establishment of requirements for those who produce, manufacture, prepare, transform, destroy, store, import, export, market, distribute, dispense, transport and carry out any other type of transaction with pharmaceutical products consisting of: **licenses, registrations, records, authorizations** or others, without detriment to other authorizations from the respective foreign trade system.
- Create prevention and education campaigns that promote awareness about the rational use of pharmaceutical products using mass media and teaching resources.
- Establish regulatory tools promoting the sustainability of programs for the treatment, rehabilitation, and social reinsertion of drug addicts.

VII. Corrective actions/Sanctions

Principles:

Measures:

VIII. Prescribing and Dispensing

Principles:

Measures:

- Establish responsibilities and set minimum requirements for prescribing controlled pharmaceutical products for physicians, dentists, and veterinarians.
- Establish a surveillance system consisting of monitoring the treatment of patients who use controlled drugs
- Establish norms authorizing patients to use controlled drugs when they have to travel or settle temporarily in another country, in keeping with the recommendations that have been issued for this purpose by the United Nations Commission on Narcotic Drugs (CND).
- Define procedures for the final disposal of expired and confiscated pharmaceutical products, so as to avoid harm to the environment as a result of their destruction.
- Pharmaceutical products will only be delivered upon presentation of the original medical formula or prescription.
- It should contain at least the following information:
    - Name of the physician with his/her respective data.
    - Date of issuance.
    - Identification of the patient, address and telephone.
    - Name of the drug, pharmaceutical form, total amount, and daily dose.
    - Signature of the treating physician and Physician Registration number of Professional Affiliation Card
- Determine the total amount in the prescription of controlled drugs, bearing in mind, among other things, the narcotic category of these drugs.

- Forbid duly authorized pharmaceutical establishments to dispense formulas when they have a date of expiry that is beyond the one established by the central control authority.
- Forbid the distribution of medical samples of drugs subject to special control, for marketing strategy purposes.

Annex III

EXPERT GROUP CONCERNING
PHARMACEUTICAL PRODUCTS
October 22-24, 2002
Washington, D.C.

OEA/Ser.L/XIV.4
CICAD/doc.7/02
18 October 2002
Original: Spanish

REFERENCE MANUAL

ON THE ROLE OF HEALTHCARE PROFESSIONALS

IN THE PREVENTION AND DETECTION OF THE

MISUSE AND DIVERSION OF PHARMACEUTICALS

INTO ILLICIT CHANNELS

REFERENCE MANUAL ON THE ROLE OF HEALTHCARE PROFESSIONALS IN THE PREVENTION AND DETECTION OF THE MISUSE AND DIVERSION OF PHARMACEUTICALS INTO ILLICIT CHANNELS[2]

This Reference Manual addresses the need of countries to ensure rational use of medicines and pharmaceuticals as a public health objective of the utmost importance. This involves identifying procedural weaknesses that stand in the way of preventing pharmaceutical misuse. Healthcare professionals play a crucial role in achieving this objective.

A lack of vigilance by the medical community in prescribing pharmaceuticals or medicines can lead to misconduct, vague instructions, scant information on side effects and writing prescriptions for long periods of time. Healthcare professionals must assess and overcome these issues, to improve methods of controlling pharmaceutical use.

The points below are intended as guidelines addressing potential weaknesses for healthcare professionals in the prevention and detection of pharmaceutical misuse.

Physician-Patient Relationship and Drug Treatment

- The patient must be told how long to use a medicine for treatment, and not to take the medicine except under a physician's care.

- The patient must be supervised while using the medicine, so its effects can be evaluated and described in detail in the patient's medical history.

- The patient must be told that medicines can have side effects and that any change in treatment must be evaluated by the physician.

- It is important to tell the patient about the effects of pharmacological interactions with other medicines he or she may be taking.

- The physician should monitor use of the medicine, checking the amount taken by the patient over how long, so the right prescription can be calculated.

- The physician should prescribe the smallest amount of medicine necessary to properly treat the pathology, considering the accessibility of pharmacies and how easy or difficult it is for the patient to see a physician again.

- The medicine with the least potential for abuse should always be prescribed.

[2] The pharmaceuticals and medicines discussed in the Reference Manual are those classified as subject to Special Controls or International Control.

Variables Affecting Quality in Prescribing Medicines

In order to prevent and better control misuse of medicines, the treating physician must take the following variables into account:

- Diagnosis that factors in the technical aspect of the medical practice and the interpersonal aspect of the physician-patient relationship.

- Principal indication of the medicine to be prescribed.

- Proper use of the medicine.

- Prescribed medicine corresponds to the use for which it was prescribed.

- Proper manner of administering the medicine.

- Proper daily dose.

- Proper frequency/day.

- Total time for which the medicines are prescribed.

- Contraindications.

- Drug-to-drug interactions.

- Prescriptions for medicines must include at least the following: information on the treating physician, date written, patient's identity, name of the medicine, pharmaceutical form, total quantity and daily doses, physician's signature and license number.

Education and Training for Healthcare Professionals and Patients

- Educate physicians through information campaigns on form of medication and duration of treatment with an emphasis on informing patients and their families.

- Design and execute of studies to explain the risks of taking these medicines.

- Conduct studies and make information available on the recommended schedules for using certain medicines.

- Put out relevant information on what dose frequency will not produce undesired effects for patients undergoing treatment.

- Educate the general public on the dangers of taking medicine when not under a physician's care.

Annex IV

Preliminary Action Plan

(To be redefined during the next meeting of the Group of Experts on Pharmaceutical Products)

Problem 1: Legislation / Regulations that are inadequate or out of date

Activity:	Proposed by:	Action by:
Develop and conduct regional / sub regional seminars	Mexico	Group/CICAD
Create programs for the exchange of personnel	Mexico	Group/CICAD
Compile legislation / regulations from Member States	Mexico	CICAD
Determine the need to develop model regulations	Mexico / Canada	Group
Establish, within CICAD's framework, a team of experts to provide technical assistance on the development of legislation and regulations, at the invitation of member states	United States	CICAD
Develop training seminars for judges and prosecutors concerned with the problem of drugs regarding the diversion of psychotropic medicaments	Venezuela	CICAD

Problem 2: Deficiencies in national control systems and poor application of regulations.

Activity:	Proposed by:	Action by:
Organize a forum on impediments in the application of regulations and control systems and possible solutions	Group	Group/CICAD
Create a directory of operational points of contact for pharmaceutical control (telephone, fax, email)	Mexico	CICAD
Develop a guide for national control systems	Group	Group
Develop a guide for the pharmaceutical industry	Group	Group

Problem 3: Incompatibility of control systems between different countries

Activity:	Proposed by:	Action by:
Publication on the CICAD web page a list of pharmaceutical products controlled by member states not included in the international conventions	Group	CICAD
Publication on the CICAD web page a list of authorized ports in Member states for the entry / import and exit / export of pharmaceutical products	Group	CICAD

Problem 4: Lack of timely and efficient information systems

Activity:	Proposed by:	Action by:
Examine existing automated systems, such as NDS and other national systems developed by member states like Peru and Chile, and make recommendations	Chile	Group

Problem 5: Training need for officials and health professionals

Activity:	Proposed by:	Action by:
Develop a reference manual for health professionals	Group	Group
Define the elements of a training program for inspectors and other administrative control officials		

Annex V

Work Plan Established by the Group of Experts on Pharmaceutical Products

1. Outline for the Control of Pharmaceutical Products Containing Narcotics and Psychoactive Substances
   - This activity will be coordinated by Mexico and the United States
   - Comments and suggestions for the outline should be received from Member states by December 30, 2002.
   - A draft of the outline should be completed by January 30, 2003.

2. Reference manual on the role of heath care professionals in the prevention and detection of abuse of pharmaceutical products and their diversion toward illicit channels
   - This activity will be coordinated by Venezuela and Chile, using the draft manual prepared by Colombia as a reference point
   - Comments and suggestions for the reference manual for health professionals should be received from Member states by December 30, 2002.
   - A draft of the reference manual should be completed by January 30, 2003.

3. Guide for Industry
   - This activity will be coordinated by Colombia and Brazil
   - Comments and suggestions for the guide for industry should be received from Member states by December 30, 2002.
   - A draft of the guide for industry should be completed by January 30, 2003.

4. Identification of substances to be posted to CICAD's web site
   - Lists of substances controlled by countries but that are not subject to international controls should be submitted to the Executive Secretariat by November 30, 2002.
   - Lists of authorized ports of import / export should be submitted to the Executive Secretariat by November 30.

5. Development of a Plan of Action
   - The preliminary Plan of Action for the Control of Pharmaceutical Products, developed by the Experts during the first meeting of the Group, will be further defined during the next meeting of the Group.
   - The next meeting of the Group is proposed for late March 2003. The breakdown of the work to be completed is expected to be as follows:
     - Review of elements for national control systems: 1 day
     - Enhancement of Plan of Action: 1 day
     - Review of guidelines for industry and health professionals: 1 day

Annex VI

EXPERT GROUP CONCERNING
PHARMACEUTICAL PRODUCTS
October 22-24, 2002
2002Washington, D.C.

OEA/Ser.L/XIV.4
CICAD/doc.8/02
24 October
Original: Textual

LISTA DE PARTICIPANTES / LIST OF PARTICIPANTS

(Versión Provisional / Provisional Version)

ESTADOS MIEMBROS DE LA CICAD / CICAD MEMBER STATES

ANTIGUA AND BARBUDA

Starret D. Greene
Permanent Misión of Antigua and Barbuda to the OAS
Telefono/Telephone: (202) 362-5122
Fax : (202) 362-5225
E-mail : staranu.aol.com

ARGENTINA

Silvia Merega
Ministro de Embajada, Misión Permanente de Argentina ante la OEA
Telefono/Telephone: (202)
Fax : (202) 387-4142
E-mail : argentina@oas.org

Martín Gómez Bustillo
Representante Alterno de Argentina ante la OEA
Telefono/Telephone:
Fax :
E-mail :

BAHAMAS, Commonwealth of the

BARBADOS

BELIZE

Sharon Sanchez Anderson
Chief Pharmacist, Ministry of Health
Telefono/Telephone: (501) 2277252 (501) 2245767
Fax : (501) 2277252 (501) 2277255
E-mail : sharsanch@hotmail.com

BOLIVIA

Javier Vizcarra
1 st. secretary
Telefono/Telephone: (202) 785-0218
Fax :
E-mail : javierviscarra@man.com

BRASIL

Rosângela Furtado Dias
Agência Nacional de Vigilância Sanitária (ANVISA)
Telefono/Telephone: 5502161-448-1180
Fax : 5502161-448-1228
E-mail : med.controlados@anvisa.gov.br

Paulo Ribero
Secretario
Telefono/Telephone: (202) 333-4224

Fax : (202) 333-6610
E-mail : PAULO@DELBRASUPA.ORG

CANADA

Cynthia Sunstrum
Manager, Policy and Regulation Affairs Division
Office of Controlled Substances
Telefono/Telephone: (613) 946-0125
Fax : (613) 946-4224
E-mail : CYNTHIA_SUNSTRUM@HC-SC.GC.CA

CHILE

Esteban Tomic
Embajador, Representante Permanente de Chile ante la OEA
Telefono/Telephone:
Fax :
E-mail :

Mariano Montenegro Corona
Medico Psiquiatra
Encargado de Salud del Área Técnica de Tratamiento y Rehabilitación
Consejo Nacional para el Control de Estupefacientes (CONACE)
Telefono/Telephone: 5100829 - 5100800
Fax :
E-mail : mmontenegro@conace.gov.cl

Rodrigo Hume
Representante Alterno de Chile ante la OEA
Telefono/Telephone: (202) 8875475
Fax : (202)
E-mail : rhume@chile.oas.org.

Gonzalo Ramos Núñez
Encargado unidad de Farmacia, Ministerio de Salud
Telefono/Telephone: 630-0486
Fax : 638-2238
E-mail : gramos@minsal.cl

COLOMBIA

Humberto de la Calle
Embajador, Representante Permanente ante la OEA
Telefono/Telephone: (202) 332-8003
Fax :
E-mail

Martha Ballesteros
Directora del Fondo Nacional de Estupefacientes
Telefono/Telephone: 333-1088
Fax :
E-mail : mballesteros@minsalud.gov.co

Jorge Mario Echeverri
Representante Alterno de Colombia ante la OEA
Telefono/Telephone: 332-8002
Fax :
E-mail : jmecheverry@yahoo.com

Isaura Duarte,
Represente Alterno de Colombia ante la OEA
Telefono/Telephone: (202) 234-9701
Fax :
E-mail : iduarte@qwest.net

Samira Silva Younes,
Tercer Secretario, Ministerio de Relaciones Exteriores
Telefono/Telephone: 5-628229/35 Ext. 2192/93
Fax : 5-628815
E-mail : dpmasesor01@minrelext.gov.co

Jorge Hernan Valencia
Agregado de Policia de Colombia en Washington
Telefono/Telephone: (202) 483-1740 Phone Home: (703) 385-9835
Fax : (202) 483-1740
E-mail : policeatta@aol.com

COSTA RICA

Emilia Ramírez
Dirección de Registros y Controles , Ministerio de Salud
Telefono/Telephone: (506) 256-1035
Fax : (506) 256-1035
E-mail : emiralf@yahoo.com

Flory Saborío
Control Area de Drogas Estupefacientes
Dirección de Registros y Controles, Ministerio de Salud
Telefono/Telephone: 221-6058
Fax : 222-1420
E-mail : emiralf@yahoo.com

ECUADOR

EL SALVADOR

GRENADA

GUATEMALA

Luis Arturo Paniagua Galicia
Director General de la Policia Nacional de Guatemala
Telefono/Telephone: 230-3584
Fax : 251-9382
E-mail : luispaniagua@yahoo.com

Carlos Chopén
Primer Secretario
Telefono/Telephone: (202) 833-4015
Fax : (202) 833-4011
E-mail : cachopen@aol.com

GUYANA

Debra Yaw
Alternate Representative to the OAS
Telefono/Telephone: (202) 265-6900
Fax : (202) 232-1297
E-mail :

HAITÍ

HONDURAS

JAMAICA

MÉXICO

Embajador Miguel Ruiz Cabañas Izquierdo
Representante Permanente de México ante la OEA
Telefono/Telephone:
Fax :
E-mail :

Roberto Bojorgez Cruz
Coordinador Ejecutivo de Enlace Internacional e Interinstitucional
Centro de Planeación para el Control de Drogas (CENDRO)
Telefono/Telephone: (5) 169-6513
Fax : (5) 169-6660
E-mail : dgcii@pgr.gob.mx

Juan Sandoval Mediolea
Representante Alterno de México ante la OEA
Telefono/Telephone: (202) 332-3663
Fax : (202)
E-mail : jsandoval@sre.gob.mx

Greta Spota Diercx
Secretaria Técnica
Comisión Federal para la Protección contra Riesgos Sanitarios
Secretaría de Salud
Telefono/Telephone: 52-55-55311101
Fax :
E-mail : gspota@ssa.gob.mx

Araceli García Serna
Jefe del Departamento de Estupefacientes y Psicotrópicos
COFEPRIS Secretaria de Salud
Telefono/Telephone: 52038327
Fax :
E-mail : argarcia@mail.ssa.gob.mx

NICARAGUA

PANAMÁ

PARAGUAY

PERÚ

Carlos Chocano
Consejero, Representante Alterno de Peru ante la OEA
Telefono/Telephone: (202) 232-2282
Fax : (202) 466-3068
E-mail : cchocano@deleperu.org

REPÚBLICA DOMINICANA

SAINT KITTS AND NEVIS

Ambassador Izben C. Williams
Representante Permanente de Saint Kitts y Nevis ante la OEA
Telefono/Telephone: (202) 363-7305
Fax : (202) 363-7305
E-mail : wizben@hotmail.com

SURINAME

TRINIDAD AND TOBAGO

UNITED STATES

Harry J. Matz
Senior Trial Attorney
U.S. Department of Justice
Telefono/Telephone: (202) 514-0948
Fax : (202) 514-6112
E-mail : harry.matz@usdoj.gov

Wayne A. Michaels
Staff Coorddinator
U.S. Drug Enf. ADM.
Telefono/Telephone: (202) 307-4264
Fax : (202) 307-7503
E-mail : wmichaels@dialup.usdoj.gov

Sean P. Mahoney
Chief, International Drug Unit
U.S. Drug Enforcement Administration
Telefono/Telephone: (202) 307-3668
Fax : (202) 307-7503
E-mail : seanmahoney1944@yahoo.com

Dolores Williams – Crosby
Diversion Investigator
U.S. Drug Enforcement Administration (INTERPOL)
Telefono/Telephone: 011-334-7244-7079 (France)
Fax : 011-334-7244-7632
E-mail : d.williams@interpol.int

URUGUAY

VENEZUELA

Jesús Rodríguez
Director del Observatorio Venezolano de Drogas
Telefono/Telephone: 58212-9573517
Fax : 58212-9573556
E-mail : jesusandres@vistamedica.com

Marco Palavinci
Representante Alterno
Misión Permanente de Venezuela ante la OEA
Telefono/Telephone:
Fax :
E-mail :

ORGANIZACIÓN DE LOS ESTADOS AMERICANOS / ORGANIZATION OF AMERICAN STATES

COMISIÓN INTERAMERICANA PARA EL CONTROL DEL ABUSO DE DROGAS /
INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION (CICAD)

David R. Beall
Secretario Ejecutivo / Executive Secretary

Ihor (Ziggie) Malyniwsky
Jefe de la Sección de Reducción de la Oferta y Control

Jennifer Toland
Sección de Reducción de la Oferta y Control

Rosemary Vázquez González
Organización de Eventos