

ORGANIZATION OF AMERICAN STATES



INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

**GROUP OF EXPERTS ON
CHEMICAL SUBSTANCES
GROUP OF EXPERTS ON
PHARMACEUTICAL PRODUCTS
August 4-8, 2008
Lima, Peru**

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FINAL REPORT

Introduction

During its forty-second regular session, the Inter-American Drug Abuse Control Commission (CICAD) directed that the Group of Experts on Chemical Substances and the Group of Experts on Pharmaceutical Products meet in 2008. Each group was directed to execute the plan of action each had presented. In addition to these tasks the Commission directed that each group help to review and provide suggestions regarding the indicators related to these two subject areas used in the Multilateral Evaluation Mechanism (MEM) process.

The work of these two groups is presented in this joint report.

GROUP OF EXPERTS ON CHEMICAL SUBSTANCES

I. BACKGROUND

The forty-second regular session of the Inter-American Drug Abuse Control Commission (CICAD) took place in Santa Marta, Colombia from November 27 to 30, 2007. During that meeting, Dr. Eduardo Jaramillo of Mexico, presented the report from the Group's meeting that took place in Mexico City, Mexico (September 17-18, 2007).

The Commission received the report and approved the Group's proposed plan of action for 2008, which included a meeting during the course of that year. The meeting took place in Lima, Peru (August 4-5, 2008) and was chaired by Mr. Jorge Valencia Jaúregui, Director of Supply Control in DEVIDA

II. PROCEEDINGS

A. PARTICIPANTS

MEMBER STATES OF CICAD

Participants to the meeting included sixty experts representing the following 20 member states that participated in this meeting: Antigua and Barbuda, Argentina, Bahamas, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Honduras, Mexico, Panama, Peru, Trinidad and Tobago, United States, Uruguay 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 Los Delfines Hotel in Lima. This was a joint opening session for this meeting and the meeting of the Group of Experts on Pharmaceutical Products. Dr. Bertha Santocoy, Representative of the OAS in Lima, and Mr. Romulo Pizarro, President of DEVIDA offered welcoming remarks.

2. WORKING SESSIONS

A. Presentations

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

Guide for establishing a “Fee for Service” approach in chemical control (Argentina)

- Mr. Pedro Paradelo of Argentina presented the draft guide (attached) for establishing a “Fee for Service” approach in chemical control. The draft guide was developed to serve as a reference tool for countries interested in implementing some form of “fee for service” in relation to their administrative and/or regulatory control of chemical substances. This draws on the best practices of other countries that have implemented similar systems. The draft reflects input received from members of the working group assigned this task as well as comments received during the current meeting. After a review of the document, the Group adopted the Guide and submits it for consideration and approval by the Commission.

“Peru’s New Chemical Control System” (Peru)

- Ms. Rosa Maria Del Castillo of the Ministry of Production (PRODUCE) delivered a presentation on Peru’s new system to control chemicals. This is an integrated, interagency system that was established in accordance with the new chemical control legislation. The presentation generated a great deal of interest and discussion regarding the system.

B. Working Groups

Working groups were established to further elaborate draft documents related to issues raised at the last meeting. During the round table introduction of participants, experts also identified the challenges and issues of concern that they are facing with the respect to the control of chemicals. All of these issues

served as the basis for discussions during this meeting or for inclusion in the plan of action for future proposed meetings. The working groups considered the following issues:

Comprehensive chemical control training program in the areas of “technical” interdiction, operational and administrative monitoring, and judicial investigations (Colombia)

- Mr. Hector Hernan Bernal of Colombia presented the draft curriculum (attached) for a technical training program concerned with the control of chemicals. The draft proposes a series of learning modules and issues that should be included in any training program for technical and administrative staff concerned with the control of chemical substances. A working group was formed to elaborate the draft. Further to a brief discussion of the draft, the Group accepted the document and submits it for consideration and approval by the Commission.

During its discussion, the working group also examined the application of the training curriculum. To this end, the Group proposed that the Executive Secretariat send a letter to all member states requesting them to identify their training needs and the technical specialists or trainers that could deliver one or more elements of the curriculum. The individuals identified could then be used to form a pool of training resources.

The Group also proposed that the Executive Secretariat organize three national pilot training seminars based on the curriculum developed. The proposed pilot seminars would take place in Brazil, Chile and Venezuela before the Group's next meeting (subject to availability of funding).

Draft guide on the inspection and handling of chemical transshipments in port facilities (Bahamas)

- Mr. Marvin Smith of the Bahamas presented the draft guide for port inspectors in the identification and procedures in handling and processing transshipments of chemical cargos. The draft guide generated an excellent discussion and was subsequently referred to a working group for further elaboration. Members of this group will continue to work on the draft following the meeting. The more developed version of the draft will be presented to the Group at its next meeting.

Legal framework for the control of synthetic drugs (Mexico/United States)

- The delegations of Mexico and the United States co-chaired a working group that considered the control of synthetic drugs such as methamphetamine, Ecstasy and others. Effective control of these drugs depends on a sound legislative and regulatory foundation. The working group focused on identifying those elements and principles that a legislative, regulatory and administrative framework should address regarding these drugs. The final draft is attached for consideration by the Commission.

Increased public-private sector (chemical industry) coordination/cooperation (Venezuela)

- The Group of Experts noted the importance of greater coordination and cooperation between the private sector (chemical industry) and the public sector with respect to the control of chemical substances. There was insufficient time for a working group to consider this issue so the delegation of Venezuela offered to prepare a draft guide on how to establish or enhance this type of public/private sector relationship for presentation at the next meeting.

Mechanism to assess legitimate national need for chemicals and precursors (Trinidad and Tobago/Ecuador)

- Chemical substances and precursors used in the production of illicit drugs also have legitimate commercial uses. Several experts spoke of the problem where imports of these substances exceed what is required for these legitimate purposes. This serves as a warning sign of possible problems with respect to the diversion of the substances for use in illicit drug production. Under these circumstances it is essential that countries are able to assess their national legitimate needs for these substances. There was insufficient time to consider this issue in greater depth. The delegations of Trinidad and Tobago and Ecuador offered to prepare a draft guide on how to assess national legitimate needs for these chemicals for presentation and consideration at the Group's next meeting.

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:

Draft guide on the inspection and handling of chemical transshipments in port facilities (Bahamas)

Increased public-private sector (chemical industry) coordination/cooperation (Venezuela)

Mechanism to assess legitimate national need for chemicals and precursors (Trinidad and Tobago/Ecuador)

Other issues for discussion at the next meeting:

- Increased awareness regarding use of chemicals and precursors (especially Ephedrine and pseudo ephedrine) in the production of illicit drugs for:
 - o Judges
 - o Prosecutors
 - o Administrative/regulatory officials

- Law enforcement/customs
 - Industry
- pre-export notification
- risk management/targeting of chemical shipments
 - Parameters/criteria
- methods used to divert chemicals
 - concealment
 - labeling
 - falsification/altering documents
- diversion/illicit use diversion of ketamine

4. CLOSING SESSION

The Group of Experts concluded its work at 5:30 on August 5. At that time, the delegation of Costa Rica expressed its interest in hosting and chairing the next meetings of the Group of Experts on Chemical Substances and the Group of Experts on Pharmaceutical Products. The chair thanked the members of the Group for their participation and contribution and closed the meeting

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS FORTY-FOURTH REGULAR SESSION:

The Group of Experts on Chemical Substances recommends that the Commission:

1. Consider and accept the following guide or documents and direct the Executive Secretariat to post them to the CICAD web page:
 - **“Guide for establishing a “Fee for Service” approach in chemical control”**
 - **“Training Curriculum Outline for technical interdiction, operational and administrative monitoring, and judicial investigations”**
 - **Legal framework for the control of synthetic drugs**
2. Consider and accept the plan of action proposed by the Group of Experts and direct that the Group meet in 2009 to consider the issues in the plan as well as other new trends or threats identified in the area of chemical control.
3. Consider and accept the offer made by Costa Rica to host and chair the Group’s next meeting.

IV. DECISION BY CICAD DURING ITS FORTY-FOURTH REGULAR SESSION

The Commission accepted the report and recommendations presented by this Group of Experts with the exception of two items. **The Commission accepted the “Legal framework for the control of synthetic drugs” but directed that it not be posted to CICAD’s web page.** In addition, the Group was directed not to pursue further work on developing a “Mechanism to assess legitimate national need for chemicals and precursors”. Finally, the Commission directed the Group to meet during 2009 to continue its work, electing Peru to chair this meeting.

REVIEW OF INDICATORS IN THE MULTILATERAL EVALUATION MECHANISMS RELATED TO CHEMICAL SUBSTANCES AND PHARMACEUTICAL PRODUCTS.

I. BACKGROUND

During its March 2008 review of indicator proposals for the Fifth Evaluation Round of the Multilateral Evaluation Mechanism (MEM), the Preparatory Intergovernmental Working Group (Pre-IWG) included in its report to CICAD that the indicators on the control of pharmaceutical products (#27-#30) and on the control of chemical substances (#31-35) needed to be reviewed for the next MEM evaluation cycle, and that the assistance of the CICAD Group of Experts and their expertise would be sought in this regard. The CICAD Commission approved the report at its forty-third regular session in April 2008.

II. PLENARY SESSION AND REVIEW OF INDICATORS

Ms. Angela Crowdy, Head of the CICAD MEM Section, and Mr. Martin Cubas, MEM Section Specialist, presented proposed modifications to the Plenary on August 6, 2008, for discussion. The proposals had been drafted prior to the Plenary by a number of countries who had expressed an interest in developing preparatory modifications with the MEM Section.

Indicators were reviewed in Plenary by delegations from Antigua and Barbuda, Argentina, the Bahamas, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Honduras, Mexico, Panama, Peru, Trinidad and Tobago, United States, Uruguay and Venezuela with the support of the head of the Supply Section of CICAD, Mr. Ziggie Malyniwsky. Given the tight agenda, three indicators (#33-35) could not be discussed during the Plenary and were circulated via e-mail to all participants for their electronic review.

Areas covered included indicators on the scope of the mechanisms for the control of the diversion of pharmaceutical products and chemical substances, national laws and regulations for sanctions against the diversion of these products, and seizures/final disposition of substances.

The proposed indicator questions will be uploaded on-line for review by all member states, prior to the February 2009 meeting of the Intergovernmental

Working Group (IWG) where all indicator proposals will be reviewed and discussed. The final approval will take place in 2009 during the forty-fifth CICAD regular session prior to the onset of the MEM's Fifth Evaluation Round.

GROUP OF EXPERTS ON PHARMACEUTICAL PRODUCTS

I. BACKGROUND

The forty-second regular session of the Inter-American Drug Abuse Control Commission (CICAD) took place in Santa Marta, Colombia from November 27 to 30, 2007. During that meeting, Dr. Eduardo Jaramillo of Mexico, the chair of the Group of Experts on Pharmaceutical Products presented the report from the Group's meeting that took place in Mexico City, Mexico from September 19-20, 2007.

The Commission received the report and approved the Group's proposed plan of action for 2008, which included a meeting during the course of that year. The meeting took place in Lima, Peru from August 7-8, 2008 and was chaired by Mr. Victor Dongo, Director General of Medications and Drugs in Peru's Ministry of Health.

II. PROCEEDINGS

A. PARTICIPANTS

MEMBER STATES OF CICAD

Sixty experts from the following 20 member states participated in this meeting: Antigua and Barbuda, Argentina, Bahamas, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Honduras, Mexico, Panama, Peru, Trinidad and Tobago, United States, Uruguay and Venezuela.

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

The opening session of the meeting of this Group took place in the Los Delfines Hotel in Lima at 9:00 on August 7, 2008. Mr. Victor Dongo welcomed the participants and offered some preliminary remarks.

2. WORKING SESSIONS

A. Presentations

System to control pharmaceutical products in Argentina

- Ms. Rachel Mendez delivered a presentation on the system in place in Argentina to control pharmaceutical products and deal with the problem of counterfeit drugs. The system takes various actions in parallel to monitor the distribution of drugs and initiate a multi-agency response when counterfeit, adulterated or contraband drugs are identified. The availability of counterfeit pharmaceutical drugs represents a serious problem for many of the countries present and the presentation generated a great deal of interest and discussion.

Presentation on the “black market” of counterfeit medicines: modus operandi, investigations, real cases

- Mr. Fredy Sierra of Pfizer Inc. delivered a presentation on the problem of counterfeit drugs making their way into the “black market”. In his presentation he spoke of the methods used by groups to produce and distribute counterfeit drugs and how investigations are conducted using real cases as examples. The presentation generated a great deal of discussion.

Regulatory control of Pseudoephedrine in Mexico

- Dr. Eduardo Jaramillo delivered a presentation on the steps taken by Mexico to control the sales and diversion of pseudoephedrine. While this drug is used for legitimate medical purposes, it also serves as a precursor in the production of methamphetamine. Dr. Jaramillo described how Mexico determined its legitimate need for pseudoephedrine and how imports clearly exceeded these needs. In an effort to protect human health in Mexico, the Government implemented legislation that prohibits the use and consumption of ephedrine and pseudoephedrine.

Guide for health professionals concerning counterfeit drugs (Bahamas)

- Mr. Marvin Smith of the Health Ministry of the Bahamas presented the draft guide for health professionals concerning counterfeit drugs. This is a revised version of the draft that was presented to and considered by the Group at its last meeting. The revised draft reflected the input and suggestions received from participants. It 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 includes practical tools that health professionals can use to help address this problem. Drawing on the discussion and comments, the draft was finalized and is offered to the Commission for its consideration.

General overview of Peru's system to control pharmaceutical products

- Mr. Victor Dongo provided an overview of the system used in Peru to control the distribution of pharmaceutical products.

B. Working Groups

Several working groups were established to consider the following issues of concern raised during the roundtable discussion:

Control of Ephedrine and Pseudoephedrine (Mexico)

A working group was formed to prepare a reference tool drawing on Mexico's experience with the control of ephedrine and pseudoephedrine. The working group presented their draft to the Group for discussion. The draft was accepted with some amendments and is submitted for the Commission's approval. In addition to the foregoing, the delegation of Mexico agreed to prepare a second, more detailed document outlining the steps taken and challenges they faced in strengthening their controls over ephedrine and pseudoephedrine. This draft document will be presented at the Group's next meeting.

Counterfeit pharmaceutical drugs (Bahamas/Argentina)

The issue of counterfeit pharmaceutical products represents a serious health hazard for many CICAD member states. A working group was formed to develop a practical guide for combating counterfeit pharmaceutical products through investigational and increased awareness methodologies. The draft guide will be presented at the Group's next meeting for review and approval.

Internet sales of drugs (US)

The sales of drugs via the internet is a growing problem. There is limited information on how and the extent to which member states are affected by this problem. A working group was formed to develop a practical guide to help countries establish a mechanism to determine how, in what way and to what extent they are involved in or affected by the sale of or trafficking in drugs via the internet.

3. PLAN OF ACTION

The Group of experts has prepared the following plan of action that includes the assigned products as well as other issues for possible consideration when the Group next meets:

Control of Ephedrine and Pseudoephedrine (Mexico)

Practical guide for combating counterfeit pharmaceutical products through investigational and increased awareness methodologies (Bahamas/Argentina)

Internet sales of drugs (US)

Other issues for discussion at the next meeting:

- supply chain control
- ephedrine and pseudoephedrine
- disposal of pharmaceutical products
- trafficking of pharmaceutical products between countries
- pre-export notification
- diversion/illicit use diversion of ketamine

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS FORTY-FOURTH REGULAR SESSION:

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

1. Consider and accept the following guide or documents and direct the Executive Secretariat to post them to the CICAD web page:
 - **“Control of Ephedrine and Pseudoephedrine”**
 - **“Guide for health professionals concerning counterfeit drugs”**
2. Consider and accept the plan of action proposed by the Group of Experts and direct that the Group meet in 2009 to consider the issues in the plan as well as other new trends or threats identified in the area of chemical control.

IV. DECISION BY CICAD DURING ITS FORTY-FOURTH REGULAR SESSION

The Commission accepted the report and recommendations presented by this Group of Experts. The Commission directed that the Group meet during 2009 to continue its work, electing Peru to chair this meeting.



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GROUP OF EXPERTS CONCERNING CHEMICAL SUBSTANCES

Guide on Fee for Service
Argentina

Lima, Peru

FEE FOR SERVICE

The Argentine model for levying fees was identified as an effective system that could be used by other countries of the Hemisphere as a means of obtaining independent funds to control the diversion of chemical precursors.

The exclusive purpose of this system is to raise the funds needed to improve and modernize the diverse chemical precursor registries or departments.

This system can be easily adapted to the specific characteristics of each country, with the following points taking into account in its adaptation and introduction:

- 1- The existence of an appropriate legal framework: each state will have to conduct pertinent research on the existence of laws allowing the cooperating entity to exist. In other words, there must be an appropriate framework or jurisprudence that supports and justifies the adoption of the fee system in each country.
- 2- Selection of a cooperating entity capable of providing efficient management, in keeping with the needs of each register. Preferably private companies.
- 3- Analysis of the economic potential: This item consists basically in projecting potential income and comparing it with potential costs. An analysis of potential income must take into account the number of companies already signed up with each registry and an approximate number of companies that are not yet registered but should be. This projection is made with the help of the various manufacturers' associations and industrial conglomerates composed of companies that may use precursors in their line of business.
- 4- Setting the fee assessment base: Establishment of the processes on which fees can be levied: registration, re-registration, reporting, importation or exportation requests, merchandise in transit, transshipments, etc. These processes on which fees may be levied will depend exclusively on the legislation in force in each country.
- 5- Establishment of the different amounts to charge for each process: These amounts must be set together with the different business associations and industrial unions in each country and with their agreement. They should never be set unilaterally.
- 6- Design of forms according to the type of process. It should be clarified that the form is the document that the user obtains to carry out a process; it is

different from the certificate, which is the document that authorizes the user to do so.

- 7- Establishment of a supervisory commission responsible for overseeing the work of the cooperating entity with regard to expenditures, purchase of inputs, correct payment of salaries, etc.
- 8- Creation of an information mechanism between the state and the cooperating entity to report to the former on income and outlays.



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GROUP OF EXPERTS CONCERNING CHEMICAL SUBSTANCES

**COMPREHENSIVE TRAINING ON ISSUES RELATING TO CHEMICAL
SUBSTANCES**

Colombia

Lima, Peru

COMPREHENSIVE TRAINING ON ISSUES RELATING TO CHEMICAL SUBSTANCES

Pursuant to the commitments assumed at the meeting of the CICAD Expert Group on Chemical Substances held in Mexico City in September 2007 regarding a hemispheric pilot training program on chemical substances used in the production of illegal natural and synthetic drugs, in 2008 CICAD and the Academic Coordination developed two pilot training processes, with emphasis on safe technical procedures for handling chemical substances, proper final disposal complying with national standards and minimizing environmental effects, and administrative procedures allowing collaboration among private companies' technical staff (chemical industry), governmental officials, and multilateral organizations, the goal being to facilitate and increase controls.

PROPOSED TRAINING ON TECHNICAL ASPECTS OF CHEMICAL SUBSTANCES

The CICAD Coordinating Group and Colombia's technical team (National Narcotics Directorate) assumed responsibility for designing a program suited to subject-related requirements, based on information regarding the technical weaknesses that the Colombian and Panamanian institutions (the two countries that were selected for the respective seminars) indicated with respect to the management and technical control of controlled and seized chemical substances placed under state control.

Based on experience in the pilot training processes, the Colombian technical team is pleased to offer CICAD's Group of Experts the following training program on technical aspects relating to illicit chemical substances and drugs, directed at public officials engaged in control and interdiction activities.

SUBJECT MATTER

Legislation: Both the Colombian and Panamanian training processes took into account national legislation, United Nations provisions (Article 12 of the 1988 Vienna Convention), and CICAD's Model Regulations to Control Chemical Substances.

Processes for interdiction of chemical substances: Camouflage methods (chemical and typical); document forgery; frequent routes; international traffic; use of substitute substances.

Physical-chemical characteristics and proper handling of substances: Technical information on groups of chemical substances used for the clandestine production of drugs (bases, salts, acids, solvents, catalysts, oxidants, etc.),

based on key information in the Safety Sheets for each substance. Relevant aspects taken into account include: physical-chemical properties (density, appearance, solubility, physical state), substance synonyms, lawful uses, unlawful uses; health effects, first aid; measures in case of fire; accident prevention measures; storage and handling; and toxicological and ecological information.

Clandestine laboratories: Classification of structures used in the extraction, refining, conversion, and dosing of illegal drugs. General characteristics; processes carried out; equipment and paraphernalia used in processes; chemical substances frequently found by type of structure. Interdiction mechanisms: correct dismantling taking the agent's biosafety into account and minimizing environmental impact.

Proper temporary storage of chemical substances: Characteristics of seized chemical substances: condition of containers, volumes, site of seizure. Minimum adequate conditions for storage areas: signage, chemical incompatibility, safety equipment, and first aid.

Final disposal of seized chemical substances: Neutralization, conversion, destruction. Sale or auction. Donation.

Illegal drugs of natural origin: Coca derivatives – cocaine base paste, cocaine base, cocaine chlorhydrate, crack, unpurified cocaine, free base, others. Opiate derivatives: morphine, codeine, narcotine, papaverine, heroin. Cannabis derivatives: natural cannabis, cannabis oil, hashish.

Emerging drugs: Ecstasy family, methamphetamines. Poppers. LSD. Medications subject to special controls (barbiturates, benzodiazepines, opiate derivatives and opioids, etc.). Anabolic substances.

Final disposal of seized drugs: chemical destruction; incineration; solubilization.

Drug information systems: General characteristics of information systems. Variables and descriptors, standardization and validation of information, preparation of technical manuals and user manuals.

PILOT TRAINING PROGRAM

OBJECTIVE:

Acquire and assimilate knowledge relating to techniques for the investigation, interdiction, handling, transport, storage, and proper final disposal of seized chemical substances.

First Module

International legislation on chemical substances.

National legislation on chemical substances

Conceptualization and standardization of terminology used in processes to control and interdict chemical substances

Processes for control and interdiction of chemical substances

Administrative control processes

Second Module

Clandestine laboratories

Final disposal of seized chemical substances: administrative processes (sale, auction, donation).

Technical processes: neutralization, transformation, and destruction

Third Module

Physical and chemical properties of substances used in the extraction and refinement of natural drugs: Acids, Bases, Solvents, Salts. Finished products

Proper handling of chemical substances

Process for neutralizing acids and strong bases

Potassium permanganate and other oxidizing substances.

Interdiction of clandestine laboratories

Final disposal of seized chemical substances

Fourth Module

Illegal drugs of natural origin: cocaine and derivatives; opiates and cannabis derivatives: General information on illicit production processes and chemical and toxicological aspects

Emerging drugs: General information on illicit production processes and chemical and toxicological aspects

Proper final disposal of seized drugs

Fifth Module

Drug information systems: variables on interdiction – standardization for information gathering.

Preparation of manuals

General Coordination: Rafael A. Parada – CICAD/OAS

Technical and Academic Coordination: Héctor Hernando Bernal Contreras
National Narcotics Directorate – Colombia



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**DOCUMENTS OF THE
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GROUP OF EXPERTS ON PHARMACEUTICAL PRODUCTS

Guide for health professionals concerning counterfeit drugs

Bahamas

Lima, Peru

TEMPLATE CHECKLIST FOR PROCUREMENT ENTITIES

- 1. Name and address of applicant/supplier(s)**
- 2. Name and address of “Marketing Authorization Holder”**
- 3. Name of pharmaceutical**
- 4. Name and address of manufacturer of pharmaceutical**
- 5. Country of original manufacture and export**
- 6. DRA registration number of the product (or applicable registration number)**
- 7. Product specifications:**
 - a. Product International Nonproprietary Name**
 - b. NDC or DIN number**
 - c. Formulation**
 - d. Strength**
 - e. Package size and primary container**
 - f. Therapeutic class (list all applicable)**
 - g. Therapeutic code (if applicable)**
 - h. Domestic (or institutional ID number)**
 - i. Listing of all active ingredients**
 - j. Therapeutic indication(s)**
 - k. Route of Administration**
- 8. Notarized copies of the following must be presented:**
 - a. Official labeling and package insert for product**
 - b. Registration/licensure certificate for each supplier (or from applicable authority)**
 - c. DRA registration certificate for the product (or from applicable authority)**
 - d. Import certificate (if applicable)**
- 9. All other applicable domestic/international requirements deemed necessary**

Template Checklist for Drug Regulatory Authorities
Manufacturers & Distributors

1. Name and address of applicant/supplier(s)
2. Name and address of “Marketing Authorization Holder”
3. Name of pharmaceutical
4. Name and address of manufacturer of pharmaceutical
5. Country of original manufacture and export
6. Product specifications:
 - a. Product International Nonproprietary Name
 - b. NDC or DIN number
 - c. Formulation & Strength
 - d. Route of Administration
 - e. Package size and primary container
 - f. Therapeutic class (list all applicable) and code
 - g. Domestic (or institutional ID number)
 - h. Listing of all active ingredients
 - i. Therapeutic indication(s)
7. Notarized copies of the following must be presented:
 - a. Official labeling and package insert, with official product monograph
 - b. WHO-type certificate from the country of origin for the product
 - c. Proof of current GMP certification (or accepted equivalent) for the manufacturer
 - d. Proof of current GSP & GTDP certification (or accepted equivalent) for manufacturer and each supplier
 - e. Domestic business license (where applicable)
8. Pedigree records are accessible and in good order for all pharmaceuticals
9. Estimate of amount of the product to be repackaged (if applicable)
10. Relevant authorization for export/import of bulk API.
11. All other applicable domestic/international requirements deemed necessary

Template Checklist for Drug Regulatory Authorities
Pharmacy Facility

- 1. Name and address of facility**
- 2. Name and address of applicant representing the facility**
- 3. Position of person representing the facility**
- 4. Type(s) of business/practice to be conducted within the facility and its grounds**
- 5. Listing of pharmacy personnel and registration/licensure numbers**
- 6. Inspection process should ensure that:**
 - a. Storage and supply conditions meet all current GSP standards**
 - b. Trade and distribution processes meet all current GTDP standards**
 - c. All concerns noted at the previous inspection have been addressed**
 - d. All pharmaceuticals in the facility have current DRA registration certificates**
 - e. All pharmaceuticals present in the facility correspond to the products on record**
 - f. All mandatory records are accessible and in good order**
 - g. Institutional processes exist for the reporting of adverse pharmaceutical events**
 - h. Institutional processes exist for the reporting of suspected counterfeit pharmaceuticals**
 - i. Pedigree records exist for all pharmaceuticals on the premises**
 - j. Mechanisms exist for patient feedback relative to their pharmaceutical products and care**
 - k. All domestic/international licenses are current relative to the stated scope of practice of the facility.**
- 7. All other applicable domestic/international requirements deemed necessary**

**Template Checklist for Incident Reporting by Health Professionals
Concerning Counterfeit Pharmaceuticals to DRA's**

1. Name of pharmaceutical
2. Name and address of manufacturer of pharmaceutical
3. Name and address of applicant/supplier(s)
4. DRA registration number of the product (or applicable registration number)
5. Name and address of facility where product was made/distributed/dispensed
6. Name and address of patient (if applicable)
7. Product specifications:
 - a. Product International Nonproprietary Name
 - b. NDC or DIN number
 - c. Formulation & Route of administration
 - d. Strength
 - e. Package size and primary container
 - f. Therapeutic class (list all applicable)
 - g. Therapeutic code (if applicable)
 - h. Domestic (or institutional ID number)
 - i. Listing of all active ingredients
 - j. Therapeutic indication(s)
 - k. Lot and/or batch number
8. Indication for which the product is used for in this case
9. Specific nature of complaint with product
10. List all documented adverse effects or physical abnormalities of product
11. List all undocumented reports of adverse effects or physical abnormalities of product
12. Strength, regimen, route of administration, and duration of treatment
13. If regimen was modified or discontinued, what effect was seen on the adverse effects?
14. If regimen was reintroduced, what effect was seen on the adverse effects?
15. Have you experienced any other difficulties with this product? If yes, give details.

Template Checklist for Patient-Education by Health Professionals Concerning Suspected Counterfeit Pharmaceuticals

NB. This information has been adapted from guidelines developed by Bryan A. Liang, MD, PhD, JD of the Institute of Health Law Studies, California Western School of Law and the San Diego Center for Patient Safety.¹⁹ This information is meant only as a template for areas that can be covered by the health professional during patient counseling or education sessions. The dialogue listed is intended as a guide, and is not intended as a definitive detailing of patient counseling.

“If your physician has prescribed a medication that you have never taken before, request samples from your physician. This will allow you to compare the appearance, taste, texture, and reaction later to medications you receive later. It is important to note that manufacturer samples are usually only available for brand medications and not generics. You can save the sample’s packaging for comparison later.”

“If you are using the Internet to purchase medicines, please ensure that the Web site is a certified site. In this jurisdiction, the regulatory body that certifies Internet pharmacies is..... **OR**there is no authority to certify Internet pharmacies, so you may need to check for international certification like the VIPPS program in the USA.”

“ A good way to compare the prescription medicine you receive with what it is supposed to look like, is by taking pictures of the original manufacturer's drug and the packaging. You may also find pictures of these products in the Physicians Desk Reference available at your local library, or online in various credible sites. You will need to look for differences in paper quality, printing characteristics (is it the same size, raised print, embossed, etc.), color, and fonts. Pharmaceutical companies are very strict about the characteristics on their product and packaging, so any noticeable differences may be an indication that your product may not be genuine.”

“Please note that if you are prescribed or dispensed a generic product, it may differ in shape or color and still be a safe and effective product. If you have any questions on the identification of medications, please feel free to ask me... **OR...** talk to your pharmacist.”

“Take note of the prescription drug’s taste and any associated feeling once you take it, especially if it feels different than usual. For example, if injecting a medication, is it supposed to burn? Is there anything unusual in your body’s reaction compared to when you took it before? Remember that counterfeit drugs can contain no active ingredient, not enough, or even too much of it. So if your drugs do not seem to have the same taste, or if you feel different than usual, immediately write down your symptoms and contact your doctor and pharmacist.”

“Do you feel that you are benefiting from the medication? Is your condition improving, stabilizing, or do you feel worse now that you are being treated with this drug? What did your physician or pharmacist tell you about how you should expect to feel while being treated, and when you should expect to begin feeling relief or improvement? If you should be feeling better by now, but are not, maybe we should evaluate the product you are taking.”

“If you find strong indications that the medicine you have been taking may be a counterfeit pharmaceutical, immediately remove it from your medicine cabinet. Distinctly mark the packaging so you will not mistakenly take it again. You can mark it with a red pen, or put tape around the top of the drug container so that it will be unavailable to you or others in your family. Take the medications to your local law enforcement officials and contact our local Drug Regulatory Authority for more information. In our jurisdiction, the local DRA is and is located.....”

“In our jurisdiction, the website for our local DRA isand the phone contact is.....”

“Before you contact the local DRA office you will need to have information related to how you got the counterfeit medication and how long you have been taking it. One of the key issues is where you purchased the medication. Did you buy it from a website, a mail order facility, or from a local pharmacy? When did you purchase the medication? Do you still have the packaging? How long have you been taking the counterfeit drugs? These are all questions that you will be asked in order to process your complaint.”

“If you need to take this medicine routinely, you will have to contact your physician or pharmacist to arrange for a new supply so that you can resume your treatment.”

Template Form – Incident/Product Report for General Public

- 1. What is the name of the medicine that you are taking? If there are more than one name on your product packaging, list all of them.**
- 2. Have you ever taken this medication before? If so, was it the same brand or generic that you are taking now?**
- 3. What condition are you taking this medication for?**
- 4. What is the name of the prescribing physician or health professional?**
- 5. What is the name of the healthcare facility where you were treated?**
- 6. Where (or who) did you obtain the medication?**
- 7. What does your medication look like?**
- 8. Describe how it made you feel after taking it?**
- 9. Have you noticed anything different about how the medication looks, feels or tastes?**
- 10. Have you noticed anything different about how the packaging looks or feels?**



ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

GROUP OF EXPERTS CONCERNING PHARMACEUTICAL PRODUCTS

**A GUIDE FOR WISE USE AND CONTROL OF PRODUCTS CONTAINING
EPHEDRINE AND PSEUDOEPHEDRINE**

MEXICO-COLOMBIA

August 2008

1. Introduction

The Ephedrine and pseudoephedrine according to International law is seen as a chemical precursor and is classified as psychotropic substance, either the raw material itself or pharmaceutical products containing them.

For therapeutic purposes it is used to produce anti-flu and decongestants.

The regulatory strategy for this type of precursors (pseudoephedrine in Mexico) is based on three basic guidelines:

- ü Strengthening Law to control the sale and use of controlled substances.
- ü The implementation of public policies for the protection against health risks.
- ü To avoid the diversion of precursors from licit channels (for therapeutic purposes) to illicit channels, through effective control mechanisms, in the process of importing, exporting and distribution of Pseudoephedrine and Ephedrine, as well as manufacturing and selling of medicines contain them.
- ü A close relationship with the pharmaceutical industry.
- ü The licit supply of pharmaceutical products containing ephedrine and pseudoephedrine must respond directly to the real needs of the pharmaceutical industry. The needs could be established through statistical analysis of historical consumption of them, which would allow susceptible increases to show.

2. Background

The Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna / Austria, December 20, 1988-or the Vienna Convention, Red List as is known internationally, is the main international legal framework cited as a reference for the development of effective action against organized crime in the form of drug trafficking. Apart from promoting international cooperation, it recommends the adoption of appropriate measures to prevent the diversion of precursors and other chemicals used in the illicit manufacture of narcotic drugs and psychotropic substances.

In addition, in April 1990, comes another important legal framework in the international arena. This is the Model Regulations for the Control of Precursors

and Chemicals, Machinery and Elements, adopted by the Inter-American Drug Abuse Control, the Organization of American States - CIC / OAS at its seventh session, approved at the Ministerial Meeting held in the town of Ixtapa / Mexico. As its name indicates, the regulation aims to encourage OAS member States to exercise control and supervision of chemical inputs to be used in the illicit manufacture of narcotic drugs and psychotropic substances. For that purpose, it recommends the development of control systems for such products, improvement in the mechanisms to exchange information between the supervisory bodies and taking orders to criminalize the illegal marketing of precursor and chemicals substances under control.

3. Legislator

The absence of a legal instrument that allows the development and implementation of measures of control and fiscalization of chemicals most commonly used in processing illegal drugs can lead to an uncomfortable situation for most of the countries, knowing that there are international recommendations for the purposes of supervision and control over such products.

The law should manage the fiscalization and control of chemicals precursor that could be used in the illicit production of narcotic and psychotropic substances, allowing control and monitoring of production, marketing, distribution and final purpose of these substances, so that they can have an essential legal support for improving the control mechanisms and to implement new measures deemed appropriate, given the current national and international reality.

It is essential that all officials of the institutions involved know in depth the legislation governing the monitoring and control of precursors and related crimes as well as the list of substances subject to control.

4. Control mechanism

It is necessary to identify the institutions responsible for monitoring administrative and operational activities related to precursors that could be used in producing narcotic and/or psychotropic substances.

To exercise such control mechanisms it is necessary to create documents for that control. In addition, groups specialized in monitoring and research should deploy field activities and documentary analysis with intentions of preventing and suppressing the diversion of inputs for drug trafficking.

Another important factor is to identify the countries with which agreements are of mutual cooperation for combating drug trafficking, promote information sharing, and strengthen international cooperation mechanisms and strengthen international institutions involved in combating the drug phenomenon.

4.1 Administrative control

It is necessary to have an overall picture based on reliable information that is capable of providing the current status of these substances in each country and the same situation of this country on the same issue at the international level.

This involves knowing the origin, destination or use of precursors through information strengthened by the competent authorities of each Member State.

It is proposed that each country has a registration of authorized companies and identify those that are exporting and importing to promote a very close coordination between the various organizations for the control of precursors.

Activities related to the manufacturing, production, processing, packaging, packing, buying, selling, marketing, acquisition, possession, donation, exchange, transfer, shipment, distribution, import, export, sale, use, recycling, loan, reuse, destruction, transport and storage of precursors that could be used in the production of narcotic drugs and other substances might be prescribed for physical or psychological dependence should be subject to review by the responsible institution. That administrative control can be exercised by taking the following measures:

4.1.1 Registration

This is the recording of data related to the identification of the person interested in exercising an activity that involves some precursor subject to control and audition. The recorded information required by the supervisory organ may be more complete when it comes to legal person performing long lasting activities, as the production and processing industries and businesses importers, exporters and distributors of those products. This allows detailed knowledge of the activities carried out by each entity operator and, consequently, an overview of the domestic market.

Such a register should be kept updated by the user before the body control, reporting any change in the conditions originally approved (address, phone, fax, e-mail, legal representative, technical direction, the name of society, economic activity, etc.). Being subject to any changes to the conditions originally approved than reported, shall be grounds for the automatic cancellation of registration.

4.1.2 Allocation of forecasts

It refers to the mandatory application of quotas by the registered referred to in the previous item, submitted no later than thirty (30) of March each year, total forecasts required and Pseudoephedrine Ephedrine for the following year, attaching the medical, scientific and marketing studies as well as the historical consumption of the three (3) years.

4.1.3 Authorization for Foreign Trade

In general, apart from registration, the person intending to import or export a controlled chemical must have a specific authorization, except in the event of certain products for which, by their nature, origin or destination region do not represent risk of diversion to illicit markets. The Foreign Trade specific authorization is valid for a single transaction for a single product and for a short specified period.

Prior to the issuance of the Authorization for Foreign Trade, it is important to contemplate the possibility of including as a control mechanism, approved by all health authorities and control that exist in each country and having competence in the subject, so check compliance with existing legislation for the proper handling of such substances (Good Manufacturing Practice, Good Practices storage, existing health records, etc.).

4.1.4 Prior notification

This is a procedure taken to exchange information between the competent foreign institutions as it relates to the international control of chemicals that could be destined for illicit drug production. Board instituted by the International Narcotics Control (JIF), prior notification is a mandatory procedure for all countries signatories of the Vienna Convention. It consists primarily on communication making the monitoring body of the exporting country to control body of the importing country, reporting on the export of a precursor listed in Table I, considering its raw material as the finished product, so that is known before boarding, the legitimacy of the operation. It is advised to use the system on line-PEN Board of International Narcotics Control (JIF).

It is important to adopt an internal mechanism that would allow the dissemination of information relating to foreign trade in precursors among the bodies responsible for supervision and control.

4.1.5 Information System

This is a control mechanism that can be done from crossing data and information at regular intervals and incorporating that into a database. Companies and institutions active in the system must send data and information to the supervisory body, about the activities they develop with precursors. The computerized system, should review the congruence of data and information received and, if detect any discrepancies, should produce alerts that may indicate a mere administrative irregularity or evidence of a criminal diversion, to take actions which may apply.

4.2 Operational preventive control

It is the need to verify "in situ" the veracity of the information provided by enterprises, and determine the materialization of possible detours indicating the existence of administrative violations, strengthening the prevention of diversion of precursors for illicit markets, which should lead to conducting an audition of the respective supervisory bodies to businesses.

There should be mechanisms for training and information referent to the control exercised at the Pseudoephedrine and Ephedrine, addressed to:

- Officials of customs, ports and airports that are allowed access to such substances.
- Authorities with banishing character and/or police.
- People interested in handling precursors, to have clear legal and administrative controls of each Member State.

Another preventive measure is operating the restriction to certain customs, ports or airports, which can make an effective control for the entry of such substances to different countries.

4.3 Operational control repressive

Another aspect of control is the repressive operational, as embodied by the investigation of diversion. If there are indications of diversion of precursors for illicit markets, we must initiate an investigation aimed at determining the possible criminal responsibility of those involved.

Such research must be undertaken by law enforcement agencies responsible for monitoring and controlling of chemical precursors. The execution of investigations of this nature requires training for judges and prosecutors, specific knowledge on the subject and adequate equipment, since it is necessary to ascertain the nature of intentional conduct designed to deflect or provide an input for chemical production or development of illegal.

For this reason, police officers engaged in such research must realize facts through evidence establishing a link between the results of crime and the offender's conduct agent directed to that end.

4.3.1 Research diversion of chemicals

Effective control of precursors allows knowledge of facts that may constitute an administrative irregularity or strong indications of diversion of such products to illicit markets. At that moment, control actions are intensified, starting the research work using appropriate techniques, with the main objectives of:

- Getting to know points and modalities of diversion;
- Identify routes and transport groups;
- Identify the final recipient of precursors;
- Choosing the most appropriate time to adopt relevant judicial measures, taking into account the generation of evidence and information gathering.

The investigation is conducted through the analysis and processing of operational data in order to meet specific offence relating to the diversion of precursors for illicit drug production. Focusing on the activities of police investigation, the investigation of diversion of precursors requires the use of the same investigative techniques that are used against illicit drug trafficking. Thus, the agent must gather intelligence qualities that enable it perform its functions, namely, patience, motivation, modesty, dedication to service, discretion and good cultural level.

4.3.2 Methods of diversion

The experiences in the exercise of monitoring and control of precursors, especially in countries where issues related to illicit drug trafficking is more pronounced identified the following types of diversion were identified:

4.3.2.1 Generic

- Fictitious names and addresses;
- Fictitious Companies;
- Companies "facade";
- False reports;
- Intermediaries (brokers);
- Theft/robbery;
- Theft fictitious

4.3.2.2 Related to foreign trade

- False names and generic labeling;
- Misuse of free zones;
- Leakage of customs control points;
- Contendedores/merchandise unreported;
- Contraband;
- Loss/disappearance;
- Using false documents or obtained through bribery.
- Hide in the body of pseudoephedrine and ephedrine.

4.3.2.3. Related to transport

- Using false document;
- Concealment of proceeds;
- Replacing package;
- Replacing part of the product;
- False reports of theft/larceny.
- Robbery / theft;
- Divert routes.
- Shipments by parcel

4.3.3 Suspicious Operations

The investigation of diversion of precursors for illicit markets requires special care, failing to generate negative consequences for honest businesses that operate legally and unquestionably constitute an important segment of the national economy. It is not an easy task to recognize that a commercial operation, conducted in the normal commercial arrangements, aimed at satisfying a need of drug trafficking. However, some behaviors observed during the acquisition, transport and possession of controlled precursors indicate that such products may be being diverted. Here are some examples:

- Cash payment;
- Transportation on behalf of purchasers of products;
- indirect routes (detours);
- activities other than the declared in the register of the company;
- Deposit prolonged;
- excessive inventory;
- Frequent changes of address and/or company name;
- inventory/supply of precursors without label;
- Excessive or exclusive retail sales, according to the nature of the business;
- offer by the buyer to use their own transport;

5. Analysis of customs control

The control of foreign trade has to be exercised by national authorities through the authorization of foreign trade. This measure should be preceded by an analysis of registration and licensing of the company.

Those interested in conducting such activities must fill out an application, attaching to the file documentation for commercial, with the name, quantity, concentration or the content or purity, the value of the goods, apart from identifying the exporter/importer, the manufacturer and the available data relating to transport and authorization, no-objection certificate or equivalent document issued by the competent organ of the importing country and country of final destination, where appropriate. This documentation will be sent later to national control.

After issuing the authorization of foreign trade, customs formalities for the customs authority must be notified in writing or through a computer system, to adopt measures within its sphere of responsibility.

Proposal of Control Action

1. Require the submission of annual consumption forecasts, which could be susceptible to comply by the health authority according to the legitimate needs.
2. Conduct direct and restrictive control to dealers of Pseudoephedrine and Ephedrine as feedstock.
3. Establish an obligation to notify the health and judicial authority in case of thefts or losses.
4. Restrict the sale of medicines containing Pseudoephedrine and Ephedrine and pharmaceutical establishments with qualified professionals to track customized to buyers, for example by requiring the identification of the person who acquires the medicine, so we can keep a database that enables crossing information and detect possible illegal activities with this type of medication.
5. Establish specific customs for the entry or departure of by Pseudoephedrine and Ephedrine.
6. For security reasons the transport of substances in question takes place in custody and is tracked by GPS, since their internment in the country until pharmaceutical laboratory importer.
7. To align the computer systems that are currently Member States, in order to validate information in them.

8. To instruct the pharmaceutical industry on the reformulation of drugs to replace the pseudoephedrine or phenylephrine by substances of similar therapeutic effects, prior concept of the World Health Organization on the therapeutic implications of this change.

9. While these actions are implemented, self-regulatory agreements with the various associations of pharmacists and pharmaceutical distributors to set limits on the sale of medicines based Pseudoephedrine and ephedrine.

10. Require accountability that the product has a health registry either as finished product or drug to be manufactured with raw materials.

11. It is intended to adopt some sort of identification system such as radio frequency that offers greater security even before the GPS cargo handling.