



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.