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Final Report of the Group of Experts on Pharmaceutical Products

EXPERT GROUP CONCERNING PHARMACEUTICAL PRODUCTS
August 25-27, 2003
Brasilia, Brazil

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FINAL REPORT

Preliminary Version

I. BACKGROUND

During the Thirty-second Regular Session of CICAD held in Mexico City, Mexico, December 2-5, 2002, the Commission directed that the Expert Group on Pharmaceutical Products meet to examine the issue of diversion control, and make recommendations thereon to the Commission.

CICAD's Expert Group on Pharmaceuticals subsequently met from Aug 25-27, 2003 in Brasilia, Brazil.

II. PROCEEDINGS

A. PARTICIPANTS

1. MEMBER STATES OF CICAD

Thirty-nine experts from the following member states participated in this meeting: Argentina, Bolivia, Brazil, Canada, Chile, Colombia, Dominican Republic, Mexico, Peru, United States, and Uruguay. (Directory of Experts attached).

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

A joint opening session for this expert group meeting and the one on chemical control took place at 9:30 a.m. on August 25 in the Carleton Hotel in Brasilia. The following individuals offered opening remarks:

- José Augusto de Barros, Sub Secretário Nacional Antidrogas
- Delegado Zulmar Pimental Dos Santos, Department of the Federal Police
- Mr. Cláudio Maierovitch Pessanha Henriques, Ministry of Health
- Ministro Marcos Vinicius Pinta Gama, Ministry of Foreign Affairs
- Delegado Ronaldo Urbano, President of the meeting of the Expert Group on Chemical Substances
- Mr. Paulo Morais Santa Rosa, President of the meeting of the Expert Group on Pharmaceutical Products
- Ziggie Malyniwsky, Chief or the Supply Reduction and Control Section, OAS/CICAD

2. WORKING SESSIONS

The Group of Experts on Pharmaceutical Products met during five working sessions to review and finalize the guides for control systems, industry and health professionals that were initiated during the last meeting of the group in October 2002. The Experts were also tasked with reviewing the items remaining on the plan of action that they had previously prepared with consideration to new issues of concern as well as the recommendations concerning the control of pharmaceutical products found in the Hemispheric Report of the Multilateral Evaluation Mechanism (MEM).

In addition to discussing and considering the foregoing, the Expert Group received a presentation by the delegation of Brazil concerning the national pharmaceutical control system that is currently being developed and implemented in Brazil.

A. Review of Manuals/Guides

The Experts considered the three manuals or guides proposed during the last meeting of the group (October 2002). The first draft of the Elements for the Control of Pharmaceutical Products Containing Narcotics and Psychoactive Substances was prepared by Colombia and presented at the October 2002 meeting. Following that meeting the delegations of Mexico and the United States coordinated the further drafting and elaboration of this document.

During the current meeting, the Experts reviewed the draft and made further changes to the text. A copy of the finalized version is attached.

The Group submits this guide concerning elements of pharmaceutical control systems for the consideration of the Commission. Further to any changes that the Commission might propose or direct be made, the final version of this guide will be made available for distribution and will be posted to the CICAD web page.

In considering the draft guides for industry and health professionals (doctors, dentists, veterinarians, pharmacists, nurses), the Group found them to be comprehensive and full of important information. At the same time, the scope of the guides extended beyond the focus originally intended. This objective of these guides was to provide practical information and best practices that might be employed by these two groups in order to minimize their unknowing/unwitting involvement if the diversion of pharmaceutical products.

Using the time available, the Experts defined the scope of the health professionals guide, identifying specific sections that they might include, such as:

- Preamble
- Responsibilities of prescribers
- Physician-patient relationship

- Basic requirements for prescribing
- Security
- Vigilance against diversion
- Treatment of chronic pain/diseases
- Abuse of benzodiazepines
- Problems of self medication
- Education/training
- Physician-Pharmacist relationship
- Social responsibilities of health care professionals
- Record keeping
- Professional samples
- Responsibilities of pharmacists
- Cross border issues related to prescribing and dispensing

The delegations of Canada and Uruguay offered to coordinate the preparation of this guide, which will be reviewed and finalized during the next meeting of the Expert Group. It is understood that these elements may be revised as the guide evolves.

In the case of the guide for industry, the Experts identified the following areas that should be included:

- Preamble
- Responsibilities of Industry
- Government-Industry relations
- Criteria for licensing
- Promotion and professional samples
- Security
- Record keeping
- Guides to self audit and verification

None of the delegations offered to coordinate the preparation of a first draft of this guide. As such, further discussion and development of this document was deferred until the next meeting of the group or until a coordinator could be identified.

B. MEM Hemispheric recommendations:

IThe Expert Group considered the two recommendations concerning the control of pharmaceutical products found in the Hemispheric Report of the MEM. In doing so, the Group considered what actions might be taken to implement these recommendations.

> **8. Conduct a thorough review of domestic regulations for the control of Pharmaceuticals and strengthen coordination mechanisms among the relevant sectors.**

The national legislation and regulations form the framework for effective control of pharmaceutical products. These two components are critical for any serious efforts in

this regard. Legislation and regulations must respond to the needs and circumstances of each country while ensuring compliance with international treaties and agreements. Frequently, legislation remains unchanged until a specific event impose the need for a review and updating. Regulations tend to change on an on-going basis in response to circumstances and needs. Periodically it is necessary to review and consolidate regulations.

In considering this recommendation, the Experts agreed that a review of this nature is essential. Each country should review its legislation and regulations to ensure that they are consistent with the spirit and responsibilities of the International Conventions. They also must provide the necessary powers and conditions that would allow for the effective control of pharmaceutical products containing psychotropic substances.

In conduction a review of this nature, member states could benefit from the experience of others in this regard. Access to information regarding existing legislation and regulations and issues related to the control of pharmaceuticals would facilitate such a review. Technical legal assistance from the Executive Secretariat would also be helpful.

The issues of coordination and communication are also featured in MEM Hemispheric recommendation 10 and will be considered under that item.

The Experts propose the following actions:

- The Executive Secretariat should establish a section in the CICAD web page concerning the control of pharmaceutical products and, as a start, include the following information:

    - links to web pages maintained by member states that contain their national chemical control legislation and regulations as well as the substances that they control and, where such web pages do not exist, the name and contact information of a person that interested parties can consult

- The Executive Secretariat should provide technical legal assistance to member states requiring this type of support as they review their national legislation and regulations.

The Experts offer the following recommendation:

- The Commission should encourage member states to review and update their national legislation and regulations for the control of pharmaceutical products and should follow-up on the implementation of this review through the MEM process

10. Implement a hemispheric communication and coordination system in order to improve and facilitate cooperation and coordination among member states on matters related to control of pharmaceutical products and controlled chemical substances at the national and international levels.

The Group of Experts recognized the importance of open communication and close cooperation and coordination in the effective control of pharmaceutical products, highlighted by this recommendation. At the same time, the Group was not clear as to what exactly the recommendation was proposing. Specifically, the Group was unclear as to what was meant by a "hemispheric communication and coordination system".

In discussing this recommendation, the Group identified a number of possible interpretations. In the end, while recognizing the importance of communication and coordination among the various entities involved in the control of pharmaceutical products, the Experts did not believe that it was necessary to develop a formal hemispheric system for this purpose. Rather, the Group proposed that entities in member states should make use of existing tools and resources for this purpose. These resources can assist member states in coordinating their activities both at the inter-agency level within a country and internationally. In addition, the Experts proposed that member states could also benefit from the experiences and best practices of others to enhance their communication and coordination activities.

The Expert Group also proposed that as an active entity it also served to promote communication and coordination among the participating entities and member states as it addressed issues of mutual concern.

Finally, the Experts highlighted the decision reached by the Commission during its XXXIII regular session to adopt the National Drug Control System (NDS) as the software it encouraged member states to use in the control pharmaceutical products. The NDS software provides a means for agencies in a country to access common national databases concerned with the control of pharmaceuticals. NDS also provides the means for inter-agency communication as well as communication with counterparts in other countries.

The Experts propose the following actions:

- Include the following information in the web page referenced above:

    - a directory of operational points of contact in member states concerned with the control of pharmaceutical products (the Executive Secretariat will examine existing directories of this nature maintained by other groups or organizations including the Andean Group and Mercosur)
    - a directory of official Competent Authorities in member states responsible for the control of pharmaceutical products. The information will be either extracted from the directory maintained by the International Narcotics Control

Board (INCB) or through a link to an existing electronic directory maintained by that organization

- The Executive Secretariat should work with the INCB to develop and execute a plan of action for the expanded implementation of NDS in interested CICAD member states
- Members of the expert group should review existing best practices for communication and coordination (Inter-sectoral, inter-agency, international) for discussion during the next expert group meeting leading to the development of a reference paper of best practices in this regard.

The Experts also offer the following recommendation:

- That the Commission direct the Expert Group on Pharmaceutical Products to meet on a regular basis and serve as an on-going forum to promote communication and coordination and to address issues of concern to member states regarding the control of pharmaceutical products

C. OTHER ISSUES

During its last meeting in October 2002, the Experts prepared a plan of action that included the preparation of the guides referenced above as well as other activities. While the Group and Executive Secretariat addressed some of these activities, others remained to be initiated. The Group considered these initiatives along with other new ones that covered a range of issue areas including legislation/regulations, control systems and training. Some of the items included in the plan of action were addressed in the discussion of the Hemispheric recommendations to the MEM. In some instances, the Experts decided to drop some of the actions that were included in the original plan.

Following a very active discussion and exchange of views, **the Experts identified the following activities or initiatives:**

- The Executive Secretariat should develop a pilot training seminar for delivery in the Caribbean on the implementation of the elements guide referenced above and subject to the results of this pilot will consider expansion to other sub-regions.
- The delegation from Chile should prepare a draft of “best practices” to overcome impediments to the effective application of regulations and control systems for presentation and discussion (setting aside a full day for this purpose) during the Group’s next meeting
- The Executive Secretariat should consult with member states to gather information on ports and airports that they have designated for importing or exporting pharmaceutical products for discussion during the Group’s next meeting

- Members of the Expert Group should consider mechanisms to strengthen inspection, investigation and other active control activities concerning pharmaceutical products for discussion during the Group's next meeting.

The Experts also offer the following recommendation:

- That the Commission direct the CICAD Observatory and the Expert Group on Demand Reduction examine ways to enhance the capacity of member states to gather and analyze epidemiological and other data concerning the abuse/inappropriate use of pharmaceutical products (with particular consideration for use without prescription)

D. GENERAL ISSUES

While legislative frameworks and comprehensive control systems are important, countries often encounter a gap between these critical elements and their actual implementation. Frequently this is due to a number of reasons including a lack of political will, failure to apply the necessary resources (human and financial) and professional staff that lack the knowledge and skills to fulfill their responsibilities.

CICAD member states need to take note of the foregoing and work toward minimizing this gap.

During the meeting the Experts expressed certain concerns related to the logistics of organizing meetings of Experts. In particular, they were concerned as to the criteria that member states use in selecting their representatives for such meetings. There was a concern that in some instances the people with the necessary expertise or skill sets are not always selected to attend such meetings. In addition, at times there are changes in representatives from one meeting to another. This lack of continuity can present problems for the Group in that it is often necessary to revisit issues that have already been addressed.

On a related matter, Experts raised concerns about requests for information sent out by the Executive Secretariat for which replies by member states are incomplete, late or not actioned. A related problem identified concerns the distribution of documents and other materials by the Executive Secretariat. The procedures call for the Executive Secretariat to distribute these materials to the Permanent Missions to the OAS with copies to the Commissions and, where the information is available, directly to the country representatives to the meeting in question. The materials are normally distributed by several means such as courier, email and fax. In some instances, member states and representatives to meetings report that they did not receive the materials. The reasons for this problem are not clear but may relate to issues such as inaccurate contact information (email and fax numbers) or gaps in the internal distribution or communication procedures used by some member states.

The Experts also offer the following recommendation:

- That the Commission remind member states of the need to carefully select their country representatives to the Expert Group, working group and other meetings with consideration to the nature of the meeting in question, the skills required and the importance of continuity in subsequent meetings.
- That the Commission encourage member states to respond to requests from the Executive Secretariat in a timely manner
- That the Executive Secretariat examine the procedures used to distribute information to and receive information from member states. In doing so, the Executive Secretariat should work with member states to identify potential problems in the procedures used by both parties that may contribute to interrupted or inefficient information exchange and possible solutions to address the foregoing

3. CLOSING SESSION

The Expert Group concluded its work at 12:30 on August 27. The Chair of the Group closed the meeting.

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS THIRTY-FOURTH REGULAR SESSION:

1. That the Commission consider and accept the guide entitled "**Elements for the Control of Pharmaceutical Products Containing Narcotics and Psychoactive Substances"** and direct the Executive Secretariat to distribute and post the guide to the CICAD web page.

<u>Recommendations to Member States</u>

2. That the Commission encourage member states to review and update their national legislation and regulations concerning pharmaceutical products and to follow-up implementation of this review through the MEM process

3. That the Commission encourage member states to review and update the administrative procedures, mechanisms and systems that they have in place for the control of pharmaceutical products and to follow-up on the implementation of this review through the MEM process

4. That the Commission remind member states of the need to carefully select their country representatives to the Expert Group, working group and other meetings with consideration to the nature of the meeting in question, the skills required and the importance of continuity in subsequent meetings

5. That the Commission encourage member states to respond to requests for information or other input received from the Executive Secretariat in a timely manner

Recommendations to the Executive Secretariat

6. That the Commission direct the CICAD Observatory and the Expert Group on Demand Reduction to examine ways to enhance the capacity of member states to gather and analyze epidemiological and other data concerning the abuse/inappropriate use of pharmaceutical products

7. That the Commission direct the Executive Secretariat to examine the procedures used to distribute information to and receive information from member states. In doing so, the Executive Secretariat should work with member states to identify potential problems in the procedures used by both parties that may contribute to interrupted or inefficient information exchange and possible solutions to address the foregoing.

8. That the Commission direct the Executive Secretariat to establish a section in the CICAD web page concerning the control of pharmaceutical products and, as a start, include the following information:
   - links to web pages maintained by member states that contain their national chemical control legislation and regulations as well as the substances that they control and, where such web pages do not exist, the name and contact information of a person that interested parties can consult
   - a directory of operational points of contact in member states concerned with the control of pharmaceutical products (the Executive Secretariat will examine existing directories of this nature maintained by other groups or organizations including the Andean Group and Mercosur)
   - a directory of official Competent Authorities in member states responsible for the control of pharmaceutical products. The information will be either extracted from the directory maintained by the International Narcotics Control Board (INCB) or through a link to an existing electronic directory maintained by that organization

9. That the Commission direct the Executive Secretariat to provide technical legal assistance to member states requiring this type of support as they review their national legislation and regulations

10. That the Commission direct the Executive Secretariat to work with the INCB to develop and execute a plan of action for the expanded implementation of NDS in interested CICAD member states

11. That the Commission direct the Executive Secretariat to develop a pilot training seminar for delivery in the Caribbean on the implementation of the elements guide referenced above and subject to the results of this pilot will consider expansion to other sub-regions

12. That the Commission direct the Executive Secretariat to consult with member states to gather information on ports and airports that they have designated for importing or exporting pharmaceutical products for discussion during the Group's next meeting

Recommendations to the Expert Group

13. That the Commission direct the Expert Group on Pharmaceutical Products to meet on a regular basis and serve as an on-going forum to promote communication and coordination and to address issues of concern to member states regarding the control of chemical substances

14. That the Commission direct the Expert Group on Pharmaceutical Products to meet in 2004 to complete the following tasks:
    - review existing best practices for communication and coordination (Inter-sectoral, inter-agency, international) for discussion during the next expert group meeting leading to the development of a reference paper of best practices in this regard.
    - with coordination by the delegation from Chile, prepare a draft of "best practices" to overcome impediments to the effective application of regulations and control systems for presentation and discussion (during the Group's next meeting
    - consider mechanisms to strengthen inspection, investigation and other active control activities concerning pharmaceutical products during the Group's next meeting

Annex I

ELEMENTS FOR THE CONTROL OF PHARMACEUTICAL PRODUCTS CONTAINING NARCOTICS AND PSYCHOACTIVE SUBSTANCES

PREAMBLE

Taking into account the problem of the abuse and diversion of pharmaceutical products containing psychotropic substances and narcotics (hereinafter "pharmaceutical substances and products"), the member states undertake to promote the effective control of such substances.

The member countries should continue to implement controls and fulfill their obligations under international agreements[1], and should promote the signature of these agreements by member states that have not yet done so.

Considering that national controls must be geared toward the particular problems of diversion and abuse identified in each country and that the member countries have achieved varying degrees of implementation, at the national and hemispheric levels, of legal and regulatory structures for the control of pharmaceutical substances and products.

The member countries recommend the adoption of the following guidelines for a viable system of control. The proposed elements represent best practices implemented among a number of Member states. Although these elements are not compulsory, their adoption by the competent authorities, whether partial or total, is desirable.

I. INTRODUCTION

Any control system should be based upon the following principles:

- To promote measures ranging from legislation and regulation to the application of corrective measures.
- To balance the control of pharmaceutical products against the need to ensure availability for medical, scientific, and other legitimate purposes.
- To foster international cooperation, which is essential to preventing diversion.

[1] "International agreements" means all applicable agreements and treaties, especially the 1961 Single Convention on Narcotic Drugs, amended by the 1972 Protocol of Amendment to that Convention; the 1971 Convention on Psychotropic Substances; and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

II. LEGISLATIVE FOUNDATION AND REGULATORY FRAMEWORK

A. Legislation

Principles:

- Legislation and regulations must:
  - Provide the authority to create a closed system of distribution by regulating pharmaceutical products at all stages, from importation and manufacture to distribution and final use.
  - Identify the government components responsible for control and regulation, to include the specific functions of each component in order to provide a complete, non-duplicative system of control.
  - Identify activities involving pharmaceutical products (e.g., manufacture, importation, sale) that are part of the system of control and are therefore subject to licensure or registration.[2]
  - Prescribe a mechanism for licensing specific activities and the standards to be met by each class of licensee.
  - Identify which substances are to be controlled and provide the means to remove, transfer, or add substances as required.
  - Define violative conduct and establish administrative, civil, and criminal sanctions.

Measures:

- Countries should enact a reasonable system to control and monitor the flow of pharmaceutical products at all stages up to the final user or point of destruction
- Countries should consider as criminal activities:
  - the organization, management, direction and financing;
  - incitement, inducement, or advice;
  - conspiracy, collusion, participation, or aiding and abetting;
  - harboring, association, and accessory after the fact;
  - attempt; and
  - facilitation of illegal activities in which pharmaceutical products are involved.
- To address conduct contrary to the laws and regulations governing control of pharmaceutical products, and provide for administrative and civil penalties consisting of:
  - reprimands, fines, confiscation, suspension or revocation of licenses and permits (e.g., import/export permits),
  - temporary or permanent closure of establishments, and
  - imprisonment
- In addition, countries should provide for corrective actions and sanctions along the lines laid out in Part IV. C
- National laws should provide for the placement of substances on one of a series of lists or schedules with varying controls e.g. this document refers to five schedules. The scheduling of substances should be consistent with provisions set forth in international Conventions. The schedules should classify substances (including

[2] The drafters understand the terms “license” and “register” to be nearly synonymous. In order not to burden the text, we have chosen to use only the term “license” in this document.

pharmaceutical products that contain them) according to the following criteria:
  - Health risks, including potential for abuse, addiction and diversion
  - Degree of accepted use under medical supervision in the country

B. Licensing

Principles:

- Only qualified persons, firms, and institutions should be authorized to conduct regulated activities with pharmaceutical products.
- Each competent authority should issue licenses to persons, firms, and institutions (including academic and research facilities) that apply and meet the legal and regulatory criteria.
- Each competent authority may consider issuing a license to handle controlled substances separately from other professional or business licenses. This will provide the competent authority with a means to take action on a licensee's authority to handle controlled substances while allowing the licensee to continue other aspects of business or practice
- Licensure to conduct activities with controlled substances (this is a privilege, not a right) may be conditioned, suspended, or revoked, subject to due process, in order to protect the public.
- All competent authorities should establish activity-specific security standards for licensees to provide effective controls and procedures to guard against theft and diversion of pharmaceutical products.
- Each competent authority should establish procedures for the proper and documented destruction of controlled substances and products that are expired, outdated, or contaminated.

Measures:

- Persons, firms, and institutions engaged in the following activities should be required to be licensed with the competent authority. The following is one suggested system to match each activity with a license category.

Activities	**License Category**[3]
Import	Importer
Export	Exporter
Manufacture, Production, Cultivation, Preparation, and Repacking	Manufacturer
Distribution, Wholesaling, Marketing, Sale, Destruction (special procedures apply)	Distributor
Prescribing, Dispensing, and Administering to patients	Practitioner (doctor, veterinarian, dentist, etc.)
Dispensing at retail to, or on behalf of, the final user (i.e., patient); Dispensing for administration in a healthcare institution	Pharmacies

[3] For Practitioners and Pharmacies, the competent authority may delegate this authority to provincial or state licensing authorities for health professionals.

Analytical Laboratories and Research	Analyst / Researcher
Transportation	Transporter (as appropriate)

Note: Brokers or their representatives who do not take legal ownership of the pharmaceutical product are not required to be licensed. Brokers who do take legal ownership are required to be licensed for the category of registration applicable to their activities.

- **An up-to date registry of persons, firms, and institutions (preferably automated) authorized to conduct each licensed activity should be maintained by or accessible to the competent authority.**
- The competent authority should establish appropriate criteria for licensing, including for example:
    - Maintenance of effective controls (e.g. inventories and transaction records) against diversion of pharmaceutical products into illicit channels.
    - The applicant's history of compliance with applicable laws and regulations
    - Prior conviction record of offenses relating to pharmaceutical products or other significant crimes (felonies) by an individual applicant or the principals in a firm applying for a license.
- Licenses should be subject to periodic renewal.
- A reasonable fee should be charged for registration and renewal. (Note: Countries may seek to set fees at levels to cover the costs of administering the control program, including registration activities, monitoring, and enforcement.)
- Licenses may be denied, suspended, or revoked, subject to due process, based on violation of the country's applicable laws and regulations, and for other specified circumstances, for example:
    - That the original application for licensure or any renewal contains material false statements
    - A principal of the licensee has been convicted of an offense relating to pharmaceutical products or another significant crime (felonies)
    - Another government entity has taken adverse action against the licensee or one of its principals
    - The licensee has engaged in acts that would render its continued licensure in violation of the public interest
- Each competent authority should establish a time interval for each category of licensee to take periodic physical inventories of pharmaceutical products (e.g., annually, biennially).
- Each competent authority should establish a system of records that each licensee should maintain so as to provide for full accountability of pharmaceutical products that are imported, exported, manufactured, distributed, dispensed, lost/stolen, destroyed, or disposed.
- Persons and firms licensed to conduct activities with pharmaceutical products are deemed to consent to inspections of business premises and of required records (in paper or electronic form), stocks, inventories, equipment, security systems, and other business records relevant to compliance with applicable laws.

III. ACTIVITIES COVERED

A. Import/Export

Principles:

- Quantities and procedures for importing and exporting pharmaceutical products (raw of finished forms) should be consistent with International Conventions.
- Quantities of imported pharmaceutical products (raw or finished forms) should be consistent with medical, scientific, or other legitimate needs.
- The competent authorities should establish a mechanism for supervising imports and exports of pharmaceutical products.
- Imports and exports should only take place between duly licensed persons, companies, and institutions
- Due to the inherently international nature of import and export transactions, international cooperation between competent authorities is essential.
- Countries should apply measures to monitor shipments of pharmaceutical products and to detect and suppress illicit traffic in pharmaceutical products in free ports and free trade zones
- Countries through which pharmaceutical products are shipped in transit are treated as part of the international control system

Measures:

- The competent authority of each country should establish a mechanism to assess medical, scientific, and other legitimate needs for pharmaceutical products to be imported.
- The competent authorities should develop mechanisms for issuing import and export permits, as well as other procedures in accordance with International Conventions, with particular respect to the following areas:
    - Total annual imports will not exceed the estimates declared by the competent authority based on the national assessment of needs.
    - A mechanism should be established for reporting to the competent authority the details of the actual import or export shipment, including date, quantity, product, packaging, and routing. For example, the law might require Customs to file a report (or “return”) on imports, and the exporting firm to file a report (or “return”) on exports.
- The exporter should ensure that appropriate security controls are in place during transit of the pharmaceutical product, and should select a carrier that has adequate controls, to safeguard against loss or theft.
- Where a pharmaceutical product is controlled in one country (import/export) but not in the other country, competent authorities are encouraged to provide a letter/certificate of no objection to the requesting country.
- A substance or pharmaceutical product may transit a country (including free ports and free trade zones) only if the competent authority of the exporting country notifies the competent authority of the transit and importing countries in advance and the export permit with reference to this notification accompanies the shipment

B. Manufacture/Production

Principles:

- Only licensees authorized to do so should manufacture/produce pharmaceutical products.
- Each competent authority should develop a system to sure that the yearly quantity of each controlled substance manufactured and produced does not exceed the total estimated needs for:
    - Domestic medical, scientific, research or industrial needs
    - Exports to foreign countries
- Competent authorities should determine appropriate records to be kept by manufacturers to ensure accountability and avoid diversion.
- Manufacturers should be authorized to distribute only those pharmaceutical products they manufacture. Distribution of other products should require a separate license as a distributor.

Measures:

- Each competent authority should develop a system for the procurement of controlled substance raw materials to be used in the manufacture of pharmaceutical products.
- Each manufacturer should maintain records to provide accountability for controlled substances used through each stage of the manufacturing process, including:
    - Manufacture/production of bulk material
    -Manufacture of finished product
    -Packaging of finished product
- Each manufacturer should take a complete physical inventory of all pharmaceutical product stocks on at least a yearly basis including:
    - Raw material
    -In-process material
    -Bulk dosage form
    -Packaged goods
    -Waste material awaiting destruction
    - Pharmochemicals used in the manufacturing process
- Manufacturers should maintain records at each stage of the manufacturing process to account for the use of controlled substances. Records should include:
    -Identification of product to be manufactured, including name and strength of product
    -Batch number and date started and completed
    -Theoretical yield
    -Quantity of raw material entered into production
    -Actual yield
    -Quantity used in quality control
    -Quantity of material recovered during production (i.e., recovered waste)
    -Quantity of non-recovered loss and reason for loss, if known
    -Such other information as is necessary to account for all controlled substances, including destruction
- Manufacturers should maintain a record of pharmaceutical product (bulk or finished form) distributed to other persons in accordance with the provisions of Section III.C., Distribution.

- If a manufacturer holds more than one license (e.g., exporter) the manufacturer should maintain a record of pharmaceutical products transferred to the activities covered by the other license.
- Manufacturing records should be maintained in either manual hard copy or electronic form, or both.
- Competent authorities should ensure that all records and reports of manufacturers comply with pertinent international Conventions and obligations.

C. Distribution

Principle:

- Distributors should be regulated as part of a closed system of distribution.

Measures:

- Only licensees authorized to do so should distribute or supply pharmaceutical products to other licensees.
- Distributors should maintain records of their activities involving pharmaceutical products
- Records should contain, at a minimum, the following information (including as appropriate, dates, names, quantities, dosage form, presentation, concentration etc):
  - An inventory conducted at regular intervals (e.g., biennial, monthly).
  - The following documents:
    - Purchase Invoices
    - Sales Invoices
    - Returns of Distributed Products
    - Destruction Records, and
    - Theft or Lost Records.
- Normal business records, if they meet the above standards, should be deemed sufficient.
- Records should be updated on a timely basis, (e.g., within 24 hrs.)
- Records should be retained and be available for inspection for a reasonable time period (e.g., 3 years).
- Distributors should design a system to detect suspicious or unusual orders – i.e., orders of a volume, type, or nature not in keeping with normal commerce – and should report such suspicious orders to the competent authority promptly upon discovery.
- Competent authorities should develop guidelines of good practices for distribution, including circumstances where (if feasible) a suspicious or unusual order should not be filled.
- All distributors should report thefts or loss of pharmaceutical products, immediately upon discovery, to the competent authority and, if different, to the designated law enforcement authority responsible for investigating such incidents.

D. Prescribing

Principles:

- The primary responsibility for proper prescribing, and dispensing rests upon the prescribing practitioner, but a corresponding liability rests upon the pharmacy that fills the prescription
- A prescription for a controlled substance may be issued only for a legitimate medical purpose by an authorized practitioner acting in the usual course of his professional practice, and based upon an established face-to-face relationship with the patient

Measures:

- Legislation adopted by countries should define the acceptable means through which prescriptions may be issued, e.g. written, verbal, electronic. These means may vary by drug schedule.
- Countries should periodically review authority and provisions for prescribing (e.g. what type or specialty of health practitioner should be able to prescribe what drugs)
- An Authorized Practitioner means any health practitioner who, under the national law (including reference to the laws of states or provinces, where applicable), may prescribe pharmaceutical products (Note: As used in Part IV, B, practitioner and prescriber mean the same as authorized practitioner)
- A prescription issued other than for a legitimate medical purpose and outside the usual course of professional practice is invalid, and persons knowingly issuing or filling such prescriptions may be subject to penalties.
- When issuing a prescription, the practitioner should include the following information as a minimum:
    - Identification of the patient
    - Identification of the practitioner
    - Date of issue
    - Name, strength, and total quantity of drug
    - Directions for use
- A practitioner should keep a record of the prescription he or she issues for a period of time as determined by the competent authority.
- The pharmacy filling the prescription should maintain the original prescription on site for a minimum period of time as determined by the competent authority.
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- A practitioner may dispense pharmaceutical products directly to the patient and should maintain dispensing records, including at a minimum, drug name, strength, quantity, and date dispensed.
- Competent authorities should establish procedures for patients who use pharmaceutical products and travel or settle temporarily in another country, to carry or obtain their prescription drugs in accordance with International Conventions.
- Practitioners and pharmacies may not send controlled substances through the mail or by common carrier directly to citizens of another country unless authorized by national competent authorities, in accordance with International Conventions.
- Dispensers should maintain a record of pharmaceutical products purchased, obtained, or entered into stock/inventory.
- Dispensers should take a physical inventory of pharmaceutical products on a periodic basis as established by the competent authority (yearly, biennially).

E. Dispensing

Principles:

- Pharmaceutical products may only be dispensed upon issuance of a lawful prescription or medical order
- A prescription may only be dispensed by a licensed and authorized pharmacy or authorized agent.
- A prescription for a controlled substance may be issued only for a legitimate medical purpose by an authorized practitioner acting in the usual course of his professional practice, and based upon an established face-to-face relationship with the patient
- The primary responsibility for proper prescribing, and dispensing rests upon the prescribing practitioner, but a corresponding liability rests upon the pharmacy that fills the prescription.

Measures:

- A supposed prescription issued other than for a legitimate medical purpose and outside the usual course of professional practice is invalid, and persons issuing or filling such prescriptions may be subject to penalties.
- The pharmacist who fills the prescription should sign or initial the prescription and should date it as of the date of filling or refilling.
- The pharmacy filling the prescription should maintain the original prescription on site for a minimum period of time as determined by the competent authority.
- In the case of a prescription transmitted orally by a practitioner (or his agent), the pharmacist should commit the prescription to writing and maintain the record for a minimum period of time as determined by the competent authority.
- Prescriptions for controlled substances may be kept in hard copy or electronic form. If the pharmacy chooses to keep electronic records, the original hard copy of prescriptions for substances that are required because of their scheduling should also be kept
- Countries, through their legislation, should determine the conditions and circumstances of how a prescription may be filled, partially filled and refilled, and this may vary from schedule to schedule
- The pharmacist who fills the prescription should sign or initial the prescription and should date it as of the date of filling or refilling.
- The pharmacist filling the prescription should affix a label to the container or package including:
  - Name/address of pharmacy
  - Date of filling
  - Prescription number (a unique number should be issued for each prescription)
  - Name of patient
  - Prescribing practitioner
  - Drug and quantity dispensed
- Periodic partial filling of prescriptions may be permitted with the following procedures:
  -Each partial filling is recorded with date and quantity dispensed
  -The total quantity dispensed does not exceed the total quantity prescribed

-No dispensing occurs beyond the period for which the prescription is valid.

IV. ADMINISTRATION AND ENFORCEMENT

A. Monitoring, Inspection, and Investigation

Principles:

- Each licensee authorized to handle pharmaceutical products is subject to inspection by the competent authority.
- Each competent authority should establish procedures for the inspection of licensees to ensure compliance with established laws, regulations, and procedures.
- Violations of established laws and/or regulations uncovered during inspections should be reported to the competent authority for further investigation and/or sanctions, subject to due process of the country.
- Countries should adopt an automated information system for the control and monitoring of pharmaceutical products.

Measures:

- Each competent authority should establish criteria for inspection to include, but not be limited to, frequency and scope, and cause required for inspection.
- Inspection of licensees should include at minimum:
    - Physical and procedural security measures
    - Required records, reports, or documents
    - Physical inventories
    - Equipment used in manufacturing
    - Collecting of samples for analysis
    - Records that are appropriate for verifying required records, reports, or documents
- Each competent authority should identify items, if any, that should not be subject to inspection.
- Each Competent Authority should maintain a system to track the results of inspections and on-going compliance.
- The competent national authorities should evaluate the existing National Drug Control Software (NDS), developed by the International Narcotics Control Board (INCB) and other available database systems for use as an automated tracking system for pharmaceutical products.

B. Corrective Actions and Sanctions

Principles:

- A range of administrative, civil, and criminal corrective actions and sanctions should be available and utilized in appropriate circumstances, depending on the severity of the violations. Civil and administrative sanctions available should include those set

forth in Section II.A., Legislative foundation and regulatory framework (Measures). Criminal sanctions should include those generally available under the penal law.

- Criminal, civil, and administrative sanctions available under the law should be sufficiently strong to deter violations and ensure compliance.
- In some instances, a combination of corrective actions and sanctions is most appropriate – e.g., criminal prosecution of employees of a firm responsible for diversion of pharmaceutical products coupled with administrative sanctions or civil penalties against the firm that failed to adequately supervise the employees or to detect unlawful conduct or diversion.

Measures:

- Infractions and offences should be defined to include any violations of laws or regulations involving pharmaceutical products. Without prejudice to the generality of the preceding statement, the law may further enumerate specific types of violations, including:
  - Unlawful import, export, or transit
  - Unlawful manufacture, distribution, or possession for the purpose of distribution
  - Unlawful distribution and transportation
  - Unlawful prescribing or dispensing of pharmaceutical products
    - For other than a legitimate medical purpose, or
    - Outside the usual course of professional practice or scope of license of the prescriber or dispenser
  - Unlawful possession for purposes other than for trafficking subject to considerably reduced penalties, including treatment as an alternative to punishment
  - For a licensed person, firm, or institution to engage in activities that exceed those permitted by the applicable license
  - To refuse make or maintain any information or documents required by law or regulations
  - To furnish false or fraudulent information or omit any information required by law or regulations
  - To refuse lawful entry for inspection of premises as permitted by law or regulation
  - To distribute, seek to acquire or to acquire a pharmaceutical product by misrepresentation, fraud, forgery, deception, or theft

C. Coordination and the Exchange of Information

Principles:

- Effective control of pharmaceutical products depends upon continuous coordination, cooperation, and exchange of information between the following parties:
  -The competent authorities of member countries
  -The competent authority of each country and other national or state/provincial regulatory, customs, health, and law enforcement agencies
  -The competent authority of each country and the pharmaceutical industry
  -The competent authority of each country and regional, multilateral, and UN-based organizations
  -The competent authority and the citizens of the country

Measures:

- Competent authorities of all member countries should establish a means of coordination and cooperation to provide current and rapid exchange of information regarding:
  - Legitimate international trade of pharmaceutical products
  - Irregular or suspicious international movement of pharmaceutical products
  - Thefts, losses, or disappearances of pharmaceutical products while in international transit
- Competent authorities of each member country should establish a means of coordination and cooperation with other national or state/provincial regulatory, customs, health, and law enforcement agencies to provide rapid and current exchange of information regarding:
  - Irregular or suspicious movement or patterns of domestic trade or consumption of pharmaceutical products
  - Domestic thefts, losses, or disappearances of pharmaceutical products
  - Illegal or violative activities of individuals, firms, or institutions
- Competent authorities should establish a means of cooperation and communication with licensed individuals, firms, and institutions to promote:
  - Compliance with laws and regulations
  - Reporting of suspicious orders, activities, patterns, or trends involving pharmaceutical products
  - Recommended actions to deter or suspend these suspicious orders, activities, patterns, or trends
- Competent authorities should:
  - Comply with all provisions of international conventions and obligations pertaining to drug control
  - Fully support and participate in drug control initiatives by regional, multilateral or UN-based organizations
- Competent authorities should establish a means of coordination and information exchange to facilitate:
  - Studies on the consumption of pharmaceutical products within the hemisphere, with emphasis on the epidemiology of legitimate use and patterns of abuse
  - Educational and consumer awareness programs regarding the potential risks and dangers of pharmaceutical products and strategies to prevent their improper use or abuse