

ORGANIZATION OF AMERICAN STATES



INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

FORTIETH REGULAR SESSION
November 29 – December 1, 2006
Santa Cruz de la Sierra, Bolivia

OEA/Ser.L/XIV.2.40
CICAD/doc.1522/06
21 November 2006
Original: English

FINAL REPORT
Preliminary Version

GROUP OF EXPERTS ON
PHARMACEUTICAL PRODUCTS

ORGANIZATION OF AMERICAN STATES



INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

**GROUP OF EXPERTS ON
PHARMACEUTICAL PRODUCTS
August 23 - 25, 2006
Buenos Aires, Argentina**

**OEA/Ser.L/XIV.4
CICAD/doc.3/06
August 29, 2006
Original: English**

FINAL REPORT

Preliminary Version

I. BACKGROUND

The thirty-eighth Regular Session Commission of the Inter-American Drug Abuse Control Commission (CICAD) took place in Washington, D.C. from December 6-9, 2005). During that meeting, Mr. Gabriel Abboud of SEDRONAR, speaking on behalf of the chairman of the Group of Experts on Pharmaceutical Products, presented the report from the Group's meeting that took place in Buenos Aires, Argentina from August 24 to 26, 2005.

The Commission received the report and approved the Group's proposed plan of action for 2006, which included a meeting during the course of that year

The Group of Experts subsequently met in Buenos Aires, Argentina from August 24 to 26, 2005 under the chairmanship of Dr. Oscar E. Cavarra, Director of the Directorate of Border Registration, Inspection, and Health. Ministry of Health and the Environment

II. PROCEEDINGS

A. PARTICIPANTS

1. MEMBER STATES OF CICAD

Forty-three experts from the following 18 member states participated in this meeting: Argentina, Bahamas, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Jamaica, Mexico, Panama, Trinidad and Tobago, United States, and Venezuela.

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

The opening session for the meeting of this Group of Experts took place in the Hotel Pestana Buenos Aires on August 23, 2006. Dr. Oscar E. Cavarra, Director of the Directorate of Border Registration, Inspection, and Health. Ministry of Health and the Environment welcomed the participants to the meeting and offered some preliminary remarks.

2. WORKING SESSIONS

A. Presentations

The Group of Experts on Pharmaceutical Products met in five (5) working sessions during which the following presentations were delivered:

Control of Pharmaceutical Products in Argentina

Dr. Oscar E. Cavarra, Dra. Raquel Mendez and Mrs. Marcela A. Andina Silva provided an overview of the systems and programs that are in place in Argentina to control pharmaceutical products. Responsibility for this administrative and regulatory program is shared among several departments or agencies.

Abuse and Diversion of Controlled Substances

Ms. Theresa Schopf of Health Canada delivered a presentation on some of the programs that they have implemented in relation to the control of pharmaceutical products. In doing so, she stressed that the problematic use of pharmaceuticals is an issue of concern across Canada. It is defined as a deliberate, excessive or illegal use and abuse of pharmaceutical drugs. Addressing this issue requires a collaborative and coordinated approach by all levels of government, health care professionals, law enforcement, and other stakeholders. Canada is in the early phase of developing an action plan which addresses 6 key priority areas: research and epidemiology; tracking and monitoring; regulatory issues; public awareness and health promotion; diversion and criminal related activities; and, Health Care Professionals/Health System Needs and Resources.

One recent initiative within this framework of activity involved the preparation of a reference document entitled "Abuse and Diversion of Controlled Substances: A guide for Health Professionals". This document was adapted from the Model Reference Guide for Health

Professionals: Prevention and Detection of Abuse of Narcotics and Controlled Substances and Their Diversion to Illicit Channels developed by the CICAD Expert Group on Pharmaceutical Products. As the title implies, the guide provides health professionals with information on how to detect individuals seeking drugs for non-medical reasons and how to prevent the diversion of pharmaceutical controlled substances to illicit channels. The guide is being distributed to Colleges (licensing bodies) and associations of the health professions in Canada.

Investigation of Internet Sales of Drugs

Mr. Luiz Carlos Da Silva and Mr. Klebber Pessoa of Brazil delivered a presentation on an investigation that the Federal Police had conducted regarding the sale of drugs over the internet. This case involved a group that had established an international operation involving a number of different countries. Through this network, the group had been able to successfully sell drugs illegally since 1998. The presentation described the operation and investigation that finally ended the illegal activities of this group. Mr. Luiz Carlos Da Silva underlined the complexity of the investigation and the critical role that international cooperation among many agencies inside Brazil and in other countries played in the successful conclusion of the case.

B. Working Groups

Model Reference Guide for the Pharmaceutical Industry

When the Group of Experts last met, participants gave preliminary consideration to a draft model reference guide for the pharmaceutical industry prepared by the delegations of Colombia and Costa Rica. Further to this preliminary discussion, the draft guide was further modified for presentation at this meeting.

The delegation of Costa Rica introduced the revised draft for consideration by the participants. Based on the comments and suggestions received, the Group finalized the draft model guide (copy attached) and submits it for consideration and approval by the Commission.

Sale of Drugs over the Internet

During the round table introduction of participants, experts identified a number of issues of concern related to the control of pharmaceutical substances. The one issue for which there seemed to be a common concern among participants was the sale of drugs via the internet.

During the last meeting of this Group, this issue had been the subject of a presentation and considerable discussion. Based on that discussion, the delegation of the United States agreed to prepare a guide related to internet sales of drugs and their investigation.

The delegation of the United States presented the draft document entitled "Drugs in Cyberspace: Understanding and Investigating Diversion and Distribution of

Controlled Substances via the Internet”. This issue and the guide generated a great deal of discussion such that the balance of the meeting was dedicated the subject. During the course of an active exchange on the issue, participants offered comments and suggestions to enrich the draft guide. The finalized version of this draft guide is attached and is offered for the consideration and approval of the Commission.

C. Other issues

In addition to the foregoing, the Group identified a number of other issues of concern related to the control of chemicals. They are as follows:

Counterfeit Pharmaceutical Products

CICAD member states implement comprehensive programs to control pharmaceutical products and prevent their diversion into illicit channels. At the same time, many member states face a growing problem involving the distribution of counterfeit drugs. In some instances these drugs find their way into the country either by means of smuggling or through the authorized systems and channels for distribution through legitimate pharmacies and/or “black market” outlets. The sale or availability of these counterfeit drugs present serious health implications for the people of the CICAD member states where these drugs are made available.

The delegations of Bahamas and Brazil offered to prepare a guide for health professionals concerning counterfeit drugs. This draft guide will be prepared by these two delegations for presentation at the next meeting of this Group.

Rational Use of Products Containing Ephedrine and Pseudoephedrine

Ephedrine and pseudoephedrine are contained in many products sold to relieve cold and flu symptoms. At the same time these products are being diverted either to be taken for non-medical reasons or to be used in the manufacture of methamphetamine. Some member states are facing significant problems in controlling the diversion of these products while still ensuring their availability for medical purposes. Some member states have been able to implement specific strategies to achieve this balance of control and availability.

The delegations of Colombia and Mexico agreed to prepare a draft guide for the rational use and control (administrative/regulatory) of products containing ephedrine or pseudoephedrine (including natural products). This draft guide will be presented to the Group when it next meets.

3. PLAN OF ACTION

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

Guide for health professionals concerning counterfeit drugs (Bahamas / Brazil)

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

Training Curriculum in the Control of Pharmaceutical Products (United States)

4. CLOSING SESSION

The Group of Experts concluded its work at 13:00 on August 25. Dr. Cavarra thanked the members of the Group for their important contributions to the success of the meeting. He further stressed that the diversion of pharmaceutical products impacts all member states, underlining the need for increased efforts by all to deal with this problem.

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS FORTIETH REGULAR SESSION:

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

1. Consider and accept the guide or documents and direct the Executive Secretariat to post them to the CICAD web page:
 - **“Model Reference Guide for the Pharmaceutical Industry**
 - **“Drugs in Cyberspace: Understanding and Investigating Diversion and Distribution of Controlled Substances via the Internet”.**
2. Consider and accept the plan of action proposed by the Group of Experts and direct that the Group meets in 2007 to consider the issues in the plan as well as other new trends or threats identified in the area of control of pharmaceutical products



ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

**MEETING OF THE GROUP OF EXPERTS
CONCERNING PHARMACEUTICAL PRODUCTS
August 23 - 25, 2006
Buenos Aires, Argentina**

SCHEDULE OF ACTIVITIES

Wednesday, August 23

- | | |
|----------------------|---|
| 13h00 – 14h00 | Registration |
| 14h00 – 14h30 | Introduction and Review <ul style="list-style-type: none">• Background• Objectives and CICAD Commission expectations• Schedule of work• Proposed work methodology• Status report on Recommendations• Other issues |
| 14h30 – 15h15 | Roundtable introductions and identification of issues of concern |
| 15h15 – 15h30 | Break |
| 15h30 – 16h30 | Control of Pharmaceutical Products in Argentina |
| 16h30 – 17h30 | Presentation on “Abuse and Diversion of Controlled Substances: A guide for Health Professional” (Canada) |

Thursday, August 24

- 09h00 – 10h30** **Review and finalize the draft model reference guide for pharmaceutical industry**
- 10h30 – 10h45** **Break**
- 10h45 – 11h30** **Discussion by Working Group to identify issues**
- Ketamine questionnaire
- Guide for the Control of Drug Sales Over the Internet
- Diversion and Control of Pharmaceutical Products containing Ephedrine and Pseudoephedrine
- Counterfeit drugs, smuggling and effective border controls
- Guide for health professionals on the rationale use of pharmaceutical products
- Inter-agency cooperation in the control of pharmaceutical products
- Others identified during round table discussion
- 11h30 – 12h30** **Selection of issues for Working Groups**
- 12h30 – 14h00** **Lunch**
- 14h00 – 15h45** **Working group discussions**
- 15h45 – 16h00** **Break**
- 16h00 – 17h00** **Working group discussions (con't)**

Friday, August 25

- 09h00 – 10h45** **Working group discussions (con't)**
- 10h45 – 11h00** **Break**
- 11h00 – 12h30** **Working group discussions (con't)**
- 12h30 – 14h00** **Lunch**
- 14h00 – 15h30** **Working Group Presentations**
- 15h30 – 16h30** **Conclusions, issues, commitments and recommendations for action by the Expert Group**

16h30

Closing



ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

Model Reference Guide for the Pharmaceutical Industry

**MODEL REFERENCE GUIDE FOR PROFESSIONALS WITH
PHARMACEUTICAL ESTABLISHMENTS THAT HANDLE
CONTROLLED SUBSTANCES**

TABLE OF CONTENTS

Introduction. -----	3
Definitions -----	4
Responsibility of the Pharmaceutical Industry -----	5
Relationship between the Pharmaceutical Industry and Government Authorities -----	6
Preconditions for authorization to handle controlled substances -----	6
Criteria for authorizing the handling of raw materials subject to special control and the medications that contain them -----	6
Special provisions for monitoring controlled substances -----	7
Security in handling controlled substances -----	7
Record keeping. -----	8
Self-audit -----	10

INTRODUCTION.

This reference guide is for professionals in charge of pharmaceutical establishments that handle narcotic drugs, psychotropic substances, precursor substances and pharmaceutical preparations that contain them. Substances of this kind are subject to a series of international control measures, stipulated in three major treaties, namely: the 1961 Single Convention on Narcotic Drugs (amended by the 1972 Protocol); the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

The three conventions recognize the therapeutic value of these substances. Hence, one of their basic objectives is to ensure the availability of narcotic drugs and psychotropic substances for medical treatment and scientific uses. At the same time, however, they also advocate cautious use of such substances, confined to strictly legitimate purposes. The 1988 Convention states that measures need to be taken to monitor precursors and some pharmaceutical preparations from which those precursors can be obtained and whose ready availability has caused an increase in the clandestine manufacture of synthetic drugs.

Regrettably, illicit trade in medications containing narcotic drugs and psychotropic substances and preparations containing the precursors listed in Table 1 of the 1988 Convention is currently on the rise. In its 2005 Report, the International Narcotics Control Board drew the international community's attention to pharmacies operating over the Internet, unlawfully selling substances subject to international control. It also reported on the smuggling of drugs – controlled medications and drugs produced in clandestine laboratories- sent via the postal system. This has become an important means of keeping illicit markets supplied. Some of medications being “trafficked” in significant volumes were found to have been obtained from legitimate manufacturers and distributors through theft, falsified trade authorizations and individual prescriptions, or because of a failure to abide by prescription requirements.¹ Substances whose abuse is on the rise and in demand on illicit markets include hydrocodone and oxycodone, methadone, fentanyl, amphetamine and dexamfetamine, methylphenidate, tablets containing ephedrine and pseudoephedrine. However, these are not the only controlled medications being diverted and abused, which is why it is so important to reinforce the systems for control, coordination and cooperation between the authorities and the pharmaceutical establishments that handle these substances, given the social, moral and legal responsibility they bear.

¹ Press Release No. 4, International Narcotics Control Board (03-01-2006)

DEFINITIONS

WHOLESALE DISTRIBUTOR: An establishment that engages in wholesale distribution of controlled medications and that sells them to pharmacies.

RETAIL DISTRIBUTOR: A pharmaceutical establishment that dispenses medications to patients or to someone who collects the medications on a patient's behalf. In most Spanish-speaking countries retail distributors are referred to as *farmacias* [pharmacies].

REGULATORY AGENCY: The government authority in charge of the national controlled substances monitoring systems and the establishments or professionals that handle, prescribe, distribute, and dispense them, etc. .

PHARMACEUTICAL ESTABLISHMENTS: Establishments that play a role in manufacturing, distributing, storing and dispensing medications. They include pharmaceutical laboratories and wholesale and retail distributors.

NARCOTIC DRUGS: Substances that appear on the lists included in the 1961 Single Convention on Narcotic Drugs (which can be viewed at www.incb.org/pdf/e/list/46thedition.pdf).

PHARMACEUTICAL LABORATORY: An establishment engaged in the manufacture of pharmaceutical preparations using controlled raw materials as active principles.

OFFICIAL PRESCRIPTION: The legal document that attests to the prescription authorizing dispensation of controlled medications. It has two parts, both of which must be legible: the prescription *per se* and the directions for use.

PHARMACEUTICAL SECTOR: That segment of industry and business comprising pharmaceutical establishments

PSYCHOTROPICS OR PSYCHOTROPIC SUBSTANCES: Substances listed in the 1971 Convention on Psychotropic Substances (which can be viewed at <http://www.incb.org/pdf/e/list/green.pdf>).

CONTROLLED MEDICATIONS: Pharmaceutical preparations that contain narcotic drugs or psychotropic substances that appear on the list of medications subject to international control.

CONTROLLED SUBSTANCES: Any of the substances listed in the 1961 Convention and its 1972 protocol of amendment , in the 1971 Convention and in List I of the 1988 Convention, and the pharmaceutical preparations that contain them.

RESPONSIBILITY OF THE PHARMACEUTICAL INDUSTRY

Both management and the professional staff charged with operating pharmaceutical establishments that handle controlled substances must be apprised of the risks of diversion associated with these substances. Although in most cases management and professionals are very cognizant of the importance of safeguarding the quality and availability of medications in general and controlled pharmaceuticals in particular, they should be equally aware of how susceptible controlled substances are to diversion into illicit uses. Hence, more rigorous controls and strict compliance with domestic and international regulations on controlled substances are needed to ensure that they are used carefully and lawfully, thus averting the social, economic, legal and criminal consequences that improper handling of controlled substances can have.

RELATIONSHIP BETWEEN THE PHARMACEUTICAL INDUSTRY AND GOVERNMENT AUTHORITIES

Government authorities should cultivate better coordination and communication with the pharmaceutical sector to make certain that the sector understands and complies with the regulations governing the manufacture and distribution of controlled substances. Correspondingly, suitable channels should be in place to enable government authorities to hear the pharmaceutical sector's suggestions and concerns and to foster steady improvements in the control systems, without obstructing the normal growth of legitimate business and taking special care to ensure the availability of and access to these substances for those patients who legitimately require them for treatment of their pathologies.

PRECONDITIONS FOR AUTHORIZATION TO HANDLE CONTROLLED SUBSTANCES

Pharmaceutical establishments that will engage in activities involving controlled substances must first comply with the health regulations for establishments of this kind. Specifically, they must have the operating licenses that are the guarantee that these establishments have the minimum practical conditions essential for preparation and/or storage and distribution of medications. They must also comply with the requirements established for registration of substances (medications) so as to ensure that those medications are properly

evaluated by the health authorities and approved for domestic marketing and/or international trade (importation/exportation).

LICENSURE FOR AUTHORIZING THE HANDLING OF RAW MATERIALS SUBJECT TO SPECIAL CONTROL AND THE MEDICATIONS THAT CONTAIN THEM

Natural persons, legal persons and/or government agencies interested in engaging in medical and scientific activities involving importation, exportation, processing, synthesis, manufacture, distribution, sale, supply or procurement of controlled substances (raw materials or medications that contain them), are to file an application with the appropriate regulatory agency seeking the respective license, following the requirements appropriate to their particular activity. They are also to comply with all attendant obligations.

SPECIAL PROVISIONS FOR MONITORING CONTROLLED SUBSTANCES

In response to the international conventions, special resolutions and warnings produced by international organizations regarding control of narcotic drugs and psychotropic substances having medical uses, the following provisions are established, whose compliance will be mandatory for the pharmaceutical sector:

- 1. The manufacture and distribution of medical samples of narcotic and psychotropic substances and the pharmaceutical preparations that contain them is prohibited.**
- 2. Advertising of controlled substances, targeted at the public, is banned.**
- 3. International marketing of these substances via the internet is impermissible, as they are subject to the prior licensing that international treaties require for purposes of importation/exportation.**
- 4. Shipments by conventional mail or parcel post will be done in accordance with the regulations governing the importation and exportation of controlled substances; in particular, the license issued by the competent authority that has authorized the exportation will be enclosed with the shipment.**
- 5. Updated record keepings of controlled pharmaceutical products and their final disposal should be supported with the application of the legal process.**
- 6. Competent authorities should be notified in case of disappearance or robbery of pharmaceutical control products.**

The regulatory agency will promptly inform the pharmaceutical sector of

any new resolution or provision that amends, supplements, replaces or makes additions to the previously listed resolutions or provisions.

SECURITY IN THE HANDLING OF CONTROLLED SUBSTANCES.

In general, a pharmaceutical laboratory properly documents its activities, in keeping with the best practices in manufacturing. This ensures that operations can be tracked and is particularly useful when the pharmaceutical establishment is one that handles controlled substances. However, when such substances are being handled, additional controls have to be introduced, which will minimally include the following:

- The laboratory must have separate storage areas reserved for controlled substances and located so as not to be directly accessible from the exterior of the physical facilities.
- Rigorous screening, both pre-employment and on an on-going basis should be undertaken for all staff members, especially those who have authorization for access to the storage areas or to authorize the release of controlled substances from those storage areas, or who are charged with any type of handling of such substances. Mechanisms for screening may include criminal record checks, background and credit checks and verification of academic or professional credentials. It may be necessary to have employees sign a release form or other instrument allowing for this type of screening.
- Access to areas where controlled substances are stored is to be restricted to personnel already evaluated and given access authorization.
- Personnel are to be properly trained and have a command of the administrative and legal provisions regulating the handling of controlled substances.
- Security devices such as alarms, surveillance cameras and the like will be installed in the storage areas.

The same applies to storage areas of pharmaceutical establishments engaged in wholesale or retail distribution of controlled substances and their staff.

RECORD KEEPING.

Pharmaceutical establishments that handle controlled substances are to keep up-to-date and reliable records of the inventory and movements of such substances, which records are to minimally show the following information:

1. PHARMACEUTICAL LABORATORIES. These establishments are to record arrivals of raw materials; releases for production, quality control, disposal and other activity; preparations and the master formulas for those preparations; substances in quarantine; preparations in warehouses storing the finished product ready to be released; shipments of completed substances, whether for domestic sale or export, and any other type of movement. Arrivals and shipments are always to be properly documented.

2. WHOLESALE DISTRIBUTORS:

Records will be kept of materials received, with specific information on imports and/or local purchases, detailing the following at a minimum:

- a. The manufacturer or supplier,
- b. The brand name of the product,
- c. The dates of manufacture and expiration,
- d. Lot number,
- e. Date received at establishment,
- f. Invoice number and other data that makes full identification of the transaction possible.

In the case of shipments, the following is the minimum that should be recorded:

- g. Purchaser,
- h. Sales invoice number,
- i. Date of sale,
- j. Product brand name,
- k. Dosage form,
- l. Amount purchased by the client,
- m. Number of the license for handling controlled substances and any other data that the national authorities deem pertinent.

3. RETAIL DISTRIBUTORS:

The records of controlled substances received must show the following:

- a. Name of the laboratory that manufactured the product or the wholesale distributor that sold it,

- b. Date the product was received at the establishment,
- c. Preparation's brand name,
- d. Dosage form,
- e. Amount received,
- f. Dates of manufacture and expiration,
- g. Lot number,
- h. Number of the business invoice for the product's purchase and any other data that the competent authorities require.

Records for the controlled medications dispensed must minimally include the following data:

- i. Name and address of recipient
- j. Name of prescriber
- k. Number of the official prescription authorizing the dispensing of the product (where this exists),
- l. Product name
- m. Dosage form,
- n. Amount dispensed,
- o. Date dispensed and any other information required by domestic law.

Furthermore, the establishment should keep the documents supporting each transaction on file for at least two years, or as required by national legislation. These include purchase invoices, official prescriptions, and sales invoices.

SELF-AUDIT

Pharmaceutical laboratories or manufacturers routinely conduct internal quality checks (self-inspections) in keeping with the requirements to ensure best manufacturing practices. Similarly, establishments that handle controlled substances need to routinely conduct self-audits to detect any diversion and to be able to take the necessary corrective action before having to face administrative or criminal penalties for failure to carry out the adequate regulatory control measures. The self-audit must check to ensure that the control systems are functioning properly; records, including handwritten records, ledgers, or computerized data, are to be checked against the tangible physical inventories of the substances to verify them and ensure their reliability. Ideally, an independent section separate from the one responsible for handling these substances should conduct these self-audits.

Wholesale or retail distributors are to periodically check and test their control mechanisms against the regulations governing the handling of controlled substances, so as to ensure that they are in compliance. Pharmaceutical laboratories should also check their records against their physical inventories to make certain they match.



ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

**Drugs in Cyberspace:
Understanding & Investigating
Diversion & Distribution of
Controlled Substances via the
Internet**

Drugs in Cyberspace: Understanding & Investigating Diversion & Distribution of Controlled Substances via the Internet

Prepared for the CICAD Experts Group Meetings
August 2006 – Buenos Aires, Argentina
By Harry Matz and Sivashree Sundaram

TABLE OF CONTENTS

PART I: Introduction

- Chapter 1: Scope of the Problem
 - A. Purpose of the Guide
 - B. Two Categories of Substances Sold Over the Internet
 - C. Varying Stages of the Internet Drug Distribution Problem
 - D. Scope of the Problem in the Present and Future
- Chapter 2: Understanding the Internet as a Vehicle
 - A. Unique Aspects of the Internet
 - B. Investigative Challenges

PART II: Prevention

- Chapter 3: Awareness, Education, and Training

PART III: Addressing the Problem

- Chapter 4: Recognizing the Problem
- Chapter 5: Legislative and Regulatory Basis
 - A. The Need for Legislation
 - B. Key Components in Legislation
- Chapter 6: Conducting an Investigation
- Chapter 7: Coordination (Domestic and International)
- Chapter 8: Actions Against Perpetrators
- Chapter 9: Costs of Investigation

PART I: INTRODUCTION

CHAPTER 1: SCOPE OF THE PROBLEM

A. Purpose of this Guide

While the abuse and trafficking of narcotic and psychotropic drugs is a long-existing concern, the rise and spread of new technologies, specifically the Internet, exacerbates the issue. Illegal distribution of drugs over the Internet, in many forms, is a major concern in some countries and is likely to affect other countries soon. Countries may find that domestic abusers turn to the Internet to obtain prescription drugs. This is likely to occur increasingly as countries begin to implement legislation (or stricter legislation) to curb pharmaceutical abuse at traditional “brick and mortar” pharmacies. Countries may also find that their territories are used as one in a number of nodes in the complex web of Internet-based trafficking. This Guide will outline the scope of the issue, its elements, and the tools for governments to respond to the issue.

B. Two Categories of Substances Sold Over the Internet

The Internet is used in the illegal trafficking of two categories of controlled substances:

- (1) illicit controlled substances (e.g. heroin, cocaine, MDMA (“Ecstasy”), marijuana)²; and
- (2) licitly produced pharmaceutical controlled substances (e.g. oxycodone / OxyContin, hydrocodone, and benzodiazepines); and

² Although substances such as cocaine, heroin, methamphetamine, and gamma hydroxybutate (GHB) may be licitly manufactured, distributed, and dispensed, their legal use is so limited compared to their trafficking for illegal use that they are considered illicit controlled substances

(3) counterfeit controlled substances represented as legitimate pharmaceuticals. Illicit controlled substances are illegal from production/importation to ultimate use; that is, they are illegally produced, usually in clandestine laboratories, or illegally imported and then illegally distributed (trafficked). The second category includes substances that were produced legally, in closely regulated pharmaceutical settings, but are then offered for sale over the Internet under circumstances so uncontrolled as to virtually guarantee, and even promote, diversion to illicit uses. The third category is comprised of counterfeit controlled substances that are represented as legitimate pharmaceutical products, intentionally created and marketed as a licitly produced pharmaceutical drug. For the purposes of this Guide, pharmaceutical products may include the second and third categories.

Selling illicit controlled substances over the Internet is, on its face, illegal; they are contraband. On the other hand, legitimate pharmaceutical substances sold over the Internet are not necessarily illegal. They *may* be offered and sold over the Internet for legal consumption, assuming: (1) that the consumers, authorized prescribers, and pharmacies are all located within the same country; and (2) that they operate with procedures that mirror the protections against fraud and abuse that are present in a conventional pharmacy. Within the United States there are several legitimate Internet pharmacies. They operate similarly to normal “brick and mortar” pharmacies, requiring legitimate prescriptions based on a doctor-patient relationship, a diagnosis, and treatment of a bona fide medical condition. However, the majority of Internet pharmacies sell drugs without safeguards against diversion. Online websites typically

allow pharmaceutical substances to be sold without a paper prescription or medical consultation. If there is a consultation requirement, it may merely be an “online consultation,” typically a questionnaire with the default answers pre-filled to justify the drug sought, followed by an after-the-fact sign-off by a cooperating medical practitioner.

While Internet distribution of both types of substances should concern law enforcement, this Guide will focus primarily on the distribution of pharmaceutical drugs.

C. Varying Stages of the Internet Drug Distribution Problem

With respect to Internet pharmacies, countries generally fall into one of three categories.

1. Some countries, such as the United States, are already in the grip of the problem. Such countries need to investigate cases as well as prevent further proliferation of rogue online pharmacies.
2. Some countries are not yet afflicted but likely will be as the more affected countries clamp down on online pharmacies, and operators seek a weaker regulatory environment. These countries need to be aware of the problem and the prophylactic measures that may be implemented.³
3. Still other countries may not believe that they are afflicted when, in reality, they simply have failed to detect illegal Internet operations within their borders. These countries need to understand how to recognize the problem

³ The experience of one state in the United States is illustrative. After Internet pharmacies began operating in the state, regulatory and law enforcement authorities did not respond in a timely or dispositive manner. This led more online operators to be drawn to that state, where they have flourished.

and then proceed with investigative efforts and preventative measures for the future.

D. Scope of the Problem in the Present and Future

Internet pharmacies have facilitated a growing problem: prescription drug abuse. In the United States, prescription drug abuse is the only “growth area” in illegal substance abuse today. According to the 2004 annual National Survey on Drug Use and Health (NSDUH), 6.0 million persons, or 2.5% of Americans age 12 and older, engaged in nonmedical use of pharmaceutical controlled substances in the past month; 14.6 million people, or 6.1%, had misused such drugs in the past year; and 48 million persons had abused pharmaceuticals at least once in their lifetimes.⁴ More Americans now abuse prescription drugs than all the other drugs of abuse combined, except marijuana,⁵ and the NSDUH survey showed that this is the category of drugs with the most new abusers (2.4 million in 2004).⁶

The dispensing of pharmaceutical drugs over the Internet facilitates this prescription drug abuse problem. The Internet makes the process more accessible, convenient, and virtually anonymous for both the buyer and seller. Although it is difficult to ascertain the number of websites selling prescription drugs, it has clearly increased in recent years, with most offering either an “online consultation” or a limited telephonic interview with a physician. These online consultations could simply involve the consumer filling out an online questionnaire that may or may not require review by a

4 The NSDUH is conducted under the auspices of the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the Department of Health and Human Services. It can be accessed at <https://nsduhweb.rti.org>.

5 NSDUH 2004, Figure 2.

doctor. While this procedure may have the appearance of legitimate involvement by a health practitioner, it fails to constitute a proper doctor-patient relationship, as would an in-person visit and physical examination by a doctor.

Youth access to and comfort with the Internet exacerbates the problem. There are no controls in place to prevent the sale of pharmaceuticals over the Internet to children, who are especially vulnerable. It is even possible for children to obtain pharmaceutical substances after entering true and accurate information regarding their age, as long as they have access to a credit card. In 2003, 2.3 million teens (ages 12-17) admitted to abusing a prescription drug in the past year. A 2005 survey revealed that 19% of teens admit to abusing prescription drugs in their lifetime. Fifty-six percent of teens believe that the availability of prescription drugs is easier than illicit drugs, likely due in part to the lack of regulation of rogue Internet pharmacies.

Currently, the most frequently offered controlled prescription drug over the Internet are opioids such as hydrocodone and oxycodone, benzodiazepines such as Xanax and Valium, and weight loss medications such as phentermine.

CHAPTER 2: UNDERSTANDING INTERNET PHARMACIES

A. Unique Aspects of the Internet

Globally, the Internet may be increasingly commonplace, but its technical complexities remain a mystery to many people. Use of the Internet as a vehicle to dispense drugs presents novel investigative challenges as well as opportunities to the trained investigator. The primary challenge lies in identifying who or what constitutes an

“Internet pharmacy,” such that the culpable individual or entity may then be appropriately targeted, investigated, and prosecuted. Because of the nature of the technology, this identification is not a simple matter. There are a number of players including the website, web host, ISP, web entrepreneur, pharmacist, physician, source of supply, and so on. For purposes of effectively responding to the problem of illegal distribution of drugs via the Internet, it is necessary to delineate the participants and elements of an illicit online drug distribution system, approaching each element with an understanding of their roles, the evidence they may supply, and their likely culpability.

Participants:

- (1) pharmacist or other individual responsible for the drug dispensation
- (2) physician/practitioner authorizing dispensing of drugs
- (3) courier and delivery services; other drug transportation methods
- (4) credit card and third party financing companies
- (5) payment facilitating and processing companies/websites
- (6) manufacturing and drug distribution companies
- (7) call centers and operators
- (8) web entrepreneur: creator of the website

Locations:

- (9) countries of drug origin
- (10) countries from which drugs are distributed to ultimate user
- (11) countries through which drugs are transported
- (12) countries involved in the money trail

Technology:

- (13) website: collection of web pages, typically common to a particular domain name on the Internet; can originate from an individual, business, or organization; often contains hyperlinks to other websites, blurring the line between distinct websites; can be dynamic with frequently changing information
- (14) web host/server: a company that provides server space and hosts the website; analogous to a publisher for books; provides Internet connectivity, typically in a data center; can also be provided for servers not located in their data center, complicating tracking matters
- (15) Internet Service Provider (ISP): a company that provides an Internet connection; can be started by almost anyone; has physical control over the content of the website, but may or may not be the web entrepreneur
- (16) Domain name: the address or URL of a web site; in technical terms, the text name corresponding to the numeric IP address of a computer on the Internet (for example: www.netlingo.com is the domain name for the numeric IP address "66.201.69.207")
- (17) IP address: unique address of each computer on the Internet; aids in tracking location
- (18) Domain name registrars: organizations through which one can register a unique domain name, for a fee (for example: www.networksolutions.com and www.GoDaddy.com)

B. Investigative Challenges

It is difficult for authorities to track, monitor, and shut down illegally operating Internet pharmacies because websites are easily created, removed, or altered by, for example, changing their name or web address, all in a very short period of time. Rogue pharmacy websites typically do not provide identifying information regarding their location or source, lending a sense of anonymity to the process. Savvy web entrepreneurs and online operators routinely relocate, without any real reason, as a precaution against detection. A routine web search illustrates this phenomenon; sometimes a link to a closed down site will automatically redirect the user to a new site by the same site owner, as indicated by similar layout and wording.

Many of the bigger Internet pharmacies have several “portal sites”— a network of sites that refer users to one online anchor pharmacy, which is the site that actually offers to sell the drugs. It is on the anchor site that the customer places their order and pays. At some point, the drugs must come from a physical, brick-and-mortar pharmacy (or warehouse or other distributor) that provides the drugs. The pharmacy may itself operate the website, or the anchor site may then send orders to a pharmacy. Different websites, located anywhere in the world, might use the same pharmacy. Some investigative challenges include determining the physical location of the anchor site, the identity of the website operator, as well as the physical location of the physical pharmacy and the identity of the pharmacy’s operators.

The notion of what constitutes an “Internet pharmacy” and where it is “located” can have various meanings, each aspect giving rise to unique investigative challenges and opportunities.

(1) The place of origin of drugs as advertised by the website: The origin of the drugs as advertised would be useful to know, but websites may or may not provide this information. At any rate, statements of drug origin by websites are notoriously unreliable.

(2) The physical location of the computer containing the website data: The location is of very limited use because data on the Internet can be transmitted from anywhere in the world, but the data on the computer is helpful in building the case.

(3) The location of the business or individual running the website: While this information could potentially lead to prosecuting the individual responsible for the website, it can be difficult to ascertain because registration information provided, for example, to a domain registrar or ISP may be inaccurate. (Domain registrars and ISPs are high-volume operations and are not presently set up to verify the identifying information provided.)

(4) The physical address from which the drugs are actually shipped: The drugs themselves cannot exist in cyberspace (assuming that the website is not a total fraud and the drugs are actually ordered and shipped). The fact that they must originate from somewhere and go somewhere else brings Internet investigations back in line with traditional investigations.

PART II: PREVENTION

CHAPTER 3: AWARENESS, EDUCATION AND TRAINING

Consumer education would go a long way toward decreasing the number of websites which illegally sell pharmaceutical drugs. Industry should be encouraged to provide Internet advertisements, pop-ups, and the like when searches for illegal prescription drugs are conducted. For example, at the time this Guide was drafted, a simple Google search for obtaining prescription drugs without a prescription yielded not only several Internet pharmacy websites, but also several accompanying consumer alert websites. These alerts lead potential consumers to sites explaining the dangers and illegalities of obtaining controlled substances online. Moreover, the financial services industry, including credit card companies and payment services, should be made aware of this problem in order to flag rogue Internet pharmacies and avoid the use of their services for improper and illegal transactions. Transportation courier firms and internet service providers must also be made aware of the problem as their services are being used to conduct illegal business transactions.

Furthermore, public service announcements and media exposure would help spread the message to parents and teens unaware of the extent of pharmaceutical drug abuse and its easy online availability. Parents, especially, may not be aware of the ease with which their children and teens can access and order drugs from Internet

pharmacies, due to the anonymity involved and lack of in-person interaction. In addition, hotlines and teen websites provide further education.

The public should also be educated that their chances of receiving counterfeit drug products from illegally operating Internet pharmacies are high. For example, in the United States, only about 50% of consumers receive the authentic product.

Public awareness campaigns should, however, be sensitive to the nature of the problem at hand, and should not get ahead of the problem. In countries where Internet pharmacies are non-existent or very limited, a public awareness blitz may give drug abusers and unsavory entrepreneurs ideas they had not previously considered about how to access drugs or to start a lucrative, illicit business. Where information is provided, it should be accurate and balanced.

Government officials must also be educated about the extent of the problem. Obviously, a much greater level of awareness and training is needed for regulatory drug control and law enforcement authorities. To effectively investigate an allegedly illegal sale of pharmaceutical drugs via the Internet, authorities need to understand the issue of Internet pharmacies and the technology (see Chapter 2). Training classes should be provided to all investigators, especially if they do not already have a scientific and/or technological background. For example, authorities should understand the common warning indicators for a website illegally selling pharmaceutical drugs—lack of prescription requirements, discreet shipment methods, delivery by mail or to a P.O. Box, quantities, and other sales procedures. In recruiting law enforcement to conduct Internet pharmacy investigations, training and appropriate technical backgrounds are vital to consider.

PART III: ADDRESSING THE PROBLEM

CHAPTER 4: RECOGNIZING THE PROBLEM

A country may be host to one or more aspects of an Internet pharmacy but be unaware of its existence. Increased awareness for the public and Governments as noted in Part II will go far in helping to recognize this issue; however, each country also needs to perform a concrete self-evaluation to determine whether and to what extent it plays a role in the illegal sale of pharmaceutical drugs via the Internet.

In recognizing the existence of a problem, the following questions should be asked by each country of itself:

- (1) whether individuals and/or groups use the Internet in their country to sell and/or purchase controlled or non-controlled substance pharmaceutical drugs (or counterfeit pharmaceutical drugs)
 - a. if yes —
 - i. identify whether these activities are occurring domestically and/or internationally, and
 - ii. determine whether any of these activities are legal under domestic or international law
- (2) whether the country has any licensure requirements or regulatory approvals necessary to conduct domestic/international sales of pharmaceutical drugs, including those containing controlled substances, over the Internet

- a. if yes, determine —
 - i. which law enforcement/regulatory entities are responsible for investigating Internet pharmacy cases
 - ii. whether these agencies received any specialized training in this area
 - iii. whether these law enforcement entities have the capacity
 - by law or regulation, and
 - by practical means –to investigate and enforce laws that prohibit the illegal sales of drugs over the Internet through –
 - 1. interception of Internet communications,
 - 2. preservation of electronic communications,
 - 3. undercover purchases, and
 - 4. exchange of information with other states, including financial information.
- (3) whether the country has undertaken measures such as increasing public awareness of the problem, educating health care providers, and engaging the private industry in voluntary cooperation

A concrete and searching inquiry along these lines will help countries assess their strengths and weaknesses in combating sales of pharmaceutical substances via the Internet. These are simply basic guidelines, but when a country identifies a weak point, it can then address it in a manner that is effective and suited to its national system of drug control and enforcement.

CHAPTER 5: LEGISLATIVE AND REGULATORY BASIS

A. The Need for Legislation

In many countries, there is a need to institute legislative and regulatory controls, thereby facilitating prosecution of the illegal sales of pharmaceuticals via the Internet. New substantive legislation criminalizing unlawful sales of drugs may or may not be necessary to reach illegal Internet sales; national laws and regulations should be reviewed to determine whether the basic laws defining drug trafficking crimes are adequate in the Internet context. Given the nature of Internet pharmacies and the means needed to regulate them, it is more likely that countries will need to enhance investigative powers of law enforcement agencies, and new procedures for registering Internet pharmacies—and determining whether they will operate lawfully prior to granting their registration—will be necessary.

It is now axiomatic that the distribution and trafficking of controlled substances and precursor chemicals is a worldwide phenomenon. However, the Internet is the most quintessentially global means of communication and commerce available today. This expansive nature and the potential worldwide reach of Internet pharmacies argues for an attempt to harmonize national laws, as well as unprecedented cooperation, to prevent rogue online pharmacies from spreading their tentacles across the globe.

B. Key Components of Legislation

As suggested by the questions in Chapter 4, in composing new legislation or amending existing legislation, several elements should be included. First, however, if an individual country decides to prohibit the existence/operation of any Internet

pharmacy—that is, disallow the dispensing of pharmaceuticals via the Internet regardless of regulations—then that country may do so. Such countries should not end their legislative inquiry at that point. The nature of the Internet is such that perpetrators may continue to run websites which dispense pharmaceuticals, regardless of prohibitive legislation, due to the anonymity involved in conducting such an operation. In this case, countries will likely find themselves investigating Internet pharmacy cases and needing some of the latter elements of legislation outlined below, specifically items (4) through (9), to aid in their investigative techniques. If an individual country chooses to allow the existence/operation of websites dispensing pharmaceuticals, then items (1) through (3) in the list below should additionally be considered:

- (1) Require a registration or license for Internet pharmacy websites and web entrepreneurs –
 - a. Subject to a pre-registration in-person interview and on-site inspection and
 - b. Subject to disclosure of the identity and location of individuals and/or entities that operate the site, pharmacies that fill their orders/prescriptions, and health professionals associated with the website
- (2) Only permit physicians or other authorized prescribers to issue prescriptions, and Internet pharmacies to fill them, where the prescription is bona fide in that it is based on an in-person medical evaluation of a patient by his or her physician

- a. Ensure that a legitimate doctor-patient relationship exists for this in-person medical evaluation
 - i. An online questionnaire should be considered insufficient
 - b. Ensure that the examination is conducted by a duly authorized health practitioner
- (3) Designate clear lines of authority and responsibility for regulating and investigating Internet pharmacy operations
- a. If authority lies in more than one entity, clearly define lines of coordination and authority between entities to avoid gaps and duplication
- (4) Provide for authority to conduct undercover operations, including undercover purchases of controlled substances
- (5) Provide for the ability to intercept communications, electronic or otherwise, between all parties, including the website and online pharmacy operators, the health practitioners, the pharmacy, and others.
- (6) Provide for the authority for government investigators to require online operators to preserve communication and other evidence pursuant to a duly authorized request
- a. Require the support of Internet service providers (ISPs) and other service industries such as credit card companies and courier services
- (7) Ensure adequate authority to execute search warrants on all elements of Internet pharmacy operations

- (8) Ensure that investigators have the authority to seize –
 - a. Computers and other technological hardware involved
 - b. Assets accrued from Internet narco-trafficking
- (9) Provide for any other measures required to effectively institute investigative procedures against Internet pharmacies as outlined in Chapter 6

CHAPTER 6: INITIATING AND CONDUCTING AN INVESTIGATION

Identifying the illegal sale of pharmaceutical drugs via the Internet is generally accomplished through traditional investigative methods such as complaints from the general public, drugs found during routine traffic stops or search warrants, intelligence information obtained from various sources, and tips received from other law enforcement or regulatory agencies. Elements to consider when initiating the investigation are: (1) importation and exportation trends, in order to understand the flow of drugs; (2) illicit pharmacies, repackaging, and manufacturing facilities; (3) prescribing doctors; and (4) methods of financial processing. It is also important once a target has been established to perform case deconfliction and coordination (see next chapter).

One proven and successful approach to initiating an investigation is to perform undercover buys from a target website. It is imperative that the buys be conducted utilizing equipment and payment methods that ensure the anonymity of the investigator. The investigation should not end at just one undercover buy—it should continue in order to evaluate changes in drug sources, methods of shipment, and the flow of money—useful indicators of the operation of drug distribution rings.

Another source that may be used to initiate investigations is information received via seized packages or information provided by package delivery companies. Search warrants or other legally authorized processes should be executed to obtain the credit card statements of purchasers of pharmaceutical drugs via the Internet. This serves to trace the money back to the seller, or “criminal entity” via the credit card invoice. The money can be followed from the customer to the credit card processor to escrow or other financial accounts being used to launder the drug proceeds by the target websites. If evidence of illegal activity leads to other countries, the competent authorities of the initiating country should investigate the matter with the assistance and cooperation of foreign law enforcement counterparts. Furthermore, this money trail allows authorities to identify individuals or businesses associated with the website from which the drugs were purchased and evaluate their ordering process—that is, whether the site required a legitimate prescription or consultation prior to purchasing drugs. At this point the investigation would most likely proceed to undercover purchases as described in the preceding paragraph.

In order to trace the web host and ISP, the investigator would submit the website address into a registry information search engine to view domain name registration. Information obtained from such a query usually includes registrar, contact identifiers (names, addresses, phone numbers, and email addresses of administrative and technical contacts), IP address and location, website title and description, and web host. The request would also identify additional websites operated by the same person. Registry information obtained in this manner may be fraudulent and should not be independently relied upon. If the investigator discovers that the information listed is

false, he or she should employ traditional investigative methods, such as backtracking the financial information or establishing the point of origin through parcel carriers of the drugs. Authorities should then execute a preservation letter to the custodian of such account records to preserve the evidence for a specified number of days, as related to the ongoing investigation. This preservation letter is necessary to preserve the evidence while investigators write and execute a search warrant on the location of the web host and its computer. These search warrants are aimed at finding incriminating electronic communications. Intercepts of electronic communications may also be implemented.

Ideally, the result of all these search warrants and intercepts on email accounts would be to identify the components of the drug distribution organization in its entirety, estimate the sales, and identify all related domain names as well as operational pharmaceutical websites. Once the above entities are identified, the next goal(s) may be as follows: execute search and seizure warrants; interview customers; freeze assets (e.g. bank accounts, property), and mirror computer hard drives. Internet pharmacy investigations are fluid and may disclose many unexpected scenarios. Adequate staffing and technical support will help to ensure a successful outcome.

CHAPTER 7: COORDINATION (DOMESTIC AND INTERNATIONAL)

Coordination would also avoid duplication and waste of resources. In this spirit, governments of all countries should respond to requests quickly and handle inquiries on Internet pharmacy cases seriously, provide any necessary support, and, if necessary, initiate criminal action against offenders.

Ideally, the establishment of an “Internet coordination center” would further facilitate coordination. A coordination center should involve one entity or at least oversight by one entity, with national and international agencies participating and providing input. Before initiating an investigation, law enforcement should check with the coordination center to make sure there are no other ongoing investigations regarding that same website. If there are, the coordination center should provide appropriate contact information such that the multiple countries or agencies may coordinate their efforts. The coordination center should also be a source for those in the service industry as well as for the public to call in suspicious activity.

CHAPTER 8: ACTIONS AGAINST PERPETRATORS

Penalties for use of the Internet in drug trafficking should be enhanced as compared to those for more routine illegal drug distribution. There must be a strong deterrent effect to its punishment for several reasons. First, the scope of harm to the public is greater when the Internet is involved. The nature of the Internet allows operators to sell in far greater volume, reaping far greater profits than ordinary drug trafficking, while taking advantage of the anonymity offered by the Internet. The cumulative impact of the multiplier effect and anonymity aspect is that the Internet facilitates drug trafficking on an unprecedented scale. Second, in enhancing the penalties, asset forfeiture and/or criminal fines should be considered as the Internet pharmacy business is a lucrative one and certainly is a lure for criminal organizations. Not only would this help deter future criminals, but it would also help offset the major

costs incurred in such investigations (see Chapter 9), provided that rules for the use of forfeited funds allow application of those assets to law enforcement.

In order to ensure that cases are brought to conclusion, able prosecutors must be engaged. And because the worldwide web and Internet-based investigations are not universally understood, some orientation, education, and training of prosecutors and, if possible, the judiciary would be extremely useful. As the number, scale, and sophistication of investigations warrant, it may be advisable to create a unit of specially trained prosecutors and investigators to undertake these types of cases.

CHAPTER 9: COSTS OF INVESTIGATION

Investigations into an illegally operating Internet pharmacy, or for that matter an Internet-facilitated routine drug trafficking organization, costs far more for law enforcement agencies than most other investigations. There are several reasons for this. First, the expansive nature of the Internet has a multiplicative effect as well as an anonymity factor, as discussed above. The multiplicative effect means that more people and/or entities are easily involved, requiring more resources to appropriately investigate all involved parties. Anonymity implies that more resources are required to track down and identify these involved parties in the first place. The Internet facilitates global operations as well, which means investigations must often expand overseas, involving foreign authorities and/or travel by domestic authorities. Additionally, these types of investigations generally result in a high volume of documentary evidence. The investigator needs to consider the transport, storage, review, and analysis of this evidence. Private corporations, with government clearance, can be utilized to digitally

scan and sequentially stamp the documents for easier analysis. These types of investigations require more money, more time, and more people—in short, more resources all around. This extra cost must be anticipated by governments when initiating such investigations.

However, the additional costs should not deter governments. Unlike street-level drug investigations, many steps in Internet investigations can be undertaken by trained staff using the computer and the Internet – ironically, the same means as the illegal web operators – and intercepts that do not require extensive work in the field. Moreover, governments that fail to undertake these investigations may soon find themselves inundated with Internet pharmacy operators who, like other international criminals, seek out the weakest regulatory and enforcement environment to proliferate their harm.