ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

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DRAFT FINAL REPORT

GROUP OF EXPERTS ON PHARMACEUTICAL PRODUCTS

ORGANIZATION OF AMERICAN STATES

INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

cicad

GROUP OF EXPERTS ON	**OEA/Ser.L/XIV.4**
PHARMACEUTICAL PRODUCTS	**CICAD/doc.3/04**
May 31 - June 2, 2004	**June 3, 2004**
Brasilia, Brazil	**Original: English**

FINAL REPORT

Preliminary Version

I. BACKGROUND

During the Thirty-fourth Regular Session of CICAD held in Montreal, Canada, November 17-20, 2003, the Commission considered the report for the Group of Experts on Pharmaceutical Products further to its meeting from August 25-27, 2003 in Brasilia, Brazil. The Commission accepted the report and the recommendations offered by this Group of Experts. In doing so, the Commission directed that the Group should meet during 2004 to deal with the recommendations in the aforementioned report and possibly identify new issues related to the control of pharmaceutical products.

CICAD's Expert Group on Pharmaceuticals subsequently met from May 31 to June 2, 2004 in Brasilia, Brazil. The Group was chaired by Mr. Kleber Pessoa de Melo, Chief, Unit of Controlled Substances, ANVISA, Ministry of Health of Brazil.

II. PROCEEDINGS

A. PARTICIPANTS

1. MEMBER STATES OF CICAD

Twenty-one experts from the following member states participated in this meeting: Argentina, Bahamas, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Mexico, Paraguay, Peru, and United States. (List of Participants 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 9:00 a.m. on May 31 in the Hotel Grand Bittar in Brasilia. The following individuals offered opening remarks:

- Mrs. Maria Ribeiro Luiza Lopez Da Silva, Ministry of Foreign Affairs
- Mr. Paulo Lacerda, Director General, Department of the Federal Police
- Mr. Cláudio Maierovitch Pessanha Henriques, Director of ANVISA, Ministry of Health
- Mr. 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 model guide for health professionals; to consider ways to strengthen inspection and investigation activities related to the control of pharmaceutical products; to examine the issue of communication and coordination; consider best practices to overcome impediments to the effective application of regulations and control systems. A copy of the schedule of activities is attached.

In addition to discussing and considering the foregoing, the Group received two presentations by the delegation of Chile concerning a national system that they have implemented for the control of pharmaceutical products and the results of a school-based epidemiological survey of licit and illicit drug use.

A. Review of Manuals/Guides

The Experts considered a draft **Model Reference Guide for Health Professionals: Prevention and Detection of Abuse of Narcotics and Controlled Substances and Their Diversion to Illicit Channels** prepared by the delegates of Canada and Uruguay. The delegate of Canada presented the draft model guide. In doing so she explained that the guide was designed as model that countries could modify and supplement based on specific issues of concern, national legislation or regulations and circumstances that exist in each country.

The Group of Experts reviewed the draft and made further changes to the text. A copy of the finalized version is attached.

The Group submits this model guide for health professionals to the Commission for its consideration. Further to review by the Commission and the inclusion of any changes that it requests, the final version of this model guide will be available to be posted to the CICAD web page.

During the discussion of this model guide, participants raised a number of issues related to the pharmaceutical industry, including sampling to health professionals. This caused participants to reopen discussions regarding the need for a model guide for the pharmaceutical industry. The Group discussed the preparation of such a guide during its last meeting (August 25-27, 2003). At that time the Experts identified the following areas that should be included in such a guide:

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

Further to this renewed discussion, the delegations of Colombia and Costa Rica offered to coordinate the preparation of this guide. In doing so, they will use the foregoing as an outline of elements to be included. As with the guide for health professionals, it will be a model guide that member states can modify or elaborate to reflect their particular circumstances, regulations and needs.

B. Mechanisms to Strengthen Inspections and Investigations related to the Control of Pharmaceutical Products:

The control of pharmaceutical products depends on having the necessary legal and regulatory framework and the administrative systems to control these drugs. In addition, countries need to have a strong capacity to monitor, inspect and investigate the distribution and use of pharmaceutical products as part of an effective national regulatory and administrative control program. The characteristics and components of such a program and the inspection activities will vary from country to country and will be defined by the legislation and regulations in place. These will determine powers and authorities of the inspectors and investigative officers as well as what they can do and how.

The participants underlined the importance of monitoring and investigating regulatory compliance and possible diversion of pharmaceutical products. At the same time, member states face serious challenges in implementing such programs. The largest challenge is the availability of inspectors and investigators with the appropriate professional qualifications as well as the financial resources to support them. A second issue relates to providing these personnel with the necessary knowledge and training to fulfill their responsibilities.

Some participants shared information regarding the challenges they face in controlling pharmaceutical products such as large scale compounding. They also spoke of the efforts they are taking in their respective country to establish the framework for effective monitoring and investigations and tools that they developed to accomplish this. At the national level and sub regionally, countries have prepared instruments such as guides for inspection, manuals, procedures and formats for information gathering related to the control of pharmaceutical products.

During its last meeting, the Group of Experts recommended the development of a guide of best practices for the strengthening inspection and investigative activities. At the same time, as mentioned above, various tools have already been developed at the national and sub-regional levels. Before proceeding further, the Group proposes to determine what currently exists and make that available for the use of member states. It can then give further consideration to developing a new guide if gaps in information needs still exist. The Executive Secretariat will contact member states regarding the existence of manuals, procedures, guides or other instruments that they may have prepared concerning the monitoring and investigation of pharmaceutical drug distribution and ask for either electronic copies or links where the foregoing might be located on-line for posting to the CICAD web page on pharmaceutical products. The Executive Secretariat will also work with the delegation of the United States to identify the basic elements or categories of information that member states might need in a guide to help strengthen their capacity for inspection and investigation. This information could then be used to assess what is currently available and to develop a new guide if this is later deemed to be required by the Group.

C. Mechanisms to Strengthen Communication and Coordination in the Control of Pharmaceutical Products

The exchange of information and coordination at the strategic and operational levels are critical in any real effort to control pharmaceutical products. This is true at the inter-agency level both nationally and international and at the inter-sectoral level, linking government agencies/departments with the private sector.

All parties concerned face various impediments to effective communication and coordination. They include, but are not limited to, legislative limitations or prohibitions, organizational rivalry, lack of contact information for counterparts and trust or confidence issues.

Members of the Group of Experts shared their experiences regarding these challenges and mechanisms that they have used to try and overcome the impediments encountered. The mechanisms that they employ depend on a variety of circumstances. The Executive Secretariat presented a matrix that demonstrated this point. The mechanisms for communication and coordination depend on a number of factors including the following:

- the purpose of the communication, information exchange or coordination
- the nature of the information or objective(s) of coordination
- the party or parties involved
- the scope or nature of the communication (bilateral, multilateral, direct, indirect etc)
- security considerations

The nature of the foregoing mix will determine what mechanism or mechanisms are most appropriate and most practical. In selecting the precise approach, parties need to consider the foregoing within the framework of the circumstances and restrictions with

which they are presented. For this reason it is difficult to develop a guide or paper of best practices for communication and coordination. Having said that, the participants did share some of the approaches that they have implemented. They include establishing inter-agency or inter-sectoral working groups that meet on a regular basis to share information on trends and problems. The discussions that take place then lead to efforts at collaborative problem solving or planning operational activities as the case may be. The same approach is applied internationally involving two or more countries that share a common border. In both cases, the objectives are to share information, identify and resolve problems and coordinate activities to address a common or shared concern. Countries also implement procedures that promote or facilitate the routine exchange of information. This could involve reaching an agreement for the routine exchange of information concerning such things as seizures, arrests, new trends in smuggling or drugs use, etc.. This information would then be circulated at a set interval or under other defined terms.

The keys to success in this area are that parties need to be proactive in seeking out counterparts and creative in finding the means that suit their particular needs and circumstances. This and other operational meetings provide participants with an opportunity to share experiences regarding mechanisms for enhanced communication and coordination that others can then take, modify and apply as possible.

The Group underlined the importance of having access to current information regarding the operational points of contact found on the CICAD web page. In doing so, the Group stressed the need for member states to inform the Executive Secretariat of any changes or additions to the information in the directory as quickly as possible to ensure the integrity and utility of the directory for officials of other member states.

Beyond providing member states with an opportunity for this type of exchange through the meeting of this group and others, and updating the directory of operational points of contact, the Group does not propose any further specific action regarding this matter at this time.

D. Best Practices to Overcome Impediments to the Effective Application of Regulations and Control Systems

Member states implement administrative control systems to support the legislative and regulatory frameworks that they have established for the control of pharmaceutical products. The scope of these systems vary from country to country as does the extent to which countries are able to implement them and effectively control pharmaceutical products. In some member states, the systems that are in place are very basic.

Members of the Group of Experts shared information concerning elements of their control systems and some of the problems or challenges that they have encountered. Some countries pointed to the lack of sufficient resources to support the effective control of pharmaceutical products. This includes both financial resources and professionals to implement the systems.

Some participants also cited the lack of a technical infrastructure as a problem. Most countries had systems in place to deal with the international movement of these drugs but lacked the systems required to control the domestic distribution and use. While the National Drug Control System (NDS) developed by the United Nations helps with the international aspects it does not satisfy the needs related to domestic control. Some countries including Brazil made note of their efforts to develop systems to address these needs. More basic to the domestic control of pharmaceuticals was the limited availability of trained professionals who could conduct investigations, inspections and other monitoring and control functions.

The delegation of Chile delivered a presentation on a computerized system that they currently have in place regarding the distribution of pharmaceutical products. The system, in place since 1995, makes use of a multiple copy prescription pad. The 1500 pharmacies in Chile are required to forward one copy of the prescription to the national body that is responsible for the system. Support specialists then manually transfers information from the approximately 300,000 prescriptions per year to the computerized system. Once in the system, officials are able to conduct detailed analyses of the distribution and use of specific pharmaceutical products. They are able to track the use of these substances to the patient level if necessary. The officials in Chile work closely with the licensing bodies of medicine regarding possible problem physicians identified through the system.

A number of participants identified limitations in the regulations and corresponding control systems. In some instances, hospitals and certain health professionals such as veterinarians fell outside of the regulatory and control framework in place in some countries.

Some member states pointed to problems of volume. This relates to transaction volumes involving wholesale sales and distribution as well as prescription sales. This underscores the need for member states to target their efforts according to criteria they establish in response to specific problems or concerns that they identify.

At the same time, countries pointed to other challenges caused by volumes related to the number of pharmacies, manufacturers and distributors operating. Finally, a number of countries pointed to the large number of physicians that are licensed and able to prescribe pharmaceutical products or that are added to this list each month. These countries underlined the problems that they and their pharmacists face in trying to keep track of these physicians and ensure that the names on prescriptions they received are in fact legitimate and authorized physicians. Some participants spoke of the significant problem they face with forged prescriptions.

A problem that many shared was the fine line that they encounter between legitimate medical use of pharmaceutical products and prescribing for what appears to be inappropriate use. In some instances, regulatory bodies encounter prescribing by physicians involving large quantities of certain pharmaceutical products that appear to be excessive or prescribing of others for conditions not normally associated with these drugs. Treatment protocols can serve to facilitate the assessment of such cases but

frequently there is little agreement on what is an acceptable treatment protocol for that drug or condition. It is essential that the agencies responsible for the control of these drugs maintain a close working relationship with the regulatory or licensing bodies of the health professions in the country including those for physicians, pharmacists, nurses and others.

Some participants noted that we apply pressure to the distribution and use of illicit drugs, users and traffickers look for alternatives. Increasingly they are turning to pharmaceutical products. This has implications that extend beyond the illicit users and traffickers but also impacts health care professionals as well as the health care services and programs that are in place in the countries.

The Group of Experts proposes that the Executive Secretariat communicate with member states to determine which ones have implemented computerized systems to control the national distribution and use of pharmaceutical products. In doing so the Executive Secretariat should obtain an short description of the system and the name of a point of contact and post this information to the CICAD web page.

E. Other Issues

Internet Sales of Pharmaceutical Products

The sale of pharmaceutical products via the Internet is a growing concern and taking place to varying degrees in CICAD member states. The problem concerns both internet sales originating in a member state as well as purchases being made in and delivered to individuals in member states.

The delegation of the United States delivered a presentation on this issue and how officials in that country are responding. The issue breaks brown into two components. The sale of pharmaceutical products by pharmacies authorized to transact business in this manner and the sale of drugs either by unauthorized pharmacies or by another party.

The United States currently has currently authorized 14 pharmacies or chains to sell pharmaceutical products via the Internet. The test for such distribution is the existence of a patient-physician relationship regarding the treatment of the condition for which the prescription is required. The Drug Enforcement Administration (DEA) has been investigating cases and making arrests regarding Internet sales of drugs. These cases are extremely difficult to investigate and frequently involve multiple parties located in different cities and states in the United States. Internet purchases of pharmaceutical products and other substances originating outside of the United States are even more difficult to detect. Screening by customs and postal services remain one of the few ways to do so at this time. When the DEA identifies such cases, officers communicate with law enforcement officials in the source country to coordinate further investigation and arrests as appropriate.

Knowledge of the extent of Internet sales of pharmaceutical products and other drugs in member states represented in the Group of Experts varied. Some participants were aware that such sales were taking place but information was limited as was their capacity to investigate and take action. In many instances, responsibility for monitoring and investigating Internet sales of drugs and other products did not rest with the agency responsible for pharmaceutical products but rather fell to law enforcement or a trade agency.

While information is limited, Internet sales of pharmaceutical products and other controlled substances such as cocaine, heroin, amphetamines and other amphetamine-type stimulants is an emerging problem and a growing concern for CICAD member states. It is a relatively new issue for most member states for which there is insufficient information at present and for which there is no clear solution at this time. At the same time, this issue has been recognized as a concern in other fora such as the United Nations Commission on Narcotic Drugs (CND) where during its forty-seventh session in March 2004 the Commission adopted a resolution regarding Internet sales of drugs.

The Group proposes that the Executive Secretariat consult with international bodies such as United Nations, Interpol and others regarding Internet sale of drugs and what they are doing to deal with this emerging problem. The Executive Secretariat could then use this information to develop and deliver training initiatives for law enforcement to identify and investigate cases of Internet sales of drugs and to help member states develop their own programs.

3. CLOSING SESSION

The Group of Experts concluded its work at 12:00 on June 2. The Chair of the Group closed the meeting and thanked the members for their participation.

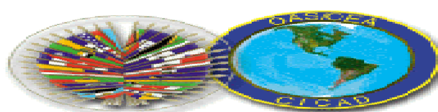
III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS THIRTY-SIXTH REGULAR SESSION:

1. That the Commission consider and accept the guide entitled "**Model Reference Guide for Health Professionals: Prevention and Detection of Abuse of Narcotics and Controlled Substances and Their Diversion to Illicit Channels"** and direct the Executive Secretariat to post the guide to the CICAD web page.

2. That the Commission direct the Expert Group on Pharmaceutical Products to complete the following tasks and report to the Commission during its XXXVI regular session:
   - with coordination by the delegations from Colombia and Costa Rica, prepare and finalize a draft Model Guide for Industry regarding the Control of Pharmaceutical Products.
   - with coordination by the Executive Secretariat and the delegation of the United States, prepare an outline of the basic elements or categories of information that member states might need in a guide to help strengthen their capacity for inspection and investigation concerning pharmaceutical products for further elaboration during the Group's next meeting

3. That the Commission direct the Executive Secretariat to:
   - consult with member states regarding the availability of guides, manuals and other instruments concerning the monitoring, inspection and investigation of pharmaceutical drug distribution and either post electronic copies of the foregoing on the CICAD web page on pharmaceutical products or links where the foregoing might be located;
   - communicate with member states to determine which ones have implemented computerized systems to control the national distribution and use of pharmaceutical products. In doing so the Executive Secretariat should obtain a short description of the system and the name of a point of contact and post this information to the CICAD web page.
   - consult with international bodies such as United Nations, Interpol and others regarding Internet sale of drugs and what they are doing to deal with this emerging problem and training activities that might be adapted for use with member states



Reunión del Grupo de Expertos sobre Produtos Farmaceuticos
31 Mayo – 2 de Junio, 2004
Brasília, D.F.

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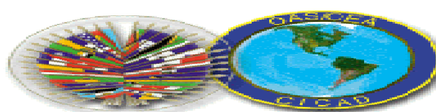

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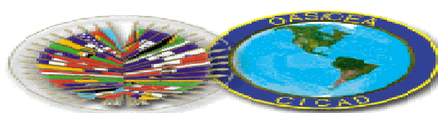

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MODEL
REFERENCE GUIDE FOR HEALTH PROFESSIONALS: PREVENTION AND DETECTION OF ABUSE OF NARCOTICS AND CONTROLLED SUBSTANCES AND THEIR DIVERSION TO ILLICIT CHANNELS

MODEL
REFERENCE GUIDE FOR HEALTH PROFESSIONALS: PREVENTION AND DETECTION OF ABUSE OF NARCOTICS AND CONTROLLED SUBSTANCES AND THEIR DIVERSION TO ILLICIT CHANNELS

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In some jurisdictions, a duplicate/triplicate prescription program is in place to monitor the use of certain drugs prone to misuse, abuse and diversion. Under these programs, the original prescription is given to the patient to present to the pharmacist; a copy is sent to the regulatory authority for analysis. Multiple-doctoring and excessive prescribing can be more easily detected using these programs. Some jurisdictions required that all prescriptions dispensed by pharmacies be recorded through an on-line computer system which allows pharmacists to check if the individual has obtained controlled drugs at other pharmacies or from other physicians.

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PREAMBLE

The purpose of this guide is to strengthen the rationale use of narcotics and other controlled substances and to minimize their abuse and diversion through increased awareness.

All health care professionals have a critical role to play in minimizing the abuse and diversion of narcotics and controlled substances. The information in this guide is specifically targeted to health professionals who are authorized to prescribe narcotics and controlled substances, those who are authorized to dispense (e.g., pharmacists), as well as all those involved in administering these drugs (e.g., nurses). There needs to be a collaborative effort among health care providers and regulators to promote appropriate use of narcotics and controlled substances while at the same time minimizing their abuse and diversion.

Drug abusers may be difficult to distinguish from legitimate patients. The person who presents to a clinic or office with a migraine headache or back pain may be a legitimate sufferer. On the other hand, the individual may be seeking a controlled substance to feed an addiction, or a criminal looking for controlled substances to sell. To take a balanced approach to the prevention of drug abuse and diversion, health professionals must be knowledgeable of the best evidence-based treatment plans for caring for patients who present with a medical condition requiring a narcotic or other controlled substance but must also be aware of the methods for recognizing and discouraging drug abusers and diverters.

The advice in this guide is intended to present a balance between the benefits and risks of treatment with narcotics and controlled substances. It provides practical guidance to assist health professionals in recognizing and minimizing abuse and diversion, without compromising the care of those patients that require narcotics and controlled substances for medical reasons.

DRUG ABUSE AND DIVERSION

Definition of the problem

The abuse, misuse and diversion of prescription drugs is not well documented and, as a result, patterns of abuse and the problems that arise are difficult to describe. Much of what is known comes from anecdotal reports.

In some cases, individuals who abuse controlled substances may have started to use a pharmaceutical product for a legitimate medical need but later lose control of their use because they do not comply with instructions or because of medical mismanagement. For example, older people are prescribed medication about three times more frequently than the general population, and have poorer compliance with directions for use.[1] Misuse of prescribed medication may be the most common form of drug abuse among the elderly. At the other end of the spectrum, many children are prescribed psychoactive drugs, such as methylphenidate or antidepressants although there drugs may not be the most effective means to treat their medical conditions. In Uruguay, the consumption of methyphenidate has double between 2000 and 2004.

Other individuals abuse controlled drugs for their psychoactive properties. A US 2001 National Household Survey on Drug Abuse showed about 15% of 18 and 19 year olds used prescription medications non-medically in the past year, and, for 12 to 17 year olds, the figure was 7.9%.[2]

The huge demand and supply for prescription drugs has created a lucrative black market for pharmaceutical products. Pharmaceutical products containing narcotics or psychotropic substances are sought for several reasons:

- they have guaranteed safety, quality and potency;
- oral products can be used without the risk of HIV and Hepatitis C associated with injection drug use;
- the cost of obtaining controlled substances from health professionals is generally far less than their cost on the street;
- they can be obtained in the security of the doctor's office rather than on the street where there is risk from dealing with dangerous drug dealers and undercover police officers;
- they may be used by abusers as trade to obtain their drugs of choice.

Drugs sought after include opioid analgesics (e.g. morphine, oxycodone, meperidine, hydromorphone and codeine preparations), sedatives/hypnotics (e.g. benzodiazepines) as well as stimulants (e.g. amphetamines, methylphenidate). Anecdotal evidence from family physicians in Canada indicates that the drugs most commonly requested by name in the office setting are sedatives/hypnotics and weak narcotics (e.g., Tylenol No.3).[3] Most potent narcotics were crushed, diluted and then injected intravenously.

The potential street value of prescription drugs may illustrate why drug abusers are motivated to seek out these products. Prices vary according to buyer experience, available supply and time of the month (e.g., before or after the day of issue of social assistance cheques).

[*Insert examples for particular country; example for Canada follows*]

According to a Vancouver study published in the *Canadian Medical Association Journal*[4], the street value for Valium 10 mg varied within a range between $0.10 and $2.00 per pill. The street value of narcotic drugs ranged from $0.25 per pill for weak narcotics (.e.g, Tylenol No.3) to $75 per pill for potent opioids (e.g. MS Contin 30 mg).

Balancing benefit and risk

Treatment of certain medical conditions with narcotics and other controlled drugs can be very beneficial when they are used appropriately. Some health professionals may, however, be over cautious in their recommendations regarding use of these pharmaceutical products. For example, pain is more often under-treated than over-treated. Treatment should be tailored to the level of pain the patient is experiencing. In the palliative care setting, the use of opioid analgesics is well recognized. For these patients, the goal is opioid titration to achieve adequate pain control without opioid toxicity. Opioid analgesics are also indicated in chronic non-malignant pain and are considered appropriate when pain is a significant barrier to function, an unremitting source of distress and if there are otherwise no significant contraindication.[5] The presence of a chronic pain syndrome in rheumatoid arthritis is increasingly recognized.[6] A wide variety of adjunctive medications, including opioids (.e.g, morphine, hydromorhone, oxycodone), are being used. In the treatment of non-malignant pain, the goal of therapy with opioid analgesics is not pain elimination but achievement of tolerable pain and/or improvement of function.

A history of drug dependence, the type and dose of drug use, and psychiatric co-morbidity are risk factors for the development of dependence on controlled drugs. When prescribing controlled substances, the following may minimize the risk of dependence:

- Ø use of long-acting opioids
- Ø small amounts prescribed for short periods only
- Ø use of a treatment contract between the physician and patient, where certain rules are laid out (e.g., one prescriber only),see Appendix A for a sample treatment contract) for the treatment

Guidelines are important and should be worked through with the patient. The choice of pharmaceutical product should be based on factors such as the prescriber's experience with the drug and the side effect profile seen in individual patients. By following general principles of sound medical practice and using recognized guidelines on the proper use of narcotics and controlled substances in the management of patients with pain and other medical conditions, health professionals can help minimize abuse and diversion.

Behaviour of drug abusers

Three types of individuals will seek prescriptions for narcotics and other controlled substances:

- Ø the patient who has a legitimate medical need for treatment with a controlled substance;
- Ø drug abusers who are addicted to or dependent on these drugs; and
- Ø con artists whose sole motivation is to obtain and sell drugs for money.

Unlike drug abusers, legitimate patients lack suspicious features - they aren't in a hurry and if unfamiliar to the doctor, will cooperate with attempts to verify their history. Although it's important to trust your patients and accept what they tell you at face value, it is also important to maintain a healthy degree of scepticism.

Drug abusers come in many forms and appearances may be deceptive. Better indicators are their behaviours and their stories.

*Drug abuser*s generally present to physicians seeking particular controlled drugs. Some patients may exploit a legitimate medical condition to obtain excessive quantities of controlled drugs. Other drug abusers may feign an illness. They often present to physicians who do not know them with complaints of acute recurrent pain such as migraine headaches or back pain; in some cases, however, the individual may be well known to the physician. Typically, drug abusers will seek controlled drugs from a number of doctors who are unaware of each other; this is known as double- or multiple-doctoring.

An obvious indicator of addiction is a driven insistence concerning the prescription of a specific drug to the exclusion of alternatives. Patients with an addiction may present with acute withdrawal symptoms (see Table 1 on the following page). They may become extremely agitated, tearful and even violent if they cannot obtain their drug of choice.

Con artists , also referred to as *entrepreneurial drug abusers* or *diverters* , 'earn a living' by obtaining prescription drugs that they, in turn, sell on the street or to other drug dealers. They

seek medications that have a ready market on the street. Drug seekers generally target physicians who have a reputation for prescribing narcotics or controlled substances on demand or without taking a detailed history. They tend to visit several prescribers in a day and travel from town to town posing as unfamiliar patients. The typical diverter is a man or woman age 20 to 40 who is generally well-dressed and groomed.[7] Diverters tend to be well versed in medical terminology. Table 2 lists some of the suspicious features to watch for.

Table 1 Features of a drug abuser with chemical dependence[a]

- Ø pupils: pinpoint or extremely dilated; use of eye drops or dark glasses
- Ø droopy eyelids
- Ø constant runny nose and rubbing of nose
- Ø complexion either pale or flushed
- Ø excessive itching and scratching
- Ø sweating
- Ø tremors
- Ø rigid movements and muscle cramps
- Ø fearful and agitated (in withdrawal)
- Ø emotionally volatile (in withdrawal)
- Ø lethargic and disinterested (using drug)
- Ø giddy and overly friendly (using drug)
- Ø evasive answers
- Ø asks for specific drug by name
- Ø claims of chronic pain with uncertain etiology

[a] Adapted from: Goldman B. Preventing Drug Diversion: A program for physicians and pharmacists - Study guide

Table 2 Suspicious features of drug diverters[a]

- Ø refuses or is reluctant to present identification
- Ø patient claiming to be visiting from another town
- Ø telephone requests for narcotics
- Ø presents at times when the regular physician cannot be reached
- Ø appears to be in a hurry
- Ø asks for a specific drug by name
- Ø tries to take control of the interview
- Ø maintains eye contact with doctor
- Ø well versed in medical terminology
- Ø claims allergy to other drugs such as NSAIDs, local anaesthetics, or codeine
- Ø evasive answers, strange stories
- Ø does not show up for follow-up appointments

[a] Adapted from: Goldman B. Preventing Drug Diversion: A program for physicians and pharmacists - Study guide

Drug abusers or con artists frequently present to an emergency department or acute care clinic with a pre-existing disorder in need of immediate symptomatic relief. They may pretend to be suffering from a disorder which will depend on the drug desired (see Table 3). Self-induced injuries to dentition or reparative work have also been reported. Drug abusers sometimes traumatize their gums in order to cause inflammation and infection. Or they may create a false sense of urgency by pretending to have severe symptoms that cannot wait. Some drug abusers

bear authentic-appearing surgical scars (self-inflicted lacerations) intended to corroborate a history of prior surgery. Others may try to obtain drugs from a veterinarian claiming that their pet is very ill and they want to terminate its life themselves.

Table 3 Feigning an illness

Drug desired	**Feigned pre-existing disorder**
opioid analgesic	Ø a painful disorder such as migraine headache, acute back pain, renal colic or sickle cell crisis Ø dental complaints such as cracked tooth, dry socket or temporomandibular craniofacial pain.
opioid cough syrup	Ø cough due to bronchitis
stimulant	Ø narcolepsy or Ø they may coach their children to behave as if they have attention deficit disorder

Drug abusers, particularly entrepreneurial ones, seldom take their eyes off the physician. They are observing the doctor's facial expressions for indications of disbelief and will instantly change their story as required.

Another type of drug seeker is an individual who shows inordinate interest in the physical layout of the physician's office or a pharmacy; they may be "casing" the surroundings for a possible break and enter.

Methods of drug diversion

Narcotics and controlled substances can be diverted anywhere along the supply and distribution chain. Sources of diverted drugs include:
- Ø prescription forgery
- Ø telephone fraud
- Ø drug seeking from doctors, dentists or veterinarians
- Ø indiscriminate prescribing
- Ø theft: external or internal (e.g. by employees)

Prescription forgery is thought to be the key method of diversion for several reasons:
- Ø it is considered relatively easy to do;
- Ø it is perceived as a victimless crime; and
- Ø both law enforcement and penalties for conviction are perceived by criminal drug seekers as not strict enough to be worth the risk.

According to an unpublished survey conducted by the Canadian government, up to 85% of all forged prescriptions obtained as evidence by the police had been dispensed by the pharmacist.[8]

Prescription forgeries can involve:
- Ø modification of a legitimate prescription to increase the dosage or quantity of a controlled substance, such as increasing the number (for e.g. modifying the number 10 to read 40 or 100) or by adding a drug to the bottom of a legitimate prescription, for

example adding an opioid analgesic to a prescription for an antibiotic;
- Ø reproduction of prescriptions using a photocopier;
- Ø theft of prescription pads and forging entirely new ones.

Table 4 lists some more elaborate scams used by diverters that have been described.[7] Chemically dependent drug abusers are less likely to resort to an elaborate scam. Most often, they visit a number of doctors to exploit a legitimate medical problem for multiple prescriptions or simply feign an illness. Having knowledge of these scams, nevertheless, increases awareness and helps to minimize drug diversion.

Table 4 Some elaborate ways of scamming for drugs

Scam name	Description
Targeting physicians in particular	
"The phony inspector" scam	An accomplice, who plays a law enforcement officer, calls the physician's office claiming a known drug abuser is about to visit. The "officer" urges the physician to play along with the scam and write a prescription promising to apprehend the drug abuser after he/she leaves the office.
"The Friday night special" scam	This is a 3-person scam in which one person plays the patient while the other 2 pretend to be a doctor and the doctor's receptionist. The scammers break into a doctor's office on a Friday evening. Using the doctor's own prescription pad, they write prescriptions for narcotics or controlled substances. The one playing the patient attempts to have the prescriptions filled at various pharmacies. The other 2 accomplices remain in the doctor's office to take calls from any pharmacist who attempts to verify the prescription.
Targeting pharmacists in particular	
Telephone scam	A common pharmacy scam: posing as a practising physician, the drug abuser telephones a prescription on behalf of a bogus patient. A further take on this is that some drug abusers, using the physician's answering service, instruct the answering service to hold his or her calls for a fixed period of time, then begin passing forged prescriptions. At the end of the time period, the drug abuser calls the answering service asking for messages. Pharmacies that failed to call the answering service to verify the prescription are then targeted as "easy marks".
"The garage sale" scam	The drug abuser picks houses at random by attending garage sales, looking for used clothing for sale. They ask to try on an article of clothing in order to gain access to the homeowner's bathroom where they can steal prescription vials containing narcotics or controlled substances. Once they obtain a legitimate patient's prescription container, it is easy to call the pharmacy requesting a refill. Another way drug abusers gain access to residential homes is by searching for homes for sale, then appearing during open houses.
"The pharmacy is closed" scam	The drug abuser asks for a narcotic or controlled substance to be phoned into a pharmacy. Shortly after the pharmacy closes, the drug

Scam name	Description
	abuser phones the doctor, claiming the pharmacy closed before the prescription could be filled. They ask the physician to phone a prescription into a second pharmacy. Next day the physician discovers both prescriptions were filled.
"These pills look different" scam	The drug abuser claims another pharmacist at the same pharmacy has incorrectly filled a prescription. He/she shows the pharmacist a prescription bottle labeled with a prescription for a narcotic or controlled substance that clearly contains an incorrect medication. In order to avoid a formal complaint to the regulatory body, the pharmacist offers to replace the "incorrect" medication with the narcotic or controlled substance on the label.
"You dispensed the wrong medication" scam	The drug abuser presents with a legitimately obtained prescription for a narcotic or controlled substance and an antibiotic. They empty the narcotic or controlled substance from its bottle and replace it with the antibiotic. Returning to the pharmacy, they claim that the pharmacist inadvertently dispensed the antibiotic twice and forgot to dispense the controlled substance.
"The damaged pills" scam	This scam requires a dispensing bottle with a label bearing the name of a controlled substance that has a recent dispensing date. The drug abuser places in the bottle other tablets (e.g. acetaminophen) that have been partly dissolved in water. They then visit the pharmacy where the narcotic or controlled substance was originally dispensed, claims the contents "fell accidentally" into the sink, and request a refill.

[a] Adapted from: Goldman B. Preventing Drug Diversion: A program for physicians and pharmacists - Study guide

STRATEGIES TO MINIMIZE DRUG DIVERSION

Legal requirements

Health professionals are subject to laws that control the prescribing and dispensing of narcotics and controlled substances. Federal laws governing narcotics and controlled substances are summarized Appendix B.

[Since the requirements in each country differ, the following section must be customized for each country; the following are only examples of things that could be highlighted]

The following points outline some of the key responsibilities of health professionals in prescribing and dispensing narcotics and controlled substances:

- Prescriptions for narcotic drugs are generally required to be written, dated and signed by a practitioner. It is strongly recommended that all prescriptions for narcotic and controlled drugs be issued in writing.

- Ø It is unethical for a practitioner to prescribe or administer a narcotic or controlled drug to himself or a member of his immediate family or for a pharmacist to self medicate.

- Ø Narcotic prescriptions cannot generally be refilled. A prescription for a controlled drug may be refilled or repeated by a pharmacist if the prescriber directs in writing, at the time the prescription is issued, that the prescription be refilled, the number of times that it may be refilled and the dates for or intervals between refills (in those countries where it is authorized). There are some exceptions, in some countries e.g. barbiturates, which allow for refills of verbal prescriptions.

- Ø Pharmacists must assess the legitimacy of prescriptions for narcotics and controlled substances. Pharmacists should be aware of which health care professionals may prescribe medications. Pharmacists must report prescriptions that do not comply with the law. It is important to establish a partnership with law enforcement to facilitate the investigation of drug diversion and the apprehension of those responsible.

- Ø A pharmacist is responsible for maintaining records for purchasing, receiving, transferring, disposing and dispensing narcotics and controlled substances in accordance with all applicable Acts, regulations and by-laws.

- Ø Reasonable steps must be taken to protect narcotics and controlled substances from loss or theft; any losses or thefts must be reported to the regulatory authority.

In some jurisdictions, a duplicate/triplicate prescription program is in place to monitor the use of certain drugs prone to misuse, abuse and diversion. Under these programs, the original prescription is given to the patient to present to the pharmacist; a copy is sent to the regulatory authority for analysis. Multiple-doctoring and excessive prescribing can be more easily detected using these programs.

Some jurisdictions require that all prescriptions dispensed by pharmacies be recorded through an on-line computer system which allows pharmacists to check if the individual has obtained controlled drugs at other pharmacies or from other physicians.

Strategies for the physician

Abuse and diversion prevention begins with consistent and thorough care of every patient presenting with a symptom or medical condition for which a controlled substance may be indicated. It is important that a doctor-patient relationship be established before prescribing any controlled substance. “Getting to know your client” is a strategy that is also employed by banks to prevent money laundering.

There are a number of things that can be done in practice to prevent medication abuse and diversion:

- Ø ***identify the patient if not known to you*** using 2 or 3 pieces of identification (e.g. driver's license, health card, social insurance number)

- Ø ***verify the presenting complaint*** and ***observe for drug abuse behaviour***. Take an independent history and observe closely for evasiveness. Screen for current and past alcohol drug prescription and over-the-counter medicine use. Know the features that suggest drug-seeking behaviour (see Tables 1 and 2). Be suspicious of patients who refuse appropriate confirmatory tests (e.g. blood tests, x-rays, etc). Watch for injuries that don't heal. Many addicts will prevent healing until they can't bear the pain anymore.

- Ø ***talk to the patient's regular practitioner or family doctor***. Ask the patient to provide the name and address. If a patient provides a letter from a consultant, verify its authenticity in the same way.

- Ø ***use safe prescribing strategies.*** If you are prescribing an opioid analgesic, limit prescriptions for acute pain to a duration of no greater than 3-5 days; for long-term treatment, switch to a long-acting opioid.

- Ø ***implement a treatment contract with the patient.*** Appendix A provides a sample of a treatment contract that communicates to the patient the rules around providing a prescription for opioids: one prescriber, the amount to be dispensed, no early refills consequences for breaking the contract.

- Ø ***reassess the patient at appropriate intervals.*** A suggested time frame is every 6 to 9 weeks. Patients who do not return for follow-up appointments should be viewed suspiciously. Keep a record of all prescriptions issued on the patient's chart (see Appendix C). Do not continue to prescribe controlled substances when there is evidence of non-compliance, escalation of dose, misrepresentation, or fraud

- Ø ***prevent prescription forgery***: Prescriptions should be written so as to make them difficult to alter (see Table 5 for tips on preventing prescription forgery)

- Ø ***prevent telephone scams***. Do not telephone prescriptions for unfamiliar patients.

- Ø ***keep drugs out of sight*** in the office and never leave your medical bag unattended or in plain view.

- Ø ***Caution when distributing professional; samples***. Where the distribution of professional samples of pharmaceutical products is permitted, practitioners need to exercise caution when doing so when the patient is new or unknown to them.

Table 5 Tips to prevent prescription forgery

Ø Do not leave a space between the number and dosage unit, for e.g. 10mg.
Ø Write the quantity of dispensed dosages in longhand followed by the corresponding number in parentheses, for e.g. eight (8)
Ø for added protection, write the word "only" immediately following the numeral and leaving no space, for e.g. eight (8only)
Ø Do not leave blank spaces in the prescription; instead, fill the unused portion of the prescription with a pen stroke)
Ø Use a numbered prescription pad for narcotics and controlled drugs so that stolen prescriptions can be quickly identified
Ø Use one prescription pad at a time and keep it in your pocket or under lock and key.
Ø Use photocopy-proof prescription pads. There are some technologies available that increase the likelihood that photocopied prescriptions will be detected (e.g. distinctive icon disappears when photocopied)
Ø Spell out patients' addresses
Ø Never sign blank prescriptions in advance.
Ø Use prescription pads only for prescribing. Make other notes or instructions on stationery.
Ø Have a strong relationship with local pharmacists, who are often the first to detect a diversion attempt

Strategies for the pharmacist

Pharmacists also play an important role in the prevention of prescription drug misuse by providing clear information and advice about how to take a medication appropriately and effects the medication may have or possible drug interactions. Poor compliance may contribute to abuse.

The following suggestions provide a framework to enable pharmacists to stop drug abusers while treating legitimate patients compassionately

Ø ***examine the prescription to ensure its authenticity***. Look for obvious clues to a forged prescription which could include any alteration in the amount, dosage, number of refills, name of drug, spelling mistakes, directions written in full with no abbreviations, different coloured inks, writing more legible than usual. Look for prescriptions where the narcotic or controlled drug appears to have been added on. Look for photocopy blotches or dust marks or traces of adhesives as signs that the prescription has been photocopied. Watch for prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time. Become familiar with the drugs that are popular in your area for abuse and resale on the streets.

Ø ***identify the patient***. Be alert for a number of people appearing within a short time all bearing similar prescriptions from the same physician. Ask all new patients for 2-3 pieces of identification. Post a sign informing patients of the policy; this alone will discourage many drug abusers. When you check the patient's identification,(identification) record his or her driver's licence number or other

appropriate identification on the back of the prescription and place a pharmacy stamp on it. This will prevent it from being used elsewhere if you do not fill it. Most legitimate patients have no difficulty complying with a request for identification, especially if the reasons for the request are explained to them.

- ***talk to the patient***. Observe for signs of drug intoxication and drug withdrawal.
- ***contact the physician directly to verify the prescription***. Verify that the physician exists and that the physician is treating the patient. If possible, know the prescribers's signature. Take the time to verify the prescription. Where a prescription is suspicious, stalling for time is a good tactic as it generally frustrates diverters who are usually in a hurry.
- ***install a private telephone line for telephone prescriptions*** and only give the number out to legitimate physicians. Any prescriptions phoned in on the pharmacy's main telephone line can then be viewed with suspicion.
- ***provide adequate security for the storage of controlled substances*** and limit access to those who have need.
- ***keep records of all receipts and disbursements and check inventory regularly*** to be able to detect any losses.

WHAT TO DO WHEN YOU DISCOVER A DIVERSION ATTEMPT

It is illegal to knowingly prescribe or dispense a narcotic or controlled drug for anything other than a legitimate medical purpose.

If you detect a drug abuser:

- inform the physician(s) who have issued prescriptions to the individual or, in the case of suspected forgeries, the physician(s) whose name(s) appears on the prescription;
- inform other pharmacies: some jurisdictions have initiated a telephone alert system in your area
- if the patient resorts to verbal abuse or acts of violence, contact law enforcement authorities if you are threatened in any way

CONCLUSION

The magnitude of the drug abuse and diversion problem and the cost to every one require that health professionals make a meaningful collective effort to prevent abuse and diversion. Collaboration between prescribers, pharmacists and regulators is necessary to minimize abuse and diversion

With prescribers, pharmacists and regulators working together to prevent drug abuse and diversion, this will help safeguard the availability of narcotics and controlled substances for patients whose function and quality of life depend on them.

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Appendix A - Sample treatment contract

I understand that I am receiving opioid medication from Dr. .... to treat my pain condition.

I agree to the following conditions under which this medication is prescribed.

- I will not seek opioid medication from another physician. Only Dr. .... will prescribe opioid for me.
- I will not take opioid medication in larger amounts or more frequently than is prescribed by Dr. ....
- I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else.
- I will not use over-the-counter opioid medications such as 222's and Tylenol #1.
- I understand that if my prescription runs out early for any reason (for example if I lose the medication or take more than prescribed), Dr. .... will not prescribe extra medications for me; I will have to wait until the next prescription is due.
- I understand that if I break these conditions, Dr. .... may choose to cease writing opioid prescriptions for me.

Patient's signature:

____

Physician's signature:____

Date:

____

Reproduced from: College of Physicians and Surgeons of Ontario, Canada. Evidence-based recommendations for medical management of chronic non-malignant pain: reference guide for clinicians. 2000. Available from: www.cpso.on.ca/Publications/pain.htm.

Appendix B- Summary of Federal Laws Governing Narcotics and Controlled Drugs

Classification	Description	Prescription Requirements	Ordering	Purchase Records	Sales Records	Filing
NARCOTICS	*[list drugs included in this category]*	*[requirements for prescription (e.g. written); state if refills or part-fills are allowed, etc.; indicate requirements to transfer prescription from one pharmacy to another if permitted]*	*[requirements for ordering from manufacturer or wholesaler e.g. electronic? By fax?]*	*[requirements for recording purchases/receipts into inventory]*	*[requirements for recording sales/disbursements from inventory]*	*[requirements for filing prescriptions and maintaining inventory records (incl. Sales, purchases)*
CONTROLLED DRUGS						

ʼegulations and acceptability of faxed prescriptions varies between provinces

IOTE: This is a summary only. Please refer to *Narcotic Control Regulations, Controlled Drugs and Substances Regulations* and *Targeted Substances Regulations* for complete details.
)rug names are examples only. Not a complete listing. Legislation may change.

Appendix C - Sample Controlled Drug Prescription Record

Patient Name:
....

Chart number:
....

Prescribing Physician:
____

Date	Medication	Dose	Direction	Number dispensed	Comments

Reproduced with permission from: College of Physicians and Surgeons of Ontario. Evidence-based recommendations for medical management of chronic non-malignant pain: reference guide for clinicians. 2000. Available from: www.cpso.on.ca/Publications/pain.htm.