

# **Guide on Reducing the Diversion of Controlled Substance Pharmaceuticals via the Internet November 2010**

## **1. Introduction**

While the existence of the Internet has had a significant impact on the evolution of information collection and exchange, and even business and trade, its very global and fluid nature has been exploited by those engaged in criminal activities such as the dissemination of child pornography, the promotion of hate literature, and even the fraudulent/illegal sale of goods and services.

Included in the latter category of criminal activities facilitated by the Internet is the diversion of controlled substance pharmaceuticals, which encompasses two inter-related but separate types of drug distribution activity: 1) the illegal distribution of pharmaceuticals containing controlled substances, and 2) the illegal distribution of counterfeit controlled substance pharmaceuticals that may or may not contain a purported controlled substance. Both activities pose an ever-increasing threat to health and safety, especially when the general level of consumer awareness and understanding about the controls imposed on parties involved in the legitimate distribution of legal pharmaceutical products in any one jurisdiction is often very low.

While some websites that offer pharmaceuticals containing controlled substances for sale may be licensed by the competent authority in which they operate, many have been created to look like legitimate pharmacies and offer these products for sale without the requirement for a prescription. Some sell drugs that have not even been approved for sale in that country. Many offer pharmaceuticals containing controlled substances based on answers to online questionnaires that may or may not be reviewed by a physician or that are simply reviewed by a “script doctor” whose job is to write prescriptions for patients they never see. What they do not tell potential customers is that it is dangerous to take pharmaceuticals containing controlled substances without being examined in person and monitored by a health care practitioner, i.e., that a concrete doctor-patient relationship is critical to the legitimate use of controlled substances for medical purposes. It is well universally understood that these measures are important in order to make sure that patients get the most appropriate treatment and that the opportunities for abuse and/or dependence are minimized.

Buying pharmaceuticals containing controlled substances from companies via websites that do not provide a street address or telephone number means that there is no way of knowing where these companies are located, where they get the drugs they are selling, or how they can be reached if there is a problem. Buying from these websites also places consumers at risk of buying counterfeit drugs that contain the incorrect dose, wrong ingredients, dangerous additives, no active ingredients at all, or drugs that are past their expiry date, all of which could result in potentially serious health consequences. Consumers may also put themselves at risk for drug interactions, or other harmful side effects that interaction with a qualified professional could potentially avoid.

Buying pharmaceuticals containing controlled substances via the Internet may also pose financial risks. In some cases, the product purchased may never arrive, or if it has to come from another country, it could be stopped at the border by local customs authorities. Individuals might also have their personal and/or credit card information stolen.

In the absence of regulations governing use of the Internet, the illegal distribution of controlled substance pharmaceuticals via the Internet continues to present challenges to member states.

## **2. Purpose**

The purpose of this paper is twofold. Of the first order, it aims to assist member states in assessing the nature and the extent of the diversion of controlled substance pharmaceuticals via the Internet and/or the existence of any component thereof within their jurisdictions. Of the second order, this document aims to propose a number of strategies that member states could apply in reducing the incidence of said diversion.

This guide does not however, address the legal sale of pharmaceuticals (whether or not they contain controlled substances) via established internet pharmacies, i.e., business operations where consumers submit prescriptions issued by licensed medical professionals further to personal consultation and then receive the required pharmaceutical products by mail further to dispensing by a licensed pharmacist. This is because the decision to allow the legal distribution of pharmaceutical products via these types of businesses, and the controls imposed on them, is best left to member states.

Similarly, this guide does not seek to address the use of the Internet to traffic illicit drugs<sup>1</sup> such as methamphetamine and ecstasy, given that such activity is well-established as illegal under the United Nations Drug Control Conventions<sup>2</sup>, and thus should already be addressed by drug control legislation in place within each member state.

Lastly, this guide does not address the use of the Internet to sell counterfeit pharmaceuticals containing controlled substances, as this issue is already being dealt with successfully through the WHO Impact initiative.

## **3. Assessing the Nature and the Extent of the Diversion of Controlled Substance Pharmaceuticals via the Internet**

Before attempting to set out strategies by which jurisdictions can assess the nature and extent of the diversion of counterfeit or legitimate controlled substance pharmaceuticals via the Internet, it is important to understand the varied participants that may be involved in these transactions. As these illegal operations may vary significantly in scope and level of sophistication, the following list may not be exhaustive:

- business facilitators, i.e., individuals who set up the websites that advertise the sale of controlled substances pharmaceuticals, usually at very cheap prices and usually without stating the source of

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<sup>1</sup> Where this refers to drugs not having a legitimate medical or scientific purpose.

<sup>2</sup> Where this refers to the Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances, and the United Nations Convention Against the Illicit Traffic of Narcotic Drugs and Psychotropic Substances (1988)

the pharmaceuticals being sold;

- Internet service providers, i.e., companies who host the websites and who may not know whether their clients are operating legitimate businesses or not;
- domain name companies who sell the rights to individual website names, and who may or may not have standards preventing the registration of domain names that appear to promote illegal activity in place;
- Internet search engine companies, who may or may not have standards in place establishing the types of businesses who are allowed to advertise on their search engine and thus from whom they will collect advertising revenues;
- call centers involved in processing customer orders, who may be legitimate companies contracted by illegal businesses to facilitate what they believe are legitimate transactions, or illegal operations established by the business facilitator in order to serve his/her own specific purposes;
- merchant payment processors, who may be legitimate companies contracted by illegal businesses to facilitate what they believe are legitimate transactions, or illegal operations established by the business facilitator in order to serve his/her own specific purposes;
- the banking industry, whose clients may be duped into purchasing controlled substances pharmaceuticals via these illegal companies and who thus use banks to make payments for goods received; the banking industry may also be involved in funding the establishment of companies involved in these types of transactions via loans and mortgages, etc.;
- practitioners, who may be associated with businesses who sell pharmaceuticals containing controlled substances via the Internet illegally, and thus whose names are used to “legitimize” the sale of pharmaceuticals that would ordinarily require an in-person patient consultation and the issuance of a personal prescription;
- pharmacists, who may be associated with the above-mentioned businesses, and thus whose names are used to “legitimize” the illegal dispensing of legitimate controlled substance pharmaceuticals;
- suppliers of controlled substance pharmaceuticals, i.e., legitimate (licensed) wholesalers, distributors or manufacturers who may be involved in providing products that are then distributed by the businesses who sell pharmaceuticals containing controlled substances;
- courier companies and/or the postal system, who are involved in moving the illegally obtained controlled substances pharmaceuticals from one place to another, either domestically or internationally; and
- clients, i.e., the consumers who perceive that it is safe and legal to purchase controlled substances pharmaceuticals via these businesses, and who thus, believe they are engaging in legitimate transactions and/or that they are dealing with a legitimate internet pharmacy.

In consideration of the above, the following is a list of some of the actions member states could consider in assessing the nature and extent of controlled substance pharmaceutical diversion via the Internet within their respective jurisdictions.

- a. Asking law enforcement agencies to, in the course of ongoing investigations, specifically question informants and/or those arrested for trafficking in controlled substance pharmaceuticals whether the drugs involved were purchased via the Internet, and if yes, whether they will divulge the specific websites involved and/or the names of other persons involved in these operations. Law enforcement agencies should also be advised to obtain

physical evidence, e.g., pill bottles, receipts, etc., of the illegal transactions for use in related prosecutions and/or investigations.

- b. Asking municipal/state health authorities to interview drug counselors and/or other responsible individuals at drug treatment facilities about what they know to be the sources of supply used by their clients, and if the Internet is listed as a source of supply, to encourage these individuals to probe further with their clients about specific websites used, etc.
- c. Working with relevant authorities to coordinate the measures required to prevent the illegal importation of controlled substance pharmaceuticals. If no specific measures are in place, encouraging the development, with the cooperation of relevant government agencies, of a strategy to safeguard the legitimate drug supply chain. Such a strategy could include the random sampling of packages entering and/or leaving the country, and where pharmaceutical products are found to have entered the country illegally, to have the relevant authority take samples in order to carry out laboratory analysis aimed at identifying the specific substances involved, the quality of the products involved and any possible information as to source of supply. Records of their random sampling operations should be retained so that trends in terms of source countries, suppliers and specific products involved can be analyzed over time. This intelligence can also then be shared with the relevant authorities in neighbouring countries and/or in identified source countries.
- d. Encouraging the cybercrime units of law enforcement agencies to randomly assess what controlled substances pharmaceuticals can be purchased illegally via the Internet and/or to carry out undercover purchasing operations/ related investigations. These investigations could help determine what other jurisdictions are involved if any, and where suppliers are located, which can then be useful in closing off sources<sup>3</sup>.
- e. Asking the pharmaceutical industry and consumer protection authorities to furnish information on relevant complaints submitted to them with respect to the illegal distribution of pharmaceuticals containing controlled substances via the Internet, i.e. suspicious services.
- f. Asking relevant business sectors, e.g., internet service providers, domain name registries, internet search engine companies, merchant payment processors, the banking industry and the courier industry, what internal tracking mechanisms they currently have in place that could assist in gathering information about the ongoing extent and nature of the illegal sale of pharmaceuticals containing controlled substances via the Internet.

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<sup>3</sup> It is important to note the types of law enforcement action possible in the context of internet pharmacy investigation will always be limited by what laws are applicable in the country where the server is hosted, not necessarily where consumers are being targeted etc. It is generally accepted that one of the greatest law enforcement challenges associated with impeding this type of illegal activity is the fact that many businesses involved are not physically located in the country where they generate their income or perhaps purposefully ship purchased products via several countries en route between the country where the business is located and the country where the consumer is located.

#### **4. Reducing the Diversion of Controlled Substance Pharmaceuticals via the Internet**

Once it has been ascertained that there is a problem with the diversion of controlled substance pharmaceuticals via the Internet, the competent authorities for drug control are encouraged to take steps to reduce the risk to health and safety posed by this type of illegal activity. Potential actions member states could consider in this regard are listed below.

- a. Identifying a means of informing and educating the public about the potential illegality and health risks of obtaining pharmaceutical products containing controlled substances via the Internet. A suggestion might be to post a clear policy statement or warning on relevant government agency websites.
- b. Working with the media, e.g., radio/television broadcast outlets, to create public service announcements that disseminate information regarding the risks associated with the illegal purchase of pharmaceuticals containing controlled substances via the Internet.
- c. Working with schools and youth groups in order to facilitate the dissemination of information regarding the health/safety or applicable legal risks associated with the illegal purchase of pharmaceuticals containing controlled substances via the Internet.
- d. Working with law enforcement agencies, customs authorities and even the regulated pharmaceutical industry to provide a mechanism for citizens to report suspected illegal activity involving the sale of pharmaceutical products containing controlled substances, e.g., establishing a toll free number for reporting suspicious pharmacies.
- e. Creating a plain language fact sheet/guidance document clearly identifying what, if any, activities with respect to the purchase of pharmaceuticals containing controlled substances via the Internet are illegal versus those that are legal, and also setting out the risks associated with the purchase of pharmaceuticals containing controlled substances via the Internet. In the case where internet pharmacy is legal, the information sheet/guidance document should clearly identify the parties involved in regulating those businesses<sup>4</sup>. f. Determining the appropriate agency or authority to establish effective working relationships with responsible individuals within the relevant business sectors, e.g., internet service providers, domain name registries, internet search engine companies, merchant payment processors, the banking industry and the courier industry, for the purposes of sensitizing these companies as to the nature of the problem and the need for due diligence in knowing their clients and the nature of their clients' business so that they do not inadvertently contribute to the problem. Aspects of such a dialogue could include encouraging Internet service providers not to sell advertising space to entities engaged in the sale of controlled substances. A secondary outcome of these relationships could be the enhanced reporting of suspicious activity to relevant competent authorities.

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<sup>4</sup> The Expert Group on Pharmaceutical Products and Chemical Substances has prepared a model fact sheet for consideration of member states. It is also posted on the CICAD website.

- g. Identifying responsible individuals from relevant business sectors as well as relevant federal/state/municipal agencies who can share intelligence relating to this issue amongst themselves but also with other member states.
- h. Contacting the licensing authorities for all relevant health professionals, e.g., medicine, pharmacy, etc., in order to communicate to their members the importance of not engaging in the illegal distribution of pharmaceuticals containing controlled substances via the Internet, and assisting them in integrating information about the extent to which pharmaceuticals containing controlled substances are distributed illegally via the Internet into the continuing education programs provided to their members. Competent authorities should also encourage licensing authorities to report suspicious activity to whichever agency is most appropriate.
- i. In countries where internet pharmacy is legal for either regular pharmaceuticals and/or those containing controlled substances, working with the licensing authority for pharmacy to encourage the development of a voluntary accreditation scheme for the pharmacies involved, so as to help consumers identify those websites that are duly authorized to dispense pharmaceuticals via the Internet. An example of such a system is the Verified Internet Pharmacy Practice Sites (VIPPS) scheme administered by the United States National Association of Pharmacy Boards ([www.vipps.napb.net](http://www.vipps.napb.net)).
- j. Working with customs authorities and the agencies responsible for mail and courier services to establish protocols for the random sampling of incoming international mail and courier parcels known to contain pharmaceutical products (as indicated by X-ray scanning) in order to identify the source of any pharmaceuticals containing controlled substances found to have been distributed illegally, i.e., purchased via the Internet in the absence of a legitimate prescription, etc. Such random sampling exercises, if carried out on a regular basis, can also serve to complement national understanding as to the level of counterfeit and/or illegal trade in pharmaceutical products writ large.
- k. Working with the legitimate controlled substance pharmaceutical industry to encourage them to “know their customers” and/or implement measures to ensure that none of their stock is diverted to illegal distribution via the Internet. For example, encouraging wholesalers to obtain information about potential customers as to whether they are currently engaged in legitimate internet pharmacy activities, checking with relevant licensing authorities for pharmacy and/or medicine in order to determine if their customer is in good standing; conducting Internet searches to determine whether their customer is associated with any suspicious websites; monitoring for suspicious orders; and, conducting periodic reviews of cumulative orders from the same customer over time in order to evaluate trends in purchasing patterns. The controlled substance pharmaceutical industry should always be encouraged to report “suspicious” activities to law enforcement.
- l. Working with relevant consumer protection authorities to establish legislation or regulations that prohibit the advertising of pharmaceuticals containing controlled substances via the

Internet (if not already covered in relevant drug legislation) and to develop education tools on how to submit complaints about misrepresentations, scam offerings, issues with products, or other problems with websites illegally offering pharmaceuticals containing controlled substances for sale, and guidance as to how to check whether a particular pharmacy doing business on the Internet is legitimate. Outreach should also focus on ways to protect personal information when purchasing goods via the Internet, e.g., checking the privacy policy usually found at the bottom of a website's home page, refusing to give out personal information or credit card information to companies that are not well known, protecting passwords and impeding spam as much as possible.

- m. Working with the legitimate pharmaceutical industry to employ and train personnel to monitor for and report on all suspicious orders. It is recommended that training be conducted for all personnel involved in receiving, shipping, handling, record-keeping, sales, or in establishing new accounts.
- n. Working with law enforcement to identify any new trends associated with the sale of controlled substances via the Internet, e.g., e-marketplace websites that act as brokers of pharmaceuticals and chemicals within a community of many buyers and many sellers.
- o. Encourage law enforcement to be trained on cybercrime investigations.

## **5. Conclusion**

The diversion of pharmaceutical containing controlled substances via the Internet is a multi-faceted one. There are many potential players; legal and illegal internet operations with varying levels of sophistication; and even the requirement for understanding the prevailing legislative frameworks for drug control and pharmaceutical distribution. As such, an important consideration in implementing any of the actions recommended above is to ensure consistency with and/or the application of domestic legislation and regulatory frameworks. This must also include not only pharmaceutical regulations but also a country's banking, business and privacy laws.

Lastly, the fact that the Internet is a global medium where websites targeting consumers in one country can be hosted in another, and where the financial transactions underpinning the activities described above may be taking place in yet a third location, means that addressing the issue of the diversion of pharmaceuticals containing controlled substance via the Internet involves not only intra-jurisdictional cooperation among an array of federal and/or state/provincial agencies, e.g., law enforcement, border control, health product regulators, competent authorities for drug control, health professional licensing authorities, etc., but also strong inter-jurisdictional collaboration during both investigation and enforcement activities.