FORTY-EIGHTH REGULAR SESSION
December 6 - 8, 2010
Washington, D.C.

FINAL REPORT
GROUP OF EXPERTS ON CHEMICAL SUBSTANCES AND PHARMACEUTICAL PRODUCTS
Executive Summary

During its forty-sixth regular session (November 18-20, 2009) in Miami, Florida, the Inter-American Drug Abuse Control Commission (CICAD) received the reports of the Group of Experts on Chemical Substances and the Group of Experts on Pharmaceutical Products. In approving the proposed plans of action and recommendations the Commission directed that the two groups be combined into one and that the new Group of Experts on Chemical Substances and Pharmaceutical Products meet in 2010. The Government of Costa Rica offered to chair and host this meeting.

The Group of Experts met in the Hotel La Condesa in San Jose, Costa Rica from August 23 to 27, 2010. Mr. Carlos Alvarado Valverde, Acting Director of the Costa Rican Drug Institute (ICD), and Dr. Darling López Medrano, Chief of the Drug Information and National Statistics Section of ICD chaired this meeting which included approximately 44 participants from 15 Member States and observers (Argentina, Bolivia, Brazil, Canada, Chile, Costa Rica, Ecuador, El Salvador, Dominican Republic, Guatemala, Mexico, Panama, Peru, United States, and Uruguay). An observer from PRELAC, “Prevención del Desvío de Sustancias Precursoras de Drogas en América Latina y el Caribe” was also present.

Following the attached schedule of activities the Group worked on the tasks assigned in the plans of action approved by the Commission during its forty-sixth regular session as set out in the attached schedule of activities.

The Group of Experts offers the following priority recommendations for the Commission’s consideration:

1. That the Commission:

   • **accept** the following resource documents:
     - Guide on Reducing the Diversion of Controlled Substance Pharmaceuticals via the Internet
     - Model Fact Sheet on Buying Pharmaceuticals Containing Controlled Substances over the Internet
     - Concept Paper Regarding the Regulation of Equipment Used in the Production of Illegal Drugs
     - Guide to increase private sector involvement in the control of chemical substances and pharmaceutical products

   • **direct** the Group of Experts to continue its work on the issues initiated for consideration and finalizing at the next meeting

   • **direct** the Group of Experts continue its work in revising and update CICAD’s Model Regulations on chemical substances, using electronic means to exchange and gather information and, if
required, meet on this specific issue prior to the Group's next general meeting

- **accept** the proposed plan of action for the Group of Experts
- **direct** the Group of Experts to meet during 2011 and implement the plan as proposed, allowing for the consideration of new or emerging issues
I. BACKGROUND

The Inter-American Drug Abuse Control Commission (CICAD) met for its forty-sixth regular session in Miami, Florida (November 18-20, 2009). During that meeting, the Commission received the reports of the Group of Experts on Chemical Substances and the Group of Experts on Pharmaceutical Products. In considering the reports the Commission accepted the proposed plans of action and recommendations of the two groups. One of the recommendations proposed that the two groups be combined into one which would consider issues related to both chemical substances and pharmaceutical products. The Commission directed that this combined group meet in 2010 to execute the consolidated plan of action.

Mr. Carlos Alvarado Valverde, Acting Director of the Costa Rican Drug Institute (ICD), and Dr. Darling López Medrano, ICD’s Chief of the Drug Information and National Statistics Section chaired the meeting which took place in the Hotel la Condesa in San Jose, Costa Rica from August 23 to 27, 2010.

II. PROCEEDINGS

A. PARTICIPANTS

MEMBER STATES OF CICAD

Participants to the meeting included approximately 44 experts representing 15 member states and observers (Argentina, Bolivia, Brazil, Canada, Chile, Costa Rica, Ecuador, El Salvador, Dominican Republic, Guatemala, Mexico, Panama, Peru, United States, and Uruguay). An observer from PRELAC, “Prevención del Desvío de Sustancias Precursoras de Drogas en América Latina y el Caribe” was also present.

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. OPENING SESSION

The opening session for the meeting of this Group of Experts took place at 9:00 on August 23 at the Hotel la Condesa. Mr. Carlos Alvarado Valverde, Acting Director of the Costa Rican Drug Institute (ICD), and Mr. Allan Solano Aguilar, Director of the Drug Control Police of the Ministry of Public Security welcomed the participants and offered opening remarks. In doing so they emphasized that chemical diversion remains an on-going problem. At the same time there exists
an increasing problem with the diversion of psychoactive pharmaceutical products. The speakers pointed out that the discussions and products of the Group of Experts are invaluable tools for regulatory officials, law enforcement and others concerned with the control of chemical substances and pharmaceutical products.

2. WORKING SESSIONS

A. Presentations

During the meeting several delegations delivered presentations to the plenary. The presentations delivered included the following:

- **Presentation by the delegation of the United States on the Drug Information Program (CDI)**

Mrs. Vilma Bonilla-Foote and Mr. Hayward Lamply of the delegation of the United States delivered a presentation on the Drug Information Program (CDI). CDI is a computer and internet-based communications network that allows participants to share information and communicate with each other.

This presentation was a follow-up to a presentation that was delivered to the Group during its meeting in 2009. The Group agreed use this system as a means for members of the Group and others concerned with the control of chemical substances and pharmaceutical products to communicate.

Further to the presentation participants were asked to identify a point of contact and coordination in each country present. This point of contact and coordination would be responsible for identifying individuals who could or should be included in the network as well as receiving, approving and passing along their requests for accounts to access and use the network. CICAD will serve as the point of coordination for the network and the US managers of the system will be responsible for delivering the necessary training to users.

The communication network will serve as an option for the exchange of information among the members of this group of experts related to the control of chemical substances and pharmaceutical products. The Executive Secretariat will work with the US CDI coordinators to prepare a number of forms to facilitate data exchange.
- Presentation by the delegation of Costa Rica on Trafficking of Counterfeit Medications

The delegation of Costa Rica delivered a presentation on the trafficking of counterfeit medications in Costa Rica. The speakers provided an overview of the problem. Counterfeiting of pharmaceutical products takes place through several means including modification of packaging, changing expiration dates, adulterating formulations and preparing final dosage forms containing non-medicinal ingredients. All of these methods represent a danger to the public ranging from failure to deliver the intended therapeutic medications to the consumption of potentially toxic or poisonous substances. Using a real case the speakers demonstrated some of the methods used to counterfeit drugs. One example involved the use of white cement that was then pressed into a tablet.

The speakers described the steps that Costa Rica had taken to address this problem. This included a review and enhancement of legislation to cover administrative, penal/criminal and civil sanctions. Costa Rica has also taken a multi-agency approach to deal with the various dimensions of this problem.

The presentation generated a great deal of discussion regarding the problem of counterfeiting pharmaceutical products. Several delegations spoke of the work of other international organizations including the World Health Organization (WHO) IMPACT initiative, among others, which is aimed at reducing the incidence of counterfeit medicines through information-sharing and collaborative investigation. The Executive Secretariat invited participants to share any information and web links that they might have regarding such efforts and this would be posted to CICAD for the information of all CICAD member states.

- Presentation by the delegation of Costa Rica on the Suspicious Container Program (SCP)

The delegation of Costa Rica delivered a presentation on its Suspicious Container Program. The SCP is a program sponsored by the World Customs Organization (WCO) and the United Nations Office on Drugs and Crime (ONDCP) intended to increase the capacity of countries to profile and target containers that may be carrying contraband.

Within the framework of the program countries must sign an agreement with UNODC and WCO regarding the implementation of the program. In doing so the countries must commit to provide a certain level of operational and capital (equipment) support as well as the necessary space in the port for inspection of containers. WCO and UNODC provide the necessary training for the officials
assigned to the program. Typically this is an initiative that requires the participation of officers from many different agencies.

In implementing the program the participating country must define priorities for the program for targeting purposes. In Costa Rica’s case it identified chemicals and illicit drugs as its priority targets.

Costa Rica started the program in late 2009 and is now in the early stages of implementation.

**Overview of Chemical Control in Mexico**

The delegation of Mexico presented the situation of methamphetamine production in that country, the substances used in its production (phenyl acetic acid, its salts and ethers, and methylamine), seizures of these substances, and destruction of equipment found in clandestine laboratories that were destroyed.

The presentation also included an update of the Mexican law banning the importation, possession and production of pseudoephedrine and ephedrine in an effort to reduce the illicit production of methamphetamine.

**B. Plenary Discussions:**

The Group of Experts considered the following tasks and related documents generated by working groups further to discussions during the meeting in 2009:

**Draft guide on the inspection and handling of chemical transshipments in port facilities (Bahamas)**

This subject was discussed during the Group’s last meeting and assigned to a working group for further elaboration. The delegation of Bahamas was not able attend the current meeting and the draft guide was therefore not progressed at this meeting.

**Draft guide for an administrative and criminal framework for the control of materials chemical substances (Chile)**

The delegation of Chile presented the draft guide for establishing an administrative and criminal framework for the control of chemicals. Drawing on the experiences of Chile and several other countries, this comprehensive guide
outlines the major elements that must be considered when establishing mechanisms for the control of chemicals.

The presentation and draft guide generated a great deal of discussion among the participants. Much of the discussion related to terminology and the need for the document to take into account differences in legal systems between member states. In this regard the contents of the draft guide must match with the chemical control model regulations. Both of these documents need to be compatible. For this reason the Group decided to set aside work on the draft guide until the model regulations have been reviewed and updated. At that time the working group will review and revise the draft guide ensuring that the two documents are consistent.

**Concept Paper Regarding the Regulation of Equipment Used in the Production of Illegal Drugs (Canada)**

Member states have taken steps to control the diversion of precursors and other chemicals used in the production of synthetic and other illicit drugs. At the same time there is equipment that is used by narcotraffickers in the production of these drugs. This includes certain specialized glassware and tablet presses among others.

The Working Group chaired by Canada prepared and presented a concept paper related to the control of equipment that could be used in the production of illicit drugs. This concept paper provides an overview of the elements that need to be addressed by countries wishing to develop and implement mechanisms (legislation, regulations, and administrative procedures) to control this type of equipment.

With some minor modifications the Group accepted the concept paper. At the same time the Group considered the possibility of using the concept paper as a platform for drafting model regulations to control this type of equipment. Following an active discussion the Group decided not to proceed in this way at the present time but rather to post the concept paper to the CICAD web page once approved by the Commission. Countries that have proceeded to develop regulations or other controls over this equipment used in the production of illicit synthetic drugs will be invited to share their experiences at the next meeting.

**Guide on Reducing the Diversion of Controlled Substance Pharmaceuticals via the Internet (Canada and US)**

In previous meetings the Group has addressed different aspects of the problems associated with the illegal sale of controlled substances and drugs containing
controlled substances via the internet. The current document builds on these discussions and offers member states a comprehensive and practical guide for elements that need to be considered in identifying whether there is a problem with illegal internet drug sales and also how to address such activity once identified.

In discussing this document the participants noted the distinction between legitimate pharmacies which are authorized to sell pharmaceutical products containing controlled substances over the internet and websites/businesses that are not authorized and which in many instances offer these products for sale with no medical consultation or even the requirement for a prescription. These websites/businesses offer to sell illicit drugs and/or deal in pharmaceutical products that in many cases are counterfeit.

In this regard the guide is accompanied by a model fact sheet aimed at promoting awareness regarding the dangers associated with buying pharmaceutical products over the internet.

These documents generated a very productive discussion. With some minor changes the Group finalized and accepted the two documents.

Guide to increase private sector involvement in the control of chemical substances and pharmaceutical products (Peru)

The private sector concerned with the production and sales of chemical substances and/or pharmaceutical products can play an important role in preventing their diversion to illicit channels. The regulatory agencies, customs, police and others concerned with the control of these substances in certain countries have successfully established close working relationships with companies in these sectors to assist in their control efforts.

This issue and how best to engage the private sector was the subject of discussion in both Groups of Experts during their meetings in 2009. A working group chaired by Peru was tasked with preparing a guide on how best to engage the private sector in the control of these substances.

The delegation of Peru delivered a presentation outlining the major elements of a practical approach to engage the private sector in the control of chemical substances.

The Group accepted the presentation and suggested that it be posted to the CICAD web page.
C. Working Groups

Working groups were established to further elaborate draft documents related to challenges and issues raised during the roundtable introduction of participants. These issues served as the basis for discussions during this meeting or will be included in the plan of action for future proposed meetings. Working groups considered the following issues:

Review of CICAD’s model chemical control regulation (Costa Rica)

During the Group of Experts’ meeting in 2009 the experts discussed the need to review and update the CICAD’s model chemical control regulations. The Commission directed that the Group undertake this review during it’s meeting in 2010.

Costa Rica chaired the working group tasked with the proposed review. The Working Group began a paragraph by paragraph review of the model regulations dealing with the first 33 articles. The Group proposes to continue its review, amending existing articles and definitions and adding news ones as required. If feasible the Working Group proposes to meet prior to the next Group of Experts meeting in order to finalize their review and be able to table an updated draft set of model regulations for review and approval by the Group. The chair of the Working Group and the Executive Secretariat will consult on this proposal and discuss the possibility of an additional meeting with potential hosts countries.

Training of Judges and Prosecutors (Chile)

While law enforcement, customs, regulators and others concerned with the control of chemicals are realizing success in their investigations and other administrative enforcement activities it would seem that sometimes the prosecution of offenders does not always result in a conviction or the sentence handed down is light when considering the gravity of the offences. Frequently this has in part been attributed to a failure on the part of the judges and prosecutors involved to understand elements of what are often complex/technical cases. For example, some officers of the court fail to understand the significance of seizures involving routinely used cold medications like ephedrine and pseudoephedrine.

A Working Group was tasked with preparing a guide and model training curriculum for judges and prosecutors. The resultant product will serve to increase the knowledge and awareness of judges and prosecutors regarding the diversion and use of chemicals in the illicit production of synthetic drugs. The guide will provide users with an overview of illicit drugs production and the use of
legitimate chemical substances in this process. The model curriculum will provide member states with a program that could be used in national and regional training seminars for prosecutors and judges with the optional participation of law enforcement officers.

The Working Group proposes to continue its work and finalize the proposed document when the Group of Experts next meets in 2011.

**Chemicals Used in the Production of Illicit Drugs - Early Warning (Mexico)**

Certain chemicals are essential in the production of illicit drugs. With increased controls on many chemicals narcotraffickers are seeking alternatives, moving to use pre-precursors that are not yet controlled.

A Working Group was formed to develop a mechanism to share information concerning new chemicals being seen in illicit drug production and trends in their movement. The mechanism will note the chemicals and how they are used both for legitimate purposes and as substitutes for controlled chemicals in the production of illicit drugs. The Working Group anticipates using the Drug Information network (CDI) referenced above to share this information. It will continue its work and finalize a methodology the product when the Group of Experts next meets in 2011.

### 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:

Preparation of guides, manuals or other papers associated with the following:

- Review of CICAD’s model chemical control regulations (Costa Rica)
- Training of Judges and Prosecutors (Chile)
- Chemicals used in the Production of Illicit Drugs - Early Warning (Mexico)
- Draft guide for an administrative and criminal framework for the control of materials chemical substances (Chile)
Other issues for discussion at the next meeting:

In addition to the foregoing, the Group identified the following topic as a potential issue for further discussion at the next meeting:

- Criteria for scheduling chemicals

4. CLOSING SESSION

The Group of Experts concluded its work at 11:30 on August 27. Ambassador Patricio Zuquilanda, OAS Representative in Costa Rica and Mr. Carlos Alvarado Valverde, Acting Director of the Costa Rican Drug Institute (ICD), offered closing remarks and thanked the members of the Group of Experts for their participation and contribution in dealing with the control of chemical substances and pharmaceutical products.
III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

RECOMMENDATIONS TO CICAD IN ITS FORTY-SIXTH REGULAR SESSION:

The Group of Experts on Chemical Substances recommends that the Commission:

1. That the Commission:

   • accept the following resource documents:
     - Guide on Reducing the Diversion of Controlled Substance Pharmaceuticals via the Internet
     - Model Fact Sheet on Buying Pharmaceuticals Containing Controlled Substances over the Internet
     - Concept Paper Regarding the Regulation of Equipment Used in the Production of Illegal Drugs
     - Guide to increase private sector involvement in the control of chemical substances and pharmaceutical products

   • direct the Group of Experts to continue its work on the issues initiated for consideration and finalizing at the next meeting

   • direct the Group of Experts continue its work in revising and update CICAD’s Model Regulations on chemical substances, using electronic means to exchange and gather information and, if required, meet on this specific issue prior to the Group's next general meeting

   • accept the proposed plan of action for the Group of Experts

   • direct the Group of Experts to meet during 2011 and implement the plan as proposed, allowing for the consideration of new or emerging issues
GROUP OF EXPERTS ON CHEMICAL SUBSTANCES AND PHARMACEUTICAL PRODUCTS
August, 23 to 27
San Jose, Costa Rica

SCHEDULE OF ACTIVITIES

Monday, August 23

08h30 – 09h00  Registration
09h00 – 09h30  Opening Remarks
09h30 – 09h45  Introduction and Review
  • Background
  • Objectives and CICAD Commission expectations
  • Schedule of work
  • Proposed work methodology
  • Status report on Recommendations
  • Other issues
09h45 – 10h15  Roundtable introductions and identification of issues of concern
10h15 – 10h30  Break
10h30 – 11h15  Presentation on a communications network in the control of chemical substances (United States)
11h15 – 11h45  Draft guide for an administrative and criminal framework for the control of materials chemical substances (Chile)
11h45 – 12h30  Best practices for the development of regulatory controls over equipment used to produce synthetic drugs (Canada)
12h30 – 14h00  Lunch

14h00 – 17h30  Working Groups
-  Guide for joint, interagency investigations
-  Model training curriculum for law enforcement training regarding synthetic drugs including methamphetamine
-  Field testing of suspected ephedrine and pseudoephedrine
-  to be determined based on “roundtable” discussion

Tuesday, August 24
09h00 – 10h00  Presentation by Costa Rica
               Trafficking of Counterfeit Medications – Health Ministry
10h00 – 10h30  Internet sales of drugs (Canada and US)
10h30 – 10h45  Break
10h45 – 13h00  Working groups (cont.)
13h00 – 14h30  Lunch
14h30 – 17h00  Working groups (cont)

Wednesday, August 25
09h00 – 09h30  Presentation by Costa Rica
               Suspicious Container Program – Costa Rica’s Drug Institute (ICD)
09h30 – 10h00  Guide to increase private sector involvement in the control of chemical substances and pharmaceutical products (Peru)
10h00 – 10h15  Break
10h15 – 13h00  Presentations by Working Groups
13h00 – 14h30  Lunch
14h30 – 17h00  Special Activities: to be determined
Thursday, August 26

09h00 – 13h00 Working groups (new tasks)
13h00 – 14h30 Lunch
14h30 – 17h00 Working group discussions (con’t)

Friday, August 27

09h00 – 11h00 Presentations by working groups
11h00 – 11h15 Break
11h15 – 12h00 Conclusions, commitments and recommendations for action by the Working Group
12h100 Closing
GUIDE ON REDUCING THE DIVERSION OF CONTROLLED SUBSTANCE PHARMACEUTICALS VIA THE INTERNET
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 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\(^1\) such as methamphetamine and ecstasy, given that such activity is well-established as illegal under the United Nations Drug Control Conventions\(^2\), 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

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\(^1\) Where this refers to drugs not having a legitimate medical or scientific purpose.

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 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.

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.

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.

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3 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.
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.  

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.

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

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4 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.
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).

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.
MODEL FACT SHEET ON BUYING PHARMACEUTICALS CONTAINING CONTROLLED SUBSTANCES OVER THE INTERNET
The Issue

If you buy pharmaceuticals containing controlled substances -- pain relievers like OxyContin® and Percocet®, depressants like Valium® and Xaanax®, and stimulants like Ritalin® and Adderall® -- via the Internet, you may be putting your health and even your life at serious risk. This is especially true if you order these types of drugs without obtaining a valid prescription from a licensed health care professional.

The Status of Internet Pharmacy in [name of country]

[Description of legitimate internet pharmacies operating within the country and how they are regulated by the competent authority]

Risks Associated with Buying Controlled Substances Online

While some internet pharmacy sites may be licensed by [name of competent authority], many have been created to look like legitimate pharmacies and offer pharmaceuticals containing controlled substances by advertising that no prescription is needed. Some sell drugs that have not been approved for sale in [name of 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 hundreds of prescriptions a day without ever seeing a patient. What they do not tell you is that it is dangerous to take pharmaceuticals containing controlled substances without being examined in person and monitored by a health care practitioner. These measures are important in order to make sure that you get the drugs that are right for you and to reduce the risk of abuse and/or dependence.

Buying pharmaceuticals containing controlled substances from internet pharmacies that do not provide a street address and telephone number means that you have no way of knowing where these companies are located, where they get the drugs they are selling you, what is in the drugs they are selling, or how to reach them if there is a problem.

If you order from these websites, you may get 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 risks.
Counterfeit pharmaceuticals products may have labels with spelling mistakes, labels with no [type of drug registration number used by the competent authority] or look different, e.g., different markings on tablets, different pill colours, or even have a different taste or flavour than the legitimate product that you are trying to purchase.

If you order pharmaceuticals containing controlled substances without being examined and monitored by a health care practitioner, you may be misdiagnosed, and miss the opportunity to get the most appropriate treatment. You may also put yourself at risk for drug interactions, or other harmful side effects that a qualified health professional could better foresee. Buying pharmaceuticals containing controlled substances on the Internet may also pose financial risks. In some cases, you may never receive the product you pay for, or if it is coming from another country, it could be stopped at the border by the [name of customs authority]. You might also have your personal and/or credit card information stolen.

Minimizing Your Risk

If you do decide to purchase your medication via the Internet, do not do business with a site that:

$ refuses to give a street address, telephone number and a way of contacting a pharmacist; offers prescription drugs without requiring a prescription from a licensed health care practitioner;

$ offers to issue a prescription drug based on answers to an online questionnaire;

$ sells products that have not been approved for sale in [name of country]; or

$ sells products that are listed as coming from other countries.

Be aware of the name of the drugs you are taking and be familiar with their usual colour, size, shape and any imprints or markings on the drug. If you suspect that you have received counterfeit drugs you should contact [name of competent authority for health product regulation].

If you have questions or complaints about prescription drug products containing controlled substances that you have purchased via the Internet, please call [name of competent authority for health products or controlled substances].

More Information

To learn more about the process for drug approval in [name of country], visit:
[applicable website].

To learn more about how controlled substances are regulated in [name of country], visit [applicable website].
Concept Paper Regarding the Regulation of Equipment Used
in the Illegal Production of Synthetic Drugs
1.0 Introduction

Article 13 of the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988 states "The Parties shall take such measures as they deem appropriate to prevent trade in and the diversion of materials and equipment for illicit production or manufacture of narcotic drugs and psychotropic substances and shall co-operate to this end".

Several different types of equipment are commonly used in the production of illicit synthetic drugs, as indicated by the materials that are seized by law enforcement agencies (LEA) in the process of dismantling clandestine drug laboratories. Examples of such equipment include mixers, pill/tablet presses and encapsulators among others.

While a limited number of countries, e.g. the United States, Australia, etc. have implemented a regulatory scheme for equipment, the vast majority of signatories of the 1988 Convention have not implemented any such form of controls.

It is in this regard that discussions on preliminary concepts relevant to a regulatory scheme for equipment used in the production of illegal synthetic drugs took place at the August 2009 meeting of the Expert Group on Chemical Substances. This paper is the product of those discussions as well as further discussions at the August 2010 meeting of the Expert Group on Pharmaceutical Products and Chemical Substances.

2.0 Purpose

The purpose of this document is to outline the overarching principles and key elements for the regulation of the aforementioned equipment, with a view to guiding Member States interested in establishing such controls.

3.0 Overarching Principles

A regulatory scheme governing activities with equipment used in the illegal production of synthetic drugs should:
serve to reduce any unnecessary domestic and/or international movement of regulated equipment;
be supported by appropriate national resources, e.g., for administration, compliance monitoring and enforcement;
be supported by appropriate civil, administrative and/or other punishable offences and means with which contraventions of the regulations are dealt;
able to share appropriate information amongst the different domestic agencies involved in control;
able and encourage cooperation and collaboration between the private sector and between Member States; and
not hinder domestic production and/or distribution for legitimate purposes by imposing a burden on the legitimate industry requiring the use of regulated equipment

The process of developing a regulatory scheme for equipment used in the illegal production of synthetic drugs should be transparent and involve sufficient consultation with national authorities and the private sector. National authorities should clearly delineate the means by which they will work horizontally within their jurisdictions.

4.0 Key Elements of Equipment Regulation

A regulatory scheme should establish baseline controls in order to curb the illicit movement of implicated equipment. As such, the scheme should include the key elements outlined below:
- the scope of regulated equipment;
- which activities will be restricted under the scheme;
- which parties will be regulated;
- definitions for terms used within the regulatory scheme;
- an effective compliance monitoring and enforcement scheme; and
- appropriate record-keeping and reporting requirements.

4.1 Scope of Regulated Equipment

Initially, the scheme should cover a limited range of equipment, e.g., tabletting machines, encapsulating machines, pharmaceutical mixers, etc., as defined in a Schedule to the regulations.

4.2 Restricted Activities

Controlled activities should include possession, sale, import, export, transport, production, distribution and/or other types of transactions involving regulated equipment.

4.3 Parties Subject to the Regulation
Regulated parties should include individuals, non-profit entities, and both domestic and international businesses/corporations that conduct restricted activities.

4.4 Definitions

The scheme should clearly define all terms utilized within them that are important for its consistent and correct administration. This may include the types of regulated equipment and activities, parties referenced in the regulations such as international bodies, controls applied such as requirements for licences and permits, etc.

4.5 Licensing and Permit Scheme

The scheme should involve a licensing scheme in which regulated parties must obtain pre-authorization from the appropriate competent authority in order to carry out restricted activities involving regulated

A licence should be valid for a specific period of time. In addition, pre-authorization in the form of a permit should be required for individual transactions related to import, export, transit and/or transshipment. The requirement to surrender permits to border authorities at the time of import/export should also be explored.

Finally, the scheme should also require permit holders to notify competent authorities of plans for export, transit, or transshipment, and if possible, the use of a common system, e.g., the INCB PEN-Online system, should be explored.

4.6 Security

Authorized parties should be required to ensure that reasonable security measures aimed at preventing the diversion of regulated equipment, are used at each site where restricted activities take place, and during transport/delivery.

4.7 Destruction of and/or Removal of Regulated Equipment from a Licensed Site

The scheme should require the appropriate disposition of all unuseable/seized/abandoned equipment (which may include the return of goods to the country of origin where appropriate) and identification of this to competent authorities within a specific time period.

4.8 Compliance Monitoring and Enforcement
The scheme should clearly set out who is responsible for administrative enforcement, where this includes compliance promotion and monitoring, and the authority to amend, refuse, suspend and/or revoke licences and/or permits as required.

The scheme should also include provisions for the investigation and/or inspection of regulated parties by appropriate competent authorities. The scheme should also include the authority to securely share information (preferably electronically) among law enforcement agencies and between law enforcement and the appropriate competent authority in order to facilitate the investigation/inspection of multinational regulated parties and track trends in the movement of equipment. Finally, the scheme should set out the penalties (administrative or criminal) applicable in the instance of non-compliance.

### 4.9 Record-Keeping and Reporting

Regulated parties should be required to keep accurate and reliable records, e.g., in relation to licensed sites and activities, security measures taken by the licensee, suspicious transactions, theft, etc., for an agreed-upon period of time. The scheme should enable the request and provision of such records to competent authorities.
GUIDE FOR BETTER COORDINATION BETWEEN THE PUBLIC AND PRIVATE SECTORS FOR CONTROL OF CHEMICAL SUBSTANCES
GUIDE FOR BETTER COORDINATION BETWEEN THE PUBLIC AND PRIVATE SECTORS FOR CONTROL OF CHEMICAL SUBSTANCES

THE BUSINESS SECTOR’S CHALLENGE

The business sector’s social responsibility used to be limited to the creation of wealth, jobs, and fiscal revenue, but today it is much broader—extending to areas of social concern such as the environment, the fight against drugs, civic participation, etc.

It is a new area of challenges for the business sector, and for public sector officials, especially those involved with control, who must provide mechanisms for cooperation and collaboration with the business sector.

CODE OF CONDUCT FOR RESPONSIBLE COMPLIANCE WITH REGULATIONS FOR CONTROL OF CHEMICAL INPUTS AND CONTROLLED PRODUCTS

OBJECTIVE OF THE VOLUNTARY CODE FOR RESPONSIBLE CONDUCT

As part of the business sector’s voluntary commitment that is encouraged by its associations and in coordination with the Administrative Control Authority, the Code is intended to support authorities responsible for monitoring controlled chemical substances in the fight against diversion, through close communication and the expansion of mutual cooperation.

PURPOSES OF THE CODE

• To make corporate employees aware of the problem of controlled chemical substances.

• To promote the responsible use of controlled chemical substances, especially in the stages of production, storage, sale, and transportation.

• To improve coordination and exchange of information between the companies and the authorities.

AREA OF APPLICATION

The voluntary code has been designed so that companies that use controlled chemical substances in a scheme of social responsibility can implement it in the organizational culture under the main idea of “KNOW YOUR CLIENT.”
CORPORATE PROCEDURES

A. Designation of a "contact person"

• A “contact person” will be chosen and the business association will be informed.

• Preferably, he or she will be from the management, sales, logistics, security, legal, or administrative areas.

The “contact person” plays a key role in the success of the voluntary system for responsible conduct.

Role of the “contact person”

• The “contact person” promotes close cooperation between the company and the Ministry of Production.

• The “contact person” stimulates:

  - Corporate actions to teach staff about special care in the use of controlled chemical substances (CCS).

  - The exercise of special care by personnel responsible for maintaining the special registers.

  - Identification and reporting of any suspicious or unusual action involving CCS.

The “contact person” plays a key role in the success of the voluntary system for responsible conduct.

B. Information and awareness-building

Information:

• The “contact person” will give information to the personnel about the civil and criminal penalties they will face if they assist drug traffickers through negligence or imprudence.
Awareness-building:
- Awareness-building of the personnel targets those likely to be involved with CCS and whose work involves their storage, handling, sale, transportation, and use.

- Awareness-building is supplemented with the introduction of internal procedures that support proper surveillance and monitoring.

C. Follow-up of operations
- When the “contact person,” acting as discreetly as possible and based on his or her experience, identifies any suspicious circumstance, he or she immediately notifies the administrative authority or the authority’s representative without tipping off the questionable buyer.

- The “contact person” will do his or her best to get the questionable buyer’s fax and telephone number, e-mail, etc. This information will enable the administrative authority or the authority’s representative to transmit the information to the police.

- The “contact person” will provide notification of:
  - Any suspicious purchase order
  - Suspicious deliveries and any other unusual circumstances
  - Any other fact of which they become aware that could be relevant for investigation of the suspicion (unjustified breaking of the cargo, abnormal routing, destruction, taking of samples, missing items, etc.)

The “contact person” will transmit communications regarding the suspicious action.

D. Dissemination of the Code
The company’s “contact person” will promote dissemination of this Voluntary Code of Responsible Conduct, organizing meetings with the personnel for that purpose in coordination with management, in order to transmit information on the Code, receiving assistance for that purpose from the administrative authority or the authority’s representative.
CHARACTERISTIC ELEMENTS THAT AROUSE SUSPICIONS

- Identification of the client and the client’s behavior
  - New client (unknown in the sector, insufficient technical knowledge of chemical substances.
  - Client who appears without contact or prior recommendation.
  - Client lacking business sense, for example one that shows no interest in negotiating the price.
  - Reluctance (or refusal) to provide a telephone number or address or to submit a written order.
  - Orders from previously unknown corporations or ones that are hard to find in the directories.
  - Orders from a company that cannot provide normal commercial references.

- Business practices
  - Unregistered address for delivery of products or from which the order was placed.
  - Orders from companies not found in the Register.
  - Orders received at irregular intervals.
  - Unusual request for payment in cash or money order.
  - Proposal that includes payment of an excessive price for a specific type of product or for rapid delivery.
  - Orders from universities or well-known corporations that are issued following established procedures but for delivery to be made to a person whose name or address is not registered.
  - Delivery order to a third party who is not registered, at variance with internal procedures.

- Delivery methods
  - Pick up of chemical substances with the aid of an unknown private vehicle.
  - Request to package the substances in small individual lots even though the delivery is ostensibly for industrial use.
β Request for delivery in non-commercial or unlabeled packages.
β Unjustified requests for air delivery.
β Complicated delivery itinerary (e.g., involving apparent deviation from regular routes) or unjustified transfers (seeking to justify breakage or losses).
β Requests for which the delivery or shipping charges exceed the cost of the substances.

γ Use of the products

β Requests for CCS in amounts that are excessive or abnormal for the stated use.
β Unplanned internal use.
β Losses of CCS outside the production process through spills, filtrations, leaks, accidents, or other losses.
β Shipping of CCS outside the established hours

ACTION TO BE TAKEN REGARDING A SUSPICIOUS ORDER

What should be done in the case of suspicious orders for CCS?
1. Ask the client to provide the tax ID number and contact information (telephone number, fax, e-mail).
2. Ask for an explanation of the final use.
3. After the conversation:
   β Verify the accuracy of the information after checking the registers.
   β Review the documents provided by the company.
4. Inform the administrative authority or designated representative.

This information must be placed near the telephones and computers in the company’s sales office.