

17th St. & Constitution Avenue N.W. Washington, D.C. 20006 United States of America INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION

CICAD

Organization of American States

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FINAL REPORT GROUP OF EXPERTS ON CHEMICAL SUBSTANCES AND PHARMACEUTICAL PRODUCTS (DRAFT)



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GROUP OF EXPERTS ON CHEMICAL SUBSTANCES AND PHARMACEUTICAL PRODUCTS August 18 to 22, 2014 Lima, Peru OEA/Ser.L/XIV.4.7 CICAD/SRGE/doc. 2/14 25 August 2014 Original: English

FINAL REPORT

GROUP OF EXPERTS ON CHEMICAL SUBSTANCES AND PHARMACEUTICAL PRODUCTS Draft

Executive Summary

The meeting of the Group of Experts took place at the Estelar Hotel in Lima, Peru from August 18 to 22, 2014. Rosa María Vásquez Hidalgo, National Head Officer, Chemical substances and controlled goods, SUNAT, and Marcia Gisele Bellido Luglio, Operational Manager, Registry of Controlled Goods, SUNAT, chaired the meeting. A total of 41 experts representing 12 member states (Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Panama, Paraguay, Peru, Trinidad and Tobago, United States, and Uruguay) and the United Nations Office on Drugs and Crime (UNODC/PRELAC and SMART Program) participated in this meeting.

The Group of Experts followed the plan of action the CICAD Commission approved during its fifty-fourth regular session in Bogota, Colombia (December 11-13, 2013).

The Group of Experts submits the following recommendations for the Commission's consideration:

- accept and approve the following guides and other documents;
 - Model Administrative Control System for the Control of Chemical Substances <u>http://www.cicad.oas.org/apps/Document.aspx?Id=2802</u>
 - Disposal of Pharmaceutical Drugs: Fentanyl Transdermal Patches <u>http://www.cicad.oas.org/apps/Document.aspx?ld=2784</u>
 - Suggestions for Establishing Designated Ports of Entry for Chemical Substances and Pharmaceutical Products http://www.cicad.oas.org/apps/Document.aspx?Id=2813
- **direct** the Group of Experts to continue its work on the issues initiated for consideration and finalizing at the next meeting;
- **direct** the creation of a technical sub group to develop model legislation and/or guidelines with appropriate alternatives for NPS control.
- **direct** the creation of a technical sub group to develop recommendations concerning the control of chemical substances and pharmaceutical products as well as NPS for consideration in the review of the plan of action to the Hemispheric Drug Strategy
- accept the proposed plan of action for the Group of Experts;
- **direct** the Group of Experts to meet during 2015 and implement the plan as proposed, allowing for the consideration of new or emerging issues

I. BACKGROUND

The fifty-fourth regular session of the Inter-American Drug Abuse Control Commission (CICAD) took place from December 11 to 13, 2013 in Bogota, Colombia. The Commission considered and approved the report of the Group of Experts on Chemical Substances and Pharmaceutical Products presented by the Peruvian Chair from the meeting that took place in Lima, Peru (August 5-9, 2013). The Commission approved the products presented, the plan of action and the draft plan of action presented by the Group. In doing so the Commission also directed the group to meet in 2014, accepting the nomination and re-election of Peru as host and chair of that meeting.

II. PROCEEDINGS

A. PARTICIPANTS

Twelve member states (Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Panama, Paraguay, Peru, Trinidad and Tobago, United States, and Uruguay) and the United Nations Office on Drugs and Crime (UNODC/PRELAC and SMART Program) and 41 experts participated in this meeting in Lima.

B. SESSIONS AND ORGANIZATION OF THE MEETING

1. **Opening Session**

The Group of Experts met at the Hotel Estelar in Miraflores, Lima, Peru on August 18, 2014. Ms. Rosa María Vásquez Hidalgo, National Head Officer, Chemical substances and controlled goods, SUNAT, Minister José Antonio García Torres, Director of Global Commitment, DEVIDA and Mr. Pablo Zúñiga, OAS Representative, OAS National Office in Peru offered welcoming remarks to the participants and invited guests. Rosa Maria Vasquez Hidalgo and Gisele Bellido Luglio of the National Customs Service (SUNAT) chaired the meeting of the Group of Experts.

In addition to the plenary session, participants were provided with the time and place to conduct bilateral meetings. These meetings provided an opportunity to address issues of mutual or shared concern regarding the control of chemical substances or pharmaceutical products.

2. Working Sessions

2.1. Presentations

The following presentations were delivered to the plenary during the meeting:

Model Policy and Procedures on Clandestine Drug Laboratories

The clandestine laboratories used to produce synthetic drugs (including New Psychoactive Substances - NPS) are very different from those used to produce cocaine or heroin. Many of the chemicals used in these laboratories are toxic and otherwise quite dangerous to anyone who is exposed to these substances. This includes not only the "cooks' working in these labs but also for the first responders (emergency personnel, fire fighters etc.), police investigating such lab and those tasked with dismantling

clandestine laboratories. Because of these inherent dangers it is critical that entities dealing with such clandestine laboratories need to have appropriate policies and procedures in place to protect their officials.

The Executive Secretariat presented the *Model Policy and Procedures on Clandestine Drug Laboratories*. This document was developed by the Executive Secretariat with the cooperation and assistance of the Royal Canadian Mounted Police (RCMP). The Executive Secretariat recognized and thanked the RCMP for this support.

The document provides important information on the steps that countries should take into consideration in defining how officers proceed in dealing with clandestine laboratory and the steps they need to take after they are exposed to such facilities.

Copies of the policy and procedures document were distributed to all delegations. Electronic versions were also made available to all participants during the meeting. Given the nature of this document it will not be posted on the CICAD web page. Member states not represented at the meeting of the Group of Experts may request electronic copies from the Executive Secretariat.

Presentation on the strategy of controlling chemicals in Peru by SUNAT

Mr. Paul Vera Regalado, Manager of the chemical control section of the National Customs Service (SUNAT) delivered a presentation on the strategy implemented by SUNAT to control chemicals. SUNAT controls 28 chemicals and 7 fuels within this strategy. As part of this strategy SUNAT has been reaching out to neighboring countries to establish mechanisms for the exchange of information. In regards to the chemicals used to produce cocaine, Peru produces Sulfuric Acid and Hydrochloric Acid. As such Peru is an exporter of these chemicals underlining the need for cooperation and communication with neighboring countries.

The strategy includes 4 defined targets:

- reducing importation of chemical precursors that can be used in illegal activities
- increasing the price of chemical precursors used in the production of cocaine hydrochloride in cocaine production areas
- reducing demand for fuel in areas of illegal drug production
- reducing the registry of users of chemicals not complying with regulatory control standards

The presentation included a review of specific actions and steps taken in the execution of their strategy during 2014. Among the main topics, the following were addressed:

- Importing of main chemical precursors and their statistical evolution
- Control actions being taken to transport chemical precursors
- The seizures: result of non-compliance with the requirements established
- Control actions related to fuel monitoring and control

• Actions related to the compliance with formal standards of production and trade of chemical precursors

All these actions together with the legal framework in place, as well as the achieved results, are a product of SUNAT's efforts.

Global Synthetic Drugs Assessment 2014: Amphetamine-type stimulants (ATS) and new psychoactive substances (NPS)

Mr. Juan Carlos Araneda is the SMART Project Coordinator from UNODC working in CICAD. Mr. Araneda briefed participants on the recently published report on amphetamine-type stimulants (ATS) based on the most recent Global report in these substances. The second part of the presentation focused on the report's findings on new psychoactive substances (NPS) in Latin America.

According to the global report, there has been a significant increase world-wide related to ATS. Methamphetamine trafficking has expanded over the 2008-12 period. West Africa has played an important role in this expansion.

ATS trafficking to and through Latin America and the Caribbean relate mainly to methamphetamine. Seizures in Eastern Asia were determined to come from Peru and Brazil. Methamphetamine trafficking from Mexico has been moving primarily to the United States. This movement to the US has increased between 2008 and 2012. Methamphetamine has primarily been moved by land and air through Southern California.

Ecstasy use in Latin America and Caribbean is primarily among youth. Use of stimulants among school age has increased in the Caribbean, Honduras and Costa Rica.

Mr. Araneda shared information on the increasing incidence of ATS seizures and discovery of clandestine laboratories producing these drugs in specific countries in South and Central America.

Regarding NPS, there has been an expansion of these substances around the world. Many of these substances have appeared in the past and now are reappearing in many countries. During the period up to 2013, 348 different NPS have been identified. NPS are particularly prevalent in Europe but are also appearing elsewhere in the world including in OAS/CICAD member states.

An important characteristic of NPS is that they are sold in the same areas as drugs like methamphetamine and LSD. They are frequently presented as ecstasy. There has been a case where NPS were sold as LSD. Under these circumstances studies reporting prevalence of use of specific drugs may be misleading.

Ketamine use is particularly high in East Asia. Use in Latin America has been noted.

New NPS are appearing weekly in Europe, frequently originating in West Africa. These are further moved to North America and elsewhere.

At present, 234 NPS have been regulated. Countries have applied different regulatory and administrative approaches to deal with NPS. There is insufficient information to determine which approaches have been successful.

Until December 2013, 9 countries in Latin America have reported the appearance of NPS

The challenges for Latin America regarding the appearance of NPS include the lack of information as to what users are actually taking. The effects of these drugs on the body remain to be fully understood. Health facilities may not be aware of the range of NPS on the market, their pharmacology and toxicology or the best way to help in emergency situations. Laboratories remain ill prepared with appropriate procedures to analysis and identify these substances.

The Commission on Narcotic Drugs (CND) has passed a number of resolutions regarding NPS.

UNODC has prepared guidelines for NPS identification and has developed a portable device to analyze such drugs. These units can be as expense as US\$40,000.

The global expansion of the ATS market and the dynamic nature of the NPS situation increases the need for global monitoring and knowledge-sharing from the experiences by member states.. UNODC has developed an early warning system that will provide current information on the appearance of NPS. Additional information regarding ATS and NPS is available on the following web pages:

www.unodc.org www.apaic.org www.cicad.oas.org

Multilateral Evaluation Mechanism (MEM), Preliminary results of the recommendations to member states on the control of pharmaceutical products and chemical substances

Mr. Adrian Noble of the MEM Unit of CICAD delivered a presentation on the recommendations to member states dealing with the thematic area of pharmaceutical and chemical control and illicit trafficking coming from the most recent round of the Multilateral Evaluation Mechanism (MEM) process.

In his presentation, Mr. Noble provided some background on CICAD's Executive Secretariat and the MEM process. In doing so he noted the changes that have been made to the MEM process and the linking of indicators to the plan of action of the Hemispheric Drug Strategy (2010).

There are five areas in the MEM that relate to the corresponding areas of interest in the Hemispheric Strategy. In addition there are 27 recommendations covering these areas. The recommendations (17, 18 and 19) concerned with the control of chemicals and pharmaceuticals and fall within the Control Measures Section of the MEM process. These recommendations define those actions that member states should take regarding the control of these substances.

These recommendations read as follows:

Recommendation 17 - Adopt or strengthen control measures in order to prevent the diversion of controlled chemical substances towards illicit activities.

Recommendation 18 - Adopt or strengthen control measures to prevent the diversion of narcotics, psychotropic substances, pharmaceutical products with psychoactive properties and those used in the production of synthetic drugs

Recommendation 19 - Ensure the adequate availability of narcotics needed for medical and scientific use Mr. Noble shared preliminary results related to the various recommendations 17, 18 and 19 further to the sixth round of the MEM process. Once finalized the results of the sixth round will be presented to the CICAD Commission meeting this fall.

Preparedness of Five Countries in the Region on the Precursors of Synthetic Drugs

Mr. Hernan Bernal delivered a presentation on the results of a study undertaken by UNODC-PRELAC. The study focused on the degree to which the selected countries are prepared to control the precursors for synthetic drugs. The studied examined the technical and logistical capacity of forensic laboratories in Argentina, Panama, Chile, Guatemala and Colombia to deal with synthetic drugs. A total of 60 laboratories were included in the study.

The capacity of these facilities is critical to the effective control and judicial consideration of cases related to synthetic drugs and their production.

Mr. Hernan reviewed the methodology of the study and the specific objectives of each element as well as the facilities in each country that were examined.

The general conclusions of the study indicated the following:

Regulations

- Updating of the regulations is slow and complex.
- The lists for control of chemical substances are not efficient.
- The legal system does not understand the problem of synthetic drugs and generally seems not to care about it.
- There is no systematic training for legal system personnel.
- Judges and prosecutors focus on plant-based drugs.
- Retail drug trafficking is not prosecuted because the justice system does not care about a few pills or paper stamps.
- There is little communication between the forensic team and the justice system.

Capacity for operations and interdiction

- It is necessary to train specialized teams: intelligence, investigation, interdiction.
- There is no data on procedures for dismantling and final disposal of precursors.
- The data must be handled differently than that for plant-based drugs. Micro-trafficking does not arouse great interest because of the statistical indicators.
- Lack of knowledge by enforcement authorities is widespread.

Customs control

• Customs officials generally consider that this is a police problem.

• There is a need for technical training; acquisition of the latest technology for identification of precursors and drugs; upgrading areas for inspection of merchandise (precursors) and upgrading temporary storage facilities.

Administrative control

• Division of control of chemical substances and precursors among various entities seriously hampers controls: little coordination, different mission and objectives, different levels of interagency coordination, lists of chemical substances with different levels of control.

Forensic and criminal evidence capacity

- The interest of forensic and crime investigators in the subject is evident, but institutional support is minimal.
- Generally there is the necessary technology to conduct the instrumental analysis of synthetic drugs and precursors.
- There are not sufficient chemical standards, and methodologies for instrumental analysis have not been validated.
- It is necessary that the laboratories work on the accreditation process of ISO-17025 and The Scientific Working Group for the Analysis of Seized Drugs (SWGDRUGS)
- Human resources are insufficient, not trained, and poorly paid.
- They do not carry out standardized preliminary drug identification (PIPH), or sampling techniques.
- Laboratories receive the least resources of any agencies dealing with the drug problem.

The problem of cocaine production and trafficking has been the priority and focus of attention of many of the countries in the hemisphere for a very long time. Systems and capacities have been defined in a way to deal with this particular problem. As such the interest in and capacity of countries to deal with synthetic drugs is understandably low. While cocaine production will likely continue, the production, trafficking and use of synthetic drugs and NPS represent the future of drugs. This is a global problem that has been growing and making its way around the world therefore countries need to begin to prepare to deal effectively with these substances. This will require increased awareness, legislation, training and capacity, the necessary resources and political will.

Preliminary Results of a Study on Criminal Sentencing: Diversion of Chemical Substances for Use in the Illicit Production of Drugs

Mr. Michel Diban of PRELAC provided an overview of the study that was undertaken regarding sentencing related to chemical diversion. The study was started in 2010 within the framework of the PRELAC project. The objective of the study was to learn the real magnitude of the application of the laws and penalties in place and available.

The study included an examination of data from various sources and consultations with entities in the PRELAC countries. The information available was fractured in that it was difficult to track cases from start to final sentencing or resolution. Other problems encountered included the following: the lack of

follow-up and record-keeping of cases, and the fact that many cases end in lower courts because they are not subject to appeal, cassation, or nullification.

The results of the 180 sentences that could be examined were broken down as follows:

Argentina (7) Bolivia (2) Brasil (2) Colombia (7) Chile (31 desde 2005) Costa Rica (2) Ecuador (1) El Salvador(2) México (1) Panamá (1) Paraguay (1) Perú (11)

There were a number of countries that reported no sentences related to chemical diversion.

It is interesting to note that information from the Multilateral Evaluation Mechanism (MEM) indicates a significant number of criminal sentences reported by member states. The study was not able to verify this information as is noted from the above noted results presented. It would be interesting if the MEM process could include a follow-up with the reporting member states to secure additional information regarding the cases reported.

Lessons learned from this study included the following:

Ratifying, the crime of diversion:

- It is not a priority for authorities in several countries of the PRELAC project
- Lack of relevance in the criminal prosecution policies
- The function has not been sufficiently executed:
 - Lack of trained personnel
 - Constant turnover of officials with experience in the investigation area.

Most of the investigations of inspection and control end up with administrative proceedings and penalties (fine or seizure):

- Few criminal trials start with information from the control authorities
- Lack of in-depth analysis of operations to determine whether the irregular conduct is a crime
- Limited cooperation between control authorities and the police and prosecutor's offices.

Many criminal sentences are for low fines or jail terms:

- Less than one year, some not more than two years
- Serving sentence at home
- Option of recognizing extenuating circumstances, or the trials are simplified or abbreviated, with substantial reduction of penalties
- Low cost to the offender

Few sentences punish the autonomous offense:

- The investigation does not extend to facts that constitute other crimes such as:
 - Conspiracy
 - o Elaboration
 - Illegal drug trafficking
 - Money laundering

Failure to apply new legislation on forfeiture of assets obtained illicitly.

Most criminal trials and verdicts are for individuals and not corporations:

- Little cooperation with private corporations
- Lack of information on unusual and suspicious operations

The results of the study include the following:

- Criminal prosecution policies must include broad investigation
 - Other crimes, other participants (including as a crime criminal participation in the eventual offense, culpable or negligent conduct)
 - Do seek only the administrative penalty
- Cooperation between control agencies and the police and prosecutor's office
- Joint training for officials of control agencies, police, and the prosecutor's office
 - Assistance of experts for testimony required by the courts.
 - The training should include:
 - Characteristics of the substances
 - Special investigation techniques
 - Evidence gathering
- Records and follow-up of criminal cases from the start to the final judgment
 - Evaluate the results
 - Identify weaknesses that affect the verdicts
- Confidentiality and protection in the delivery of information

The study included two recommendations for amendments to CICAD's model regulations.

• Include a broad definition of the substances; do not limit the lists of regulations.

• Criminalize criminal negligence.

International Narcotics Control Board Update

It had been hoped that officials from the International Narcotics Control Board (INCB) could attend the meeting. Unfortunately this was not possible as the INCB Board was to meet the following week.

Under the circumstances the Executive Secretariat presented an update of information on behalf of the INCB covering the following issues:

Non-scheduled substances survey

In March 2014 the INCB distributed a questionnaire requesting the production of NPS. The objective of the survey was to gather information about chemicals that have been encountered for use as pre-precursors or alternatives to scheduled substances. Unfortunately no CICAD member states responded to this questionnaire. The INCB asked for the cooperation of member states to submit the requested information. Officials of INCB are available to respond to any questions regarding this initiative.

Guidelines for a voluntary code of practice for the chemical industry

 Some years ago the INCB developed a document on the voluntary code of conduct for the chemical industry. This document has been revised. It is currently available on the INCB secure web page. Member states who have not registered and have access to this secure web page were encouraged to contact INCB to obtain a user name and password.

Limited International Special Surveillance List (LSSL)

• The Limited International Special Surveillance List (LSSL) has also been updated. This list is also available on the INCB secure web page.

PEN Online V2

Many member states have registered to use the Pre-export Notification (PEN) on-line system. This system facilitates the exchange of information regarding the movement of chemical substances. A revised version of the PEN system is being developed. It will provide an improved mechanism for replies to PENs and follow-up communication. In addition it will provide full user authority over the management of the company data. Part of this updating process includes the need for member states to "clean up" the data on companies. Officials at INCB are available to respond to any questions that member states might have regarding this process. The deadline for this process is September 15, 2014 using the following link:

https://pen-companycleanup.incb.org

PICS V3

• PICs is a platform for the real time exchange of information concerning seizures of chemical substances or the interruption of suspicious shipments of these substances. This system is currently being revised. It will include a multilingual interface (French and Spanish). Member states are encouraged to register and use PICs.

Other Issues

- The INCB wished to remind CICAD member states of the importance of invoking article 12 paragraph 10 b) of the 1988 Convention. In doing so pre-export notifications would be required for chemicals going to that country. PENs have been found to be an effective way to minimize the diversion of chemical substances. Unfortunately not all member states have invoked article 12 paragraph 10b) so the INCB encourages all to take this action. Officials of the INCB are prepared to help member states to prepare the necessary letter required for this purpose.
- The INCB wished to remind member states of the importance of estimating annual national needs of chemicals. This is one way to help minimize the diversion of chemicals for use in the illicit production of drugs

2.2. Plenary Discussions:

The Group of Experts considered the following issues:

A review of the Group of Experts and how it works

The delegation of the United States proposed that the Group review what it does and how it functions. This included consideration of what the focus of the Group should be and other aspects of its operation.

During the resultant discussions some delegations noted that this is the only technical forum available for the exchange of information and to address issues of common concern regarding chemical substances and pharmaceutical products. The forum provides for the early identification of new threats and challenges regarding the control of these substances and new strategies being used by narcotraffickers.

Some delegations acknowledged that it is difficult to determine to what extent documents generated by the Group were actually being used by member states. Having said that a number of countries reported on their own experiences with documents generated by the Group of Experts. Some noted that certain documents were used as the basis for change in their own country with the implementation of guidelines prepared by the Group. Others noted that documents and discussions undertaken by the Group were used in support of work in other fora. Finally other countries noted that documents and discussions by the Group help to support decisions and actions proposed in their country.

The Group agreed that the meetings were an important and unique forum that should continue to take place at the request and direction of the CICAD Commission. The documents generated by the Group were useful but that the Group should make special efforts to focus its discussion on the most important issues and generate the best quality products of use to member states.

Participants proposed that the issue of how the Group functions and other aspects of its operation should be re-examined in two years.

New Psychoactive Substances (NPS)

The production, trafficking and use of New Psychoactive Substances (NPS) represent elements of a growing global problem. These substances are sometimes referred to as "designer drugs", "legal highs" and "herbal highs". They are not usually regulated but mimic the effects of drugs that are already controlled.

NPS is a global phenomenon. Success in responding effectively to this threat rests in part with a multilateral effort to collect and share information.

During the Group's last meeting a working group was formed under Canada's leadership to prepare an information bulletin concerning the problem of NPS. A preliminary document was finalized with some basic information and is available on the CICAD web page.

http://www.cicad.oas.org/reduccion_oferta/grupoExpertos/PDF/NPS%20Information%20Bulletin%2020 13.pdf

It was agreed that if there was a need to do so a working group would be formed at the Group's 2014 meeting to update the information bulletin. Since Canada was not able to attend the meeting, Mr. Ziggie Malyniwsky of the CICAD Executive Secretariat introduced this issue to the Group. While initially the Group decided that no update of the information bulletin was required, this decision was revisited and a new working group was formed. The revised document will be presented to the Group for review and approval in 2015. Details on their work are noted below under Section 2.4 "Working Groups".

During a subsequent discussion of NPS, delegations noted the challenges faced by many member states in dealing with these substances. In many instances member states lacked the necessary legislative and regulatory framework to deal effectively with NPS particularly given the speed and frequency with which they appear on the illicit market and the time it normally takes to schedule these substances.

Consideration was given to the idea of forming a working group to begin the task of developing model legislation and/or guidelines with potential options to permit fast scheduling of these substances. Participants recognized that the necessary technical expertise was not present at this current meeting. As such the Group recommends to the Commission that it direct a special meeting or series of meetings be convened with the appropriate technical expertise to develop model legislation and/or guidelines with appropriate alternatives that anticipate or respond with quick scheduling of NPS when they appear. The Group recognizes that funding is not currently available to support such an initiative but that efforts should be made to secure such funds.

Model Administrative Control System for the Control of Chemical Substances:

The regulatory and administrative processes and systems implemented by countries are important elements in the control of chemical substances. Frequently gaps in these systems reduce the potential level of control that countries can apply over these substances. Problems of this nature have been noted by member states and have been identified through the work of the PRELAC project.

In 2013, a working group was established to prepare a guide on the elements of a model administrative system for the control of chemical substances. The group prepared a comprehensive outline of the proposed model. A finalized document prepared by PRELAC and Peru's agencies DEVIDA and SUNAT was then made available for the consideration of the Group of Experts.

During the current meeting, Ms. Gisele Bellido of SUNAT presented the final draft, reviewing the major elements of the document. Some delegations proposed amendments to the document. Interested parties met in a working group to revise the document. The revised document was presented to the Group for review and approval. The finalized document approved by the Group is submitted here for the consideration and approval of the Commission.

Disposal of Pharmaceutical Drugs: Used Transdermal Patches

Unused pharmaceutical drugs found in the home present an opportunity for diversion and inappropriate use. Anecdotal information suggests in some instances youth are taken quantities of these drugs from their homes for their personal use or to share with friends. Outdates pharmaceutical drugs also present a threat in the home.

During the meeting in 2013 several delegations raised the problem of diversion involving Fentanyl transdermal patches. It seems that there have been cases where such patches have been retrieved from the trash after having been used. In some instances the inappropriate reuse of these patches has led to problems for the drug user.

A working group chaired by Peru was formed to develop a guide on the safe disposal of drugs in this therapeutic format. During the current meeting, Ms. Katty Clavijo Montes of DIGEMID, Peru presented the finalized draft for the consideration of Group of Experts.

Further to a discussion, the draft was finalized and is submitted here for the consideration and approval of the Commission.

Suggestions for Establishing Designated Ports of Entry for Chemical Substances and Pharmaceutical Products

Some countries have chosen to limit the entry of chemical substances and/or pharmaceutical products into that country through ports designated for this purpose. This allows the country to focus and save limited resources and efforts in the control of these substances to a limited number of centers.

A working group chaired by Brazil was tasked with examining this matter. Further to their discussions the working group developed a series of suggestions that should be considered when exploring the possibility of establishing such designated ports of entry. A final draft was presented and reviewed by the Group of Experts. The finalized draft is presented here for the consideration and approval of the Commission.

2.3 Bilateral/Multilateral Discussions

During the meeting of the Group in Lima in 2013 delegations were given the opportunity to request bilateral or multilateral meetings to discuss issues of mutual concern or to address problems that they shared. The same offer was made to delegations during the current meeting. Several delegations met to discuss issues, seek the benefit of experiences and to address problems that they shared.

In addition to the foregoing, a larger multilateral meeting was arranged to allow interested delegations to discuss NPS. This is a growing issue in which many delegations had an interest. Some delegations are seeing manifestations of this problem. Others in fact have plants that have active ingredients used in the production of certain NPS growing in their country. The multilateral meeting provided the opportunity for interested delegations to share experiences and otherwise discuss these and other aspects of NPS.

2.4. Working Groups

Working groups were established to finalize documents already initiated and 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:

2.4.1 Best Practices Regarding the Control of Domestic Transportation of Chemicals to Prevent Diversion (Argentina/Peru)

The international Conventions provide a framework for the control of chemical substances. While diversion still takes place it has been significantly reduced over the years. Initiatives by the International Narcotics Control Board (INCB) and by CICAD through its Group of Experts as well as by sub-regional Groups and individual countries have help to minimize diversion.

At the same time chemicals continue to be diverted for use in the illicit production of drugs. It has been suggested that one source of this diversion may be through the domestic movement or transport and sale of chemical substances. While some countries have in place comprehensive controls such domestic trade or movement it is not the case in many others.

The Group of Experts therefore proposed the creation of a working group to develop a guide of best practices regarding the domestic movement of chemical substances.

The working group will finalize the document for consideration at the next meeting of the Group of Experts.

2.4.2 Updating the Information Bulletin on NPS including a self-assessment component for member states (USA/Colombia)

The Group of Experts focused a great deal of attention on the issue of NPS. In doing so it was clear that countries are at different stages both in terms of the prevalence of the problem and their ability to respond effectively. To more clearly define the preparedness of member states in this regard the Group of Experts proposed to establish a working group to update the information bulletin with a self-assessment analysis. This could be used as a tool for member states to compile the results into a national "snap shot".

The working group began to consider this task using a questionnaire developed by the G-8 for a similar analysis as a point of departure. In the process members of the working group learned that the UNODC has developed a similar and very comprehensive questionnaire some time ago. Some 17 OAS/CICAD member states had responded to this questionnaire. Rather than duplicate efforts in this regard the working group decided to update the information bulletin on NPS that was prepared in 2012. In addition

to strengthening the existing text and information the working group proposed to add recommendations regarding steps that member states could take to better prepare to deal with the growing problem of NPS.

The working group will finalize the revised information bulletin for consideration when the Group of Experts next meets.

2.4.3 Elements for Consideration in the Potential Review and Revision of the Plan of Action to the Hemispheric Drug Strategy in Matters Related to the Control of Chemical Substances and Pharmaceutical Products (Peru)

The two studies presented by PRELAC highlighted problems related to the control of chemicals and drug trafficking. Details of these studies are noted above. The presentations generated a great deal of discussion by the experts. The presentation by Mr Adrian Noble on the MEM included reference to the possible review and updating of the plan of action to the Hemispheric Drug Strategy when it expires in the near future.

Given the results of the studies presented and the gaps that they highlighted, the Group offers its technical expertise should the CICAD Commission initiate a review of the plan of action to the Hemispheric Drug Strategy. To this end the Group of Experts would proposed to form a technical sub group lead by Peru with experts from member states as well as other countries and organizations such as INCB, UNODC and PRELAC among others. This group would develop elements or recommendations related to the control of chemical substances and pharmaceutical products as well as NPS for consideration by the Commission or other body created to revise the plan of action.

2.4.4 Update of the Best Practices Guideline for Investigations of Chemical Substances (Uruguay)

Experts have on a number of occasions raised the importance of regulatory controls regarding chemical substances. This includes chemical inspection and investigation. Some number of years ago the then Group of Experts on Chemical Substances developed a best practices guide regarding these aspects of chemical control.

During the current meeting the importance of the inspection and investigation function was once again raised. During the plenary discussion it was suggested that a working group be formed to update the previously prepared guide. The delegation of Uruguay reported that the Mercosur was in fact using this document as the basis for the development of an updated guide for use by their member states. It was therefore proposed that the representatives of the Mercosur countries present the revised document when the Group of Experts next meets. At that time working group could be formed to review the document and provide experts from the other member states to offer comments and suggestions that would include additional elements that address their particular needs and circumstances. The finalized document could then be used as an updated version of previously prepared guide.

3. Plan of Action

The Group of Experts chaired by Peru 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:

- Best Practices Regarding the Control of Domestic Transportation of Chemicals to Prevent Diversion (Argentina/Peru)
- Update the Information Bulletin on NPS including a self-assessment component for member states (USA/Colombia)
- Update of the Best Practices Guideline for Investigations of Chemical Substances (Uruguay)

Creation of the following technical sub groups:

- Development of elements or recommendations related to the control of chemical substances and pharmaceutical products as well as NPS for consideration by the Commission or other body created to revise the plan of action of the Hemispheric Drug Strategy.
- Development of model legislation and/or guidelines with appropriate alternatives that anticipate or respond with quick scheduling of NPS when they appear

4. Closing Session

The Group of Experts concluded its work on August 22. Ms. Marcia Gisele Bellido Luglio, Operational Manager, Registry of Controlled Goods of SUNAT and Minister José Antonio García Torres Director of Global Commitment, DEVIDA spoke at the closing session, thanking the members of the Group of Experts for their participation.

III. CONCLUSIONS AND RECOMMENDATIONS OF THE GROUP OF EXPERTS

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

- accept and approve the following guides and other documents;
 - Model Administrative Control System for the Control of Chemical Substances <u>http://www.cicad.oas.org/apps/Document.aspx?Id=2802</u>
 - Disposal of Pharmaceutical Drugs: Fentanyl Transdermal Patches <u>http://www.cicad.oas.org/apps/Document.aspx?ld=2784</u>
 - Suggestions for Establishing Designated Ports of Entry for Chemical Substances and Pharmaceutical Products
 - http://www.cicad.oas.org/apps/Document.aspx?Id=2813
- **direct** the Group of Experts to continue its work on the issues initiated for consideration and finalizing at the next meeting;
- **direct** the creation of a technical sub group to develop model legislation and/or regulations with appropriate alternatives that anticipate or respond with quick scheduling of NPS when they appear
- **direct** the creation of a technical sub group to develop recommendations concerning the control of chemical substances and pharmaceutical products as well as NPS for consideration in the review of the plan of action to the Hemispheric Drug Strategy
- accept the proposed plan of action for the Group of Experts;
- **direct** the Group of Experts to meet during 2015 and implement the plan as proposed, allowing for the consideration of new or emerging issues