INTERNATIONAL NARCOTICS CONTROL BOARD

Additional courses of action in support of the implementation of the 2007 INCB Guidelines for the import and export of drug and precursor reference standards

for use by national drug testing laboratories
and competent national authorities

February 2012

I. Introduction

1. In 2007, the Board issued its 'Guidelines for the import and export of drug and precursor reference standards' in which it recognized the importance of forensic laboratories as well as the need to ensure that these laboratories are granted the tools they need to pursue their work, including 'high quality reference standards'.

2. In the Guidelines, the Board identified obstacles to the availability of reference samples which it grouped into the following categories: inadequate awareness of procedural requirements for issuing import authorization; the length of time sometimes required for issuing authorization; legislation or other regulations that impede the import of controlled substances; and a lack of appropriate infrastructure for the shipment of controlled substances into or out of a country. In response to these continued obstacles to the availability of test and reference samples, the Guidelines also set forth concrete courses of action to be undertaken by Governments to foster and facilitate availability.

3. Despite the recognition of the importance of ensuring the availability of test and reference samples and the progress having already been made on this issue, many laboratories continue to experience difficulties and/or delays in obtaining all the test and reference samples they require. Governments have noted that many known obstacles to the adequate availability of samples continue to adversely affect the process making it overly complex, time-consuming and financially onerous, and having negative repercussions on the effectiveness and the viability of the work undertaken by drug testing laboratories.

4. These concerns were reiterated by Governments participating in the fifty-fourth session of the Commission on Narcotic Drugs in March 2011 through their adoption of resolution 54/3 entitled 'Ensuring the availability of reference and test samples of controlled substances at drug testing laboratories for scientific purposes' (Annex I). Resolution 54/3 reiterates the need for Governments to take further action aimed at facilitating the availability of internationally controlled substances for use as test and reference samples by drug testing laboratories in consultation with INCB and UNODC. The resolution invites both parties to work together to establish 'feasible mechanisms that will facilitate the provision of minimal and sufficient amounts of reference and test samples of controlled substances to drug testing laboratories' (operative paragraph 3).

II. INCB/UNODC study on obstacles to the availability of test and reference samples

5. At its hundred and first session in May 2011, the Board directed the INCB Secretariat to work with the Laboratory and Scientific Section (LSS) of UNODC to prepare a study that would identify obstacles to the availability of test and reference samples of internationally controlled substances and suggest possible courses of remedial action. The INCB Secretariat and UNODC prepared and disseminated a survey aimed at soliciting input from the competent authorities who are responsible for the approval of shipments of test and reference samples as well as from the laboratories requiring these samples including those participating in UNODC's International Collaborative Exercise (ICE) and quality assurance programme.

6. At its hundred-and-second session, in November 2011, the Board reviewed the study prepared by the INCB Secretariat and UNODC. Based on input received from national competent authorities and drug testing laboratories, the Board noted that many of the obstacles identified in its 2007 Guidelines continue to impede access to test and reference samples by drug testing laboratories. The Board also noted additional difficulties expressed by the respondents to the INCB/UNODC survey.

7. The present document details these findings, reiterates key Board recommendations shown by the study to be of continued relevance and puts forth a number of suggested courses of action additional to those identified by the Board in its 2007 Guidelines to address the problems identified by the Board in those Guidelines.

III. Continuing obstacles to the availability of test and reference samples

8. The questionnaires for the national competent authorities and drug testing laboratories addressed the following thematic areas: availability of test and reference samples including from domestic sources; import authorization procedures, validity and applicable time frames; shipping modalities and associated formalities; awareness and inter-agency cooperation; mechanisms adopted to facilitate availability; and for drug testing laboratories: UNODC's International Collaborative Exercise (ICE) and quality assurance programme.

9. The majority of laboratories that responded to the survey continue to encounter difficulties in obtaining the test and reference samples that they require, especially when those standards are not available from domestic sources. The four most common difficulties reported by laboratories are related to the following: shipping, approval by national competent authorities; customs and costs.

10. The following is a summary of problems identified by the respondents to the questionnaires sent to national competent authorities and drug testing laboratories respectively:

Problem 1. The vast majority of laboratories having responded to the survey are required to obtain at least some of their samples abroad, however a limited number of countries completely prohibit the import of all or some internationally controlled substances for use as test and reference samples by drug testing laboratories;

Problem 2. Many laboratories are unaware of all procedures to be followed for licensing to import and/or for the submission of applications for import/export authorizations or that these requests are not correctly filled out and accompanied by the documents required;

Problem 3. In the vast majority of countries that responded, the import of test and reference samples is not given priority in customs clearance and import authorization processes.

Problem 4. The majority of countries surveyed do not waive charges related to import/export authorizations and customs duties for drug testing laboratories importing test and reference samples. In a significant number of respondent countries, laboratories apply for import authorizations of more than one substance in the same request. Among the countries allowing the multiple listing of substances within the same form, the vast majority report that this measure does not lead to a reduction of costs when compared to those associated with one request per

substance, thus failing to address the financial burden related to the acquisition of test and reference samples.

Problem 5. In some instances, delays in the exporting country mean that the shipment is not authorized prior to the expiry of the export/import authorizations. A significant number of respondents to both questionnaires stated that the validity period in their country for import/export authorizations was three months or less, while only a small minority of competent authorities reported validity periods of six months or more;

Problem 6. Respondent laboratories which are not part of the ICE programme reported significantly greater difficulties in obtaining samples than participating laboratories. Laboratories not participating in the ICE programme also reported significantly longer approval processing times for import authorizations than participants;

Problem 7. The costs of test and reference samples has significantly increased in recent years. The limited demand for certain substances frequently leads to manufacturers deciding not to manufacture the substances in question, to delay production, and inflates the pricing of samples of these substances. Changing trends and the rapid appearance of new substances with chemical variations (particularly synthetic substances) represent additional difficulties;

Problem 8. Several national competent authorities have reported refusing the import of substances where the import would lead them to exceed the estimates reported to the Board for the substances in question. Only a very small number of countries reported engaging in a regular dialogue with drug testing laboratories to appraise needs;

Problem 9. The shipping of test and reference samples of controlled substances continues to pose difficulties for the availability of the substances. The majority of national competent authorities do not have any procedural requirements in place for postal services and shipping companies for the shipping of test and reference samples of internationally controlled substances;

Problem 10. The vast majority of national competent authorities indicated in their responses that there were no formal or informal mechanisms in place in their country to foster inter-agency cooperation aimed at facilitating the access of drug testing laboratories to test and reference samples;

Problem 11. More than half of national competent authorities reported no mechanism in place to facilitate cooperation between national competent authorities and drug testing laboratories;

Problem 12. The majority of national competent authorities indicated that no measures had been taken in their country to raise awareness of the importance of test and reference samples for the work of drug testing laboratories among relevant stakeholders.

IV. Recommendations

In paragraphs 315 and 316 of its Annual Report for 2011, the Board once again emphasized that the key to removing obstacles to the availability of test and reference samples of international controlled substances is awareness raising and inter-agency cooperation. The Board also asked all Governments to renew their efforts to ensure that drug testing laboratories are in possession of the tools they need to carry out their work. In view of the obstacles identified above, the Board invites Governments to also consider implementing the following recommendations. Reference to

corresponding paragraphs from the 2007 Guidelines is included, where relevant, between parenthesis.

Recommendation 1. It is of primary importance that laboratories are able to source test and reference samples of internationally controlled substances from abroad. The few countries which still prohibit the import of test and reference samples of internationally controlled substances should consider amending their legislation (paragraph 19, 2007 Guidelines).

Recommendation 2. One of the most common grounds for the refusal of import/exports of test and reference sample materials cited in the survey was that drug testing laboratories do not follow established procedures and/or do not complete required forms and provide required documentation. National competent authorities should work with laboratories to improve knowledge of import/export authorization application procedures and should establish contact points to assist drug testing laboratories (paragraph 18, 2007 Guidelines).

Recommendation 3. In order to expedite the approval process and reduce costs, national authorities may wish to consider giving priority to the processing of import authorization filed by drug testing laboratories as well as customs clearance for test and reference samples and waiving applicable fees. They may also wish to provide the possibility for laboratories of requesting the import of several substances on the same form and to require less supporting documentation (paragraphs 19, 20, 22 and 23, 2007 Guidelines).

Recommendation 4. Governments may wish to consider increasing the validity period for import/export authorizations for test and reference samples to a minimum of six months (paragraph 19, 2007 Guidelines).

Recommendation 5. National authorities, particularly those in countries where access to test and reference samples is limited may wish to consider participating in the ICE programme or similar quality assurance programmes. Countries which have the resources to do so, should also be encouraged to offer funding and other forms of material support to these initiatives (paragraph 19, 2007 Guidelines).

Recommendation 6. Given the high cost of samples, Governments should be further encouraged to reduce or eliminate any fees charged by them related to test and reference samples including those for their export, import and customs clearance. Governments may also wish to consider measures to reduce the cost of commercially obtaining substance which are difficult and/or expensive to source. They may also wish to consider cost reduction measures such as bulk orders (paragraph 22 and 23, 2007 Guidelines).

Recommendation 7. In some instances, national competent authorities have refused to authorize the import of particular test and reference samples on the basis that this would lead the country to exceed its estimates for the controlled substance in question. These national competent authorities may wish to formally consult drug testing laboratories with regard to their anticipated needs in establishing their estimates, so that the substances required can be taken into account in their estimated annual requirements. Governments may also provide the Board with supplementary estimates where required (paragraph 18, 2007 Guidelines).

Recommendation 8. Governments should consider establishing clear requirements on the shipping of test and reference samples of internationally controlled substances in order to avoid unnecessary refusals of shipments caused by vague guidelines and the application of discretion in approval procedures (paragraph 19, 2007 Guidelines). Any revised requirements should also seek to prevent the diversion of the samples by requiring certain safeguards (use of couriers, etc). A

possible model may be the process established by European Council Decision 2001/419/JHA (Annex II).

Recommendation 9. In order to foster more effective inter-institutional cooperation on the issues of test and reference sample availability, Governments should consider designating a national coordinator for procurement and distribution of reference samples; institutionalizing cooperation between government agencies such as the formation of and inter-agency working group; and establishing a coordinating body for characterizing new drugs from previous seizures and distributing samples of the seized drugs to all other laboratories nationwide (paragraph 18, 2007 Guidelines).

Recommendation 10. Governments should consider establishing both formal and informal mechanisms to facilitate cooperation between national competent authorities and drug testing laboratories (paragraph 18, 2007 Guidelines).

Recommendation 11. Awareness of the importance of test and reference samples among national stakeholders being a fundamental component of ensuring the availability of these samples for scientific purposes, Governments should adopt measures aimed at improving awareness of these issues within relevant institutions (paragraph 18, 2007 Guidelines).

V. Conclusion

It remains critical that all stakeholders involved in the acquisition of test and reference samples of internationally controlled substances be made aware of their critical importance for the work of drug testing laboratories and to cooperate to facilitate access. Although the data received indicates that some Governments do have limited structures in place aimed at fostering greater inter-institutional cooperation, the nature of the problems identified indicates that greater efforts in this area continue to be needed.

Annex I

Resolution 54/3

Ensuring the availability of reference and test samples of controlled substances at drug testing laboratories for scientific purposes

The Commission on Narcotic Drugs,

Recognizing the important role entrusted to the International Narcotics Control Board, in accordance with article 9, paragraph 4, of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol,

Recalling the Convention on Psychotropic Substances of 1971, in which it is recognized that the use of psychotropic substances for scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted,

Recalling also its resolution 53/4 of 12 March 2010, in which the Commission stressed the importance of promoting adequate availability of internationally controlled drugs for scientific purposes while preventing their diversion and abuse,

Noting the requirements to meet the scientific needs for internationally controlled substances worldwide within a regulatory and legal framework that prevents their diversion and abuse,

Recognizing the important role of drug analysis laboratories as part of drug control systems and the value of laboratory results, in accordance with Commission resolutions 50/4 of 16 March 2007 and 52/7 of 20 March 2009,

Recognizing also that the reliability of the analysis and results of such laboratories has significant implications for the justice system, law enforcement and preventive health care, as well as for the international harmonization of data and worldwide exchange and coordination of drug information, and that access to reference samples of controlled substances is an essential quality assurance requirement for achieving such reliability,

Stressing the importance of the United Nations Office on Drugs and Crime quality assurance programme for drug analysis laboratories, through which minimal but sufficient amounts of reference samples are distributed to participating laboratories of Member States, enabling continuous monitoring and improvement of their performance,

Concerned that costs and complex administrative procedures for obtaining required import/export certification and making available reference materials of controlled substances are disrupting routine analytical laboratory work,

1. *Encourages* the International Narcotics Control Board to continue its efforts to ensure the adequate availability of internationally controlled substances for scientific purposes, and encourages the United Nations Office on Drugs and Crime to consider providing adequate specifications of their quality, as far as they are available;

2. *Requests* Member States, in consultation with the International Narcotics Control Board and the United Nations Office on Drugs and Crime, to review national procedures within their policy and legislative frameworks, as appropriate and in accordance with the provisions of the Conventions, in order not to impair access to reference and test samples of internationally controlled substances for scientific purposes;

3. *Invites* the International Narcotics Control Board and the United Nations Office on Drugs and Crime to work closely on feasible mechanisms that will facilitate the provision of minimal but sufficient amounts of reference and test samples of controlled substances to drug testing laboratories, including through the

reinforcement of existing national programmes, as appropriate, in order to support their analytical and quality assurance work, and notes that such mechanisms may include the designation of national contact points, preferably the laboratories that are part of the Office's International Collaborative Exercise programme, and the implementation of efficient administrative procedures governing access to reference and test samples of controlled substances;

4. *Recommends* that the United Nations Office on Drugs and Crime continue to support Member States in enhancing the analytical work of laboratories and the training of experts.

Annex II

European Council Decision 2001/419/JHA of 28 May 2001 on the transmission of samples of controlled substances

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 30, 31 and 34(2)(c) thereof,

Having regard to the initiative of the Kingdom of Sweden,
Having regard to the opinion of the European Parliament(1),

Whereas:

(1) The fight against the illicit production and trafficking of drugs is a matter of common concern for law enforcement and justice authorities in the Member States.

(2) The possibility of legally transmitting samples of seized controlled substances between the authorities of the Member States for the purposes of detection, investigation and prosecution of criminal offences or for the forensic analysis of samples would increase the effectiveness of the fight against the illicit production and trafficking of drugs.

(3) At present no legally binding rules exist regulating the transmission of seized controlled narcotic substance samples between the authorities of the Member States. A system should therefore be created at European Union level to allow for the legal transmission of such samples. Such system should apply to all forms of transmission of samples of seized controlled substances between Member States. Transmission should be based on agreement between the sending and the receiving Member State.

(4) Transmission should take place in a manner that is secure and guarantees that the transported samples cannot be abused,

HAS DECIDED AS FOLLOWS:

Article 1

Establishment of a system for the transmission of samples

1. This Decision establishes a system for the transmission between Member States of samples of controlled substances.

2. Transmission of samples of controlled substances (hereinafter referred to as "samples") shall be considered lawful in all Member States when it is conducted in accordance with this Decision.

Article 2

Definitions

For the purposes of this Decision, controlled substances means:
(a) any substance, natural or synthetic, mentioned in Schedules I or II of the United Nations Single Convention on Narcotic Drugs 1961, and that Convention as amended by the 1972 Protocol;
(b) any substance mentioned in the revised Schedules I, II, III and IV of the United Nations Convention on Psychotropic Substances 1971;
(c) any substance that is subject to control measures taken pursuant to Article 5(1) of Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs(2).

Article 3

National contact points

1. Each Member State shall designate a national contact point for the purposes of implementing this Decision.

2. Information concerning the designated national contact points, including subsequent modifications, shall be transmitted to the General Secretariat of the Council which shall publish the information in the Official Journal.

3. The national contact points shall, if appropriate in association with other relevant national bodies, be the sole bodies competent for authorising the transmission of samples under this Decision, notwithstanding relevant provisions on mutual legal assistance in criminal matters.

Article 4

Agreement to transmit samples and acknowledgement of receipt

1. The national contact point of the Member State intending to send a sample and the national contact point of the Member State intended to receive a sample shall agree on the transport before the transmission takes place. For this purpose they shall make use of the Sample Transmission Form set out in the Annex.

2. Where transmission of a sample involves transportation through the territory of another Member State (hereinafter referred as "transit Member State"), the national contact point of such a transit Member State shall subsequently be informed of the planned transport by the national contact point of the sending Member State. To that end, each transit Member State shall receive a copy of the duly completed Sample Transmission Form before the transmission begins.

3. The receiving Member State shall acknowledge to the sending Member State the receipt of the sample.

Article 5

Means of transport

1. Transport of samples shall take place in a secure way.

2. The following means of transport shall be regarded as secure:

(a) transport by an official of the sending or receiving Member State;
(b) transport by courier;
(c) transport by diplomatic bag;
(d) transport by registered (express) mail.

3. The duly completed Sample Transmission Form referred to in Article 4 shall accompany the sample during the entire transport.

4. The authorities of the Member States involved shall not hinder or detain any transport accompanied by a duly completed Sample Transmission Form unless they have doubts as to whether the transport is carried out lawfully. In case of doubts as to the legal status of the Sample Transmission Form, the national contact point of the Member State detaining the transport shall, without delay, contact the national contact points of the Member States responsible for the completion of the Sample Transmission Form in order to clarify the issue.

5. If the means of transport chosen is transport by an official of the sending or receiving Member State, that official shall not be permitted to wear a uniform. Further, he or she shall not carry out any operational tasks in connection with the transport unless this would be compatible with the applicable national legislation and agreed upon by the sending, transit or receiving Member States. When travelling by aircraft, only airline companies registered in one of the Member States shall be used.

Article 6

Quantity of the sample and its use

1. A sample shall not exceed the quantity deemed necessary for law enforcement and judicial purposes or for the analysis of samples.

2. The use of the sample within the receiving Member State shall be agreed between the sending and receiving Member States, it being understood that samples can be used for detection, investigation and prosecution of criminal offences or for the forensic analysis of samples.

Article 7

Evaluation

1. This Decision shall be subject to evaluation within the Council after at least two and no more than five years after its entry into force.

2. For the purpose of the evaluation the national contact point of each sending Member State shall hold in its archives a copy of every Sample Transmission Form issued during at least the previous five years.

Article 8

Entry into force

This Decision shall take effect on 1 July 2001.
Done at Brussels, 28 May 2001.

For the Council
The President
T. Bodström

(1) Opinion delivered 4 May 2001 (not yet published in the Official Journal).

(2) OJ L 167, 25.6.1997, p. 1.