# INCB LEARNING Frequently asked questions

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#### I. General questions

#### 1. Which forms should be furnished to INCB and where can I find them?

All competent national authorities shall submit to INCB forms containing the statistical information that Governments are required to report to the Board, pursuant to the provisions of three international drug control conventions, and the relevant ECOSOC and CND resolutions.

All forms can be downloaded from the INCB website (<u>Form A, Form C, Form B, Form A/P</u>, <u>Form P, Form B/P</u> and <u>Form D</u>). In addition, INCB sends circular letters at the beginning of each year to competent national authorities attaching the forms.

Competent national authorities are encouraged to submit to the INCB forms in the formats of:

- XML files where available,
- Excel files
- Word files in the docx format

Submitting scanned copies, hard copies or .pdf files (except for the cover page containing signature) are discouraged.

#### 2. Where can I find advice on how to fill in the forms?

All INCB Forms contain detailed instructions to guide national competent authorities in their periodical reporting obligations. Additionally, to assist competent national authorities, the INCB has developed training materials, containing detailed guidelines and examples for reporting statistics. They are available on the INCB website (Narcotic Drugs, Psychotropic Substances and Precursors). The Guide on Estimating Requirements for Substances under International Control, developed by the INCB and WHO, gives further guidance on how to identify methods for calculating the quantities of controlled substances required for medical and scientific purposes, and helps authorities to prepare the estimates and assessments of annual requirements for controlled substances.

#### 3. What statistics shall be reported to INCB?

The tables below summarize the data to be reported to INCB:

For narcotic drugs:

Form A (quarterly statistics) — statistics on imports and exports of narcotic

drugs

Form B (annual estimates) — estimates of requirements for narcotic drugs,

manufacture of synthetic drugs, and cultivation of the opium poppy, the cannabis plant and the coca

bush.

Form C (annual statistical report) – statistics on production, manufacture,

consumption, stocks and seizures of narcotic

drugs.

For psychotropic substances:

Form P (annual statistical report) — data on manufacture, stocks, total and detailed

imports and exports, consumption

Form A/P (quarterly statistics) – data on import and export of Schedule II

substances

Form B/P – assessments of annual legitimate requirements

for Schedules II, III and IV substances

For precursor chemicals:

Form D (annual information) – data on Substances Frequently Used in the

Illicit Manufacture of Narcotic Drugs and

Psychotropic Substances.

#### 4. When do the forms need to be submitted?

Form	Deadline	
Quarterly trade statistics on narcotic drugs	30 April, 31 July, 31 October and 31	
(Form A)	January	
Annual statistics on narcotic drugs (Form	30 June	
<u>C)</u>		
Estimates for narcotic drugs (Form B)	30 June	
Supplementary estimates for narcotic drugs	Whenever necessary	
(Supplement to Form B)		
Quarterly trade statistics on psychotropic	encouraged for each quarter	
substances (Form A/P)		
Annual statistics on psychotropic	30 June	
substances (Form P)		
Assessments for psychotropic substances	a review and revision or resubmission	
(Form B/P)	every three years is recommended	
Supplementary assessments for	required for amendments of	
psychotropic substances (Supplement to	assessments	
Form B/P)		
Annual statistics on precursors (Form D)	30 June (part 1), encouraged by 30	
	April	

#### II. Question specific to the International Drug Control Conventions

1. What are the International Drug Control Treaties?

The International Drug Control Treaties consist of the following three conventions:

- 1. 1961 Single Convention on Narcotic Drugs
  - Provides a framework for the international control of narcotic drugs, replacing all former drug control treaties with a single convention.
  - Establishes International Narcotics Control Board.
- 2. 1971 Convention on Psychotropic Substances

- Provides a framework for the international control of psychotropic substances.
- 3. <u>1988 UN Convention against Illicit Traffic in Narcotic Drug and Psychotropic Substances</u>
  - Provides comprehensive measures against drug trafficking, including provisions against money laundering and the diversion of precursors chemicals.
  - Provides for international cooperation through, for example, extradition of drug traffickers, controlled deliveries and transfer of proceedings.

# 2. What are the main objectives of the legal framework of the International Drug Control Treaties?

- To <u>prevent the illicit</u> production, cultivation, manufacturing and trade in controlled substances as well as their abuse.
- To ensure the <u>adequate availability</u> of controlled substances for <u>medical and scientific</u> purposes.
- To provide a system of <u>control</u> for the international movement of controlled substances for <u>licit purposes</u>.
- To provide a <u>legal basis for international cooperation</u>, such as mutual legal assistance, extradition and the exchange of information among national law enforcement agencies.

#### 3. What is the International Narcotics Control Board? And what is its role?

The International Narcotics Control Board ("INCB") is an independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions. It was established in 1968 in accordance with the 1961 Single Convention on Narcotic Drugs and replaced all predecessor bodies under the League of Nations. The INCB's primary functions are to monitor and promote treaty implementation, provide for a direct working level contact between concerned authorities, and to assist, through its secretariat, real-time exchange of information in the prevention of diversions of controlled substances.

The INCB consists of 13 members who are elected by the Economic and Social Council and who serve in their personal capacity, not as government representatives. Three members with medical, pharmacological or pharmaceutical experience are elected from a list of persons nominated by the World Health Organization (WHO) and 10 members are elected from a list of persons nominated by Governments. The term of office of each member is five years, and re-election is permitted.

#### The role of the INCB is to:

- Ensure that the use of controlled substances is limited to medical and scientific purposes, while preventing their diversion.
- Monitor the licit trade in chemicals and preventing their diversion into illicit channels.
- Assist States in preventing illicit cultivation, production, manufacture, trafficking and use of drugs.
- Evaluate and recommend chemicals for possible international control.

- Identify weaknesses in the implementation of the treaties and suggesting remedial action.
- 4. What reports are published by the INCB Secretariat?
- Annual Report of the Board
- Report on Article 12 of the 1988 Convention (Precursors)
- Technical Reports
  - o Narcotic Drugs
  - o Psychotropic Substances
- Special Reports
- 5. What are the general obligations of State Parties under the international drug control treaties?

#### The Parties shall:

- Give effect to and carry out the provisions of the Conventions within their own territories.
- Co-operate with other States in the execution of the provisions of the Conventions.
- Maintain a special administration for the purpose of applying the provision of the Conventions.

In addition, Parties shall adhere to their reporting obligations to INCB as follows:

- Under the 1961 Convention
  - Article 18: Information to be furnished by parties to the Secretary-General (competent authorities, laws, annual reports etc.)
  - o Article 19: Estimates of drug requirements (future)
  - o Article 20: Statistical returns to be furnished to the Board (past)
- Under the 1971 Convention
  - o Article 16: Reports to be furnished by the parties
- Under the 1988 Convention
  - Article 12: Substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances (seizures, methods of diversion etc.)
- 6. What are some of the risks of non-adherence to the universal application of the International Drug Control Treaties?
- States becoming vulnerable to drug trafficking.
- States being used as offshore financial centres.
- Vulnerability of those States to laundering of proceeds of drug-related crime.
- Non-adherent States may serve as safe havens for drug traffickers.

#### III. Questions specific to narcotic drugs

#### 1. What narcotic substances are under international control?

The <u>Yellow List</u> contains the full list of internationally controlled narcotic drugs under the <u>1961 Convention</u>. The Yellow List also contains information regarding the synonyms and trade names of those substances, conversion factors for calculating the pure drug content of bases and salts. The INCB updates the Yellow List as new substances are scheduled under the 1961 convention or when any information in the other parts have been updated. However, there is also an updated list of the new substances added to the 1961 Convention that can be found in the INCB website.

#### 2. What is the understanding of consumption under the 1961 Convention?

The 1961 Convention defines consumption as the transfer of drugs from manufacturer or wholesale to the retail level. According to article 1, paragraph 2, drugs are regarded as "consumed" when they have been supplied to any person or enterprise for retail distribution, medical use or scientific research, such as public and private pharmacists, doctors, hospitals, or scientific institutions. Amounts required for re-export are not reported as consumption.

#### 3. What kind of activities should I report as utilization?

According to article 19, paragraph 1b and article 20, paragraph 1b, State Parties should report estimates and statistics on the utilization of drugs for the manufacture of other drugs, or preparations in Schedule III and of substances not covered by the 1961 Convention, and utilization of poppy straw for the manufacture of drugs.

If a country only imports base drugs (active pharmaceutical ingredients, or API) to manufacture preparations of the same substance (e.g. importing a substance in powder form and using it to manufacture tablets, liquids or patches of the same substance), this is not considered utilization. If these preparations of the same substance are manufactured and intended to be consumed, the amount is included under "consumption". If they are intended to be held in stocks by 31st December of the reporting year, that amount is reported as stocks. If these preparations of the same substance are manufactured to be re-exported, they are not part of the estimate of the country and the amount would not be entered on form B.

#### 4. How do I report estimates and statistics on Schedule III preparations?

When completing Forms B and C, the quantities of drugs estimated or already used to manufacture preparations included in Schedule III of the 1961 Convention should be reported to the Board. However, the available quantities of Schedule III preparations (finished preparations) obtained from any starting material and consumed and/or held in stocks as preparations should not be reported. These quantities of Schedule III preparations should also in no way be added to the quantities of pure base drugs reported as having been manufactured, consumed or stocked.

If parties deem it appropriate to furnish any information on Schedule III preparations, then that information should be clearly provided in the remarks box on the cover page only. Please note that throughout Forms B and C, shaded areas should not be completed,

as they indicate that no manufacture of Schedule III preparations exists for these substances. This is, for example, the case for oxymorphone.

A definition of Schedule III preparation is contained in part 2 of the Yellow List, the List of Narcotic Drugs under International Control. The latest version of the Yellow List is available on the INCB website under the following link: <a href="https://www.incb.org/incb/en/narcotic-drugs/Yellowlist\_Forms/yellow-list.html">https://www.incb.org/incb/en/narcotic-drugs/Yellowlist\_Forms/yellow-list.html</a>
Examples of Schedule III preparations are those containing 500mg of acetaminophen and 30 mg codeine per dosage unit, and tablets containing 200mg of ibuprofen and 12.8mg of codeine.

#### 5. How should pure codeine be reported?

When the import of pure codeine is planned, for example, from Country Y, to be used in the manufacture of preparations included in Schedule III, this quantity should be included in the estimates to be sent to the INCB in Form B, Part II, column 2b, relative to the corresponding year.

The amount of pure codeine that is planned to be used directly for medical and scientific purposes during the year should be provided in Part II, column 1 of Form B.

The amount of the pure codeine that is planned to be kept in stock in the country at the end of the year, either to be used in the manufacture of preparations included in Schedule III or for direct use for medical and scientific purposes in the following year, must be included in Part II, column 4 of Form B.

When the codeine arrives in the country, said importation must be reported on Form A in relation to the quarter when it arrived.

The following year, the statistics of what happened with this codeine that entered the country must be reported using Form C. The amount of pure codeine used during the year for the manufacture of preparations included in Schedule III must be reported in Form C, Part I.A, column 4. This regardless of whether those preparations or substances are intended for domestic consumption or for export.

The amount of pure codeine that was used directly for medical and scientific purposes must be reported in Part I.A, column 3 of Form C.

The amount of the pure codeine that was kept in stock at the end of the year, must be included in Part I.A, column 5 of Form C.

When exporting Schedule III preparations containing codeine, countries are exempt from the obligation to report such exports, and from the obligation to verify the amount of codeine approved for the estimates of the importing country, as these do not include Schedule III preparations.

6. Do I need to submit estimates and statistics for the consumption and trade of Schedule III preparations containing codeine?

No. When it comes to codeine, all reporting obligations relate to pure codeine, as explained under question 5. above. After this codeine is used to manufacture a Schedule

III preparation, as defined in the Yellow List, countries are no longer required to report what happens to these preparations (i.e. if they are consumed domestically, exported, kept in stocks, destroyed, etc.). There is also no need to submit estimates for the consumption of Schedule III preparations. However, it is mandatory to submit estimates and statistics on the pure codeine that is going to be imported to be used for the manufacture of Schedule III preparations, as we mentioned before.

#### IV. Questions specific to psychotropic substances

#### 1. What should I be particularly aware of when preparing the reports?

#### Some key terms:

"Manufacture" under the 1971 Convention refers to all processes by which psychotropic substances may be obtained, including the separation of psychotropic substances from a plant, refining, and transformation of psychotropic substances into other psychotropic substances. It also includes the quantities of psychotropic substances contained in pharmaceutical preparations that are manufactured using non-psychotropic starting material.

Statistics on "stocks" refer to those held by manufacturers of psychotropic substances and should not include stocks of pharmaceutical preparations at the wholesale or retail level.

"Imported" and "exported" quantities of psychotropic substances to be reported to INCB shall include quantities in bulk form (powder, liquid), quantities in pharmaceutical dosage forms (tablets, ampoules) and quantities imported in finished pharmaceutical products (pharmaceutical preparations containing psychotropic substances already packed and labelled).

Quantities of psychotropic substances reported to INCB should be expressed in terms of the "pure anhydrous content" of the psychotropic substances.

#### 2. What is a conversion factor and when is it used?

A conversion factor is used calculate the pure anhydrous content of psychotropic substance in a salt or preparation and used to determine the quantity of the control substance for statistical reporting. The List of Psychotropic Substances under International Control ("Green List") contains a table showing the conversion factors of many common salts into pure anhydrous base content of psychotropic substances listed in schedules of the 1971 Convention. See Chapter II.A. of Module II in the Training Material for Competent National Authorities on the 1971 Convention for how to use a conversion factor.

#### 3. Why some salts do not have a conversion factor in the Green List?

The list of conversion factors in the <u>Green List</u> is not exhaustive. Some salts do not have an assigned conversion factor, especially if the conversion factors were not known at the time of preparing the list. The Green List is updated on a yearly basis, and conversion factors are reviewed and amended, as and when appropriate.

#### 4. Which information is most frequently omitted from the reports?

Any omission to submit requested information to INCB creates a problem and requires additional correspondence between INCB and the competent national authority to clarify the matter.

The most frequent omissions are as follows:

Form P - Information on trade in psychotropic substances is often incomplete: trade details of each substance should contain not only the total quantity traded in the year in question but also the breakdown by the countries of origin/destination and the corresponding quantities. Some authorities fail to provide information on stocks held by manufacturers and the quantities used for industrial purposes. Many countries still do not provide data on consumption of psychotropics within their territory.

Form A/P - Some authorities fail to indicate the breakdown of quantities by country/countries from where the substance has been imported and/or to where the substance has been exported.

#### 5. What are the most frequent mistakes in reporting to INCB?

In general, the mistakes happen most frequently in the following areas:

- Double counting;
- Wrong unit of measurement (grams or kilograms);
- Entry of data to a wrong column;
- Wrong country names or substances names.

Form P - Statistics on manufacture should include the quantity of psychotropic substances contained in the pharmaceutical preparations that are manufactured using non-psychotropic starting material. If the quantity of a psychotropic substance manufactured in bulk form has been included in the manufacture statistics, then the quantities of the pharmaceutical preparations manufactured from that substance should not be included in the statistics, in order to avoid double counting. Statistics on stocks should only include those held by manufacturers of psychotropic substances and not the stocks of pharmaceutical preparations held at the wholesale or retail level. Quantities of psychotropic substances indicated in all forms should not be expressed in terms of esters, ethers, or salts, but in terms of the content of pure psychotropic substance.

Form P and Form A/P - A psychotropic substance shall be reported as imported only when it has actually arrived in the importing country/territory (physical transfer). The issuance of an import certificate is not sufficient for the quantity to be included in the import statistics, if the import did not take place. Similarly, the issuance of an export authorization is not sufficient for the quantity to be included in the export statistics. The reported quantity should reflect the actual quantity imported or exported.

Form B/P – Entry of data into the wrong column of unit of measurement (grams or kilograms) and incorrect use of comma (,) or decimal point (.) when presenting the numbers. This may require further clarification with the authorities. Very often there is

no indication as to whether the assessments include quantities for export or re-export. Sometimes the assessments do not include the quantities manufactured domestically.

#### 6. Why is the high quality of my reports so important?

Timely and complete submission of all statistical reports to INCB by competent national authorities is very important for the proper functioning of the international drug control system as a whole, and the control of psychotropic substances in each individual reporting country/territory.

Assessments of annual requirements of psychotropic substances published by INCB indicate the maximum quantities of psychotropic substances that individual countries and territories may manufacture domestically and import in a year. The Parties should verify that exports of psychotropic substances to any country or territory are within the established assessments for that country or territory. Appropriate assessments are therefore important to ensure adequate availability of psychotropic substances for legitimate uses.

Failure by a competent national authority to provide statistical reports to INCB, or frequent mistakes and inconsistencies in reporting, may indicate weaknesses in the implementation of the provisions of the 1971 Convention in a country. In accordance with its treaty mandate, INCB has to bring such situation to the attention of the Government concerned in order to ensure proper implementation of the treaty provisions. Failure by a competent national authority to furnish statistical reports is also reflected in INCB publications.

INCB uses information received from competent national authorities for various studies and analyses, including the assessment of the effectiveness of national control measures. The quality of these studies and analyses depends to a large extent on the data available. For example, by analysing reports on international trade received from Governments, INCB may identify diversion attempts of psychotropic substances from licit trade into illicit traffic. Failure by any competent national authority to provide complete and accurate reports on international trade in psychotropic substances makes the identification and prevention of diversion attempts more difficult.

#### 7. Are my reports reflected in any publications?

The status of submission of statistical reports for psychotropic substances by all countries and territories is reflected in Chapter II of the INCB annual report and in Part I of the INCB annual technical publication Psychotropic Substances - Technical Reports. Past issues of the technical publication are available on the INCB website. You may wish to check whether the data reported by you were correctly included in the respective tables of this publication and inform the INCB secretariat of any discrepancies between your reports and the data published.

The assessments for psychotropic substances of all countries and territories are updated on a weekly basis and published on the INCB website (<a href="www.incb.org">www.incb.org</a>) in the section <a href="Psychotropic Substances">Psychotropic Substances</a> – <a href="Status of Assessments">Status of Assessments</a>.

#### V. Questions specific to precursor chemicals

1. Where can I find more information on precursor chemicals?

For general information **related to drug precursors and the international precursors control system** visit the Precursors Section on the INCB web page (https://www.incb.org/incb/en/precursors/index.html).

Under the subsection "Tools and Kits" you will find <u>The United Nations Toolkit on Synthetic Drugs</u> (best viewed when the link is copied in Google Chrome). In this toolkit, the Precursors Module, developed by INCB, responds to the questions below:

- Which precursors are under international control?
- Who can propose to place additional chemical(s) under international control?
- What are the estimated legitimate needs of chemicals in country X?
- What are the applicable Harmonized System (HS) codes for chemicals in Table I and Table II of the 1988 Convention as well as for non-scheduled chemicals known to be used in illicit drug manufacture?
- Where can I find information about CNAs?
- Does country X apply any system of authorization for imports and/or exports?
- Are there any chemicals under national control in country X?
- How do I establish a system of voluntary cooperation with industry?
- Which control measures apply to companies involved in the transportation of scheduled substances?
- Where can I find other practical precursor-related recommendations for implementation in my country?
- Who are my counterparts at the operational level in other countries?
- What do I need to do to receive INCB's alerts under Project Prism and Project Cohesion?

Some links in the Precursor module are reserved for the use of competent national authorities.

Competent National Authorities may also refer to the password-protected part of the INCB web site (<a href="https://www.incb.org/incb/en/precursors/cna.html">https://www.incb.org/incb/en/precursors/cna.html</a>). Access can be requested by writing to incb.precursors@un.org.

2. How to best handle suspicious transactions and follow up on objections in the PEN Online system?

Competent authorities of an importing country which object to a suspicious pre-export notification (PEN) should request copies of relevant documents related to the PEN in question from the exporting country to assist the verification of the proposed transaction and identify the actual buyers and end-users of the pre-notified chemical(s).

The authorities of the importing country should subsequently verify the information contained in the documents received, if necessary, in cooperation with their national law enforcement authorities.

From the operational point of view, if a diversion attempt is confirmed, the governments concerned may consider carrying out a controlled delivery to identify person(s) or criminal organization(s) responsible for the attempt to divert the substance from the international licit trade to the illicit market.

For more information and guidance please review the document **Tips for the authorities of importing and exporting countries and users of the PEN Online system on how to handle suspicious transactions and follow up on objections to pre-export notifications involving precursors.** 

This document is reserved for the use of competent national authorities only and can be requested by writing to <a href="mailto:incb.precursors@un.org">incb.precursors@un.org</a>.

#### VI. Questions specific to I2ES

1. If you decide to use this tool to generate import permits, would it replace the system currently used by the competent authority that wishes to opt for it?

I2ES was designed to facilitate the trade in internationally controlled substances. As many national authorities still require import and export authorizations so for substances not under international control a parallel system (paper-based or computerized) may still be necessary. INCB is working to determine if it is possible allow for the inclusion of other substances not under international control to be traded using the I2ES platform. Also, if a country's trading partner does not use I2ES it would be necessary to revert to using the legacy system in order to issue the appropriate authorizations.

#### 2. Is it needed to migrate the data from our system to I2ES?

It is not necessary, nor is it currently possible, to migrate existing import/export data into I2ES.

#### 3. How many users can access the account?

INCB will establish an initial administrator account for a country upon official request by the relevant authority. After that administrator account has been issued the official in the national authority can use the account to generate any number of user accounts for other officials and staff to work on I2ES who can be assigned differently levels of permission to execute functions in the platform.

#### 4. How different is I2ES with the PEN Online system?

I2ES is designed to allow both the importing and exporting countries involved in international trade to instantly validate and rapidly issue the relevant authorizations, endorsements and confirmations in a single secure platform designed to be in compliance with the entire trading requirements under the 1961 and 1971 Conventions. This allows for rapid clearance for a shipment of controlled substances. PEN Online is a platform that simply allows an exporting country to notify a receiving country that a shipment of precursor chemicals is inbound whether or not the receiving country is an active user of PEN Online. PEN Online does not handle any exchange of import or export authorizations.

### VII. Table: Summary of INCB Forms

Form	Information	Deadline	Email
Quarterly trade statistics on narcotic	Narcotics: Form A (quarterly statistics) - statistics on imports	30 April, 31 July, 31 October and 31	incb.narcotics@un.org
drugs (Form A) Annual statistics on narcotic drugs (Form C)	and exports of narcotic drugs  Narcotics: Form C (annual statistical report) - statistics on production, manufacture, consumption, stocks and	January 30 June	incb.narcotics@un.org
Estimates for narcotic drugs (Form B)	seizures of narcotic drugs  Narcotics: Form B (annual estimates) - estimates of requirements for narcotic drugs, manufacture of synthetic drugs, and cultivation of the opium poppy, the cannabis plant and	30 June	incb.narcotics@un.org
Supplementary estimates for narcotic drugs (Supplement to Form B)	the coca bush Narcotics: supplement to Form B - Required to modify the annual estimates of Form B	Whenever necessary	incb.narcotics@un.org
Quarterly trade statistics on psychotropic substances (Form A/P)	Psychotropics: Form A/P (quarterly statistics) - data on import and export of Schedule II substances	encouraged for each quarter	incb.psychotropics@un.org
Annual statistics on psychotropic substances (Form P)	Psychotropics: Form P (annual statistical report) - data on manufacture, stocks, total and detailed imports and exports, consumption	30 June	incb.psychotropics@un.org
Assessments for psychotropic substances (Form B/P)	Psychotropics: Form B/P - assessments of annual legitimate requirements for Schedules II, III and IV substances	a review and revision or resubmission every three years is recommended	incb.psychotropics@un.org
Supplementary assessments for psychotropic substances (Supplement to Form B/P)	Psychotropics: supplement to Form B/P - Required to modify the assessments of annual legitimate requirements of Form B/P	required for amendments of assessments	incb.psychotropics@un.org
Annual statistics on precursors (Form D)	Precursors: Form D (annual information) - data on Substances Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances	30 June (part 1), encouraged by 30 April	incb.precursors@un.org