



INTERNATIONAL NARCOTICS CONTROL BOARD
Psychotropics Control Section

CONVENTION ON PSYCHOTROPIC SUBSTANCES OF 1971

Training material for competent
national authorities

Module II.

Assessment system for psychotropic substances



UNITED NATIONS

Foreword

The present training material has been prepared by the International Narcotics Control Board (INCB) to help Governments better understand and comply with the provisions and requirements of the Convention on Psychotropic Substances of 1971 and related resolutions of the Economic and Social Council and the Commission on Narcotic Drugs. It comprises four modules:

Module I	International control and availability of psychotropic substances
Module II	Assessment system for psychotropic substances
Module III	International trade in psychotropic substances
Module IV	Guidelines for the preparation of reports to the International Narcotics Control Board

The present module contains explanations and examples of how to establish and calculate assessments of annual requirements for psychotropic substances and report them to INCB as required by the 1971 Convention and related resolutions of the Economic and Social Council and the Commission on Narcotic Drugs. In conjunction with the present module, the latest versions of the Green List and the following forms, which may be useful to competent national authorities, are available on the INCB website (www.incb.org):

- List of psychotropic substances under international control (Green List)
- Assessments of annual medical and scientific requirements for substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971 (form B/P)
- Modifications to assessments of annual medical and scientific requirements for substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971 (supplement to form B/P)
- List of current assessments as submitted by countries (updated regularly)

Competent national authorities are also encouraged to consult the INCB technical report on psychotropic substances, entitled *Psychotropic Substances: Statistics for [...]; Assessments of Annual Medical and Scientific Requirements for Substances* (available on the INCB website), which provides a detailed analysis of annual trends in the manufacture, stocks, trade and consumption of psychotropic substances that have had significant presence on the licit market, as well as additional information on new developments.

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CHAPTER I.

Assessment system for psychotropic substances

A. Introduction to the assessment system

The drug control system provided for in the Convention on Psychotropic Substances of 1971¹ is based largely on the system devised for narcotic drugs under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol.² However, at the end of the 1960s, when the 1971 Convention was drafted, it was considered that the estimate system applied to narcotic drugs was not needed for psychotropic substances.

In the late 1970s and early 1980s, attempts to divert large quantities of psychotropic substances in Schedule II were facilitated by the use of forged or counterfeit import authorizations. The lack of information available to exporting countries as to the legitimate requirements for psychotropic substances in importing countries hampered efforts to detect the illegal documents. Therefore, INCB proposed additional measures, which were then endorsed by the Economic and Social Council in its resolution 1981/7 of 6 May 1981, in which the Council invited Governments to provide INCB with assessments of their annual medical and scientific requirements for substances in Schedule II of the 1971 Convention, and to communicate that information to INCB for publication, with a view to providing guidance for manufacture and export.

The positive experience with the use of assessments for substances in Schedule II in the prevention of their diversion to illicit markets led to additional measures regarding substances in Schedules III and IV. In its resolution 1991/44, the Economic and Social Council invited Governments to provide INCB with assessments of their legitimate medical and scientific requirements for psychotropic substances in Schedules III and IV and to develop mechanisms to ensure that exports of psychotropic substances were in line with importing countries' assessments and, if necessary, to consult with the Governments of such countries or with INCB in that connection.

¹United Nations, *Treaty Series*, vol. 1019, No. 14956.

²United Nations, *Treaty Series*, vol. 976, No. 14152.

The 1971 Convention provides for a different control regime for each Schedule. This reflects the need to apply varying controls on psychotropic substances that correspond to their therapeutic value and their risk of abuse. The strictest control regime is stipulated for substances in Schedule I. Given that substances in Schedule I are deemed to have very limited to no medical value, the submission of assessments is not required.

In its resolution 1996/30, on measures to combat diversion of psychotropic substances and to establish effective control over operations carried out by intermediaries in international trade in psychotropic substances, the Economic and Social Council requested INCB to establish assessments of annual licit domestic requirements for psychotropic substances for countries that had not yet submitted such assessments. In 1997, INCB established the assessments for the first time, for 56 countries.

Since 1997, the Board has established assessments mainly for States that are newly independent, to allow them to import psychotropic substances needed for medical or scientific purposes without undue delay.

The assessments made by INCB reflect previous patterns of use of psychotropic substances in each country. To date, almost all the Governments concerned have provided INCB with their own assessments.

B. Objectives of the assessment system

The framework of control that the 1971 Convention requires Governments to establish is directed at protecting public health and welfare. The international community, in enacting the treaty, recognized that the use of psychotropic substances for medical and scientific purposes was indispensable and that their availability for such purposes should not be unduly restricted.

The main objective of the assessment system for each country is to obtain accurate and realistic information about the quantities of psychotropic substances required for medical and scientific purposes.

That information is essential for the following purposes:

- (a) To ensure that sufficient quantities are available in the health-care system in order to satisfy the needs of the population;
- (b) To contribute to preventing the diversion of those substances for illicit use;
- (c) To provide the competent national authorities of exporting countries with an indication of the approximate annual legitimate requirements of importing countries for individual psychotropic substances.

The assessments should be used by the national authorities of exporting countries to ascertain whether a requested import appears to be excessive in relation to the reported annual requirement of the importing country concerned. The competent authorities of exporting countries use that information during their pre-export examination of the legitimacy of each export to identify suspicious transactions. In such cases of suspicion, Governments of exporting countries should not authorize an export until the designated national

authority of the importing country confirms the legitimacy of the import request. INCB provides support to exporting countries by channelling enquiries as to the authenticity and legitimacy of import requests to importing countries.

Before granting an import authorization, the competent authorities of the importing country should verify whether the company requesting the authorization has the appropriate licence, as required under article 8 of the 1971 Convention, and whether the quantity to be imported is in line with the legitimate needs of the country as reported to INCB. For information on the import and export of psychotropic substances, see module III, International trade in psychotropic substances.

The diversion of legitimately manufactured substances has already been significantly reduced because the authorities of exporting countries can now easily check whether the orders they receive tally with the current needs of importing countries.

C. Key elements of assessments for psychotropic substances

Assessments for psychotropic substances should reflect the total annual medical and scientific needs of each country or territory.

Four elements should be included in assessments in order to quantify total domestic requirements:

- (a) Quantities to be imported for domestic use;
- (b) Quantities to be manufactured domestically;
- (c) Quantities to be used for the manufacture of other psychotropic substances;
- (d) Quantities to be used for the manufacture of non-psychotropic substances.

Assessments should reflect the country's previous practices and the information collected from manufacturing and trading companies. Governments are advised that quantities to be imported and quantities to be manufactured domestically should be included in the assessments, whereas quantities destined for export and re-export should be indicated separately. However, the competent authorities of the importing country should indicate on the import authorization that all or some of the quantity imported will be used for export or re-export, so as to inform the competent authorities of the exporting country in cases when the assessments do not cover the quantities to be imported.

Quantities needed for industrial purposes should also be reported, and the purpose should be indicated. Governments may wish, for example, to inform INCB that a part of the quantity of a certain psychotropic substance that is required reflects the use of that substance in the manufacture of another psychotropic substance or of a non-psychotropic substance or chemical product.

Quantities of psychotropic substances to be used for the manufacture of pharmaceutical preparations (from an imported or manufactured bulk substance or its salt) should not be included in the assessments, as the quantities of the bulk substance will have already been taken into consideration.

Substances in Schedule I of the 1971 Convention have no medical use; therefore, the submission of assessments for those substances is not required from Governments. However, some Governments that import substances listed in Schedule I for scientific purposes should do so in accordance with article 7 of the 1971 Convention and may wish to request the assistance of INCB in contacting the authorities of the exporting country in order to allow such import.

Unlike the estimates required for narcotic drugs, assessments of the annual requirements for psychotropic substances are not required from Governments every year and do not have to be approved by INCB. However, with a view to providing guidance for manufacture and export, INCB recommends submitting revised assessments every three years.

Assessments of annual medical and scientific requirements for psychotropic substances are submitted on form B/P. While the assessments are to reflect requirements for one year, in order not to unduly burden national administrations, assessments are viewed as valid for three years from the date of submission, unless a new assessment is received by INCB.

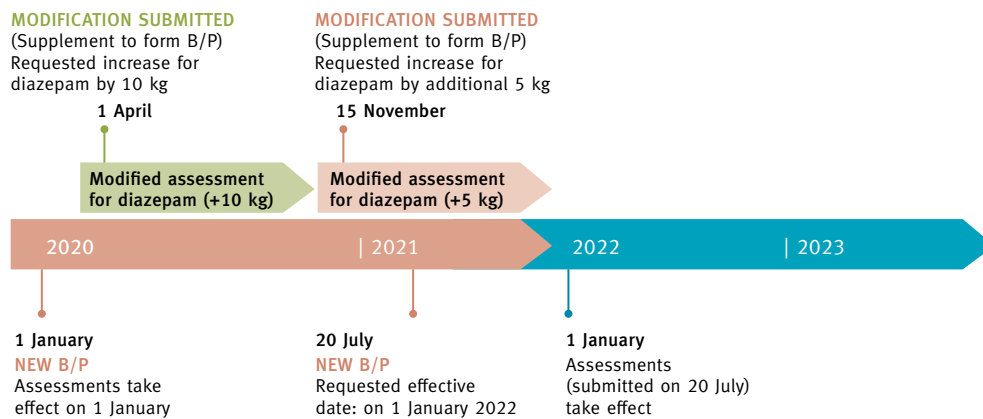
Revising and modifying assessments

Governments are free to modify their assessments at any time. When necessary, Governments should submit modifications using the supplement to form B/P, for instance, in order to add or reduce quantities needed, to add a new psychotropic substance, to replace a psychotropic substance used in the past or to add a psychotropic substance recently placed under international control. Unlike estimates for narcotic drugs, modifications to assessments for psychotropic substances submitted by Governments do not need to be confirmed by INCB. The supplement to form B/P is available on the INCB website.

KEY INFORMATION

Modifications submitted by countries alter only the established assessments that are in effect at the time when the supplement to form B/P is submitted to INCB. Modifications are not applied to previously established future assessments that have yet to come into effect. The following figure illustrates how modifications interact with established and future assessments for psychotropic substances.

Timeline for submission of assessments and modifications



D. Methods of assessing annual requirements for medical and scientific purposes

In order to establish assessments for psychotropic substances, the competent authorities should develop a method to accurately determine the legitimate requirements in their country. There are three methods that are commonly used to calculate medical and scientific requirements for psychotropic substances:

(a) **Consumption-based method.** This method is based on the use of substances in recent years. If the past use of psychotropic substances is stable and adequate, future requirements are calculated by averaging data on drug consumption in recent years and adding a margin for unforeseeable increases. This method cannot be used if no previous consumption information is available (e.g., for newly registered drugs), and in the case of rapidly changing needs or health-care systems, the calculation will result in inaccurate assessments;

(b) **Service-based method.** This approach is based on current levels of use of each substance in a sample of standard facilities. Data collected from those facilities can be extrapolated to calculate the requirements of other, similar facilities. This method targets the health services available and takes into account their current treatment levels, which may also reflect the financial and administrative constraints in a given country. However, it does not account for the needs of patients for whom the current health system is inaccessible for geographical, financial or cultural reasons;

(c) **Morbidity-based method.** In this method, the theoretical ideal need is calculated for the population, which usually results in the most generous quantities. This method is based on an epidemiological assessment of a country's diseases and health problems and on accepted or devised treatment norms.

These methods may be used alone or in combination, depending on available data. Similar methods are used for the calculation of estimates of narcotic drugs.

Further detailed information on each method is contained in the Guide on Estimating Requirements for Substances under International Control, which is available on the INCB website.

E. Establishing and calculating assessments

Having established an assessment method, the competent authorities should identify substances required for domestic needs and calculate the assessments. In the process, the following could be also taken into account:

- (a) Which substances are required for treating health problems in the country;
- (b) How much of each substance is required to meet the medical and scientific requirements of the population, including in rural and remote areas;
- (c) Procedures in place for selecting suppliers, monitoring orders and deliveries and determining the available budget;
- (d) Procedures and capacity of the country and operators to receive, distribute, store, transport and control psychotropic substances;
- (e) Procedures related to the use of those substances, i.e., prescription policies, dispensing and use of substances, and control over patients' compliance with prescriptions;
- (f) Past imports and exports;
- (g) Information on past performance by manufacturers, for example, actual quantities manufactured, sold and used in the manufacture of other substances, and stock levels.

Competent authorities should obtain quantities foreseen from operators (e.g., manufacturers, importers and exporters) in their countries to compare with the calculated assessments. Data from operators may be compared against:

- Quantities of controlled substances required for medical purposes as determined by the quantification process. In particular, quantities imported or manufactured for domestic use should not exceed the calculated requirement.
- Quantities of controlled substances imported in recent years, taking into account new health-care developments such as the introduction of a new medicine.
- Quantities manufactured or used for the manufacture of other drugs in recent years, taking into account changes in manufacturing practices.
- Assessments furnished by countries with comparable socioeconomic situations.

While information from operators is crucial, operators are only one source of information, and the information they provide may not be realistic.

Whenever possible, the information collected should not be limited to one year only, but related to a few years.

When important discrepancies arise between the newly established assessment of annual requirements on the one hand, and the calculated annual domestic requirements amended with past statistical data on industrial uses, stock levels and exports on the other, and cannot be explained by changes in population or other developments (new medicines, new health services, etc.), the method used for calculating the requirements and the resulting assessments established should be carefully checked and adjusted, as necessary. In particular, for countries that do not manufacture or export psychotropic substances, the assessments should be comparable to the calculated annual domestic requirements. The Board invites Governments to inform it of the methods used for calculating their annual requirements.

With regard to safety margins, depending on various factors, such as delivery delays, difficulties in transport and availability in endemic zones or unstable or conflict areas, the competent authorities may decide to add a certain margin to the total amount in order to prevent shortfalls and keep a buffer stock.

F. Role of the International Narcotics Control Board

The Board publishes and updates the forms used to submit assessments for psychotropic substances, namely, form B/P and the supplement to form B/P. The frequency of submission and submission deadline for each form are shown in the table below.

Form	Name	Frequency of submission	Submission deadline
Form B/P	Assessments of annual medical and scientific requirements for substances listed in Schedules II, III and IV of the 1971 Convention	At least once every three years	No fixed deadline
Supplement to form B/P	Modification of individual assessments	As necessary	Anytime

Detailed information on how to fill in form B/P and the supplement to form B/P is provided in chapter II.

The data received from Governments are published annually by INCB in its technical report entitled *Psychotropic Substances: Statistics for [...]* (available at www.incb.org). Assessments valid as at 1 January of a given year are included in table V of that report.

Updated assessments are published on the INCB website on a regular basis.

In line with its monitoring functions, INCB combines all assessments, checks regularly whether any countries imported or exported psychotropic substances in excess of the assessments applicable at the time of the import/export and brings the information to the attention of the countries concerned.

Ninety Governments regularly provide the Board with an assessment of their actual requirements for psychotropic substances for medical and scientific purposes. Some Governments furnish that information on a yearly basis. Other Governments submit only necessary modifications to previous assessments at any time.

CHAPTER II.

Guidelines for the preparation of form B/P and the supplement to form B/P

A. Green List

A list of psychotropic substances under international control, known as the Green List, is published annually by INCB to assist government officials, in particular those in drug control administrations and customs, in the execution of control functions required by the 1971 Convention. The Green List contains background information for the completion of the assessment of annual medical and scientific requirements for substances in Schedules II, III and IV of the 1971 Convention and any modifications to the assessments (form B/P and the supplement to form B/P), as requested by the Economic and Social Council in its resolutions 1576 (L) and 1981/7. More detailed information on the Green List is provided in module IV, Guidelines for the preparation of reports to the International Narcotics Control Board.

The Green List is divided into three parts and is updated as necessary to include scheduling decisions of the Commission on Narcotic Drugs and any new related data made available to INCB.

Part one of the Green List lists all the substances included in Schedules I, II, III and IV of the 1971 Convention. Each substance is indicated by its international non-proprietary name (INN), as established by the World Health Organization, or its other non-proprietary or trivial names, as well as by a chemical name.

Part two of the Green List contains a table showing the theoretical percentage of anhydrous base content of bases and salts of psychotropic substances under international control. All reports, including form B/P and the supplement to form B/P, should indicate the quantity by weight of the theoretical percentage of anhydrous base of each psychotropic substance, excluding the weight of any non-psychotropic substance that may be compounded with it. The percentage indicated for each base or salt is approximate and may differ slightly from the actual percentage. However, in order to make the statistics, reports and documents universally comparable, those figures should always be used. For any base

or salt for which no theoretical percentage of anhydrous base content is indicated, the information should be obtained from the manufacturer, and INCB should be advised accordingly.

Conversion into pure anhydrous base

EXAMPLE 1

A country plans to import 2 kg of metamfetamine hydrochloride and 2 kg of metamfetamine bitartrate. The theoretical percentages of anhydrous base (conversion factors) indicated in the Green List are 80.4 and 49.9 per cent, respectively, meaning that the quantities above correspond to 1.608 kg and 0.998 kg of pure anhydrous base. Thus, the total annual assessment for the year in question should be reported as 2.606 kg on form B/P, as shown below.

Substance in salt form	Conversion into anhydrous base	Assessment
Metamfetamine hydrochloride 2 kg	Metamfetamine base 2×0.804	Metamfetamine 1.608 kg
Metamfetamine bitartrate 2 kg	Metamfetamine base 2×0.499	Metamfetamine 0.998 kg

Total quantity of assessment to be reported: metamfetamine; 2.606 kg.

EXAMPLE 2

In the case of preparations containing two or more psychotropic substances, the quantity of each of the component psychotropic substances should be mentioned in documents and reports.

For example, a country plans to import 18 kg of Binooctal. Each tablet of this preparation contains 50 mg of amobarbital sodium (42 per cent of the preparation) and 70 mg of secobarbital sodium (58 per cent of the preparation).

Therefore, 18 kg of the preparation Binooctal contains $18 \text{ kg} \times 0.42 = 7.56 \text{ kg}$ of amobarbital sodium. Applying a conversion factor of 91.1 per cent results in 6.89 kg of pure base substance. For secobarbital sodium, the same process is applied: $18 \text{ kg} \times 0.58 = 10.44 \text{ kg}$ of secobarbital sodium. After applying the conversion factor of 90.6 per cent, this corresponds to 9.458 kg of pure base substance.

On form B/P, 6.89 kg of amobarbital (listed under Schedule IV) and 9.458 kg of secobarbital (listed under Schedule II) should be reported, as follows:

Substance in salt form in the pharmaceutical preparation Binocetol	Percentage of the substance in the preparation	Conversion into anhydrous base	Quantity of assessment
Amobarbital sodium 18 kg	Amobarbital sodium $18 \times 0.42 = 7.56$ kg	Amobarbital base $7.56 \text{ kg} \times 0.911 = 6.89$ kg	Amobarbital 6.89 kg
Secobarbital sodium 18 kg	Secobarbital sodium $18 \times 0.58 = 10.44$ kg	Secobarbital base $10.44 \times 0.906 = 9.458$ kg	Secobarbital 9.458 kg

The last column shows the figures to be reported on form B/P as assessments for the given year.

B. Reporting assessments using form B/P

Form B/P was established by INCB to obtain from Governments information on the assessments of legitimate (medical and/or scientific) requirements for psychotropic substances in Schedules II, III and IV. The form is updated and distributed annually to all Governments and can be downloaded from the INCB website. The form should be used whenever a full revision of the assessments is made. In order not to unduly burden national administrations, assessments are viewed as valid until a new assessment is submitted to INCB. Nevertheless, INCB recommends that a full revision of all assessments be carried out at least every three years.

The information to be provided on page 1 of form B/P includes the name of the country or territory for which the information is provided, the date, the competent office, the name of the officer responsible and the officer's title or function and signature. The date as of which the new assessments are valid should also be specified.

Assessments are to be submitted in the standardized format. All quantities for substances in Schedules II, III and IV should be provided in grams. Fractions of grams should be rounded up (i.e., quantities below 1 g should be reported as 1 g). Quantities exceeding 1,000 g should be indicated in the appropriate column (kilograms).

EXAMPLE 3

Assessments of 3,400 g should be indicated as follows: 3 under the column for kilograms and 400 under the column for grams.

Assessments of requirements for substances in Schedule IV

Code	Substance	Kilograms	Grams
PD 006	Diazepam	3	400

An assessment of 350 mg should be indicated as follows: 1 under the column for grams.

Assessments of requirements for substances in Schedule IV

Code	Substance	Kilograms	Grams
PD 006	Diazepam		1

EXAMPLE 4

Country A requires approximately 120.5 kg of diazepam annually for its domestic use. Assessments for diazepam should indicate 120.5 kg (120 in the column for kilograms and 500 in the column for grams).

Country A should report on form B/P:

Assessments of requirements for substances in Schedule IV

Code	Substance	Kilograms	Grams
PD 006	Diazepam	120	500

EXAMPLE 5

Country B requires approximately 100 kg of metamfetamine (a substance in Schedule II) annually, which are converted into benzfetamine (a substance in Schedule IV). The quantity to be indicated as an annual legitimate requirement in the country for metamfetamine would be 100 kg (100 in the column for kilograms).

In this instance, the Government should explain that the 100 kg are destined for conversion into another psychotropic substance. Such additional information provided by the Government would appear as footnotes in the technical report of INCB on annual assessments for psychotropic substances (table V).

Country B should report on form B/P:

Assessments of requirements for substances in Schedule II

Code	Substance	Kilograms	Grams
PM 005	Metamfetamine	100 ^a	

^a100 kg to be converted into benzfetamine.

C. Reporting modifications to assessments (supplement to form B/P)

Governments wishing to modify the assessments of psychotropic substances for their countries or to submit additional assessments are required to use the supplement to form B/P. This form can be submitted to the Board anytime during the year and should include the reasons for modifications. Quantities entered in the supplement to form B/P will be added to or deducted from previously submitted assessments. A copy of the supplement to form B/P can be downloaded from the INCB website.

In the supplement to form B/P, competent national authorities are required to indicate all quantities of substances in Schedules II, III and IV that are to be added to (+) or deducted from (-) the previously submitted assessments. All quantities should be provided in grams. Fractions of grams should be rounded up (i.e., quantities below 1 g should be reported as 1 g). Quantities exceeding 1,000 g should be indicated in the kilograms column of the form.

EXAMPLE 6

Country A submitted an annual assessment (on form B/P) for diazepam of 700 g, but needs to increase its annual assessment to 2 kg. Therefore, the amount to be added to the original annual assessment is 1,300 g. Country A should indicate the following on the supplement to form B/P:

Code	Substance	Quantity	
		kg	g
PD 006	Diazepam	+1	300

Annex

Comparison of the estimate system under the 1961 Convention as amended with the assessment system under the 1971 Convention

	Estimates for narcotic drugs	Assessments for psychotropic substances
Form	B	B/P
Period covered	One year (e.g., 1 January to 31 December)	
Frequency of submission	Once a year	Recommended at least once every three years
Deadline for submission	30 June of the preceding year	Anytime
Approval by INCB	Required	Not required
Validity	Until 31 December of each year	Until amended
Publication	INCB technical publication and website (www.incb.org)	INCB technical publication and website (www.incb.org)
Modifications/ amendments	Yes, anytime (using supplement to form B)	Yes, anytime (using supplement to form B/P)
Publication of modifications	Monthly, on INCB website	Regularly, on INCB website





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Psychotropics Control Section