

TRAINING MATERIAL

1961 SINGLE CONVENTION ON NARCOTIC DRUGS

PART 2:

**THE ESTIMATES SYSTEM FOR
NARCOTIC DRUGS**



TABLE OF CONTENTS

<u>PART 2</u>	<u>PAGE</u>
INTRODUCTION.....	3
I. GENERAL INFORMATION FOR THE PREPARATION OF ESTIMATES	3
1. UNDERSTANDING KEY CONCEPTS	3
2. WHICH NARCOTIC DRUGS ARE NEEDED.....	7
3. ABOUT THE NARCOTIC DRUGS DISTRIBUTION CIRCUIT	8
4. METHODS OF DETERMINING THE QUANTITIES NEEDED	9
5. CONSIDERATIONS FOR THE DETERMINATION OF STOCK ESTIMATES.....	11
6. PRACTICAL EXAMPLES : DETERMINATION OF THE ESTIMATES FOR CONSUMPTION AND STOCKS.....	12
II. GUIDELINES FOR THE PREPARATION OF FORM B.....	14
1. BACKGROUND INFORMATION	14
2. HOW TO INDICATE QUANTITIES ON FORM B.....	14
3. GUIDELINES FOR COMPLETING FORM B	15
<i>Cover page</i>	16
<i>Part I. Background information and statement of method(s)</i>	16
<i>Part II. Annual Estimates of Requirements of Narcotic Drugs</i>	16
<i>Part III. Annual estimates of the manufacture of synthetic narcotic drugs</i>	19
<i>Part IV. Annual estimates of opium production</i>	20
<i>Part V. Annual estimates of the cultivation of the opium poppy for purposes other than opium production</i>	20
III. SUPPLEMENTARY ESTIMATES	21
1. WHAT IS A SUPPLEMENTARY ESTIMATE?	21
2. HOW TO FILL IN THE SUPPLEMENT TO FORM B	22
3. COMMON EXPLANATIONS FOR THE NEED FOR SUPPLEMENTARY ESTIMATES	22
4. CONFIRMATION AND PUBLICATION OF THE AMENDED ESTIMATES	22
IV. ACTIONS TAKEN BY INCB CONCERNING THE ESTIMATES SYSTEM INCLUDING DIALOGUE WITH GOVERNMENTS	23
1. ESTABLISHING ESTIMATES FOR GOVERNMENTS WHICH FAIL TO FURNISH THEM	23
2. EXAMINING ESTIMATES RECEIVED FROM GOVERNMENTS AND REQUESTING CLARIFICATIONS, AS NECESSARY.....	23
3. MODIFICATIONS OF ESTIMATES BY THE BOARD - ADJUSTMENT TO STOCKS	24
4. PUBLICATION OF THE ESTIMATES	25
5. ENSURING THAT MANUFACTURE AND IMPORTS ARE WITHIN THE LIMITS OF THE ESTIMATES ..	26

INTRODUCTION

1. The Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (referred to further in the text as “Single Convention”) established a dual obligation for Governments: Governments should ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes. At the same time they should limit the availability of narcotic drugs to the medical and scientific needs of the countries. In order to achieve this objective, it is the responsibility of each Government, inter alia, to determine the legitimate requirements for narcotic drugs in its own country and to submit the estimates of those requirements to the International Narcotics Control Board (INCB) every year. After the estimates have been determined by the Government and confirmed by INCB, a country may legally manufacture or import narcotic drugs.

2. This document is intended to provide guidance for drug control officials on how to prepare estimates for narcotic drugs and furnish them to INCB, based on the provisions of the Single Convention. It also explains when and how these estimates might be modified during the year to which they pertain, as well as the impact of those modifications on the amounts that might be manufactured or imported during that year. Lastly, this document summarizes the actions taken by INCB related to estimates, in particular, how INCB monitors that estimates are realistic and actual amounts manufactured or imported correspond to legitimate requirements.

I. GENERAL INFORMATION FOR THE PREPARATION OF ANNUAL ESTIMATES

1. Understanding key concepts

Consumption as defined by the Single Convention

3. In accordance with article 1, paragraph 2, of the Single Convention, a drug shall be regarded as “**consumed**” when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research. Consumption is therefore defined as the transfer from wholesale to retail distribution. Consequently, if narcotic drugs are imported into a country or territory directly by retailers (pharmacists, hospitals, etc.), all quantities so imported should be considered, from the Convention’s point of view, as consumed during the year of their entry into the country or territory. If, on the other hand, there is a manufacturer or wholesaler (whether a private enterprise or a government service) through which all narcotic drugs are imported, only that part of narcotic drugs distributed to the retail level (mainly pharmacies and hospitals) should be considered as consumed.

4. Below is a succinct explanation of what consumption means in different distribution circuits (please see the definition of these circuits below).

Category I: Countries where the retailers obtain their supplies solely from abroad

In this case, all quantities imported should be regarded as consumed. This is the only case in which the equation “consumption equals import” is valid.

Category II: Countries where the retailers obtain their supplies solely from local manufacturers or wholesalers

In this case, quantities consumed refer to those quantities of narcotic drugs distributed by the manufacturers or wholesaler(s) to the retailers.

Category III: Countries where the retailers obtain their supplies mainly from local manufacturers or wholesalers, but where some retailers import narcotic drugs directly

In this case, quantities consumed refer to those quantities of narcotic drugs distributed by the manufacturers or wholesalers to the retailers, plus the quantities of narcotic drugs imported directly by retailers.

Drug requirements

5. Under the Single Convention, the expression “drug requirements” refers to the quantities of drugs which will be used in the country for medical and scientific consumption, manufacturing of Schedule III preparations, manufacture of other narcotic drugs or substances not controlled under the Single Convention, and for addition to “special stocks” or ordinary stocks. Drug requirements may be covered from imports, manufacture, previous stocks, seizures released for licit purposes, etc.

6. Estimates need to be furnished for drug requirements, regardless of how the drugs will be obtained. For example, if quantities required for consumption are expected to be withdrawn from stocks held in the country, estimates should be furnished for the quantities to be consumed, despite the fact that no imports are envisaged.

Estimates for imports or exports of narcotic drugs

7. It should be noted that the Single Convention does not provide for any estimate of imports. What it does provide for is a “limit on imports” (article 21) which is indirectly dependent on the estimates (see the explanations on the “total of estimates”). As a general rule, if the limits set by the estimates of drug requirements furnished by Governments and confirmed by the Board, are not exceeded, there should be no difficulty in importing the quantities desired.

8. Similarly, the Single Convention also does not provide for any estimate of exports. However, stock estimates for narcotic drugs should include the amounts necessary to allow the export during the following year. Since exports are difficult to forecast, stock estimates should also provide for the possibility of unexpected or emergency orders.

9. By the same token, a country or territory which imports a given quantity of a narcotic drug in order to re-export it in its entirety in the course of the same year does not need estimates covering the quantities to be imported or exported. The intention to re-export the drug, should, however, be clearly stated in the import certificate. However, if the drug will be partly or entirely re-exported in the following year, the estimate for stocks of the drug in question, to be kept by a wholesaler or manufacturer at the end of the year under consideration, should include the amounts of drugs which will be re-exported in the following year.

Preparations included in Schedule III of the Single Convention

10. Preparations included in Schedule III of the Single Convention are exempted from some control measures foreseen by that Convention, in view of their relatively small narcotic drug content. Also, in the presence of other components, it is felt that these preparations are not liable to abuse and cannot produce ill effects, and that the drugs contained therein are not readily recoverable. The list of preparations included in Schedule III of the Single Convention is amended from time to time by the Commission on Narcotic Drugs, in accordance with the procedure laid down in article 3 of that Convention. This list is published annually by the Board in Part 2 of the *List of Narcotic Drugs under International Control* ("Yellow List").

11. Because of the above, Governments should not furnish estimates on consumption or stocks of Schedule III preparations. Governments should furnish only estimates on the quantities of base drug used for their manufacture. It should be noted that the manufacture of Schedule III preparations that takes place at the retail level should not be included in such estimates, since in that case the drug in question is assumed to have already been "consumed" under the Single Convention. Governments should furnish estimates on the use of base drugs for manufacture of Schedule III preparations for the year when such use will take place, regardless of when those preparations will finally be disposed off, and regardless of whether those preparations are destined for domestic consumption, for stocks, or for export.

Stocks as defined by the Single Convention

12. "Stocks" under the provisions of the Single Convention are understood as the quantities of drugs held in a country or territory and intended for:

1. Consumption in the country or territory for medical and scientific purposes;
2. Utilization in the country or territory for the manufacture of other narcotic drugs, preparations included in Schedule III of the Single Convention and substances not controlled under the Single Convention, or
3. Export;

but do not include the amounts of drugs held in the country or territory:

4. By retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions, or
5. As "special stocks" (please refer to article 1, paragraph 1, subparagraph (w), of the Single Convention, or paragraph 68 below, for a definition of special stocks).

13. This definition implies that countries having a distribution circuit of the Category I type (see the part on the narcotic drugs distribution circuit) do not have stocks in accordance with the Single Convention.

14. Only quantities of narcotic drugs held in reserve by manufacturers and wholesalers at 31 December of the year to which the estimates relate, are regarded as stocks. However, they should also include stocks to be held in bonded warehouses, free ports or free zones. Stocks

may be in the form of base drug, or in the form of preparations; however, preparations included in Schedule III of the Single Convention should not be included. It is understood that manufacturers or wholesalers may be private companies or State establishments. In the latter case, it is important not to confuse “special stocks” intended for military purposes and to meet exceptional circumstances, with stocks held in reserve for the normal needs of the civilian population.

15. Stocks fulfil two main functions. Firstly, manufacturers or wholesalers may receive orders from retailers or from abroad on a daily basis, whereas manufacture, or import may sometimes take several months. Secondly, stocks constitute a reserve against any delay or temporary breakdown in supply. Therefore, stocks allow fulfilling orders on an ongoing basis.

Total of estimates

16. In accordance with article 19, paragraph 2, of the Single Convention, the Board calculates the provisional total of estimates for each narcotic drug and for each country and territory. This total is the sum of the estimated quantities to be consumed or utilized (columns 1, 2, and 3 of Part II of Form B, for details see Chapter II, Part 3, of this document). In case of a synthetic drug, the estimate of the quantity to be manufactured (Part III of Form B, see Chapter II, Part 3, of this document) is compared with this sum, and the provisional total of estimates is whatever is higher. In accordance with article 21 of the Single Convention, the provisional total of estimates for each drug furnished by Governments is also the provisional limit of import. Countries should therefore not import quantities of narcotic drugs in excess of this provisional total of estimates. In addition, the provisional total of estimates for each drug serves as a guideline for exporting countries and is therefore published annually in the Board’s technical report “Narcotic Drugs: Estimated World Requirements for (year) – Statistics for (year)” and its monthly supplements. In accordance with article 31 of the Single Convention, the competent authorities of exporting countries should not authorize the export of quantities of drugs exceeding this provisional total of estimates.

17. During the year to which the estimates pertain the Board calculates the final total of estimates, upon receipt of all statistical reports for narcotic drugs for the preceding year. The final totals of estimates become the new limits of import and are published by the Board in the following monthly supplements to the above-mentioned technical report to serve as guidance to exporting countries. See Chapter IV, modifications of the estimates by the Board – adjustments to stocks and publication of the estimates, for details.

Validity of estimates

18. The estimates of narcotic drug requirements furnished by Governments are valid only for the year to which they relate (from 1 January to 31 December) and are not transferable to the following year.

What constitutes an “adequate” estimate?

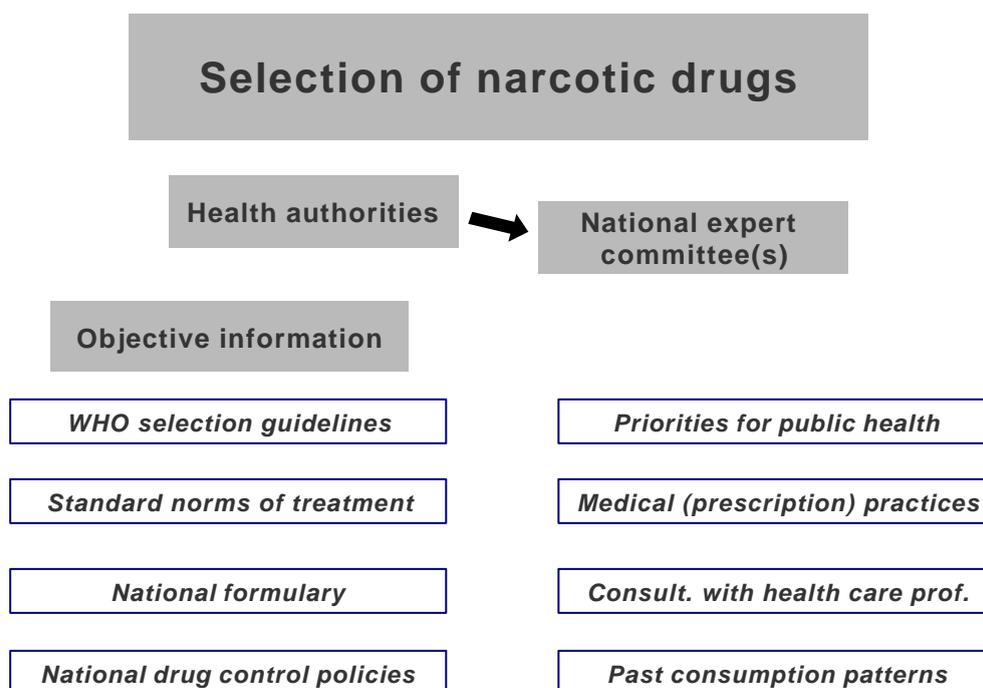
19. This question is more easily answered *a posteriori*, i.e. after the year to which the estimate relates has elapsed, as by that time a solid criterion is available, namely, the corresponding statistic on actual developments. An estimate can usually be considered “good” if it shows a maximum deviation of approximately 15 per cent from the corresponding statistic.

20. In order to prepare “adequate” estimates, officials should use a sound method, i.e. a method that has yielded satisfactory results in the past. In addition, they should test the method regularly, to modify it or to abandon it in favor of another, as required (see the part on methods for preparing estimates for more detail). Periodic official surveys, whether relating directly to consumption of narcotic drugs or only to the factors influencing consumption, will assist in evaluating the adequacy of previously furnished estimates and will make forecasting of future needs easier.

2. Which narcotic drugs are needed

21. In a well established health regulatory system, the determination of which drugs should be available in the country is usually dealt with by the national health authority, through a committee such as a “pharmaceutical or pharmacological or therapeutic committee” that provides the necessary guidelines and criteria for selection of drugs to be used in the country. This committee should prepare a list of essential drugs or national formulary to include the drugs approved to treat the main diseases affecting the population of the concerned country. Drugs included in this list or formulary should be the ones selected for manufacture or import to cover the medical needs of the population. To assist Governments, in particular, those of developing countries, who may find it difficult to select the most adequate drugs for their health needs, WHO proposed model or guiding lists of essential drugs.

22. It should be understood that the selection of essential drugs is a continuing process, which should take into account changing priorities for public health action and epidemiological conditions, as well as progress in pharmacological and pharmaceutical knowledge. The following graph describes the sources of information to be used by the competent authorities when determining the selection of narcotic drugs to be manufactured or imported.



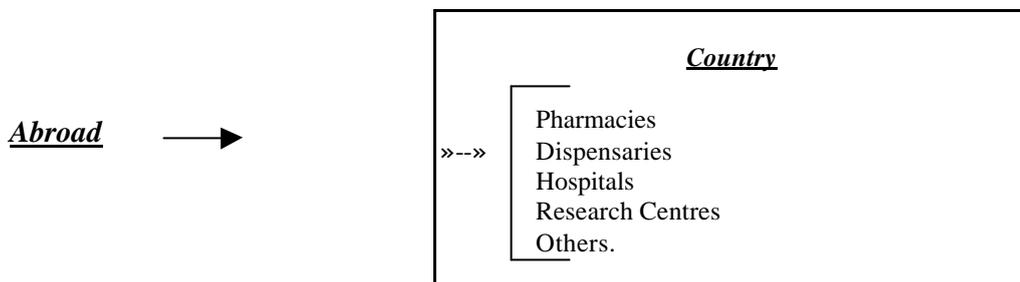
3. About the narcotic drugs distribution circuit

23. The supply of narcotic drugs for medical and scientific purposes in a country is obtained either from domestic manufacture or imported from another country or both. In general, the supply of narcotic drugs is then distributed by manufacturers or wholesalers to pharmacies and hospitals for subsequent provision to the patients by health care personnel. The participants in the drug distribution chain include the national competent authority, importing and exporting companies, manufacturers (manufacturing narcotic drugs), compounders (companies manufacturing preparations containing narcotic drugs), wholesalers, and retailers (pharmacies, hospitals, medical institutions, physicians, dentists, veterinarians, dispensaries, and scientific research centers).

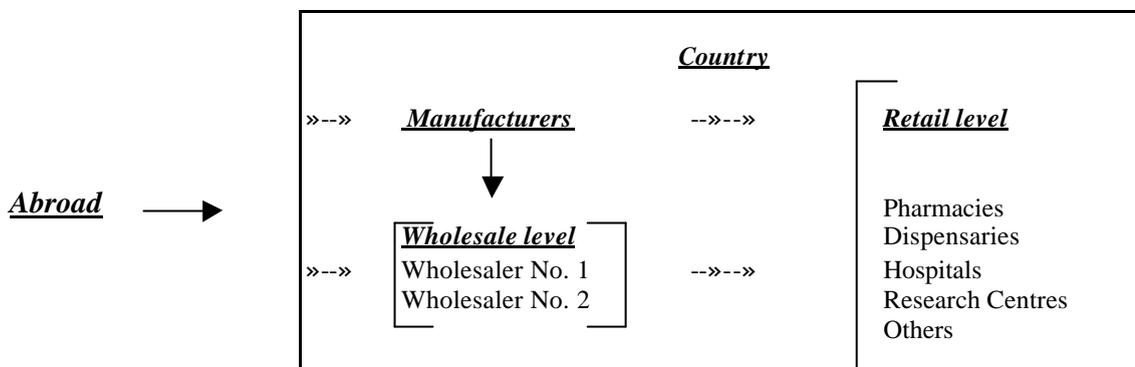
24. The definitions of consumption and stocks given in the Single Convention are legal definitions based on the distinction between the wholesale and the retail distribution circuits. Estimates for, and statistics on, narcotic drugs will therefore be reliable only if they are based on an accurate knowledge of the distribution circuit of narcotic drugs in the country concerned.

25. Distribution circuits may be divided into three different categories, according to the retailer's sources of supply, as shown below. The arrows indicate the direction of movements of narcotic drugs.

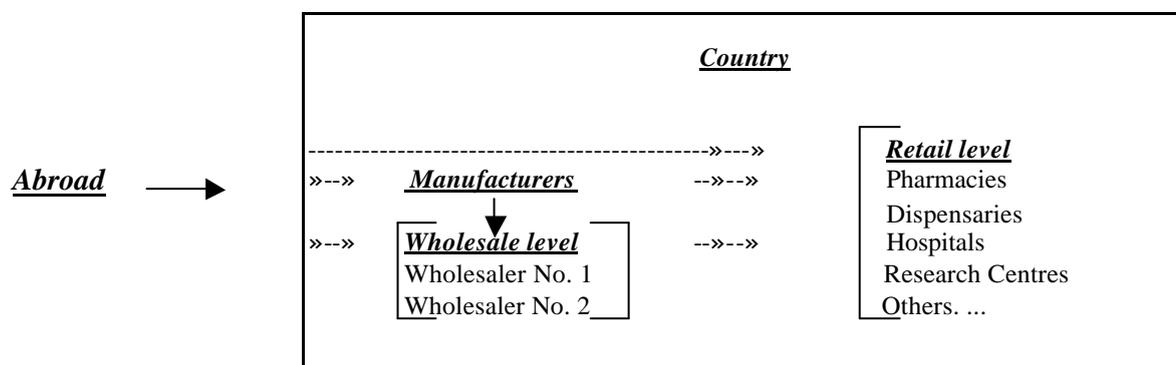
Category I: *Retailers obtain their supplies solely from abroad*



Category II: *Retailers obtain their supplies solely from local manufacturers or wholesalers*



Category III: *Retailers normally obtain their supplies from local manufacturers or wholesalers, although some also obtain supplies from abroad*



26. Depending on the distribution category, “consumption” may require different calculations of estimates and statistics. For each distribution category described above the definition of consumption can be found under “Understanding key concepts”.

4. Methods of determining the quantities needed

27. Estimates of narcotic drug requirements are based on forecasts. In planning the needs, several considerations have to be taken into account. For economic reasons, and to prevent unnecessary accumulation of stocks which might lead to diversion, estimates of excessively high quantities should be avoided. On the other hand, a shortage due to incorrect planning may result in delay in the procurement and distribution process and affect negatively the care of patients.

28. It is a common practice to base the estimates on empirical values such as past utilization of the drugs in question. In addition, population and morbidity statistics, where available, have to be taken into account for appropriated planning. Also, the accepted norms of medical treatment, in particular the prescription practices followed by the doctors (average length of treatment, dosage forms of the narcotic drugs used, etc.), results of epidemiological profiles (which diseases are particularly relevant) as well as the type of health services provided, could be sources of information.

29. In a well established drug supply system the determination of drug requirements is usually a matter of systematically monitoring drug supplies and regularly replenishing them as they are utilized. But when a new drug supply programme is being established, when an existing programme is being reorganized, or when current consumption patterns suggest inefficient or irrational drug use, then a more methodical approach to determine drug requirements is needed. Based on the main source of information used, there are three basic methods for estimating drug quantities. As can be seen below, all these methods have advantages and disadvantages; therefore, it is recommended to use a combination of them:

- Population-based: This method determines the theoretical “ideal” need for the population, and results usually in the most generous quantities of the three methods available. It is based on an epidemiological assessment of a country’s most important diseases and health problems and on accepted or devised treatment norms for the diseases in question, taking into

account the entire population. If resources for purchasing drugs are limited, this method may not be the most appropriate.

- Service-based: This method targets the health services available. Estimates are based on the capacity of the health services and health resources available (the number and types of health providers available and the diseases they will be likely to treat) and include therefore the financial and administrative constraints in a given country. However, this method does not take into account the needs of patients for which the current health system is inaccessible for geographical, financial or cultural reasons.

- Consumption-based: This method is based on past health demands. In the absence of Government data on previous drug utilization, information may be gathered from commercial sources (where available) and private voluntary organizations. In practice, an average of recently observed values is used in forecasting consumption to eliminate the randomness of past demand (“Moving Averages”). Consumption-based estimates are useful where good historical data on drug consumption exists, and where demand for health services has reached a steady state. In such cases it is the easiest method to use. However, where no previous consumption information exists (for example, in case of newly-registered drugs), this method cannot be used, and in case of rapidly changing needs or health care systems, the estimates based on past demand will result in inaccurate estimates.

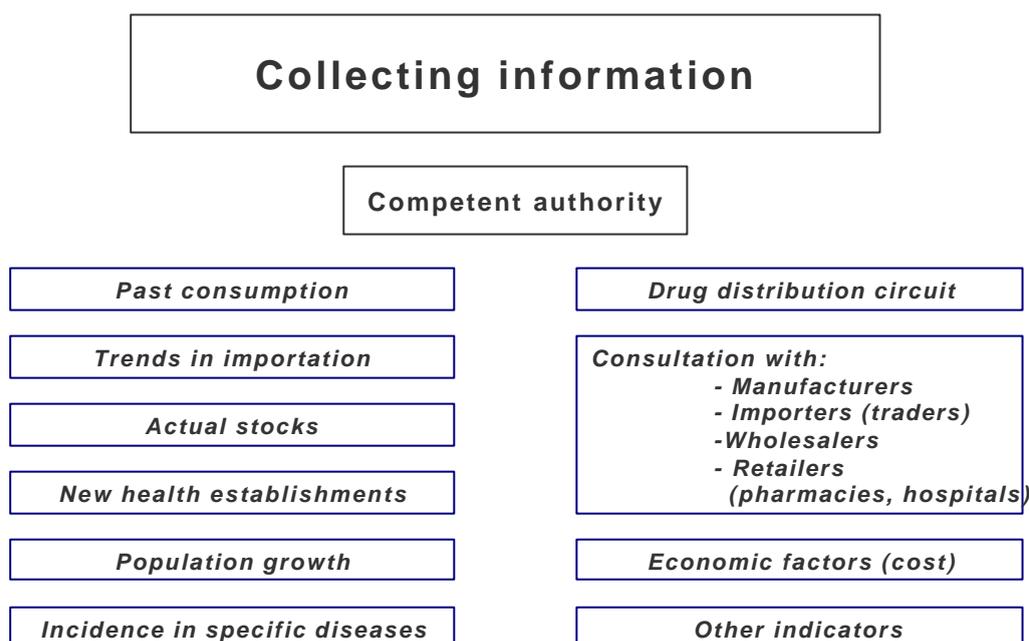
30. No model method can be proposed that will be applicable to all situations which may occur in practice. Some Governments do not use a theoretical method at all, but rely, for example, on the sales predictions of wholesalers. These predictions may be unrealistic; however, if they have proven accurate in the past, they may be taken into consideration. In addition, regardless of the method used to determine the estimates, estimates have to be tested annually to make sure that they prove sufficiently close to actual requirements; if not, the method must be altered. In the absence of an ideal method, the Board suggests a few ways (see below) of preparing estimates of narcotic drug requirements for substances which are in regular use and not subject to major fluctuations.

31. Primarily, the Board recommends using past demand as a base to determine estimates, in the absence of circumstances that might warrant a change. If past consumption trends for narcotic drugs are stable, future needs can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. Governments should add to their annual estimates of requirements for narcotic drugs a margin of 10 per cent for narcotic drugs included in Schedule I of the Single Convention, and 20 per cent for the narcotic drugs included in Schedule II, to allow for the possibility of increased consumption because of population growth, evolution of health services and trends in the incidence of diseases and their treatment.

32. If on the other hand medical needs for one or more narcotic drugs are increasing in response to unmet needs, the method of estimation should take into account the extent of unmet needs and the potential effects on future demand of efforts to improve the rational use of narcotic drugs. To that purpose Governments should establish a system to collect information from medical facilities that care for surgical, cancer and other patients, and from organizations that are working to improve the rational use of narcotic drugs. Also they should consult regularly manufacturers, distributors, exporters and importers to assist in obtaining information about changing medical needs. Governments might also use past consumption figures in countries with a comparable social and economic development. They should add a margin even greater

than 10 percent when there is rapid economic and social development or rapid expansion of the medical use of drugs, or in the case of introduction of new formulations or drugs.

33. Finally, Governments should periodically check existing supplies in order to maintain adequate supply levels. Initially prepared estimates may have under- or over-estimated demand. In particular, Governments should avoid furnishing the same estimates year after year, but adjust them taking into account information on the most recent actual utilization and changes in medical practice. Other factors requiring adjustments in estimates are changes in the delivery times for imports which might affect desirable stock levels, failure to reconcile needs and funds, losses due to damage, spoilage, expiration, theft, etc. The following graph summarizes the information which should all be considered when checking the validity of estimates.



5. Considerations for the determination of stock estimates

34. The methods described above assist in determining estimates for future use of drugs (mainly consumption, or use of the base drug in the manufacture of other narcotic drugs, substances not controlled under the Single Convention, or Schedule III preparations). For stock estimates, levels of stock maintained in the past are also important. However, in addition, trends in past exports, if applicable, the costs of maintaining large stocks and the need to avoid excessive stocks of drugs which might potentially lead to diversion should be kept in mind, as well as practical considerations, for example, the delivery time following orders for narcotic drugs.

35. In accordance with the definition of stocks by the Single Convention (the definition of stocks is explained in “Understanding key concepts”), estimates for stocks should only cover stocks held by the Government to meet the normal requirements of the civilian population, as well as the stocks held by the manufacturers, wholesalers and importers (whether they are private firms or individuals, as long as they are not retailers).

36. Small or thinly populated countries or territories might not hold wholesale or Government stocks because imported drugs are distributed entirely to retailers and “consumed” in terms of the Single Convention. Therefore, if the Government of such a country considers it necessary to provide for “stocks” held by retailers (pharmacies, hospitals, doctors, dentists, veterinarians, etc.) such quantities should be included in the estimates for consumption.

37. In most other countries on the other hand, in particular, those with a large population, wholesalers or manufacturers hold stocks of narcotic drugs, as defined by the Single Convention, since these stocks are essential to ensure a regular supply of medicines. The estimates of such stocks should not as a general rule exceed the requirements for utilization of the drug in question, including exports, if applicable, for one year. For narcotic drugs for which the demand is growing, or for countries remote from their normal sources of supply, stock estimates may reflect the requirements for two years. For countries which export narcotic drugs, stock estimates should include also additional quantities which will allow filling unexpected or emergency orders, or stocks to be held in bonded warehouses, free ports or free zones.

38. In addition, it should be noted that estimates of the amounts of drugs to be held in stock at the end of each year play a more important role in the Single Convention than in previous treaties. In particular, it is one of the aims of the Single Convention to avoid unnecessary accumulation of stocks. The estimates provided by Governments for a given year might therefore be modified during the year to which they pertain, depending on the actual stocks held at the end of the previous years. Please see the part on actions taken by INCB in relation to the estimates system (adjustments to stocks), for a detailed description of the relevant provisions of the Single Convention, and the resulting modifications of estimates done automatically by the Board. It is therefore in the interest of Governments to ensure that the estimates of stocks of narcotic drugs are not lower than the level of stocks actually held at the end of the previous year.

39. For example, if the amounts manufactured or imported during a year are neither utilized nor exported as foreseen, they will remain in stock at the end of the year. The stocks of the drug in question kept at the end of the year will therefore exceed the estimated stocks as previously furnished. In such cases the Governments in question should submit a supplementary estimate to bring the level of stocks to be held at the end of the year to a level more in conformity with existing or anticipated stocks.

6. Practical examples: Determination of the estimates for consumption and for stocks

Estimate for consumption

40. In this example, the estimate of the quantity of pethidine to be consumed in 2006 needs to be determined. In order to do so, a table is drawn up showing the estimates of consumption of pethidine from 2002 to 2005, and the corresponding actual consumption, as far as available. It is preferable to have a long series of figures, although statistics covering the last three years may be regarded as adequate. At the time this estimate is prepared (March 2005), the following information is available:

<u>Year</u>	<u>Estimates of consumption</u> (kg)	<u>Statistics of consumption</u> (kg)
2002	25	17
2003	25	15
2004	25	18
2005	25	-
2006	Figure to be determined	

The “estimates” column suggests that the estimates for previous years were prepared without the aid of any method, as the same estimate (25kg) was furnished for the past four years. Comparison of the two columns indicates that the estimated figures were, on average, 50 per cent higher than the actual figures.

If no additional information or alternative method is available, the estimate for 2006 can be prepared by taking the mean actual consumption for the years 2002 to 2004, increased by 10 per cent. In the example:

$$(17 + 15 + 18) / 3 \times 110\% = 18.333 \text{ kg} \rightarrow \text{which may be rounded up to 18.5 kg.}$$

41. As mentioned before, this method can produce satisfactory results in the cases of narcotic drugs for which the consumption is relatively stable or increasing only very slightly. It is necessary, however, to draw on a wider range of parameters when it comes to preparing estimates for drugs which have not been used in the country in the past, or when a major change in the consumption pattern is anticipated. For example, if a narcotic drug, which has recently come into use, replaces an old medicine, actual consumption of the latter can be taken as a basis for calculating the estimated consumption of the new medicine. If a considerable increase in the consumption of a drug already in use is expected because of the opening of a new hospital, the increase can be forecasted by comparing the capacity of the hospital (or any other relevant factor) with that of other hospitals in the country.

Stock estimate

42. The following method can be used for the calculation of stock estimates. A table should be prepared, showing for the past three years the total annual use of a given drug and the stocks held at 31 December of each year. A third column shows the period (in months) by the end of which the stock would have been exhausted if the rate of use remained unchanged. In the example below it is assumed that in a given country pethidine is used solely for domestic consumption.

<i>Pethidine</i>			
<i>Year</i>	<i>Consumption</i> (kg)	<i>Stocks held at</i> <i>31 December</i> (kg)	<i>Envisaged</i> <i>duration of</i> <i>stock</i>
2002	24	26	13 months
2003	22	20	11 months
2004	28	26	11 months

43. The table shows that in 2002, consumption was 24 kg, i.e. an average of 2 kg per month; the stocks of 26 kg would therefore last for 13 months. In 2003, consumption was 22 kg, i.e. an average of 1.833 kg per month; the stocks of 20 kg would therefore last for about 11 months. In 2004, consumption was 28 kg, i.e. an average of 2.333 kg per month; the stocks of 26 kg would in this case last for approximately 11 months.

44. In this example, stocks held at 31 December of each year would be enough to cover the consumption needs for approximately 12 months. The observation of developments in stock usage in the period under consideration may reveal whether stocks held at each year's end have been adequate or not. Based on these observations, the stock estimates can then be prepared. It may be felt, for example, that during a given year, the stocks came very near to running out and that, in order to avert this danger in the future, stock estimates should be raised to 15 months' consumption, instead of the average 12 months. In this case the stock estimate for 2006 could be calculated as follows:

The average consumption in the last three years is $(24 + 22 + 28) / 3 = 24.67$ kilograms

The average consumption per month is therefore $24.67 / 12 = 2.06$ kilograms

The desirable stock estimate for 2006 is therefore $2.06 \times 15 = 31$ kilograms

II. GUIDELINES FOR THE PREPARATION OF FORM B

1. Background information

45. Article 19 of the Single Convention requires Governments to furnish each year to the Board estimates of drug requirements. To assist countries and territories in complying with their reporting requirements, INCB provides all Governments, in the first quarter of each year, with copies of Form B (“Annual Estimates: Requirements of Narcotic Drugs; Manufacture of Synthetic Drugs; Opium Production; Cultivation of the Opium Poppy for Purposes Other than Opium Production”). Form B should be completed with data on the estimated requirements on narcotic drugs for the following year. Shaded areas indicate that the estimates in question are not required and those areas should therefore not be completed.

The completed form should reach the Board before 1 July of the year preceding that to which the estimates relate.

2. How to indicate quantities on Form B

46. Unless specified otherwise, quantities on Form B should be indicated in kilograms and grams without decimal points or commas, to avoid any confusion. Thus it would be preferable to express 1 gram as 001, 12 grams as 012, and so on. Generally speaking, for the purpose of estimates, fractions of grams should be omitted.

47. Quantities should be expressed in terms of the pure anhydrous drug content. For this purpose, Part 4 of the “*List of Narcotic Drugs Under International Control*” (Yellow List), which contains information on the pure anhydrous drug content of drugs listed in Schedules I and II of the Single Convention, should be consulted. Examples of how to make these

calculations are shown below.

Example 1: *Codeine phosphate*

The quantity estimated is 20 000 grams of codeine phosphate having a molecule and a half of water of crystallization (this information is usually provided by the manufacturer). According to the “Yellow List“, this salt contains 71 per cent of pure anhydrous codeine base. Therefore, the quantity to be reported to the Board is:

$$(20\,000 \times 71) / 100 = 14\,200 \text{ grams}$$

Example 2: *Pethidine hydrochloride in ampoules*

When an injectable ampoule contains a single dosage unit, its real volume exceeds its nominal volume by a percentage, which may vary between 3 and 24 per cent, depending on the nominal volume and the density of the liquid. The quantity to be reported to the Board should take into account only the nominal volume of the preparation and not the real volume.

Let us consider the case of a pharmaceutical product containing pethidine in ampoules, each ampoule having a nominal volume of 1 ml (and a real volume of 1.075 ml). The solution contains 0.1 gram of pethidine hydrochloride per milliliter. According to the “Yellow List“, this salt of pethidine contains the equivalent of 87 per cent of pure anhydrous base. Therefore, the nominal content in anhydrous pethidine base of one ampoule is:

$$0.1 \times 87 / 100 = 0.087 \text{ grams}$$

Example 3: *Morphine hydrochloride in tablets*

Let us take the case of a pharmaceutical product containing morphine in the form of tablets each containing 0.015 grams of morphine hydrochloride. The approximate pure anhydrous drug content of morphine hydrochloride (3H₂O) is 76 per cent. Therefore, the content of each tablet in terms of morphine base is:

$$0.015 \times 76 / 100 = 0.0114 \text{ grams}$$

Opium: Since opium is natural product, varying contents of alkaloids may be found in it. As the consistency of opium varies according to the moisture it contains, it is necessary to know its moisture content in order to determine the real weight of opium. To make estimates comparable, the Board requests that the weight of opium be calculated in terms of 10 percent moisture content, except in Part IV of the Form B (for that case see the specific guidelines below).

3. Guidelines for completing Form B

48. The Form is composed of a cover page, two pages of general instructions, and the following 5 parts:

- Part I: Background information and statement of the method
- Part II: Annual estimates of requirements of narcotic drugs
- Part III: Annual estimates of the manufacture of synthetic drugs

- Part IV: Annual estimates of opium production
Part V: Annual estimates of the cultivation of opium poppy for purposes other than the production of opium.

Cover page

49. The following information should be furnished:

- Name of the country or territory furnishing the estimates
- Date on which the form was completed
- Department or office from which the estimates furnished originate with the corresponding stamp (if available)
- Responsible officer's name
- Responsible officer's title/function
- Responsible officer's signature
- Year to which the estimates relate

50. The space provided under "Remarks" may be used for any additional information related to the estimates, which Governments may wish to make available to the Board.

Instructions

51. The instructions how to fill in Form B should be read carefully and should be referred to whenever there is some doubt on how to complete the Form.

Part I. Background information and statement of method(s)

52. In this part of the form, information on health resources and infrastructure should be furnished. In addition, a description of the method(s) used in the calculation of the various estimated requirements and of any changes in the said method, should also be furnished. There is also space for any other information which may be useful to the Board in examining the estimated drug requirements.

53. The description of the method should include an indication of how estimates have been calculated, and also the various elements which enter into the calculations. If the method used does not vary from one year to another, there is no need to report it each year on the form. However, it is highly important that a description of the method be given each time a major increase in the utilization of one or more narcotic drugs is anticipated or when an estimate is furnished for a narcotic drug which has not hitherto been used. It should, however, be remembered that an explanation is not required to accompany estimates of quantities of drugs to be added to "special stocks".

Part II. Annual Estimates of Requirements of Narcotic Drugs

54. The left most column of the tables on pages 7 and 8 lists the most commonly used narcotic drugs (except concentrate of poppy straw for which page 9 of Form B is reserved, see explanations below) in alphabetical order. Should a country or territory wish to furnish estimated requirements for a narcotic drug which is not listed, the empty rows on page 8 should be used for this purpose.

55. The remaining columns on pages 7 and 8 should be used for the submission of the relevant estimates for different purposes, as indicated by the columns' headings. These estimates should be furnished regardless of the means by which the drugs are to be obtained, whether by importation, acquisition from domestic sources (from a manufacturer or from stocks), or release of drugs seized from the illicit traffic. Furnishing of estimates for different purposes and regardless of the intended source enables the Board to obtain a more realistic overview of the total estimated requirements and facilitates the task of mutual verification by Governments and the Board.

COLUMN 1 QUANTITY TO BE CONSUMED FOR DOMESTIC MEDICAL AND SCIENTIFIC PURPOSES

56. In this column, the total estimated quantity to be consumed during the year to which the estimates relate should be entered. As explained above (see the definition of "consumption" under "Understanding key concepts"), the expression "quantity to be consumed" refers to quantities supplied for retail distribution for medical or scientific purposes.

57. Quantities dispensed through a national health scheme should be included in the estimates in this column, regardless of whether the scheme is administered by the State or not. Quantities used for scientific research should also be regarded as "consumed".

Consumption estimates should cover only domestic medical and scientific requirements, and not exports. Estimates for consumption should not include consumption of preparations included in Schedule III of the Single Convention.

COLUMN 2 QUANTITY TO BE UTILIZED FOR THE MANUFACTURE OF:
(2A) OTHER DRUGS
(2B) PREPARATIONS INCLUDED IN SCHEDULE III OF THE SINGLE CONVENTION
(2C) SUBSTANCES NOT COVERED BY THE SINGLE CONVENTION

58. Estimated quantities of narcotic drugs to be utilized for the manufacture of other drugs, Schedule III preparations or substances not controlled under the Single Convention should cover not only the domestic requirements, but also those for export. Column 2 is divided into three categories, which are described below.

COLUMN 2A QUANTITIES OF NARCOTIC DRUGS TO BE UTILIZED FOR THE MANUFACTURE OF OTHER DRUGS

59. This column concerns only countries and territories using narcotic drugs for the manufacture of other narcotic drugs (for example, countries manufacturing codeine from morphine). The estimates should refer to the quantities of the drug utilized (in the above example, morphine), and not to the quantities of the drug to be obtained.

60. Estimated quantities should include quantities utilized for the manufacture of isomers of narcotic drugs, and, in case of narcotic drugs included in Schedule I of the Single Convention, their esters and ethers. They should exclude, however, quantities needed for refining and for manufacture of preparations in the form of tablets or ampoules. Likewise, they should exclude quantities needed for the transformation of alkaloids into their salts.

61. As it is the case for columns 2b and 2c, drugs and substances which represent only intermediary stages in a continuous manufacturing process should not be taken into account, but only the final product. For example, in the continuous manufacturing of dihydrocodeine from morphine, codeine may be an intermediary product. In this case, only the quantity of morphine required for the manufacture of dihydrocodeine should be included in the estimates. However, when the intermediary product will remain in stocks or is going to be traded with other countries (for example, methadone intermediate and pethidine intermediate), separate estimates for these drugs have to be furnished.

62. As stated above, the requirements for drugs for manufacture of other drugs should include not only the requirements of the drug obtained for domestic consumption, but also for the replenishment of stocks, and for export, as applicable.

COLUMN 2B QUANTITIES OF NARCOTIC DRUGS TO BE UTILIZED FOR THE MANUFACTURE OF PREPARATIONS INCLUDED IN SCHEDULE III OF THE SINGLE CONVENTION

63. Schedule III preparations are exempted from certain provisions of the Single Convention, as explained in Chapter I, part 1“Understanding key concepts”. Please see the *List of Narcotic Drugs Under International Control* (Yellow List), published by the Board on an annual basis, for an updated list of preparations included in Schedule III of the Single Convention.

64. As far as estimates are concerned, Governments have to furnish only estimates for the quantities of narcotic drugs used in the country for the manufacture of these preparations. Such estimates must be furnished regardless of whether the preparations to be manufactured are to be consumed in the country, to be held in stocks or to be exported.

65. As stated in Chapter I, the quantities of narcotic drugs used for this purpose *by retailers* (hospitals, pharmacies) do not have to be taken into account for the estimates to be entered in this column, as these have already been considered as “consumed” and reflected in column 1.

COLUMN 2C QUANTITIES OF NARCOTIC DRUGS TO BE UTILIZED FOR THE MANUFACTURE OF SUBSTANCES NOT COVERED BY THE SINGLE CONVENTION

66. Substances not covered by the Single Convention include, for example, apomorphine, buprenorphine, nalorphine or naloxone, and flavoring agents obtained from coca leaf.

67. Estimated quantities in this column should cover the quantities of narcotic drugs to be utilized, and not the quantities of the substance to be obtained. For example, if apomorphine is to be obtained from morphine, an estimate is needed for the quantity of morphine to be utilized to manufacture apomorphine, whereas no estimates are needed for the quantities of apomorphine which will be obtained. Likewise, drugs obtained in intermediary stages in a continuous manufacturing process need not be covered by estimates. For example, heroin may be an intermediary product in a continuous process of the manufacture of nalorphine from morphine. In this case, only the quantity of morphine to be utilized needs to be covered by estimates and not the quantity of heroin obtained as an intermediary product.

COLUMN 3 QUANTITY TO BE ADDED TO SPECIAL STOCKS

68. “Special stocks” are defined in article 1, paragraph 1, subparagraph (w), of the Single Convention. “Special stocks” refer to the quantities of drugs held by Governments in a country

for “special Government purposes” (in particular for requirements of the armed forces) and to meet exceptional circumstances. “Exceptional circumstances” refer mainly to such catastrophic events as large-scale epidemics and major earthquakes.

69. No estimates regarding the quantities to be held in special stocks need to be furnished to the Board. However, estimates have to be furnished for the quantities required for the establishment of “special stocks” and/or for the quantities to be added to already existing “special stocks”. There is no requirement to provide the Board with any explanation in support of these estimates.

COLUMN 4. QUANTITY TO BE HELD IN STOCKS AT 31 DECEMBER OF THE YEAR TO WHICH THE ESTIMATES RELATE

70. The definition of stocks under the Single Convention and an explanation of the need for stocks are shown in Chapter I, part 1 “Understanding key concepts”. All Governments of countries where manufacturers or wholesalers sell narcotic drugs to the retail level should furnish estimates for the stocks held by the manufacturers and wholesalers by the end of the year under consideration. Only countries where retailers obtain their supplies directly from abroad need not furnish stock estimates.

71. In preparing stock estimates, care should be taken to strike a balance between two requirements: on the one hand, stocks must be large enough to provide a safeguard against any breakdown in supply. On the other hand, they must be kept within reasonable limits in order to reduce the risk of diversion into illicit channels.

Stocks of Schedule III preparations should not be included in the stock estimate.

Annual estimates of requirements for Concentrate of poppy straw

Page 9 of Form B is reserved for estimates of requirements for Concentrate of poppy straw (CPS). CPS is the material arising when poppy straw has entered into a process for the concentration of its alkaloids when such material is made available in trade. The alkaloid content in CPS, as well as the types of alkaloids contained in it, can vary, depending on the type of poppy straw used and on the industrial process applied in its manufacture. In order to ensure the comparability of data, the Board requests that the estimates furnished for CPS consist of the gross weight of CPS, as well as approximate percentages of the alkaloids it contains.

Part III. Annual estimates of the manufacture of synthetic narcotic drugs

72. The annual estimates of the manufacture of synthetic drugs concern only countries and territories where such manufacture is taking place.

73. For the purposes of preparing estimates and ensuring uniform interpretation of the term “synthetic drugs”, the definition proposed in the “Commentary on the Protocol Amending the Single Convention on Narcotic Drugs, 1961” is reproduced herein. “Synthetic drugs are all drugs appearing in Schedules I and II of the Single Convention, except those at present normally obtained from the opium poppy (its opium or straw), the coca bush or the cannabis plant.” The list of the synthetic drugs included in the Schedules I and II of the Single Convention is

reproduced on page 10 of Form B. Estimates for the manufacture of isomers of drugs contained in this list, and, in case of drugs included in Schedule I of the Single Convention, manufacture of the esters and ethers of those drugs, should also be furnished to the Board. However, manufacture of salts or preparations from synthetic drugs should not be included.

74. The information to be completed by the competent authorities refer to the quantities of each synthetic drug to be manufactured (in kilograms), and the name of the industrial establishment which will be engaged in the manufacture of the drug concerned. The term “industrial establishment” refers to the place of business of a drug manufacturer with its fixtures and organized staff, be the manufacturer an individual, a corporate entity or a state enterprise. Since a drug manufacturer may have several “establishments”, information and estimates must be given for each establishment separately.

Part IV. Annual estimates of opium production

75. This part of the form concerns only those countries and territories where the cultivation of the opium poppy is authorized for the purpose of opium production.

76. The following information should be furnished to the Board:

Column I	The names of regions in which the harvesting of opium is authorized or the geographical location of land used for the cultivation of the opium poppy for the purpose of opium production
Column II	The area of poppy cultivation for each region or geographical location (in hectares)
Column III	The approximate quantity of opium to be produced (in kilograms) and the percentage average moisture content

77. In column I, regions or geographical locations should include all those in which the production of opium is permitted in the calendar year to which the estimates relate, regardless of when the sowing takes place, in that year or in the preceding year.

78. In column II, the areas sown for the purpose of producing opium in the calendar year to which the estimates relate should be listed, even if the sowing took place in the preceding year. Areas should be expressed in hectares; 1 hectare is equivalent to 10 000 square meters.

79. In column III, the estimated quantities of opium to be produced should be entered for each region or geographical location (in kilograms), as well as an indication of the average moisture content. It is suggested that estimated quantities to be produced are calculated on the basis of the average yields during the past five years.

Part V. Annual estimates of the cultivation of the opium poppy for purposes other than opium production

80. This part of the form concerns only those countries and territories where the cultivation of the opium poppy is permitted for purposes other than opium production.

81. The following information should be furnished to the Board:

Column I	The geographical location of land used for the cultivation of the opium poppy for
----------	---

a) the production of poppy straw for the manufacture of narcotic drugs, and b) for culinary or horticultural purposes.

Column II The area (in hectares) of poppy cultivation for a) the production of poppy straw for the manufacture of narcotic drugs, and b) for nutritional or horticultural purposes.

82. In column I, the geographical location of the land used for the cultivation of opium poppy should be indicated, regardless of when the sowing takes place, in that year or in the preceding year. In column II, the area of poppy cultivation for each geographical location should be expressed in hectares; 1 hectare is equivalent to 10 000 square meters.

83. There are currently two main varieties of opium poppy cultivated for the extraction of alkaloids, one rich in morphine, the other rich in thebaine. Different alkaloids can be extracted from the poppy straw thus produced. Among them, codeine, morphine and thebaine are subject to the controls of the Single Convention. When cultivation of opium poppy is permitted for the extraction of alkaloids, separate estimates should be furnished for the cultivation of opium poppy rich in morphine and opium poppy rich in thebaine. In such case the estimates to be furnished to the Board should also include in column III the estimated quantities of the alkaloids controlled under the Single Convention to be obtained from the poppy straw (this information is required on a voluntary basis).

III. SUPPLEMENTARY ESTIMATES

1. What is a supplementary estimate?

84. Firstly, a supplementary estimate is any estimate which alters an estimate furnished originally by a Government. A supplementary estimate may increase or reduce the original estimate in order to adapt them closely to the requirements; it should be accompanied by an explanation of the circumstances necessitating it. Supplementary estimates should be furnished on a special form, "the supplement to Form B", which is communicated to all Governments together with Form B.

85. Even the most carefully calculated estimates based on sound methods may prove inadequate in the course of the year to which the estimates apply. This may happen, in particular, since Governments furnish to the Board their annual estimates of narcotic drug requirements as far as six months in advance of the year to which these estimates relate. The Single Convention provides therefore for the furnishing of supplementary estimates by which the original estimates can be modified to respond to changing circumstances and situations.

86. However, the Single Convention requires that Governments make the greatest possible effort to calculate the original estimates accurately, although these estimates may be revised through supplementary estimates. Supplementary estimates should be restricted as much as possible to unforeseen conditions.

87. Secondly, supplementary estimates are those furnished by Governments to revise estimates that were established by the Board. In accordance with article 12, paragraph 3, the Board establishes estimates for countries that have failed to furnish their own estimates. Governments are encouraged, however, to revise these estimates and communicate the revised estimates to the Board, preferably using Form B. The revised estimates will replace those established by the

Board. Those amended estimates are considered also as supplementary estimates when they are received during the year to which they pertain.

2. How to fill in the Supplement to Form B

88. The instructions given with respect to the cover page of Form B apply also for the first part of the Supplement to Form B (the year to which the supplementary estimate refers, the country concerned, the name of the authority furnishing the estimate, etc.).

89. In general, the instructions given with respect to Parts II and III of Form B apply also for the main part of the Supplement to Form B. However, in the Supplement to Form B Governments should provide only changes to the quantities furnished in the original Form B, that is quantities that are required in addition to the original estimate for the drug in question, or the quantities to be deducted from the original estimate. The (+) or (-) sign should be used to indicate whether the quantity in question is to be added to, or deducted from, the original estimate.

90. In accordance with article 19, paragraph 3, of the Single Convention, and as stated in the instructions for completing the Supplement to Form B, Governments must furnish explanations of the circumstances necessitating the requested change in the part of the form foreseen for such comments. Such explanations should include full details of the medical and/or scientific basis for the revision of the annual estimates. Without such explanations, the request for the supplementary estimate will be considered incomplete by the Board.

3. Common explanations for the need for supplementary estimates

91. The reasons why a change in drug requirements occurs vary from drug to drug and from country to country. Common reasons and explanations furnished by Governments tend to be:

Scientific purposes: the drug is to be consumed in scientific experiments and tests. As the requirements of the scientific community are difficult to forecast, the need for supplementary estimates may arise;

Sample and reference: in this case the supplementary estimates are intended to provide for the requirements of, for example, law enforcement agencies and judicial authorities;

Changes in demand or supply: the demand and supply of narcotic drugs are by no means constant but subject to short- as well as long-term changes. In most cases, such demand fluctuations and changes may be taken into account when preparing the annual estimates. In some cases, however, developments may not be easily foreseen, for example in the case of an epidemic or when new preparations are available for medical needs;

Changes in the manufacturing process: sometimes companies change the way narcotic drugs or preparations containing these drugs are manufactured; this may alter the estimates.

4. Confirmation and publication of the amended estimates

92. In accordance with article 12, paragraph 5, of the Single Convention, the request for a supplementary estimate is examined by the Board as soon as possible and the competent authorities are notified of the Board's decision to confirm the estimate in question, or to ask for

further clarification. The new estimate is in force once confirmed by the Board. The Board will also notify other relevant parties involved, such as exporting countries, of the confirmation of a supplementary estimate, if so requested by the competent authorities of the country furnishing the supplementary estimate. Finally, the Board will publish the amended estimate in the next supplement to the technical report “Narcotic Drugs: Estimated World Requirements for (year) - Statistics for (year)”, available in the worldwide web at the end of the month in which the estimate was received. In addition, on a quarterly basis the amended totals of the estimates are published in the supplement to the technical report: “Narcotic Drugs: Estimated World Requirements for (year) - Statistics for (year)”.

IV. ACTIONS TAKEN BY INCB CONCERNING THE ESTIMATES SYSTEM, INCLUDING DIALOGUE WITH GOVERNMENTS

1. Establishing estimates for Governments which fail to furnish them

93. Under the Single Convention, each country, regardless whether it is party or non-party to that Convention, must have estimates for its narcotic drug requirements, in order to be able to manufacture or import the narcotic drugs needed for its population. In accordance with article 12, paragraph 3, the Board must therefore establish estimates for countries or territories that have failed to furnish their own estimates. In doing so the Board usually relies on previous estimates of the countries in question. The Board then communicates the estimates it has established to the concerned Governments and requests them to revise these estimates in the light of the most recent needs and to inform the Board of those revisions, preferably by using Form B.

It is in the interest of Governments to establish their own estimates, and revise those established by INCB, since they have the best knowledge of actual needs for narcotic drugs in their country.

2. Examining estimates received from Governments and requesting clarifications, as necessary

94. The Board examines all estimates received from Governments, be they annual estimates or supplementary estimates, to check if they reflect actual requirements of the countries concerned. If in the opinion of the Board some of the estimates do not appear to reflect the legitimate requirements of the country concerned, the Board contacts the Government in question, either requesting clarification or additional information concerning those particular estimates, or requesting that they be revised. Only estimates of quantities of narcotic drugs for addition to special stocks cannot be queried by the Board.

It is in the interest of Governments to reply as expeditiously as possible to the queries of the Board concerning the estimates furnished, to avoid unnecessary delays in importing the drugs in question. In addition, responses received from Governments to such queries enable the Board to assess the status of control of narcotic drugs in the countries in question.

95. Depending on the reply received, and with the consent of the Government concerned, the Board will amend the estimate in question. In case of disagreement between a Government and

the Board concerning a particular estimate, the Board may establish, communicate and publish its own estimate, in addition to the estimate furnished by the country in question.

3. Modification of the estimates by the Board – adjustment to stocks

96. In accordance with the provisions of the Single Convention, the Board automatically modifies the provisional total of the estimates during the year to which they pertain, following receipt of all statistical returns for the preceding year, and calculates and publishes the final total of the estimates. These modifications may result in two possible outcomes.

97. In the first case, according to article 19, paragraph 2, of the Single Convention, the total of estimates will increase (addition to stocks). The final total of the estimates will include the quantities to be added to the actual stocks held at the end of the year preceding that to which the estimates refer, in order to bring the stocks to the estimated level. For example, let us assume that during 2004 country A furnished an estimate for stocks of pethidine of 7 000 grams to be held at the end of 2005. In June 2005 country A reports in Form C stocks of pethidine of 5 000 grams held on 31 December 2004. The provisional total of the estimates is then increased automatically by the Board by 2 000 grams, in order to allow country A to manufacture or import the additional quantities needed to bring the stocks of pethidine to the desired level of 7 000 grams.

98. In the second case, according to article 19, paragraph 2, and article 21, paragraph 3, the total of estimates will decrease (deduction from the total of estimates). The following paragraphs describe the circumstances under which such deductions take place and explain the calculations done by the Board in this respect.

99. Following receipt of the complete statistics for the preceding years the “limit of manufacture and import” is calculated automatically by the Board for that year, in accordance with its definition contained in article 21 of the Single Convention. Generally speaking, this limit for a given drug consists of the quantities corresponding to its actual needs (consumption, utilization in the manufacture of Schedule III preparations, utilization for the manufacture of other narcotic drugs and substances not covered by the Single Convention, quantity added to stocks, quantity acquired for special stocks) within the limit of the relevant estimate, and the quantity exported. “Within the limit of the relevant estimate” means that the corresponding estimated and actual figures are compared and the lower one is used in the calculation. From this sum are deducted the quantity seized and released for licit use and the quantity taken from special stocks for the requirements of the civilian population (if applicable). The limit of manufacture and import equals therefore the quantities of a drug which had to be manufactured or imported for domestic requirements and exports, since they could not be obtained from other sources such as seizures or special stocks.

100. Whenever the sum of actual manufacture and imports of a given drug during the preceding year was higher than this theoretical limit of manufacture and import, there was excess manufacture or import for that drug in question. This excess may have occurred because the estimates furnished for the uses of the drug in question were too low, because actual uses were lower than expected, or because exports fell short of expectations.

101. Whenever the excess was due to lower actual uses or exports than expected, such excess remained in stocks at the end of the preceding year. Only when such excess remained in stocks, and the stock estimate for the current year is lower than actual stocks held in the preceding year,

the Board will calculate a quantity to be deducted from the total of estimates in the current year. The idea behind this provision of the Single Convention is to re-establish the balance between supply and demand for narcotic drugs and to prevent accumulation of excessive amounts of stocks of narcotic drugs, by reminding the Government of the possibility of using existing stocks before importing or manufacturing additional quantities of the drugs in question. This deduction is therefore not a punitive measure, but a way of correcting an imbalance, which otherwise could result in a long-term oversupply of narcotics.

In practice, deductions from the total of estimates frequently result from missing or inadequate estimates for stocks to be held at the end of the current year, furnished in Form B. In such a case, Governments may resolve the problem by submitting to the Board a supplementary stock estimate for the drug in question, in order to continue manufacturing or importing that drug as planned.

4. Publication of the estimates

102. The following tables concerning estimates are included in the Board's technical report on narcotic drugs "Narcotic Drugs: Estimated World Requirements for (year) - Statistics for (year)":

103. TABLE A: ESTIMATED REQUIREMENTS OF NARCOTIC DRUGS FOR (YEAR). The table shows, for each country or territory, the provisional total of the estimates for the following year, at the date of the publication. This table serves three purposes: (a) the countries and territories that have furnished estimates are informed in this way that their estimates have been confirmed by the Board and that they have henceforth legal value; (b) the publication of the estimates enables parties to assess the manner in which they are discharging their mutual contractual obligations; (c) the totals of the estimates enable the parties to determine the maximum quantity of drugs that a State may acquire under the Single Convention through manufacture or import. Details of the estimates will be published two years later in the comparative statement of statistics and estimates, when the corresponding statistics are available.

104. To reflect amendments of the estimates, either because of supplementary estimates furnished by Governments, or because of adjustment to stocks as implemented by the Board, table A is updated by means of 12 monthly supplements available on the worldwide web. In order to facilitate the task of exporting countries to check the totals of the estimates, the 12 monthly supplements contain the whole of the updated information, not just data relating to the figures that have been amended. In this way each supplement replaces the published table A in its entirety. To accelerate transmission of the supplements to the competent national authorities, the supplements appears in English only. In addition, on a quarterly basis the amended totals of the estimates are published in the supplement to the technical report: "Narcotic Drugs: Estimated World Requirements for (year) - Statistics for (year)".

105. TABLE B: WORLD TOTALS OF ESTIMATES FROM (YEAR) TO (YEAR). Table B presents the world totals of estimates for six years, the last year being the year following that of the publication. For the first four years, this table includes both the original estimates furnished by the countries and territories or established by the Board and the estimates as they stand at the end of the corresponding year, i.e. including all the changes that may have occurred during the year due to supplementary estimates and/or adjustments to stocks. The totals of the estimates for the last two years shown are provisional and are liable to amendments in the light

of the supplementary estimates rendered necessary by unforeseeable changes, as well as by adjustments to stocks.

106. COMPARATIVE STATEMENT OF ESTIMATES AND STATISTICS FOR (YEAR). This table is a comparative table of estimates and statistics for the latest year for which information is available, i.e. the year preceding that of the publication. Its principal purpose is to enable parties to assess the manner in which they are discharging their mutual international obligations. In particular, it makes it possible to judge whether the estimates submitted were adequate, that is realistic in the light of the developments reflected by statistical data. In addition, while the other tables show only the total of the estimates, the details of the estimates furnished appear in this table.

5. Ensuring that manufacture and imports are within the limits of the estimates

107. During the year to which the estimates pertain, and in the following year, following receipt of statistics on imports and exports of narcotic drugs, INCB checks whether imports and exports of narcotic drugs were not exceeding the total of estimates of the importing country. Likewise, following the year to which the estimates pertain, after receipt of statistics on manufacture of narcotic drugs, INCB checks whether manufacture of narcotic drugs was not exceeding the total of estimates of the manufacturing country. If there was excess export, excess import or excess manufacture, INCB contacts the concerned Government, requesting remedial measures to be taken.