INTERNATIONAL NARCOTICS CONTROL BOARD

Guide on Estimating Requirements for Substances under International Control

Developed by the International Narcotics Control Board and the World Health Organization for use by Competent National Authorities

UNITED NATIONS

World Health Organization

INTERNATIONAL NARCOTICS CONTROL BOARD

WORLD HEALTH ORGANIZATION

Guide on Estimating Requirements for Substances under International Control

Developed by the International Narcotics Control Board and the World Health Organization for use by Competent National Authorities

UNITED NATIONS
New York, 2012

UNITED NATIONS PUBLICATION
ISBN: 978-92-4-150328-0

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations concerning the legal status of any country, territory, city or area, or of its authorities, or concerning the delimitation of its frontiers or boundaries.

Publishing production: English, Publishing and Library Section, United Nations Office at Vienna.

Foreword

The International Narcotics Control Board (INCB) is launching the *Guide on Estimating Requirements for Substances under International Control* on the occasion of the centennial of the first international drug control treaty, the International Opium Convention signed at The Hague on 23 January 1912, which was the cornerstone of international drug control. Drug abuse was a scourge that was widespread, affecting most regions of the world, when the 1912 Convention was adopted. Subsequently, an international drug control system was established. The current system is based on the three international drug control conventions: the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol; the Convention on Psychotropic Substances of 1971; and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The international drug control system endeavours to prevent the abuse of drugs, as well as the harm caused by such abuse, while ensuring adequate availability of drugs for the treatment of pain and mental illness.

The problem of inappropriate levels of consumption of internationally controlled substances (too high in some countries and too low in others) has been a matter of concern to INCB for many years. In January 2011, the *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*[1] was published. The *Report* contained a detailed analysis of the global situation with regard to the availability of internationally controlled drugs for medical and scientific purposes and showed the disparity in that availability among the various regions of the world.

Australia, Canada, New Zealand and the United States of America, in addition to several European countries, account for 90 per cent of global consumption of analgesics. In some of these countries, there is overconsumption of certain controlled substances, which may cause additional health problems or further compound existing conditions.

In contrast, 80 per cent of the world's population has limited or no access to these medicines, meaning that many individuals suffer unnecessarily. Many medical conditions cannot be adequately treated without access to the narcotic drugs used, for example in the treatment of pain, or to the psychotropic substances used in the treatment of mental and neurological conditions.

Impediments to the adequate availability of internationally controlled substances vary between countries, and it is the responsibility of national authorities to identify these impediments and take appropriate measures to remove them. However, INCB is of the opinion that the first step that needs to be taken is the identification of a country's actual requirements for internationally controlled substances in order to overcome underconsumption and, at the same time, prevent overconsumption.

[1]United Nations publication, Sales No. E.11.XI.7

The importance of identifying actual national requirements was reiterated by the Commission on Narcotic Drugs in its resolution 54/6 on promoting adequate availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes while preventing their diversion and abuse. In the resolution, the Commission encouraged INCB to continue its efforts, in cooperation with the World Health Organization (WHO), to develop guidelines to assist Member States in estimating their medical and scientific requirements for internationally controlled narcotic drugs and psychotropic substances.

Countries that are in a position to adequately estimate and assess their requirements for narcotic drugs and psychotropic substances are usually the ones that are able to take the steps required to improve availability. The process of establishing the mechanism and developing the expertise to make adequate estimates and assessments of legitimate requirements leads to improved supply of internationally controlled substances. Obtaining accurate information about the legitimate requirements for such substances is a prerequisite to ensuring their availability.

INCB is aware that the success of such efforts depends, to a large extent, on a well-functioning drug control system. Without an effective drug control system, countries will find it much more difficult to assess their present consumption levels, identify the additional quantities required for existing treatment facilities and define the improvements required in the health-care infrastructure and the drug distribution system so that patients can be given the medications they need.

Unfortunately, many countries still find it difficult to identify their actual requirements of narcotic drugs and psychotropic substances and are therefore unable to provide adequate estimates and assessments or, in some cases, to provide any estimates at all. In order to support these countries, a working group comprising representatives of INCB, WHO and the WHO Collaborating Centre for Pain Policy and Palliative Care, together with several independent experts, developed the present *Guide*. The national regulatory agencies of countries at different stages of development were asked to provide their comments, with a view to ensuring that the *Guide* would be as widely applicable as possible.

The *Guide* is meant to assist Governments of countries with low levels of consumption of controlled substances in calculating their requirements so that they can then submit to INCB estimates and assessments that accurately reflect those requirements. It could also be useful for Governments of countries in which the consumption levels for some substances are disproportionately high. I hope that the *Guide* will be widely used by competent national authorities and will ultimately help them to arrive at estimates and assessments that reflect their actual requirements for internationally controlled substances.

Hamid Ghodse
President
International Narcotics Control Board

Preface

The INCB-WHO *Guide on Estimating Requirements for Substances under International Control* is intended to assist competent national authorities in identifying methods for calculating the quantities of controlled substances required for medical and scientific purposes. At the same time, it will help those authorities to prepare the estimates and assessments of annual requirements for controlled substances that countries are required to furnish to the International Narcotics Control Board (INCB). It describes the system of estimates and assessments and the various methods commonly used to quantify the requirements of controlled substances for medical and scientific purposes. It also provides an overview of the major issues that need to be considered in order to apply these methods accurately.

Several methods have been developed for calculating the requirements of controlled substances for medical purposes (see section II.B and annex I). No single method should be systematically recommended for all countries because the choice of method depends on the specific conditions in each country. This *Guide* has been prepared to help competent national authorities:

(a) To identify the most appropriate method (or methods);

(b) To improve the accuracy of the method (or methods) in use;

(c) To calculate estimates and assessments of controlled substances to be furnished to INCB;

(d) To train staff working in drug regulatory administrations.

Contents

I. Introduction

1. The international drug control regime is based on three international conventions: the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971 and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The 1961 Convention as amended and the 1971 Convention established control measures for narcotic drugs and psychotropic substances, whereas the 1988 Convention established control measures for precursor chemicals used in the illicit manufacture of narcotic drugs and psychotropic substances. By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the conventions. For the purpose of this *Guide*, the substances controlled under the three conventions will be referred to as controlled substances.

2. The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse. An essential component of this regime is a system under which Governments are requested to estimate the quantities of controlled substances required for legitimate purposes and to limit the use of and trade in such substances to within those estimates. If applied correctly, this system should not hinder but rather promote access to appropriate amounts of controlled substances and should prevent their excessive use.

3. The International Narcotics Control Board (INCB) is the body responsible for monitoring the compliance of Governments with the international drug control treaties and for providing support to Governments in this respect. The ability of INCB to monitor the functioning of the international drug control mechanisms established by the conventions relies, in part, on Governments providing it with estimated quantities of controlled substances required for legitimate purposes in their countries (these quantities are known as estimates[1] when referring to narcotic drugs or precursor chemicals and as assessments when referring to psychotropic substances).

4. The World Health Organization (WHO) carries out a number of activities to ensure adequate treatment of patients, including the elaboration of treatment guidelines and the Model List of Essential Medicines.[2] WHO also provides guidance to Governments on policies and legislation on the availability, accessibility, affordability and control of medicines made from controlled substances.

5. The accurate estimation of requirements for controlled substances is an essential step in ensuring their adequate supply for medical and scientific purposes. On the one hand, underestimation of requirements can contribute to many problems in the use of controlled substances in the health-care system, notably shortages, inappropriate prescribing, distortion of demand and lack of cost-effectiveness; on the other hand, overestimation can lead to surpluses, wastage and increased risk of diversion of controlled substances.

6. In principle, the process of estimating requirements for controlled substances should be based on effective methods and systematic procedures for collecting information about the use of and

[1] See section III for information on estimates and assessments.

[2] Available from the WHO Essential Medicines Library, at http://apps.who.int/emlib/.

need for controlled substances. However, a number of factors make it difficult for the competent authorities of many countries to develop and use such methods and procedures. The most common difficulties encountered include a lack of technical knowledge, a general lack of resources, a poorly developed health-care infrastructure and the absence of an institutional framework that prioritizes access to medicines for all segments of the population. As a result, many Governments either fail to furnish any estimates or assessments at all to INCB, or they submit inaccurate estimates and assessments that exceed or fall short of their actual requirements.

A. System of estimates and assessments

Legal framework of the system

7. The present system of estimates of narcotic drugs was established by the 1961 Convention (articles 12 and 19).[3] Although the 1971 Convention did not establish a similar system for psychotropic substances, the Economic and Social Council, in its resolutions 1981/7 and 1991/44, invited Governments to provide to INCB assessments of their medical and scientific requirements for substances in Schedules II, III and IV of the 1971 Convention. Similarly, in its resolution 49/3, the Commission on Narcotic Drugs requested Member States to provide to INCB annual estimates of their legitimate requirements for 3,4-methylenedioxyphenyl-2-propanone (3,4-MDP-2-P), pseudoephedrine, ephedrine and 1-phenyl-2-propanone (P-2-P) (precursor chemicals frequently used in the illicit manufacture of amphetamine-type stimulants) and, to the extent possible, estimated requirements for imports of preparations containing those substances that could be easily used or recovered by readily applicable means.

Functions of estimates and assessments

8. Estimates and assessments should be based on legitimate medical and scientific requirements.[4] The process of calculating these estimates and assessments:

(a) Allows the competent authorities to obtain accurate and realistic information about the quantities of controlled substances actually required for medical and scientific purposes;

(b) Provides information that is essential for authorities to ensure that sufficient quantities of controlled substances are available in the health-care system;

(c) Informs authorities about the levels required for legitimate use so that they are able to limit their supply of controlled substances and take appropriate measures to prevent the diversion of those substances for illicit use.

9. The estimates and assessments furnished by Governments are examined, confirmed (if applicable) and published by INCB to provide information about quantities of controlled substances required in each country for licit purposes. By allowing the manufacture, import and export of controlled substances in quantities that do not exceed the estimates and assessments published by INCB, Governments can reduce the risk of such substances being diverted for illicit use.

[3] One of the predecessors of INCB, the Supervisory Body, was established by the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, signed at Geneva on 13 July 1931. This Convention introduced the obligatory system of estimates to limit the manufacture of and trade in narcotic drugs to medical and scientific purposes, which was later incorporated into the 1961 Convention.

[4] In the case of estimates for precursors, other requirements, such as industrial requirements, may need to be taken into account.

10. The estimates of legitimate requirements for controlled substances furnished by Governments also allow INCB to promote a balance between the global demand for and supply of such substances.

Responsibilities of the competent national authorities and the International Narcotics Control Board in ensuring the effectiveness of the system

Competent national authorities

11. The competent national authorities are responsible for the following:

(a) Developing a method to accurately determine the legitimate requirements for controlled substances for medical purposes in their countries. Information on such methods is provided in section II.B and annex I below;

(b) Calculating the estimates and assessments for controlled substances to be furnished to INCB (see annex II below);

(c) Informing operators (manufacturers, distributors, dispensers, administrators and health-care providers) about their legal obligation to provide information for preparing the estimates and assessments of controlled substances and providing training to allow them to do so;

(d) Organizing the collection of relevant data from operators and other sources;

(e) Coordinating with other Governmental bodies involved in drug supply management and public health, notably the Ministry of Health in cases where the competent national authority is not part of that ministry, to ensure that conditions are met for the accurate quantification of requirements for controlled substances (see section II.A below).

International Narcotics Control Board

12. Pursuant to the international drug control conventions, INCB assists Governments in complying with their treaty obligations. It has the following responsibilities:

(a) Examining the estimates and assessments furnished by Governments to help ensure that controlled substances are available in adequate quantities to meet medical and scientific requirements, but do not exceed such quantities;

(b) Confirming estimates for narcotic drugs furnished by Governments and, when necessary, requesting additional information about intended use prior to confirming estimates;

(c) Publishing the estimates and assessments of controlled substances provided by individual Governments, thereby sharing this public information with all Governments;

(d) Compiling and publishing estimates for the precursor chemicals 3,4-MDP-2-P, pseudoephedrine, ephedrine and P-2-P (and their preparations, as relevant), as reported by Member States, to provide the competent authorities of exporting countries with at least an indication of the legitimate requirements of importing countries, thus preventing attempts at diversion. Since March 2007, when they were published for the first time, INCB has received positive feedback on the estimates of precursor chemicals. Government officials verifying the legitimacy of shipments of such chemicals have found the estimates to be valuable.

13. There are no defined upper limits or quotas on the estimates and assessments of controlled substances that Governments should furnish to INCB; it is only required that the quantities

furnished reflect legitimate requirements. Furthermore, INCB encourages appropriate estimates and assessments of controlled substances (see section II.A below).

14. When a country fails to meet its treaty-based obligation to furnish estimates for narcotic drugs and assessments for psychotropic substances, the estimates and assessments are established by INCB to make it possible for the country in question to import controlled substances. In such cases, INCB requests the country to confirm or revise the estimates and assessments established on the country's behalf, so that they accurately reflect the country's legitimate requirements.

B. Relevant activities of the World Health Organization

15. WHO provides guidance to Governments on health-related issues, including issues related to the treatment of specific illnesses and disorders. It also gives guidance on the rational use of medicines,[5] including medicines containing controlled substances. The key means of promoting the rational use of medicines (which are applicable to this *Guide*) include the establishment of a multidisciplinary national body to coordinate policies on medicine use, the use of clinical guidelines, the development and use of national essential medicines lists, the establishment of drug and therapeutics committees, the use of appropriate and enforced regulation and sufficient Government expenditure to ensure availability of medicines.[6]

16. In *Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines*,[7] WHO recommends that "Governments should develop a practical method to estimate realistically the medical and scientific requirements for controlled substances, using all relevant information" (guideline 15) and that "Governments should furnish to … INCB estimates and assessments of the quantities of controlled substances required for legitimate medical and scientific purposes (estimates annually for narcotic drugs and certain precursors; assessments at least every three years for psychotropic substances). Governments should furnish supplementary estimates or modified assessments to … INCB if it appears that the availability of controlled substances for legitimate purposes will fall short because of initial underestimation of regular demand, emergencies or exceptional demand" (guideline 16).

17. The Access to Controlled Medications Programme, carried out as part of the work of WHO on medicine access and rational use, addresses the main causes of impaired access to controlled medicines. It focuses on regulatory barriers, the functioning of the estimate system for importing and exporting by countries, and the education of health-care professionals and other relevant personnel. The Programme supports national authorities such as regulatory authorities, national health-care administrators, health-care professionals and law enforcement officials in countries where access to controlled medicines is limited. The main categories of medicines targeted by the Programme are opioid analgesics, opioids for the treatment of opioid dependence and medicines used in childbirth.

[5]For more information on the rational use of medicines, see www.who.int/medicines/areas/rational_use/en/.

[6]Ibid.

[7]World Health Organization (Geneva, 2011).

II. Calculating requirements for controlled substances

A. Basic considerations for the calculation of accurate estimates and assessments of controlled substances for medical and scientific purposes

18. One of the main purposes of calculating estimates and assessments is to ensure that the quantities of controlled substances made available to the health-care system in a country meet the medical (and scientific) requirements of that country. To achieve this objective, the process of quantifying these requirements should not be a purely computational procedure that is carried out independently; instead, it should be a procedure conducted within the framework of the supply management system for controlled substances, of which the following components form the core:[8]

(a) Selection: deciding which controlled substances are required for treating the health problems in the country;

(b) Quantification: estimating how much of each controlled substance is required to meet medical and scientific requirements;

(c) Procurement: selecting suppliers, placing and monitoring orders, checking delivery quantities and quality, and budgeting;

(d) Storage and distribution: reception, storage, stock control, transportation, and record-keeping for monitoring and control;

(e) Use: prescription, dispensing and use of controlled substances, and patients' compliance with prescriptions.

19. These components are interdependent and form a cycle in which every step builds on the previous one and leads to the next. Weaknesses at any step will have an impact on its effectiveness and eventually on the adequate provision of the controlled substances to the health system; poor quantification will obviously result in an incorrect calculation of medical requirements. However, as discussed below, problems in selection, procurement, distribution and rational use can also affect the accuracy of the quantification process. This is especially important when quantification is based on past patterns of use (consumption-based method, see section II.B and annex I below), as is done by many of the countries that report estimates and assessments of controlled substances to INCB.[9]

20. If the components of the supply management system are managed by different agencies, coordination and information-sharing among the various agencies are essential to ensuring that the cycle is not interrupted. Each agency should be aware of its responsibilities and of the relationship between the components of the system. Furthermore, strategies should be implemented to monitor the effectiveness of each component in supplying the required quantities of controlled substances.

---

[8]See World Health Organization, Department of Essential Drugs and Medicines Policy, *Operational principles for good pharmaceutical procurement* (Geneva, 1999). Available from www.who.int/hiv/pub/amds/who_edm_par_may99.pdf.

[9]See para. 29 of *Availability of Opiates for Medical Needs* (United Nations publication, Sales No. E.96.XI.6). Available from www.incb.org/pdf/e/ar/1995/suppl1en.pdf.

21. In addition to these operational requirements, the effectiveness of the supply management system depends on a well-functioning legal and policy framework that is based on ensuring the availability and rational use of controlled substances for medical purposes. The lack of such a framework can affect the proper functioning of the supply management cycle and create barriers to the rational use of controlled substances (see annex III below). Fundamental changes to the legal and policy framework are necessary to eliminate such barriers.

22. Section II.A below contains a discussion of the key aspects of the supply management system for controlled substances that may impact the accuracy of the quantification process and the ability of the health-care system to meet needs (for an explanation of the difference between needs and requirements, see box 1). Such aspects should be well understood and addressed to ensure that estimates and assessments, calculated on the basis of the quantification process, are not distorted by weaknesses in the supply management system.

Box 1. The difference between needs and requirements for controlled substances in the system of estimates and assessments

Needs for controlled substances are the quantities that would be necessary to provide medical treatment for the health problems of a country's population.

Requirements for controlled substances are the quantities that are necessary to provide medical treatment through the existing health-care infrastructure in a country and under conditions where controlled substances are used rationally and are not diverted.

The needs for controlled substances can be much higher than the requirements in countries where the health-care system is not well developed and where drug supply management is not effective. In an ideal system, the requirements for controlled substances would equal the needs.

Selection

23. The selection of controlled substances for which requirements are to be calculated depends on the health problems encountered in a given country and the choice of controlled medicines considered appropriate to treat them. The end results of this process are usually the inclusion of such substances in the national essential medicines list and in standard treatment guidelines that specify accepted schedules for treating health problems using controlled substances (the strength, dosage and duration of use of selected controlled medicines for each health problem). Focusing on the procurement of key controlled substances may not only lower costs but also facilitate rational prescribing and dispensing. Standard treatment guidelines are essential to the quantification process (see section II.B below) and can assist in promoting the rational use of controlled substances.

24. The three international drug control conventions do not recommend which drugs and which dosages should be utilized in the treatment of specific conditions. Thus, for each country, the estimates and assessments of internationally controlled substances depend on the selection of drugs and dosages made by the competent national authorities.

25. Many countries already have in place a national essential medicines list. Competent authorities should first consult that list to determine which controlled substances are recommended. Countries without such a list can refer to the WHO Model List of Essential Medicines for guidance. For the WHO definition of essential medicines, see box 2. This list, which is published every two years, is also a useful resource for revising and updating national lists. The WHO Essential

Medicines Library (available from http://apps.who.int/emlib/) provides additional information about all medicines currently listed in the WHO Model List of Essential Medicines, including links to clinical evidence about efficacy and safety, existing WHO or other clinical guidelines, and price information.

Box 2. Essential medicines

According to WHO, essential medicines are those that "satisfy the priority health-care needs of a population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available in functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford …

The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility."[a]

[a]See online Glossary of Globalization, Trade and Health Terms of the World Health Organization (available from www.who.int/trade/glossary/en/).

26. Key provisions for selection include:

(a) Ensuring that selection is undertaken on the basis of accepted treatment norms and proven efficacy and safety;

(b) Promoting acceptance of selected controlled substances through consultation with health-care professionals and experts and the development of clinical and standard treatment guidelines;

(c) Prioritizing and selecting substances that can be procured in a cost-effective way (see paragraphs 28 and 32 below for more information on the impact of price on the process of establishing estimated requirements);

(d) Including selected controlled substances in the national essential medicines list, as this may facilitate their procurement and supply;

(e) Regularly reviewing and updating the list of selected controlled substances to reflect changes in the requirements of the health-care system and accepted treatment practices.

Quantification

27. Quantification is the process of calculating the quantities of controlled substances that will be required for medical use (for more detail on the different quantification methods, see annex I below). The resulting estimates of controlled substances should then be incorporated into the preparation of the national estimates and assessments (see annex II). Accurate quantification is an essential step in the system for managing the supply of controlled substances. The system determines the quantities of controlled substances that should be procured to avoid shortages and excesses and also assists planning and timely procurement and rationalization of the prescribing and use of controlled medicines.

28. Quantification has become more complex in recent years, with the interplay of an increasing selection of medicines, delivery systems and dosage units. In the past, there were often few medicines

to choose from for the treatment of maladies. Now, numerous medicines are available for treating a single disease or its symptoms. That means that decisions need to be made regarding what proportion of what diseases and conditions will be treated by various medicines. One result is that the steps outlined in the supply management system can become more interdependent, for example with the cost of one medicine having a large influence on the selection and quantification of other medicines. Selection, quantification and procurement should be based on the most cost-effective medicines in order to make the most efficient use of financial resources. Ensuring that the most effective medicine is available at the lowest possible cost for patients is a critical element of rational use (see paragraph 38 below).

29. The accuracy of the quantification process relies mainly on the quality of data and the effectiveness of data collection. It is therefore important to establish managerial and policy frameworks that ensure good record-keeping in facilities that use or handle controlled substances and to develop an effective mechanism to collect the relevant data for the purpose of quantification.

30. Key provisions for quantification include:

(a) Ensuring that an adequate system exists for collecting data on the use of controlled substances;

(b) Ensuring that operators and users of controlled substances are aware of their responsibility to provide the necessary data;

(c) Establishing a cycle of data collection and processing that meets the deadline for the submission of estimates and assessments to INCB (see annex II below);

(d) Promoting good record-keeping practices in facilities that use or handle controlled substances;

(e) Regularly evaluating the quality of data and taking corrective action if necessary.

Procurement

31. The procurement process for controlled substances involves budgeting, selecting suppliers, placing and monitoring orders, checking quality and checking delivery quantities. Failure in any of these areas leads to lack of access to appropriate drugs and to waste,[10] which can also have a negative impact on the quantification process and eventually result in the calculation of estimates and assessments that do not reflect the actual requirements in a country. For example, delays in shipment from a supplier might lead to a substance being out of stock for a prolonged period and a smaller amount of controlled substances being used by patients during the year. If this low level of use is then used as the basis for determining the requirements for the following year, the amount to be procured will be underestimated. This example illustrates how systemic problems in the procurement process undermine the quantification process and lead to inadequate estimates and assessments, year after year.

32. It is important to consider the health insurance and financing systems, as well as the controlled substance suppliers, including their prices and other costs that may be passed on to the purchaser. These factors can have a great influence on access to and use of controlled substances (see annex III below). For example, if there are few suppliers to choose from, an oligopoly will be created and the suppliers may ask for relatively high prices, which will result in the limited available resources being used to purchase smaller quantities of controlled substances. Thus, financial constraints, rather than the medical needs of the population, can play a greater role in

[10]World Health Organization, "Operational principles for good pharmaceutical procurement", document WHO/EDM/PAR/99.5. Available from http://whqlibdoc.who.int/hq/1999/WHO_EDM_PAR_99.5.pdf.

determining the quantities of controlled substances procured and used. In such situations, Government authorities have sometimes stepped in to identify suppliers willing to sell the medicines at lower prices so that the fundamental medical needs of the population can be met.

33. In addition to price, another important consideration relevant to the procurement of controlled substances is their quality. Controlled medicines should be registered by the national medicines regulatory authority to ensure that they are safe and effective. Selecting suppliers that provide high-quality products is key to ensuring the safety of controlled medicines. Ideally, suppliers should be able to show that their products adhere to good manufacturing practices that ensure product consistency and compliance with the quality standards appropriate to their intended use.[11] In the same way, Governments must ensure that institutions that prepare and distribute "magistral" preparations take appropriate measures to guarantee the efficacy, safety, quality and shelf life of the product. Even after registration, national authorities should encourage the reporting of potential problems relating to the quality of controlled substances and should take appropriate follow-up action, such as arranging for laboratory tests.

34. Key provisions for procurement include:

(a) Ensuring that operators are aware of and understand special regulations concerning the procurement of controlled substances (requirements for the import certificates issued by competent national authorities, licensing requirements, security and record-keeping procedures for operators etc.);

(b) Establishing procedures for competitive pricing of supplies to ensure that controlled substances are available at the lowest cost.

Storage and distribution

35. After controlled substances have been procured, manufacturers, importers or wholesalers (in some cases the Government) store and distribute the substances to pharmacies, hospitals, palliative care facilities etc., based on demand. Health-care personnel then prescribe and dispense the controlled substances to patients. Breakdowns at any point in the distribution system can lead to shortages of controlled substances in the health-care system.

36. Measures should be put in place to prevent the diversion of controlled substances from the distribution system, to be used for illicit purposes. These measures should be in accordance with the relevant provisions of the international drug control conventions and require the implementation of good distribution practices, including secure storage of controlled substances at distribution points and in retail facilities, efficient and secure transportation of such substances, good stock management and adequate record-keeping. Operators at all levels should be made aware of their responsibilities and legal obligations in ensuring the secure handling of controlled substances through the development of written standard operating procedures. Finally, it is important that health professionals receive training on prescribing and dispensing controlled substances (see paragraph 41 and annex III below). Although legal and regulatory measures are necessary to prevent the diversion of controlled substances from the distribution system, they should not be a barrier to the availability of such substances for medical purposes.

37. Key provisions for storage and distribution include:

(a) Ensuring that operators involved in the storage and distribution of controlled substances are aware of relevant laws and regulations;

[11] Further information on good manufacturing practices is available from www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html.

(b) Ensuring that central distribution points and peripheral facilities are adequately equipped to guarantee the secure storage of controlled substances;

(c) Promoting good stock management and record-keeping procedures in central distribution points and in peripheral facilities — sufficient quantities of controlled substances should be kept in stock to ensure an uninterrupted supply and prevent shortages; stock levels can be a source of information for calculating requirements and for reporting to INCB (see annexes I and II below).

Use

38. According to WHO, the rational use of medicines requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".[12] The quantification process is intended to calculate the amounts of controlled substances necessary to meet these requirements. Common examples of inappropriate use of medicines include: underuse of essential medicines, overprescribing, preference for costly medicines over cheaper but equally effective alternatives, prescribing for inappropriate indications and using medicines that are ineffective. Therapeutic failure of controlled substances in the treatment of health problems may be a consequence of their inappropriate use. Ultimately, inappropriate use of medicines may result in increased health-care costs.

39. As discussed in section II.B below, the rational use of controlled substances is also an important prerequisite for calculating accurate requirements for such substances. When past use is the basis for quantifying requirements (in the consumption-based and service-based methods), inappropriate patterns of use of controlled substances that are not corrected will distort actual requirements and perpetuate inaccuracies. Likewise, when the quantification process is based on standards of rational use (in the morbidity-based method) that are not followed by health-care professionals, the quantities of controlled substances procured will not match their use, resulting in shortages or excesses.

40. WHO advocates 12 core interventions to promote more rational use of medicines.[13] These interventions include the establishment of a multidisciplinary national body to coordinate policies on the use of medicines, the use of clinical guidelines, the inclusion of treatments of choice in national essential medicines lists (see paragraph 23 above), the inclusion of problem-based pharmacotherapy training in undergraduate curricula, continuing in-service medical education, public education about medicines, appropriate and enforced regulation, and sufficient Government expenditure to ensure the availability of medicines and trained staff. All these key interventions are also relevant for controlled substances.

41. The rational use of controlled substances depends heavily on the training of health-care professionals and raising the awareness of patients. Prescribers (a group that may include physicians, veterinarians, dentists, nurses and midwives, depending on the country) should be educated and appropriately trained to prescribe and administer controlled substances. Pharmacists should be trained in the rational dispensing of controlled substances. If they are not trained appropriately, health-care professionals may be reluctant to use controlled substances. Conversely, inappropriate prescribing and lax dispensing practices can lead to the diversion and abuse of controlled substances. Educating patients also contributes to rational use by dispelling misconceptions about the abuse potential of controlled substances, as well as about problems associated with non-medical use.

[12] See www.who.int/medicines/areas/rational_use/en/index.html.

[13] See "Promoting rational use of medicines: core components", *WHO Policy Perspectives on Medicines*, No. 5, September 2002. Available from http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.3.pdf.

42. Other factors that impede the availability of controlled substances, and ultimately their rational use, are included in annex III below.

43. Key provisions for use include:

(a) Promoting rational use of controlled substances through educational, managerial and regulatory strategies for health-care professionals;

(b) Identifying inappropriate use of controlled substances in the health-care system and its impact on the accuracy of calculated requirements;

(c) Informing the general public about the rational use of medicines.

B. Choosing methods for and improving the accuracy of the quantification of requirements for controlled substances

44. Three methods and their variants are commonly used to quantify the requirements for controlled substances: the consumption-based, service-based and morbidity-based methods. The choice of which method to use is determined by the availability of the data needed for quantification, the availability of the necessary resources and the structure of the controlled substance supply system, as discussed in section II.A above.

45. This section outlines the optimal circumstances for using each method to achieve accurate results and the main limitations of the methods. (For a more detailed description of the three methods and examples of their use, see annex I below.) In practice, all the conditions that contribute to the accuracy of the methods may not be present. However, this should not preclude the application of the methods, as achieving accuracy in quantifying requirements for controlled substances is an incremental process. It depends not only on applying the appropriate method but also on many factors outside the quantification process, such as those discussed in section II.A above. Efforts to address these factors should take place alongside a gradual refinement of the estimates of requirements.

Consumption-based method and variants

46. The consumption-based method and its variants are based on use over recent years. If past use of controlled substances is stable and adequate, future requirements can be calculated by averaging the amounts used in health-care facilities in recent years and adding a margin for unforeseeable increases. In variants of this method, calculations are based on data obtained from manufacturers, importers and wholesalers that distribute controlled substances to peripheral health-care facilities.

47. This method is appropriate in the following situations:

(a) When reliable data on past use can be collected;

(b) Where the demand for health-care services has reached a relatively steady level;

(c) When the demands of the health-care system are met by a well-functioning supply management system that ensures an uninterrupted supply of controlled substances;

(d) When the use of controlled substances is rational;

(e) In the absence of circumstances that require a change (e.g. emergency health-care situations).

48. When using the consumption-based method, it is important to be aware that:

(a) The method and its variants do not provide a basis for improving rational use and the accuracy of the quantification process. For example, if prescribing, dispensing and administering are undertaken to a poor standard and are not corrected, this method may perpetuate the cycle of inappropriate use;

(b) In the case of calculations based on quantities requested by trading companies for future sales, the calculated amount may be influenced by limited marketing possibilities or overly optimistic sales expectations and may therefore not reflect medical requirements;

(c) Controlled substances being out of stock for long periods of time and loss or wastage may reduce the accuracy of the method;

(d) Data collected under the method and its variants may be incomplete because of poor stock management, inadequate record-keeping or inadequate reporting to the authorities responsible for data collection.

Service-based method

49. The service-based method calculates requirements for controlled substance based on current levels of use of each controlled substance (for all clinical indications) in a sample of standard facilities. The data collected from those facilities can then 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 financial and administrative constraints within the existing health-care system.

50. This method is appropriate in the following situations:

(a) Where prescribing, administering and dispensing patterns in the standard facilities are considered to be rational (for increased accuracy of the method, strategies should be developed to promote rational use in all facilities — see section II.A above);

(b) Where the pattern of morbidity in the standard facilities is representative of the pattern in the region included in the quantification. If there are large differences in morbidity patterns, other methods may be more appropriate for calculating the requirements of those non-standard facilities;

(c) Where detailed data on patient morbidity or standard treatment guidelines are not available.

51. Authorities should be aware that:

(a) The service-based method may not take into account the medical needs of patients that cannot be met owing to the cultural or geographical constraints of the existing health-care system;

(b) Any inappropriate patterns of use in terms of prescribing, administering or dispensing in the standard facilities that are not corrected may be perpetuated throughout the health-care system, as they are carried over into the requirements for controlled substances for other facilities included in the quantification process;

(c) Limitations of the health-care system, such as substances being frequently out of stock, inappropriate patterns of use and poor record-keeping practices, may make it difficult to select valid standard facilities (see annex I below);

(d) The service-based method may be difficult to use for controlled substances that are prescribed not only in health-care facilities but also by individuals.

Morbidity-based method

52. The morbidity-based method calculates the requirements for controlled substances based on an assessment of the frequency of health problems (morbidity) and on accepted treatment norms for the health problems in question. Data on morbidity can be obtained from epidemiological assessments at the regional or national level. When complete data on the population morbidity for a given health problem are available, the method calculates the quantities of a controlled substance that would be required to treat that problem. However, this is a calculation for the need for controlled substances, and it may overestimate the requirements for them, which by definition are based on the existing health-care infrastructure in a country (see box 1 above); that infrastructure may not be able to treat all morbidity in the country. Furthermore, such data are rarely available and may be difficult to collect on all possible diseases that require treatment with controlled medicines. In such situations, morbidity profiles of sample health-care facilities can be used in the calculation and the requirement can then be scaled up to the regional or national level.

53. This method is appropriate in the following situations:

(a) Where data on past patterns of use of controlled substances are not available or are unreliable;

(b) When health services are rapidly changing or new — for example when starting an opioid substitution treatment programme;

(c) Where accurate and complete data on morbidity are available;

(d) Where standard treatment schedules have been devised;

(e) To promote a change towards more rational prescribing, as defined by standard treatment schedules;

(f) To verify requirements calculated with other methods.

54. Authorities should be aware that:

(a) The existing health-care infrastructure in a country may not have the capacity to treat all the morbidity or absorb the quantities of controlled substances required to treat the morbidity rate even when complete data are available to identify that rate. If such theoretical amounts of controlled substances are procured, the lack of capacity may result in inappropriate use or increase the possibility of diversion or abuse of controlled medicines;

(b) If standard treatment guidelines are not followed (including as a result of a lack of rational prescribing), the calculated requirements for controlled substances will not match their use;

(c) This method will accurately predict requirements only for a limited number of health problems for which complete morbidity data and standard treatment guidelines are available. Therefore, if a controlled substance is used to treat several health problems, it may be necessary to use other methods in addition to this one to estimate the quantities required for those other health problems;

(d) The calculated requirement will be more accurate if sample health-care facilities used in the calculation have a morbidity profile that is representative of the regions included in the quantification.

Improving the accuracy of quantification

55. The methods described in this document suit different conditions and objectives. In practice, the most effective quantification approach may be to use more than one method in combination or sequentially. The approach should also allow for progression from a simpler to a more complex method and for the addition of newly developed parts of more accurate methods, taking into account prevailing conditions.

56. For countries that use the consumption-based method, it is important to evaluate whether the calculated quantities of controlled medicines exceed or underestimate actual requirements. A useful addition to this method is to compare the calculated quantities with those obtained using the morbidity-based method, if and when data are available. In carrying out this evaluation, it is important to take into account the perspectives of both health-care professionals who use controlled medicines and relevant public health experts. If an evaluation indicates that the consumption-based method does not accurately calculate the requirements, adjustments to the quantification process should start with those controlled medicines for which the need to compensate for under- or overuse is the most urgent.

57. Ideally, the adjustment should allow the calculated requirements for controlled substances to approximate the needs that can be determined using the morbidity-based method. In a large number of countries, however, good-quality data may not be available for many of the health problems treated with controlled medicines. In such situations, countries can apply the service-based method to quantify the requirements for the controlled medicines identified as priorities in the evaluation process. Using this method, it is possible to obtain a national estimate of the requirements by extrapolating the use of controlled substances in standard health-care facilities to other similar facilities throughout a country.

58. After health-care facilities have been supplied with the calculated requirements for controlled medicines, continuous monitoring of use will help to improve the accuracy of the quantification process and correct surpluses or shortages. At the same time, it is important to promote, in all facilities, the rational use of controlled medicines and the maintenance of accurate patient registers. These records can be a future source of the good-quality data on the frequency of health problems that are required for the morbidity-based method; the records can also serve as an important example of successful, documented, rational use that has been possible without accompanying abuse or diversion.

59. For countries that already have experience using the morbidity-based method for calculating the requirements of controlled medicines for specific health problems (such as methylphenidate, used in the treatment of attention-deficit disorder (ADD), also known as attention-deficit/hyperactivity disorder (ADHD)), it is important to update the morbidity data and information in standard treatment guidelines on an ongoing basis. As good-quality data on other health problems become available, the use of the morbidity-based method can be expanded to quantify the requirements for the controlled medicines used in their treatment.

Evaluation and monitoring

60. The main objective of the quantification process is to ensure that controlled substances used for medical and scientific purposes are available in sufficient quantities. To achieve that objective, regular evaluations of the effectiveness of the quantification process and of the accuracy of the calculated requirements are necessary. Continuous monitoring of the quantification process is also important to ensure its effectiveness.

61. Evaluation refers to the periodic analysis of a process to determine whether objectives and goals are being achieved and how improvements can be made. Evaluation of the quantification process is useful for the following:

(a) To assess the effectiveness with which the various steps of the process (e.g. data collection) have been carried out. Problems at each step should be identified and corresponding solutions introduced;

(b) To determine whether modifications in the method used are warranted. These modifications should respond to changes in the prevailing conditions and available information and be aimed at achieving more accurate quantification (see section II.A above);

(c) To identify whether it is necessary to make any adjustments in response to new developments such as population growth and new medicines, programmes and facilities.

III. Preparation of estimates and assessments for submission to the International Narcotics Control Board

62. After the requirements for controlled substances have been calculated, they have to be included into the estimates and assessments submitted to INCB. Different categories of estimates and assessments must be submitted for the three classes of controlled substances. These categories are specified by the conventions and relevant resolutions on controlled substances. The rest of this section (in addition to annex II below) provides guidance to competent authorities on incorporating the calculated requirements for controlled substances into estimates and assessments.

A. Estimates for narcotic drugs

63. Under the 1961 Convention as amended, States parties must furnish to INCB estimates in respect of, among others, the six categories described below. This section provides guidance on the sources of data for the calculation of estimates to be furnished under each category.

Quantities of drugs to be consumed for medical and scientific purposes

64. The category "Quantities of drugs to be consumed for medical and scientific purposes" refers to the quantity transferred from wholesale to retail distribution. It concerns all countries that use or plan to use narcotic drugs for medical and scientific purposes. For countries that use narcotic drugs almost exclusively for medical purposes, the estimate for consumption should closely reflect the requirements for controlled substances that were calculated using the methods described in section II.B above. For countries that also use narcotic drugs for scientific purposes, quantities required for such purposes should be included in the estimate for consumption. Examples of scientific uses of narcotic drugs include:

(a) Forensic analyses and research (usually requiring only small quantities of narcotic drugs);

(b) Industrial research for the development of new pharmaceutical formulations;

(c) Clinical trials.

65. Competent authorities can obtain information on quantities required for scientific purposes directly from persons or agencies licensed to use narcotic drugs for such purposes.

Stocks of drugs to be held as at 31 December of the year to which the estimates relate

66. The category "Stocks of drugs to be held as at 31 December of the year to which the estimates relate" refers to the quantities of narcotic drugs held in reserve by manufacturers and wholesalers at the end of the year. As a general rule, stocks should not exceed the requirements for narcotic drugs calculated for one year. This category concerns all countries where manufacturers or wholesalers sell narcotic drugs to retailers (countries where retailers obtain their supplies only directly

from abroad do not need to furnish stock estimates). Manufacturers and wholesalers of narcotic drugs can provide the competent national authority with these data. In preparing stock estimates, the following should be considered:

(a) Stocks must be large enough to provide a safeguard against any breakdown in supply, for example as a result of delays in delivery (see box 3);

(b) Excessive stocks may increase the potential for diversion.

Box 3. Safety stocks

Sufficient quantities of controlled substances should be held in stock to ensure their availability at all times. Safety stocks should be kept by facilities that dispense controlled substances (e.g. pharmacies and hospitals) and also by wholesalers that supply controlled substances to peripheral facilities. The level of such safety stocks is a factor in the average use rate of a given controlled substance and the expected lead time (the time from which an order is placed until it is received). Underestimating lead times, especially for the import of controlled substances, can result in shortages and unavailability of substances.

The quantities kept as safety stocks at the retail level should be included in the total requirements for controlled substances for medical purposes. For narcotic drugs, the quantities kept as safety stocks by wholesalers should be reported to INCB under the relevant category.

Quantities of drugs to be utilized for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by the Convention

67. The third category concerns all countries that utilize narcotic drugs for the manufacture of other drugs, preparations in Schedule III of the 1961 Convention as amended and substances not covered by that Convention. This value can be derived from data collected from manufacturers of those drugs. It should be noted that estimates are not required for quantities of preparations in Schedule III of the 1961 Convention as amended that will be consumed.

Quantities of synthetic drugs to be manufactured

68. The fourth category concerns all countries where the manufacture of synthetic drugs occurs. This value can be derived from data collected from manufacturers of such drugs. The list of synthetic drugs can be found in part III of form B (Annual estimates of requirements of narcotic drugs, manufacture of synthetic drugs, opium production and cultivation of the opium poppy for purposes other than opium production), available from the INCB website (www.incb.org).

Quantities of drugs necessary for addition to special stocks

69. The fifth category refers to the quantities of drugs held by Governments for "special Government purposes" (in particular for requirements of the armed forces) and to meet exceptional circumstances (including catastrophic events such as large-scale epidemics or major earthquakes). This concerns all countries where such stocks are held. Estimates have to be furnished for the quantities required for the establishment of special stocks and/or for the quantities to be added to existing special stocks.

Approximate quantity of opium to be produced

70. The category "Approximate quantity of opium to be produced" concerns all countries where opium poppy is licitly cultivated for the production of opium.

B. Assessments for psychotropic substances

71. Assessments for psychotropic substances, which are controlled under the 1971 Convention, should include the following:

(a) Quantities to be manufactured domestically;

(b) Quantities to be imported;

(c) Quantities to be used for the manufacture of other psychotropic substances;

(d) Quantities to be used for the manufacture of non-psychotropic substances;

(e) Quantities to be exported.

72. Assessments should reflect the requirements for controlled substances for medical purposes (calculated using the methods described in section II.B above) and for scientific purposes (see paragraph 64 above). When applicable, the assessments should include additional quantities of psychotropic substances required for the manufacture of other substances, for export purposes and for maintaining stocks.

C. Estimates for precursor chemicals

73. Annual legitimate requirements for precursor chemicals include quantities of those substances that may be imported into the country to provide adequate supplies for the following:

(a) Medical requirements;

(b) Scientific and research requirements;

(c) Industrial requirements;

(d) Licit export (or re-export) requirements;

(e) Reserve stocks.

Annex I. Methods for the quantification of requirements for controlled substances

1. Three methods and their variants are commonly used for quantifying requirements for controlled substances: the consumption-based method; the service-based method; and the morbidity-based method. The main characteristics and criteria for their selection are outlined in section II.B of this publication. The present annex provides more detailed guidance on the application of the three methods. However, for detailed information on some of the specific issues, authoritative manuals[a] and textbooks on the subject, as well as organizations such as the World Health Organization (WHO) (in particular its Access to Controlled Medications Programme), the Pain and Policy Studies Group and specialist non-governmental organizations that work in this area could be consulted.

A. Consumption-based methods and variants

2. The consumption-based method and its variants are based on past health-care demands for controlled substances. Where past use of controlled substances is stable, future requirements can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. A variant of this method may also be applied when patterns of past use of controlled substances show a clear upward or downward trend and when known explanations for such trends allow for the prediction of future changes in use.

Data collection

3. The following steps should be taken when collecting data:

Step 1:
Identify the operators in the controlled substance supply management system (e.g. manufacturers and importers) and health-care system (e.g. hospitals and pharmacies) who handle or use controlled substances.

Step 2:
Obtain the quantities of controlled substances used, requested and imported during the previous three years, as a minimum. Assuming that good record-keeping practices are applied, reliable data can be obtained from stock and distribution records of operators and central distribution points and from stock and dispensing records of health-care facilities.

Step 3:
Identify new circumstances that require additional quantities of controlled substances (e.g. facilities, programmes, epidemics and population size changes).

[a]For example, World Health Organization, Action Programme on Essential Drugs and Vaccines, *Estimating Drug Requirements: A Practical Manual* (Geneva, 1988).

Calculation procedure

4. The following examples show how to calculate a country's requirements for morphine and diazepam:

Example 1: Calculating the morphine requirement of country X for 2011.

Step 1:
(a) Average the data (from step 2 of the data collection procedure described above) from the previous three years. Records kept by the competent authorities indicate that morphine use in country X for the three-year period 2008-2010 was as follows:

Year	*Morphine use (kg)*
2008	17
2009	15
2010	18

The average for the period 2008-2010 is calculated as follows:

(17 kg + 15 kg + 18 kg) / 3 = 16.7 kg

(b) Increase the calculated average by 10 per cent to allow for unforeseeable circumstances, as follows:

16.7 kg + 1.67 kg = 18.4 kg

Step 2:
Add to the value of the result from step 1 *(b)* of the calculation procedure the additional quantities mandated by changes in circumstances (from step 3 of the data collection procedure described above).

Assume that the competent authorities have been informed that a new palliative care centre will open in 2011. Based on past mortality data, it is estimated that the new palliative care centre will treat approximately 1,000 cancer patients in the first year and will require 5 kg of morphine. Therefore, this quantity should be added to the value from step 1 *(b)* of the calculation procedure, as follows:

18.4 kg + 5 kg = 23.4 kg

This is the estimated morphine requirement for country X in 2011.

Example 2: Calculating the diazepam requirement for the treatment of anxiety, insomnia, status epilepticus, febrile convulsions, adjunct in acute alcohol withdrawal and muscle spasm in country X for 2011.

Step 1:
(a) Average the data (from step 2 of the data collection procedure) from the previous three years.

Records kept by the competent authorities indicate that diazepam use for the three-year period 2008-2010 was as follows:

Year	*Diazepam use (kg)*
2008	25
2009	24.6
2010	26

The average for the period 2008-2010 is calculated as follows:

(25 kg + 24.6 kg + 26 kg) / 3 = 25.2 kg

(b) Increase the calculated average by 10 per cent to allow for unforeseeable circumstances, as follows:

25.2 kg + 2.52 kg = 27.72 kg

Step 2:

Add to the value of the result from step 1 *(b)* the additional quantities mandated by changes in circumstances (from step 3 of the data collection procedure described above).

Assume that the competent authorities have been informed that the new paediatric and neurological wards of the central hospital will require diazepam in different forms, including suppositories and injections, for the treatment of seizures of infants, children and epileptic patients, treatment of muscle spasm and peri-operative use. Based on past morbidity data of comparable paediatric and neurological hospitals, it is estimated that the new wards will require 2 kg of diazepam. Therefore, this quantity is added to the value of the result of step 1 *(b)*, as follows:

27.72 kg + 2 kg = 29.72 kg

This is the estimated diazepam requirement for the treatment of the above-mentioned conditions in country X in 2011.

B. Service-based method

5. The service-based method starts by taking the quantities of controlled substances currently in use in standard health-care facilities and extrapolating those findings to similar facilities throughout the country. For each type of health-care facility, a number of standard facilities with a representative workload, acceptable controlled substance supply and rational prescribing and use need to be identified. For the last step of the calculation, the adjusted quantities of controlled substances used per standard facility are converted into quantities per 1,000 treatment episodes,[b] and the results are then used to estimate the quantities required for all other facilities of the same type.

Data collection

6. The following steps should be taken when collecting data:

Step 1:

(a) Identify the categories of facilities that use or dispense controlled substances (e.g. hospitals, public or private clinics with general practitioners and/or specialists, palliative care providers, clinics for treatment of opioid dependence and mobile clinics);

(b) Within each category, select the facility (or facilities) that will serve as the standard. The reliability and predictive value of the service-based method increases when a controlled

[b] A treatment episode is a patient contact for which a standard course of treatment is required.

substance used at more than one standard health-care facility is taken as the basis for the calculation. It is therefore advisable to collect data from a few similar facilities. Ideally, the standard facility or facilities should have the following characteristics:

(i) *A representative pattern of morbidity and patient attendances.* The pattern of morbidity in the population served by the standard facility and the level of patient attendances should be as representative as possible of the morbidity profile of the region or country for which the estimate is being made. If there are significant differences in the morbidity patterns of patients treated by facilities, e.g. in urban and rural areas or in different geographical regions of the country, then separate standard facilities should be selected to reflect these differences;

(ii) *Acceptable patterns of rational prescribing.* The prescribing practices in the standard facilities should be sufficiently rational to be accepted as an appropriate working norm for all facilities of the type concerned (see section II.A of this *Guide*);

(iii) *Adequate and uninterrupted controlled substance supply.* The supply of controlled substances should be adequate to meet demand and enable good prescribing practices to be followed. In theory, this means that controlled substances should be in stock throughout the period for which requirement is calculated;

(iv) *Complete and accurate data on stocks and use of controlled substances.* The standard facilities should have complete, accurate and up-to-date data on their stocks, deliveries and use of controlled substances. This information is essential to the calculation;

(v) *Complete and accurate data on patient contacts.* The standard facilities should have complete, accurate and up-to-date data on the total number of patient contacts. This information is essential to the calculation.

While it may be difficult in practice to identify standard facilities that adhere to all these criteria, the best data from selected facilities should be used in the calculation and efforts should be made to address deficiencies in the standard facilities in order to increase the accuracy of the method.

Step 2:
Select the period for which the use of controlled substances within a facility is to be calculated. This period is typically one year, so that seasonal morbidity variations are covered. The period chosen should be typical in terms of morbidity for the region or country concerned. For example, a year in which an epidemic occurred would be characterized by higher-than-usual use of controlled substances for the epidemic health problems and an atypical pattern of morbidity. Therefore, this would not be a good period to choose for the calculation.

Step 3:
(a) Determine the total quantity of controlled substances used in the standard facilities in the chosen period of the calculation. The data can be obtained from two possible sources:

(i) Patient registers — if treatments using controlled substances are recorded in patient registers, the quantities dispensed may be taken from these registers. This method is only reliable if the records are well kept and complete;

(ii) Stock records of the pharmacies or dispensaries of the standard facilities, using one of the following methods:

a. Adding up the quantities dispensed;
b. Adding the quantity of stocks at the beginning of the chosen calculation period to the quantity received and subtracting the quantity of stocks at the end of the chosen calculation period;

(b) Increase the total consumption to take into account substances that are out of stock, if necessary.

If a controlled substance has been out of stock for part of the period of the calculation, then the use recorded (in data collection step 3 *(a)*) applies only to the time when the controlled substance was in stock. For example, if the period for which use is being calculated is one year and a given controlled substance was out of stock for three months of that year, the observed use covers only the nine months when the controlled substance was actually available to be prescribed and dispensed to patients. In this event, the requirement for the controlled substance should be increased proportionally.

Step 4:
Determine the following:

(a) The number of facilities in each category;

(b) The number of patient contacts in the standard facility and in all the facilities in each category.
Many facilities treat inpatients and outpatients, so both should be taken into account.

Calculation procedure

7. The following examples show how to calculate the rate of use of controlled substances:

Example: Country X has five regional cancer centres. Cancer centre Y, representative of the others, is selected as the standard facility to determine the average consumption of morphine per 1,000 patient contacts. In one year (period selected as part of data collection step 2), cancer centre Y used 100 kg of morphine sulphate tablets (data from data collection step 3 *(a)* above) and provided treatment in 20,000 patient contacts (data from data collection step 4 *(b)*).

Step 1:
Calculate the rate of use of each controlled substance, i.e. the use per 1,000 patient contacts, in the standard facility or facilities.

The quantities of controlled substances used in the standard facilities must be related to the number of patient contacts. This is achieved by dividing the total quantities used (from data collection step 3 *(a)*) by the total number (in thousands) of patient contacts (from data collection step 4 *(b)*):

$$\text{Morphine use per 1,000 patient contacts} = \frac{100 \text{ kg}}{20} = 5 \text{ kg}$$

Step 2:
Extrapolate the rate of use in the standard facility to all facilities of the same type by multiplying the rate of use of each controlled substance in the standard facility (using the data from data collection step 1 *(b)*) by the expected number of 1,000 patient contacts at all facilities in the same category (using the data from data collection step 4 *(b)*). In this example, a total of 90,000 patient contacts are expected at all five cancer centres in the upcoming year. The projected requirement of morphine sulphate tablets for all the centres is calculated as follows:

Morphine use per 1,000 patient contacts at standard facility (5 kg) multiplied by expected number of patient contacts at all regional cancer centres, in thousands (90) equals the total morphine requirements for all regional cancer centres (450 kg): 5 kg x 90 = 450 kg.

Step 3:
Repeat step 2 of the calculation procedure for each category of standard facility and then add together the estimated quantities of the controlled substance used for each category of facility to obtain the total requirement for that substance. In country X, morphine sulphate tablets are also used by the national cancer centre in the capital city and 10 hospices throughout the country. Table A.1 shows the total annual estimated morphine requirement for the country.

Table A.1 Total annual estimated morphine requirement for country X

Type of facility	*Total number of facilities in country*	*Expected number of patient contacts at all facilities*	*Average morphine consumption per 1,000 patient contacts (at standard facility)*	*Total requirement per facility type*
Regional cancer centre	5	90 000	5 kg	450 kg
National cancer centre	1	40 000	4.375 kg	175 kg
Hospice	10	50 000	6 kg	300 kg
Total				**925 kg**

Opioids and narcotic analgesics are used to treat a variety of other medical conditions and the examples given here (cancer pain) are used to illustrate the method of calculation. This is also the case for psychotropic substances with a wide spectrum of use for both physical and psychiatric conditions.

C. Morbidity-based method

8. The morbidity-based method uses data on the frequency of health problems (morbidity) and an assumption of how those health problems will be treated (average standard treatment schedules) to calculate the requirements for controlled substances. The quantity of controlled substances recommended as the standard treatment for each health problem multiplied by the number of treatment episodes for that health problem provides the quantity required. The sum of the requirements calculated for each health problem treated with that substance provides the total requirement for each controlled substance.

Data collection

9. The following steps should be taken when collecting data:

Step 1:
Draw up a list of the major health problems to be treated with a given controlled substance.

Step 2:
Establish the average quantity of the controlled substance required for a standard course of treatment for each health problem. If nationally accepted treatment schedules for the health problems are not available, they should be developed in consultation with experts, taking into account authoritative treatment guidelines, such as those from WHO, or authoritative medical literature and accepted medical practice in a given country. If possible, the standard treatment schedules should specify, for each health problem, the average dose of the controlled substance, the number of doses per day and the duration of the treatment.

Step 3:
Estimate the number of treatment episodes for each health problem.

Data on the frequency of health problems can be collected from centrally compiled patient morbidity registries (e.g. collected for epidemiological and planning purposes by the Ministry of Health). When complete centrally collected morbidity data are not available, morbidity profiles of sample facilities can be used and the calculated requirement extrapolated to other facilities in the region covered by the quantification process. If the morbidity data in sample facilities are not of adequate quality, a special study may be required to collect more complete and detailed information.

Calculation procedure

10. The following steps should be taken when calculating the quantity of a controlled substance required for each health problem:

Step 1:
Multiply the quantity of the controlled substance required for a standard course of treatment (data from step 2 of the data collection procedure) by the number of treatment episodes of a health problem (data from step 3 of the data collection procedure);

Step 2:
Repeat step 1 of the calculation procedure for each health problem included in the quantification;

Step 3:
If a controlled substance is used to treat more than one health problem, add up the various quantities calculated to obtain the total requirement.

11. The following examples show how the calculation procedure should be applied:

Example 1: Country X intends to start a pilot programme for the treatment of drug dependence for 250 patients registered in a drug dependence treatment centre. National experts have recommended the use of methadone for treatment, which is included in the WHO Model List of Essential Medicines.[c] Since the programme is new and no data are available on past patterns of use, the authorities decide to use the morbidity method for calculating the quantity of methadone required during the first year of the programme.

After consultation with national experts, the authorities suppose that the average dose will be 30 mg of methadone per patient per day for the first 12 months. Based on the above data, the quantity of methadone required for one year of the programme is calculated by multiplying the quantity of methadone per standard course of treatment (30 mg x 365 days = 10,950 mg) by the number of treatment episodes (250). For this example, the total is 2,737,500 mg, or 2.8 kg.

Example 2: The competent authorities in country X want to calculate the annual requirement for morphine. In country X, morphine is used for the treatment of moderate to severe pain in cancer and AIDS patients. There are no nationally accepted treatment norms that indicate the quantity of morphine that can be expected to be used by cancer and AIDS patients in the course of their treatment. Therefore, the competent authorities work with national experts in palliative care to identify an average quantity from an authoritative source in medical literature.

[c] Available from http://apps.who.int/emlib/.

The experts recommend using recent cancer and AIDS mortality data (or morbidity data where available) and applying the following formula: at the end of their lives, 80 per cent of cancer patients and 50 per cent of AIDS patients require an average of 60-75 mg of morphine per day for 90 days, so the mid-point of 67.5 mg per patient should be used. National morbidity estimates for the numbers of advanced cancer and AIDS patients are not available in country X. Therefore, the competent authorities decide to use the number of late-stage cancer and AIDS patients in all health-care facilities that provide care to such patients.

The calculation for the morphine requirement for late-stage cancer patients (80 per cent of whom are estimated to need morphine at an average dose of 67.5 mg per day for 90 days) is shown in table A.2.

Table A.2. Calculating the morphine requirement for late-stage cancer patients in country X

Sample facility	*Number of late-stage cancer patients*	*Total number of facilities in country*	*National approximation of late-stage cancer patients for each type of sample facility*	*80 per cent of patients who need pain treatment*	*Average amount of morphine per patient over a 90-day standard course of treatment*	*Total quantity of morphine consumed by all late-stage cancer patients*
National referral hospital with palliative care unit	1 000	1	1 000	800	6 075 mg (or 0.006075 kg)	4.86 kg
Regional hospital with palliative care unit	500	5	2 500	2 000	6 075 mg (or 0.006075 kg)	12.15 kg
Hospice with home-based care	300	10	3 000	2 400	6 075 mg (or 0.006075 kg)	14.58 kg
Total				**5 200**		**31.59 kg**

The calculation of the morphine requirement for late-stage AIDS patients (50 per cent of whom are estimated to need morphine) is shown in table A.3.

Table A.3. Calculating the morphine requirement for late-stage AIDS patients in country X

Sample facility	*Number of late-stage AIDS patients*	*Total number of facilities in country*	*National approximation of number of late-stage AIDS patients for each type of sample facility*	*Number of patients who need pain treatment (50 per cent)*	*Average amount of morphine per patient in standard course of treatment*	*Total quantity of morphine consumed by all late-stage AIDS patients*
National referral hospital with palliative care unit	1 200	1	1 200	600	6 075 mg (or 0.006075 kg)	3.65 kg
Regional hospital with palliative care unit	800	5	4 000	2 000	6 075 mg (or 0.006075 kg)	12.15 kg
Hospice with home-based care	500	10	5 000	2 500	6 075 mg (or 0.006075 kg)	15.19 kg
Total				**5 100**		**30.99 kg**

Therefore, the total annual requirement for morphine for late-stage cancer and AIDS patients would be calculated as follows: 31.59 kg + 30.99 kg = 62.58 kg. It should be noted that these figures do not comprise requirements for morphine to treat acute pain from other causes such as heart attacks, bone fractures etc. Therefore, these need to be added using similar or other methods.

D. General issues in quantification

12. In addition to issues specific to each of the three methods described above, there are some general issues that should be addressed in the quantification process:

(a) Safety stocks of controlled substances should be held to ensure availability of essential medicines at all times and avoid them being out of stock (see also box 3 in section III.A above). The level of these safety stocks is a factor in the average usage rate of a given controlled substance and expected lead time (period from the time an order is placed until it is received). Safety stocks are required for two reasons:

(i) Lead times can be very long when controlled substances are imported. They should be taken into consideration when estimating requirements, as miscalculation of lead times can result in shortages and substances being out of stock;

(ii) Starting up new programmes and facilities will mean that additional quantities are needed for safety stocks. They need to be included in the total stock requirements for controlled substances. Sufficient quantities of safety stocks should be held by wholesalers to ensure uninterrupted supply to peripheral facilities;

(b) Losses of controlled substances may occur as a result of spoilage, expiration and theft. The calculated requirements should be adjusted for such losses to avoid shortages and substances being out of stock;

(c) The accuracy of calculated estimates and assessments need to be evaluated regularly (see the box).

Evaluating the accuracy of estimates and assessments

In preparing estimates and assessments for submission to INCB, it is essential to evaluate whether they reflect actual requirements as determined by the quantification process. Such evaluation should be carried out regularly to correct estimates and assessments that under- or overestimate the requirements for controlled substances. In particular, competent authorities should avoid submitting to INCB the same estimates and assessments every year without having them evaluated. Such evaluation is especially important when competent authorities rely exclusively on information obtained from operators (e.g. manufacturers, importers and exporters) when calculating estimates and assessments for controlled substances. In performing this evaluation, information against which data obtained from operators can be compared includes:

(a) Quantities of controlled substances required for medical purposes, as determined by any quantification process. In particular, quantities imported and/or manufactured for domestic use should not exceed the calculated requirements;

(b) Quantities of controlled substances used in recent years, taking into account new health-care developments such as the introduction of a new medicine;

(c) Quantities used for the manufacture of other drugs in recent years, taking into account changes in manufacturing practices;

(d) Estimates and assessments furnished by countries with comparable socio-economic situations, morbidity and demographics.

Annex II. Administration of the system of estimates and assessments

A. Estimates for narcotic drugs

Submission of estimates and their amendments

1. Governments have an obligation to provide estimates of their legitimate requirements of narcotic drugs to the International Narcotics Control Board (INCB) on an annual basis. INCB provides all Governments, in the first quarter of each year, with form B (Annual estimates of requirements of narcotic drugs, manufacture of synthetic drugs, opium production and cultivation of the opium poppy for purposes other than opium production). Form B should be submitted to INCB by 30 June of the year preceding that to which the estimates relate (for example, estimates of drug requirements for 2013 should be submitted in form B by 30 June 2012).

2. As a result of unforeseen changes, the annual estimates furnished by Governments in form B may prove inadequate over the course of the year to which the estimates apply. Under such circumstances, Governments may amend their annual estimates by furnishing supplementary estimates to INCB. Through this process, Governments may increase or reduce their original estimates. Governments are required to provide explanations of the circumstances that make it necessary to amend their estimates.

Examination of estimates by the International Narcotics Control Board

3. INCB examines the annual estimates of drug requirements furnished by Governments. After examining the estimates provided by Governments and obtaining satisfactory explanations, INCB confirms the estimates. Supplementary estimates furnished during the course of the year are examined within a few days of submission.

Publication of estimates

4. Annual estimates confirmed by INCB are published in its technical report on narcotic drugs, which is published at the beginning of every year. In addition, amended estimates are published on a monthly basis on the INCB website (www.incb.org) and are sent to Governments in a supplement to the technical report published on a quarterly basis.

5. The annual estimates confirmed by INCB are valid until 31 December of the year to which they relate. Countries should manufacture, import or utilize narcotic drugs within the limits of the totals of estimates published by INCB. These estimates also serve as a guide for exporting countries regarding the limits to the quantities of narcotic drugs that can be exported into a country. Technical information on calculating estimates for narcotic drugs and instructions for completing form B are available in the Training Material on the Single Convention on Narcotic Drugs of 1961, available from www.incb.org/incb/narcotic_drugs.html.

B. Assessments for psychotropic substances

Submission of assessments and their amendments

6. To assist countries and territories in submitting assessments, INCB provides all Governments, in the first quarter of each year, with form B/P (Assessment of annual medical and scientific requirements for substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971). Governments may submit revisions of the assessments at any time, using form B/P.

Publication of assessments by the International Narcotics Control Board

7. Assessments are examined and explanations are requested, if required. The assessments for psychotropic substances for all countries are published annually by INCB in the technical report on assessments of annual medical and scientific requirements for substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971. In addition, the amended assessments are published on the INCB website on a monthly basis and are sent to Governments in a supplement to the technical report that is published on a quarterly basis.

8. The assessments should serve as guidelines for exporting countries regarding the quantities of psychotropic substances required for legitimate purposes in importing countries. Technical information on preparing assessments of psychotropic substances and instructions for completing form B/P are available in *Training Material: Control of Psychotropic Substances* (see www.incb.org/incb/en/psychotropic_substances.html).

C. Estimates for precursor chemicals

Submission of estimates and their amendments

9. To assist countries and territories in submitting estimated requirements for the four precursor chemicals (ephedrine, pseudoephedrine, 3,4-methylenedioxyphenyl-2-propanone and 1-phenyl-2-propanone), INCB provides all Governments, in the first quarter of each year, with form D (Annual information on substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances).[a] Form D should be submitted to INCB by 30 June of the year preceding that to which the estimates relate (for example, estimates of requirements for 2013 should be submitted in form D by 30 June 2012). Governments may submit revisions of the estimates at any time.

Publication of estimates by the International Narcotics Control Board

10. Confirmation by INCB of estimated requirements furnished by Governments is not required. The estimated requirements for the four precursors of amphetamine-type stimulants as furnished by Governments are published annually by INCB in the report on precursors and chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. In addition,

[a] In addition to the four substances mentioned above, form D allows Governments to submit approximate quantities required for all 23 chemicals in Tables I and II of the 1988 Convention.

the estimates are published and updated on the INCB website on a regular basis (see www.incb.org/incb/precursor_estimates.html).

11. The published requirements should provide the competent authorities of exporting countries with guidance on the quantities of the four precursor chemicals required for legitimate purposes in importing countries.

12. Technical details on preparing estimates on precursor chemicals are available in *Issues that Governments may consider when determining annual legitimate requirements for ephedrine and pseudoephedrine* (available from www.incb.org/incb/precursor_estimates.html).

---

13. The table below contains a summary of the key steps in the administration of estimates and assessments.

Key steps in the administration of estimates and assessments

	Estimates for narcotic drugs	*Assessments for psychotropic substances*	*Estimates for precursor chemicals*
Form used	B	B/P	D
Frequency of submission	Once a year	At least once every three years	Once a year
Submission deadline	30 June of the previous year	Any time	30 June of the previous year
Confirmation by INCB required	Yes	No	No
Validity	One year	Until amended, but preferably three years	Until amended, but preferably one year
Related publication and information source	INCB technical publication and website	INCB technical publication and website	INCB precursors report and website
Amendments possible	Yes, throughout the year	Yes, any time	Yes, throughout the year
Forms for amendment	Supplement to form B	B/P	Official correspondence from Government
Publication of amendments	Monthly on INCB website and quarterly in print	Monthly on INCB website and quarterly in print	As required, on INCB website

Annex III. Impediments to the availability and use of controlled substances for medical purposes

1. The global stocks of opioid raw materials and pharmaceutical preparations containing internationally controlled substances are sufficient to meet global demand.[a] However, adequate global supply does not lead to adequate availability in all countries. Access to these medicines is limited or almost non-existent in many countries, as shown in the *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*.[b]

2. In the report, INCB also noted that, in spite of the progress made towards meeting treaty objectives, relatively few countries in the world had an adequate drug supply management system and working mechanisms that ensured reliable, needs-based assessments, equitable availability and cost-effectiveness. Deficiencies in drug supply management remain attributable to lack of financial resources, inadequate infrastructure, the low priority given to health care, weak Government authority, inadequate education and professional training and outdated knowledge, which together affect the availability of not only controlled drugs but all medicines.

3. Substantial improvement in the availability of narcotic drugs and psychotropic substances is linked to progress in the availability of medicines in general, particularly in countries with limited resources for health care. However, in addition to general health system barriers, there is a subset of barriers that are unique to controlled substances, given their abuse potential and legal classification and their long history of being stigmatized.

4. For example, INCB surveyed national drug control authorities in 1995 and again in 2007 regarding barriers to the availability of one class of controlled substances, opioid analgesics, for medical use. Although conducted 12 years apart, it is striking how similar the barriers identified were. The barriers are listed below in descending order of the number of Governments that identified them, with those listed first being the most frequently identified by Governments.

5. The barriers to the availability and use of opioid analgesics, as identified by the 1995 INCB survey, were as follows:

(a) Fear of addiction to opioids;

(b) Lack of training of health-care professionals about the use of opioids;

(c) Laws or regulations that restrict the manufacture, distribution, prescribing or dispensing of opioids;

(d) Reluctance to prescribe or stock opioids stemming from fear of legal consequences;

(e) Overly burdensome administrative requirements related to opioids;

(f) Insufficient amount of opioids imported or manufactured in the country;

---

[a] See *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*. United Nations publication, Sales No. E.11.XI.7. Available from www.incb.org/pdf/annual-report/2010/en/supp/AR10_Supp_E.pdf.

[b] Ibid.

(g) Fear of diversion;

(h) Cost of opioids;

(i) Inadequate health-care resources, such as facilities and health-care professionals;

(j) Lack of national policy or guidelines related to opioids.

6. The barriers to the availability and use of opioid analgesics, as identified by the 2007 INCB survey, were as follows:

(a) Concerns about addiction to opioids;

(b) Reluctance to prescribe or stock opioids stemming from fear of legal consequences;

(c) Insufficient training of health-care professionals about opioids;

(d) Laws or regulations that restrict the opioid manufacture, distribution, prescribing or dispensing;

(e) Administrative burden of regulatory requirements for opioids;

(f) Cost of opioids;

(g) Difficulties encountered in the opioid distribution system;

(h) Insufficient import or manufacture of needed opioids;

(i) Lack of national policy or guidelines related to opioids.

7. This annex provides descriptions of four interrelated categories of barriers: knowledge and attitudes; controlled substance legislative and regulatory policy; controlled substance distribution barriers; and economic and procurement barriers.

8. The *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs* contains specific recommendations on how to overcome such barriers. In the report, countries were identified where consumption levels were particularly inadequate and where urgent action was required.

9. However, Governments need to take into account that regulatory systems need to ensure that controlled substances are available for medical purposes and that they protect populations against abuse and dependence. Unbalanced regulatory systems may lead to both under-prescribing and overprescribing, both of which are forms of inappropriate use.

A. Knowledge and attitudes

10. Inadequate knowledge, misinformation and negative attitudes about controlled substances and dependence syndrome ("addiction") are barriers to rational use and can also be a cause of policy and distribution barriers. If the professionals who administer a country's controlled substance regulation or those who provide health care are misinformed or have negative attitudes about controlled substances and their use in the treatment of health problems, such as in the treatment of pain, mental illnesses, anxiety and insomnia, and their use in surgery, they can create barriers to the adequate availability and use of controlled substances. The following section describes common examples of knowledge and attitude barriers to the use of controlled substances.

Inadequate education of health-care professionals

11. The Governments that responded to both the 1995 and 2007 INCB surveys frequently identified insufficient education of health-care professionals as a barrier to opioid availability. These results call attention to the need for educational initiatives to address health-care professionals' lack of knowledge about appropriate modern pain management with opioids, treatment of anxiety and insomnia with psychotropic substances, and treatment of other conditions with narcotic drugs and psychotropic substances.

12. In addition to teaching the most current clinical approach to treating pain and dependence syndrome with opioids, educational programmes can address and attempt to correct health-care professionals' negative attitudes about opioids, which often stem from myths and misinformation about the risks associated with the use of opioids, including concerns about dependence and fear of respiratory depression (or hastening death).

13. The barrier identified most often by Government authorities in both the 1995 and 2007 INCB surveys was concern about opioid dependence syndrome. There is evidence that dependence syndrome, when correctly defined, is not inevitable or even common when opioids are used to relieve pain from cancer and other conditions. Nevertheless, fears of dependence syndrome continue to impact the treatment decisions of patients and health-care professionals, often resulting in the utilization of suboptimal dosages of opioids and inadequate pain relief.

14. If provided with the necessary training and information about the proper use of opioids, health-care professionals will be well prepared and more willing to rationally prescribe, administer or dispense opioids. This will allow for the supply management system to function properly and demonstrate to the Government and other stakeholders that opioids are needed and can be used successfully. Successful examples of such educational efforts are contained in the *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs*.

Inadequate knowledge of health-care professionals regarding regulatory requirements

15. The 1995 and 2007 INCB surveys showed that Governments identified health-care professionals' fear of legal sanctions as a significant barrier to opioid availability. Indeed, World Health Organization (WHO) has recognized that health-care professionals may be reluctant to prescribe or stock opioid medications when they fear loss of their professional licence, or even criminal prosecution.

16. It should be noted that health-care professionals may not have accurate information about regulatory requirements, which can contribute to exaggerated concerns and doubts about prescribing controlled substances. Therefore, especially when policy changes are made to improve the regulatory environment for medical use of controlled medicines, it is important that health-care professionals, law enforcement and regulatory personnel be educated about modern medicine and clinical treatment guidelines in addition to the policy.

B. Controlled substance legislative and regulatory policy

17. The 1961 Convention as amended established a critically important framework to prevent diversion and abuse while ensuring that controlled substances are available for medical purposes

(relief of pain and suffering). It allows Governments to impose stricter restrictions than those in the Convention if it is necessary for the protection of public heath or welfare. However, in the preamble, the States parties recognized that adequate provision of narcotic drugs must be made to ensure the availability of such drugs for medical use.

18. The following are examples of common legislative and regulatory policy barriers that can interfere with patients' access to controlled substances for medical use:

(a) Burdensome prescription requirements, such as complicated prescription forms and special stamps and extra paperwork required to release controlled substances from a pharmacy;

(b) Restrictions on the amount of a prescription, such as a supply for only a brief period;

(c) Burdensome licensing requirements pertaining to the movement of opioids between authorized parties, such as several licences to transport opioids from a manufacturer to a hospital in another state within the country;

(d) Legal definitions that do not distinguish between patients using opioids therapeutically and people using illicit drugs.

C. Controlled substance distribution barriers

19. The distribution system for controlled substances often consists of Government-regulated distributors or wholesalers who distribute controlled substances to the health-care system, including pharmacies, hospitals, clinics, nursing homes, hospices and palliative care centres, where registered health-care professionals prescribe and dispense the medicines to patients.

20. The following are examples of common barriers to the distribution of controlled substances that can interfere with patients' access to controlled substances for medical use:

(a) Manufacturers and distributors do not distribute controlled substances in a timely way;

(b) Number and geographical distribution of health professionals, pharmacies and patient care facilities authorized to procure and dispense controlled substances are insufficient;

(c) Governments do not have the systems in place to guarantee a secure and effective transfer of controlled substances from wholesalers to retailers;

(d) Health-care facilities do not meet the national secure handling and storage requirements and are unable to accept controlled substances.

D. Economic and procurement barriers

21. The cost of controlled substances for medical use is relevant during the procurement process as well as throughout the distribution process to outlets that dispense them to patients. The retail cost of opioid analgesic products in particular has been identified by international organizations and researchers as a significant barrier to opioid availability and use.

22. The following are examples of economic and procurement barriers to using controlled substances for medical use:

(a) The Government has not made procurement arrangements for the importation or domestic manufacture of controlled substances;

(b) There are delays in Government decision-making about procurement;

(c) The Government's official estimate of type and quantity of controlled substances required is insufficient;

(d) The Government's method for estimating controlled substances is not appropriate and does not reflect the actual requirements;

(e) The retail cost of controlled substances is too high;

(f) There are inadequate incentives for commercial entities to make low-cost morphine available.

Glossary

Assessments for psychotropic substances: the quantities of psychotropic substances submitted to the International Narcotics Control Board (INCB) as being required by a country for medical, scientific and other legitimate purposes

Availability: the degree to which controlled substances are present at distribution points in a defined area for the population living in that area when they need them

Central distribution point: any of the facilities (including facilities operated by manufacturers, importers and wholesalers of controlled substances) that store bulk quantities of controlled substances for distribution to peripheral facilities

Competent national authority: national authority that is empowered to prepare estimates and assessments of legitimate requirements for controlled substances for the purpose of submission to INCB, in accordance with the relevant provisions of the international drug control conventions

Controlled substance: for the purpose of this *Guide*, a narcotic drug listed in the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, a psychotropic substance listed in the Convention on Psychotropic Substances of 1971 or a precursor listed in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988

Dependence syndrome: a cluster of behavioural, cognitive and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal state[a]

Estimates for narcotic drugs: quantities of narcotic drugs reported to INCB as being required for medical and scientific purposes

Estimates of legitimate requirements for precursor chemicals: the quantities submitted to INCB of the (currently four) precursor chemicals required for medical, scientific, research and industrial needs, including re-exports and reserve stocks

International drug control conventions: the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol; the Convention on Psychotropic Substances of 1971; and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988

Narcotic drug: any of the substances listed in the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol

Needs for controlled substances: quantities that would be necessary to provide adequate medical treatment for health problems in the population of a country

Operator: any legitimate person or agency engaged in the manufacture of, trade in or distribution of controlled substances

[a]See *WHO Expert Committee on Drug Dependence: Twenty-eighth report,* WHO Technical Report Series, No. 836 (Geneva, World Health Organization, 1993). Available from http://whqlibdoc.who.int/trs/WHO_TRS_836.pdf.

Peripheral facility: any of the facilities (including health-care facilities and regional warehouses that distribute controlled substances to retailers) that receive controlled substances from central distribution points

Precursor: any of the substances listed in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988

Psychotropic substance: any of the substances listed in the Convention on Psychotropic Substances of 1971

Requirements for controlled substances: the quantities necessary to provide medical treatment through the existing health-care infrastructure in a country, in conditions where controlled substances are used rationally and are not diverted

Standard treatment guidelines: systematically developed guidance documents to assist health-care professionals in making decisions about appropriate treatment for specific clinical conditions; ideally, such guidelines should include the standard treatment schedule for each health problem

Bibliography

International Narcotics Control Board. *Demand for and Supply of Opiates for Medical and Scientific Needs.* United Nations publication, Sales No. E.89.XI.5.

_____. *Effectiveness of the International Drug Control Treaties.* United Nations publication, Sales No. E.95.XI.5.

_____. *Availability of Opiates for Medical Needs.* United Nations publication, Sales No. E.96.XI.6.

_____. *Report of the International Narcotics Control Board for 1999.* United Nations publication, Sales No. E.00.XI.1.

_____. *Training Material: Control of Psychotropic Substances.* Vienna, 2003. Available from www.incb.org/pdf/e/psy/Training%20Material-E.pdf.

_____. *Training Material: 1961 Single Convention on Narcotic Drugs.* Vienna, 2005. Available from www.incb.org/incb/en/narcotic_drugs.html.

_____. Issues that Governments may consider when determining annual legitimate requirements for ephedrine and pseudoephedrine. Vienna, 2009.

_____. *Report of the International Narcotics Control Board on Follow-up to the Twentieth Special Session of the General Assembly.* United Nations publication, Sales No. E.09.XI.7.

_____. *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes.* United Nations publication, Sales No. E.11.XI.7.

United Nations. Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. *Treaty Series*, vol. 976, No. 14152.

_____. Convention on Psychotropic Substances of 1971. *Treaty Series*, vol. 1019, No. 14956.

_____. United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. *Treaty Series*, vol. 1582, No. 27627.

United Nations Office on Drugs and Crime, World Health Organization and Joint United Nations Programme on HIV/AIDS. A "Step-by-Step" Algorithm for the Procurement of Controlled Substances for Drug Substitution Treatment. Bangkok, 2007.

World Health Organization. *Estimating Drug Requirements: A Practical Manual.* Geneva, 1988. WHO/DAP/88.2.

_____. *WHO Expert Committee on Drug Dependence: Twenty-eighth Report.* WHO Technical Report Series, No. 836. Geneva, 1993.

_____. *Cancer Pain Relief: With a Guide to Opioid Availability.* 2nd. ed. Geneva, 1996.

_____, Programme on Substance Abuse. *Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care.* Geneva, 1996. WHO/PSA/96.17.

_____, Department of Essential Drugs and Medicines Policy. *Operational principles for good pharmaceutical procurement.* Geneva, 1999. WHO/EDM/PAR/99.5.

_____. Promoting rational use of medicines: core components. *WHO Policy Perspectives on Medicines,* No. 5, September 2002.

_____, Regional Office for South-East Asia. *The Role of Education in the Rational Use of Medicines.* SEARO Technical Publication Series No. 45. New Delhi, 2006.

_____. *WHO Expert Committee on Drug Dependence: Thirty-fourth Report.* WHO Technical Report Series, No. 942. Geneva, 2006.

_____. *Palliative Care*. Cancer Control: Knowledge into Action: WHO Guide for Effective Programmes Series, Module 5. Geneva, 2007.

_____. *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence.* Geneva, 2009.

_____. Achieving better health outcomes and efficiency gains through rational use of medicine. Technical Brief Series, No. 3, 2010.

_____. Guidance on the WHO review of psychoactive substances for international control. Geneva, 2010.

_____. *International Statistical Classification of Diseases and Related Health Problems*. 10th revision. Available from http://apps.who.int/classifications/apps/icd/icd10online/.

_____. *Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines.* Geneva, 2011.

_____. Glossary of Globalization, Trade and Health Terms. Available from www.who.int/trade/glossary/en/.

_____. WHO Model List of Essential Medicines. 17th ed. March 2011. Available from http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf.

_____. WHO Model List of Essential Medicines for Children. 3rd ed. March 2011. Available from http://whqlibdoc.who.int/hq/2011/a95054_eng.pdf.

World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Telephone: **+ 41 22 791 21 11**
Facsimile (fax): **+ 41 22 791 31 11**

ISBN: 978-92-4-150328-0

United Nations publication
Printed in Austria

V.11-87179—February 2012—250