WHO/EDM/QSM/2000.4
ENGLISH ONLY
DISTRIBUTION: GENERAL

NARCOTIC & PSYCHOTROPIC DRUGS

ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY

GUIDELINES FOR ASSESSMENT

WORLD HEALTH ORGANIZATION

authors.	lesdits auteurs.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The World Health Organization (WHO) has determined that the inadequate management of pain due to cancer is a serious public health problem in the world. Worldwide, there are 10 million new cases of cancer and 6 million deaths annually from this noncommunicable disease *(1)*. Twenty years from now, the global burden of cancer will double. The incidence of cancer, presently greatest in developed countries, will shift to developing countries, reflecting better prevention strategies in the developed world. The WHO Programme on Cancer Control has estimated that by the year 2020, approximately 70% of the annual 20 million new cancer cases will occur in developing countries *(1)*, where most patients are diagnosed when the disease is already in the late stages. Pain is prevalent in cancer, but especially in the late stages, near the end of life.

Tragically, cancer pain frequently goes untreated; when it is treated, relief is often inadequate. Yet, the WHO has demonstrated that most, if not all, pain due to cancer *could* be relieved if we implemented *existing* medical knowledge and treatments. There is a treatment gap: it is the difference between what can be done, and what *is* done about cancer pain. The treatment gap can be narrowed by educating and training health care workers, and by increasing access to pain relief and palliative care services. However, much of the treatment gap, especially in developing countries, is defined by the inadequate availability and use of pain medications, in particular the opioid analgesics.

Although there are many drug and non-drug pain treatments, the opioid analgesics such as codeine and morphine are *absolutely necessary* for the management of pain due to cancer. When cancer pain is moderate to severe, there is no substitute for opioids in the therapeutic group of morphine. The International Narcotics Control Board (INCB)[1], the international body that monitors, inter alia, global availability of narcotic drugs, emphasizes that these drugs must be available for pain relief.

Opioids are classified as narcotic drugs because they have a potential for abuse. As a consequence, they are regulated by international treaties and national drug control policies. The INCB, the WHO and national governments report that opioids are not sufficiently available for medical purposes. There are a number of reasons, including the low priority for pain management in health care systems, greatly exaggerated fears of addiction, overly restrictive national drug control policies, and problems in procurement, manufacture and distribution of opioids.

In some countries, governments and health care professionals have been working together to improve cancer pain management and palliative care; some have begun to identify and correct overly restrictive regulatory control over the medical use of opioid analgesics. Other countries have yet to address these matters. These Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO.

A 1995 INCB report *(3)* stated:

> *"...an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes"* (p.14).

[1] The International Narcotics Control Board is an independent treaty-based body that monitors implementation of the Single Convention on Narcotic Drugs, 1961, and other related treaties. For a description of the Board and its activities see: INCB, 1999 *(2)*.

SECTION I
PURPOSE AND AUDIENCE

The purpose of these self-assessment Guidelines is to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability.[2] These Guidelines may also be used to develop balanced national (including state, provincial or territorial authorities where relevant) drug control policies where none already exist. (See Annex 1 for definition of "national policy.") "Balance" refers to the dual purpose of preventing illegal trafficking and diversion, while ensuring their availability for medical and scientific purposes, in particular for the treatment of pain and suffering (see Section VII for further discussion).

This document is intended for those who make national drug control policy, as well as those who implement it. It may also be used by health care professionals and their organizations to encourage cooperation with governments and to facilitate further education.

This document accomplishes its purpose in several ways:

I. Background information is presented about the global problem of inadequate cancer pain relief (Section II);
II. Information is provided about why opioids (i.e., narcotic drugs, opiates[3]) are needed for the medical management of pain (Section III);
III. Information is given about the inadequate availability of opioid analgesics in most countries (Section IV);
IV. The reasons for inadequate availability are given, with specific reference to the overly restrictive regulation of pain medications under some national drug control policies (Section V);
V. A rationale is presented for governments to assess national policies for balance (Section VI);
VI. The method that was used to develop guidelines for conducting a self-assessment is described (Section VII);
VII. The Guidelines are presented to encourage consensus in the adoption of balanced national drug control policy. They are based on international medical and regulatory consensus that national drug control policy should be balanced (Section IX);
VIII. A checklist of questions is provided to guide the self-assessment (Section X);
IX. Reference information is provided on page 28-29;
X. Ordering information for key resources is provided in Annex 2; and
XI. A directory of the government offices responsible for narcotic regulation (National Competent Authorities) is available from the INCB at the following:

website http://www.incb.org
telephone +43-1-26060-4277, facsimile +43-1-26060-5867/5868

---

[2] There are three levels of barriers to adequate pain management: economic, medical and regulatory. While these Guidelines focus solely on regulatory issues, it is well understood that economic and medical barriers play major roles in the inadequate treatment of pain. For example, in some countries, for economic reasons, health care professionals are encouraged to use more expensive and less effective pharmaceutical products. This may exacerbate inadequate availability, both for the health care system in general, and for the individual patient. In some countries, scarce medical resources are spent on expensive curative treatments that are futile for patients with late-stage cancer *(4)*. Such policies preclude the provision of palliative care. Finally, medical education that does not address pain management contributes to inadequate pain management.

[3] See Annex 1 for an explanation of "opiate" and "opioids," and other key terms used in this publication.

SECTION II
INADEQUATE PAIN RELIEF

Pain is prevalent among people who have cancer. Cancer patients may need pain relief at every stage of the disease. More than two-thirds of patients with advanced cancer will experience pain, often severe *(5)*. For these patients, pain relief should be part of their overall treatment. For patients who have late stage cancer, the management of pain and other symptoms should be the primary aim of national cancer control programmes.

In 1996, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* stated:

> *"In most parts of the world, the majority of cancer patients present with advanced disease. For them, the only realistic treatment option is pain relief and palliative care"* (p. v).

Surveys suggest that more than 50% of cancer patients suffer unrelieved pain *(6)*. Unrelieved pain can impair all aspects of a person's life, including appetite, mood, self-esteem, relationships with others, and even the ability to move. In some countries, it has been reported that unrelieved pain can lead to the wish for death and inquiries about euthanasia and assisted suicide. Relief of pain has been demonstrated to improve quality of life.

SECTION III
MEDICAL NEED FOR OPIOID ANALGESICS

In 1986, the participants of the WHO Meeting on the Comprehensive Management of Cancer Pain *(6)* declared that:

> "*In patients with severe pain, morphine -- a strong opioid -- is the drug of choice*" (p. 18).

In 1986, the WHO announced to the world that most, if not all, cancer pain could be relieved if currently available medical knowledge was implemented *(6)*. Cancer pain can be relieved using a variety of drug and non-drug measures including opioid analgesics. However, morphine and opioids in the therapeutic group of morphine are considered essential when pain is moderate or severe *(4, 5, 6)*. Health care professionals have been encouraged to use the proven three-step Analgesic Method (see Annex 1 for definition) that was developed by the WHO as an effective method to treat pain.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* stated in 1990 that:

> *"Freedom from pain should be seen as a right of every cancer patient and access to pain therapy as a measure of respect for this right"* (p. 10).

Relief of severe cancer pain depends on the availability and use of opioids in the therapeutic group of morphine. These opioids do not have an "analgesic ceiling" (i.e., a pharmacological characteristic of a drug when an increased dose provides no additional analgesia). They can be administered safely in increasing doses until the pain is relieved, as long as side effects are tolerated *(5)*. There is no standard treatment dose for these opioids. The appropriate dose to relieve the pain should be determined by the individual needs of the patient.[4]

Morphine and one or more other opioid pain medications, as well as other drugs used for pain and symptom management, must be available in adequate amounts, when patients need them, and in the places where patients are living *(4)*.

In 1986, participants of the WHO Meeting on the Comprehensive Management of Cancer Pain *(6)* stated:

> "*Of 22 drugs commonly used for cancer pain relief, eight are covered by the 1961 Single Convention on Narcotic Drugs and one by the 1971 Convention on Psychotropic Substances...*" (p. 27).

The WHO Expert Committee on Essential Drugs *(7)* has for many years designated morphine, codeine and other opioids as "essential drugs," defined as:

> "*those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms...*" (p. 2).

The total global consumption of morphine increased significantly as some national governments and health professionals adopted the WHO Analgesic Method for cancer pain relief. However, the majority of the increasing consumption of morphine occurred in a small number of developed countries that represent a small part of the world's population *(3)*. More recently, morphine consumption has begun to increase in other countries, including in a number of developing countries. The statistical data from the INCB for the period from 1990 to 1998 show that substantial increases have occurred in both developed and developing countries, while consumption in other countries has remained stable or even decreased. Most countries use very little morphine.

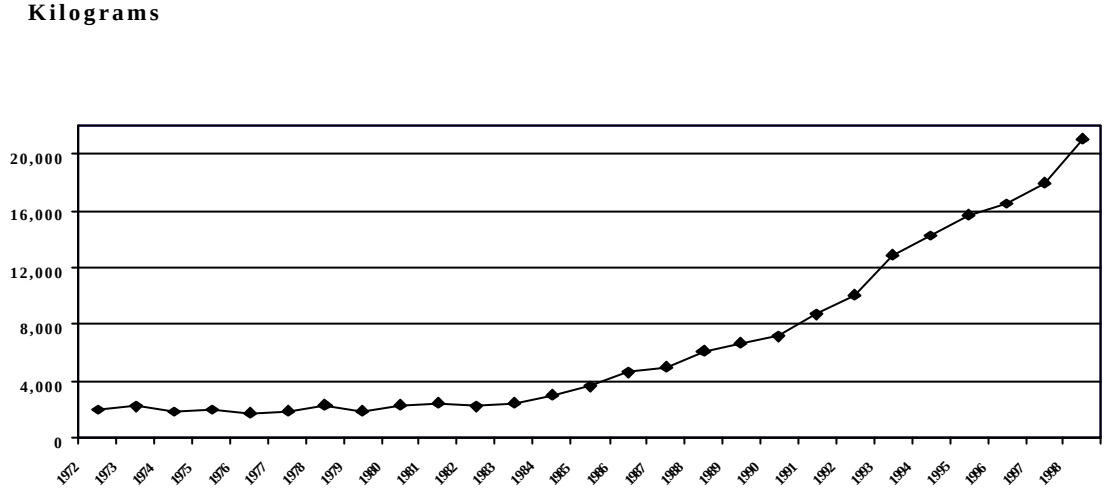
Annex 4 presents data on the consumption of a wider range of opioids stated in the form of defined daily dose (see Annex 1 for definition) per million, and expressed as a five-year average. Annex 4 allows for the comparison of the consumption of a number of opioids within and between countries. In many countries, consumption remains extremely low in comparison to the medical need, and many national governments have yet to address this important deficit *(3)*.

[4] For clinical information about how to choose and use analgesics see: WHO, 1996 *(5)*.

SECTION IV
THE INADEQUATE AVAILABILITY OF OPIOIDS

In most countries, morphine or other opioids in the therapeutic group of morphine either are not available, are available only in limited quantities or places, or are available but underused *(4)*. The publication of the WHO three-step Analgesic Method for cancer pain relief in 1986 contributed to the increased consumption of morphine throughout the world. Prior to the early 1980s, morphine consumption (see Annex 1 for definition) was low and stable (see the following figure).

Global Consumption of Morphine
1972-1998



Source: International Narcotics Control Board

In 1993, the WHO Expert Committee on Drug Dependence *(8)* recognized:

> *"...that there was a great need to ensure, in seeking to reduce the non-medical use of therapeutic psychoactive drugs, that patients with legitimate medical needs are not prevented from being treated with adequate amounts of appropriate medications. Evidence suggests that medical needs for opioids are not being fully satisfied, particularly among patients with cancer, who may require large doses of opioids to obtain optimal pain relief"* (p. 20).

According to a 1995 survey of governments by the INCB *(3)*, the injectable forms of morphine are still more available than the oral form recommended by the WHO. Although 60% of governments surveyed had endorsed the WHO Analgesic Method, approximately one-half of governments that responded to the survey reported that morphine is not available in all hospitals with cancer programmes. Success in implementing the WHO Analgesic Method has been limited by the lack of opioid analgesics; future success will depend on governmental efforts to identify and address impediments in their health care and regulatory systems.

SECTION V
IMPEDIMENTS TO OPIOID AVAILABILITY

The INCB and the WHO have called attention to the inadequate treatment of pain and have concluded that this is due, in part, to overly restrictive laws and regulations that impede the adequate availability and medical use of opioids *(3, 4, 5, 9, 10, 11)*. [5]

As early as 1986, the participants of the WHO Meeting on the Comprehensive Management of Cancer Pain *(6)* recognized the need to update national drug regulatory systems to respond to changing medical needs:

> *"Systems regulating the distribution and prescription of opioid drugs were designed before the value of the oral use of opioid drugs for cancer pain management was recognized. These systems were developed to prevent the social misuse of strong opioids; there was no intention to prevent the use of opioids for pain relief in cancer*" (p. 27).

In 1986, the participants of the WHO Meeting on the Comprehensive Management of Cancer Pain *(6)* further clarified the objectives of the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961 (hereafter referred to as "the 1961 Convention," see Annex 1) and the 1971 Convention on Psychotropic Substances:

> *"...The principal object of these two conventions is to stop trade in, and use of, controlled drugs,* ***except for medical and scientific purposes***. ***The conventions are not intended to be an impediment to the use of necessary drugs for the relief of cancer pain.*** *It is therefore important that, by complying with the conventions, national laws should not, at the same time, impede the use of these drugs in cancer patients. Some countries have gone beyond the minimal control measures laid down in the conventions. Some have established stringent controls, especially in relation to drug prescription and distribution* (Emphasis added)" (p. 27).

In 1989, the INCB *(9)* drew attention to some governments' overreaction to the drug abuse problem when:

> "*...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented*" (p. 1).
>
> *"...legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to*

[5] For a discussion of all the impediments to cancer pain relief, palliative care and opioid availability, see: WHO, 1990 *(4)*; 1996 *(5)*.

> *the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes"* (p. 15).

Indeed, the long-term use of opioids for pain has been discouraged traditionally because of the perceived risk of "drug dependence." Separation of perceptions and myths from reality requires accurate use of terminology.

Terminological confusions can deter both doctors and patients from the use of opioids even when there is a strong medical justification for their use. Two inter-related but different confusions may occur: (i) confusion between "abuse" (or "misuse") and long-term medical use, and (ii) confusion between "addiction" and "dependence."

Concerning the first confusion, the principal aim of the 1961 Convention is to prevent the abuse of narcotic drugs while ensuring their availability for medical use. It is therefore very important to make a clear distinction between abuse and medical use of narcotic drugs.

The 1961 Convention does not define the terms "misuse" or "abuse." However, "abuse" is defined by the WHO Expert Committee on Drug Dependence *(19)* as follows:

> *"persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice"* (p. 6).

From this definition, it is clear that medical use of drugs, whether long-term or not, and whether adverse drug reactions (including "drug dependence") occur or not, is not "drug abuse."

The confusion between "addiction" and "dependence" is more difficult to clarify because WHO no longer uses the term "addiction." Hence there is no authoritative WHO definition of "addiction" to compare with that of "dependence." [6]

The current definition of "dependence" [7] given by the WHO Expert Committee on Drug Dependence *(8)* is:

> *"A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high*

---

[6] In order to understand the difference between "addiction" and "drug dependence," it is necessary to briefly review the history of the evolution of the concept of "drug dependence." During the 1960s, the WHO Expert Committee on Addiction-Producing Drugs *(20)* made serious attempts to clarify the difference between "addiction" and "habituation," only to abandon this effort and to propose instead the use of the term "drug dependence." In the minds of some experts, this led to the misunderstanding that the meaning of the then new term "dependence" would be the same as "addiction" or "habituation," or both of them combined. This was not the case. As emphasized by that Expert Committee, the term "dependence" carried no connotation of the degree of risk to public health. This was a major difference from the term "addiction," which did carry such a connotation.

[7] The same Expert Committee *(8)* also recommended against efforts to distinguish between "physical dependence" and "psychic dependence," because it felt that all drug effects on the individual are potentially understandable in biological terms. In addition, the Committee noted that "physical dependence" had been confusing to some clinicians because the manifestation of withdrawal syndrome (see Annex 1 for definition) was interpreted as evidence of both "physical dependence" and "drug dependence."

priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour. Determinants and problematic consequences of drug dependence may be biological, psychological or social, and usually interact" (p. 5).

The core concept of the WHO definition of "drug dependence" requires the presence of a strong desire or a sense of compulsion to take the drug.

Clinical guidelines (ICD-10) for a definite diagnosis of "dependence" drawn up by WHO require that three or more of the following six characteristic features have been experienced or exhibited *(21)*:

(a) a strong desire or sense of compulsion to take the substance;

(b) difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use;

(c) a physiological withdrawal state when substance use has ceased or been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or a closely related) substance with the intention of relieving or avoiding withdrawal symptoms;

(d) evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses;

(e) progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects;

(f) persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm (p. 75-76).

It is clear that a cancer patient requiring increased doses of an opioid for pain relief (see Annex 1 for definition of "tolerance"), who also develops withdrawal symptoms (see Annex 1 for definition of "withdrawal syndrome") upon discontinuation of the drug, meets only two of the three required conditions for a positive diagnosis of dependence syndrome. The patient is therefore not opioid dependent, unless he or she additionally meets at least one of the four remaining conditions listed above (*a*, *b*, *e* or *f*).

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* points out that "dependence" occurs rarely in cancer patients:

"Studies have shown that, while withdrawal syndrome and tolerance do occur in patients who take opioids over a long period, [drug] dependence is extremely rare. Consequently, the risk of [drug] dependence should not be a factor in deciding whether to use opioids to treat the cancer patient with pain" (p. 58).

The adverse drug reaction reports from the WHO Collaborating Centre for International Drug Monitoring at Uppsala, Sweden, support this observation. In the framework of the WHO programme for international drug monitoring, "drug dependence" is defined as one of the adverse drug reactions to be monitored and reported to this Collaborating Centre by the participating national monitoring centres. As of 1999, 56 countries participate in this international programme and the database contains more than two million adverse drug reaction case reports. The list of drugs for which "drug dependence" has ever been reported to this system indicates that only modest numbers of drug dependence cases have been associated with the use of opioid analgesics and that "dependence" has been reported for many other drugs, controlled as well as uncontrolled *(22)*.

SECTION VI
THE IMPERATIVE TO EVALUATE NATIONAL DRUG CONTROL POLICY

Both the INCB and the WHO have called on governments to evaluate their health care systems and laws and regulations, and to identify and remove impediments to opioid availability for medical needs *(3, 4, 5, 9, 10, 11)*. While it is equally important to evaluate national drug control policy for its potential ability to prevent trafficking, diversion and abuse of controlled substances, information and guidance are available for such evaluation *(12)*.

A 1995 INCB report *(3)* commented on the extent of diversion of narcotic drugs:

> *"The international system to prevent diversion of narcotic drugs is working well. The number of incidents involving diversion of narcotic drugs is small considering the large number of transactions at the international and national level"* (p. 1).

Therefore, the sole focus of this Guideline is on the evaluation of national drug control policies that affect opioid availability.

In 1989, the INCB *(9)* stated:

> *"One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion*" (p. 3).

In 1989, the INCB *(9)* reviewed the reasons for inadequate opioid availability in cooperation with the WHO, and requested governments throughout the world to:

> *"...examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications*" (p. 17).

In 1990, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* recommended that national governments should provide for:

> *"...regular review [of legislation], with the aim of permitting importation, manufacture, prescribing, stocking, dispensing and administration of opioids for medical reasons,...[and] review of the controls governing opioid use, with a view to simplification, so that drugs are available in the necessary quantities for legitimate use..."* (p. 65-66).

In 1995, the INCB *(3)* surveyed all governments[8] to determine if they had responded to the Board's 1989 recommendation. Responses to the survey were analyzed and published, and a number of conclusions and recommendations were made, including that:

> *"Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments*" (p. 15).

> *"The Board notes that most governments in the world did not respond to its questionnaire; thus, the Board did not have sufficient information concerning approximately one half of the world's population. Among those governments that did not respond were most of the developing and least developed countries, as well as those governments that had frequently failed to submit annual estimates of narcotic drug requirements as required by the 1961 Convention. The Board is cognizant that less developed countries have more difficulty meeting basic health-care needs. Nevertheless, the Board encourages governments of such countries to make efforts to examine their medical needs for narcotic drugs as well as the impediments to their availability"* (p. 14).

> *"The Board concludes that the recommendations contained in its 1989 special report are far from being implemented and that, while there have been efforts by some governments to ensure the availability of narcotic drugs for medical and scientific purposes, it appears that many others have yet to focus on that obligation"* (p. 14).

[8] Sixty-five governments responded in time to be considered in the INCB's 1995 report, published in 1996. Since then, 57 more countries responded. Analysis of all 122 surveys indicates that problems with availability of opioids are even more severe than was thought based on the initial response (to be published in the INCB 1999 annual report).

SECTION VII
METHOD FOR PREPARING THE GUIDELINES

The 1995 INCB report *(3)* stated:

> *"The availability of narcotic drugs is guided by national policy that should be consistent with the international conventions on narcotic drugs*" (p. 5).

The validity of guidelines used in policy analysis depends on their credibility and relevance to the policies being evaluated *(13, 14)*. The present Guidelines were developed following a review and analysis[9] of sources of authority for international drug control policy. The sources of authority are found in Conventions; in the recommendations of United Nations bodies which monitor implementation of the Conventions; and in the findings and recommendations of WHO experts in the fields of substance abuse and medical and scientific policy concerning the use of opioid analgesics for pain relief. "Balance," the Central Principle of the Guidelines, is directly derived from the treaty obligations of national governments, as defined in the 1961 Convention.

The Central Principle of "balance" is intended to guide the development and implementation of international and national drug control policies. It provides a relevant and credible basis for evaluating national drug control policy and is summarized in Figure 2.

Figure 2 **The Central Principle of "Balance"**

The Central Principle of "balance" represents a dual imperative of governments to establish a system of control to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability. While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain. Opioids, including those in the therapeutic group of morphine, should be accessible to all patients who need them for relief of pain. Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes. These steps include empowering medical practitioners to provide opioids in the course of professional practice, allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and ensuring that a sufficient supply of opioids is available to meet medical demand.

When misused, opioids pose a threat to society; a system of control is necessary to prevent abuse, trafficking, and diversion, but the system of control is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care. Indeed, governments have been asked to identify and remove impediments to the availability and medical use of opioid analgesics.

The dual purposes of preventing abuse and ensuring availability could pose a question of how to balance what might appear to be competing interests. This matter is clearly addressed by the recognition that efforts to prevent abuse should not interfere with ensuring availability for medical and scientific purposes.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* stated in 1996:

[9] The review was conducted by the WHO Collaborating Centre for Policy and Communications in Cancer Care at the University of Wisconsin Pain & Policy Studies Group (PPSG), Comprehensive Cancer Center, Madison, Wisconsin, USA. For more information regarding the use of opioid analgesics for pain relief, please see the PPSG website at: http://www.medsch.wisc.edu/painpolicy.

"The Single Convention recognizes that governments have the right to impose further restrictions if they consider it necessary, to prevent diversion and misuse of opioids. However, this right must be continually balanced against the responsibility to ensure opioid availability for medical purposes...In deciding the appropriate level of regulation, governments should bear in mind the dual aims of the Single Convention" (p. 56).

SECTION VIII
USING THE GUIDELINES

The present Guidelines may be used by governments and also by health professionals. The Guidelines can be used: (1) as an educational tool to inform interested parties about the relationship between national drug control policy and the availability of opioid analgesics for pain relief; (2) as a policy evaluation tool; and (3) as a basis for formulating new policies or improving existing policies.

For educational purposes, the Guidelines can be distributed to the relevant government and non-government organizations, especially to those individuals and groups who are interested in drug control and improvement of cancer pain relief and palliative care.

The need to evaluate policy is clear, but the way to do it may not be. Several steps are recommended to governments:

I. Identify a person or committee, including the National Competent Authority and health professionals, to study the Guidelines. Governments may wish to organize a special meeting or workshop of regulators and health care practitioners to discuss the self-assessment and complete the Checklist;
II. Obtain additional information from the key resource materials (see Annex 2);
III. Obtain up-to-date copies of the national drug control policies and study them;[10]
IV. Use the Self-Assessment Checklist in Section X to assess the policies;
V. Establish dialogue with policy-makers to make the necessary changes.

SECTION IX
THE GUIDELINES

This section presents the Guidelines and provides additional documentation and guidance from authoritative sources. Six of the guidelines relate to national laws and regulations; ten guidelines relate to administrative policies, directives and practices that implement national laws and regulations. Where possible, results from the 1995 INCB survey *(3)* were used to describe what is known about the status of governments' policies in relation to the Guidelines. The Self-Assessment Checklist in Section X may be used as a practical guide to accomplish the evaluation. (See Annex 3 for a summary of the Guidelines.)

[10] For an index of national laws and regulations for narcotic drugs and psychotropic substances see: UN International Drug Control Programme, 1994 *(15)*.

Guideline 1: Governments should examine their drug control policies for the presence of overly restrictive provisions that may impact their health care system in the delivery of pain relief, and take corrective action as needed.

In 1989, the INCB *(9)* stated that governments should:

> "*...examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications*" (p. 17).

In 1995, an INCB survey *(3)* found that 57% of responding governments had examined whether there were factors in their health care systems and laws and regulations that impeded the use of opiates for medical purposes.

In response to this finding, the INCB *(3)* recommended in its 1995 report:

> *"Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments"* (p. 15).

The INCB *(3)* clearly recognized the limited resources that some countries face, when it stated in 1995 that:

> *"...less developed countries have more difficulty meeting basic health-care needs. Nevertheless, the Board encourages governments of such countries to make efforts to examine their medical needs for narcotic drugs as well as the impediments to their availability, to advise the Board of the results of those efforts and to inform the Board if it can be of assistance"* (p. 14).

Guideline 2: National drug control policies should recognize that opioids are absolutely necessary for medical care, in particular for relief of pain and suffering.

The 1995 INCB report *(3)* found that 48% of responding governments reported that their laws recognize that narcotic drugs were indispensable for the relief of pain and suffering.

The Preamble to the 1961 Convention *(16)* recognizes that:

> *"...the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering..."*

In its 1995 report, the INCB *(3)* stated that:

> *"Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the*

fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering..." (p. 16).

Guideline 3: National drug control policies should recognize the obligation of governments to ensure adequate opioid availability for all medical and scientific needs.

The 1995 INCB report *(3)* found that 63% of responding governments said that there was a provision recognizing the obligation of the national government to ensure availability of narcotic drugs for medical purposes.

The 1961 Convention *(16)*, Article 4, declares that:

> *"the Parties [national governments] shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution...and possession of drugs..."*

Likewise, the INCB report *(3)* recommended in 1995:

> *"Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account...the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...*" (p. 16).

Guideline 4: Governments should designate an authority for ensuring adequate availability of opioids for medical care.

The INCB *(3)* recommended in 1995 that:

> "*Governments should...take into account...the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...[and] that administrative responsibility has been established and that personnel are available for the implementation of those laws*" (p. 16).

Guideline 5: Governments should develop, using information from relevant sources, a practical method to estimate realistically the medical and scientific needs for opioids.

In 1995, the INCB survey *(3)* showed that 59% of responding governments had not critically examined their methods for assessing medical need for opiates.

In 1995, the INCB report *(3)* recommended that:

> *"Governments and the [International Narcotics Control] Board need to have accurate information about medical needs for narcotic drugs. In the case of narcotic drugs that are opiates, it is particularly important to accurately estimate all medical needs because the Board must make arrangements well in advance to cultivate a sufficient quantity of poppy plants. In making these decisions, the Board considers a number of factors, including recent consumption trends, Governments'*

estimates of future medical needs, trends in health problems that could affect the amount needed in the future, as well as actions being planned by Governments and others to better address those problems" (p. 1).

"Governments should establish a system to collect information from medical facilities that care for surgical, cancer and other patients, from organizations that are working to improve the rational use of narcotic drugs and from manufacturers, distributors, exporters and importers and should establish groups of knowledgeable individuals to assist in obtaining information about changing medical needs" (p. 15-16).

Article 19, paragraph 4 of the 1961 Convention *(16)* states:

"The Parties shall inform the Board of the method used for determining quantities shown in the estimates and of any changes in the said method."

The participants of the WHO Meeting on the Comprehensive Management of Cancer Pain *(6)* in 1986 suggested:

"Governments should encourage health care workers to report to the appropriate authorities any instance in which oral opioids are not available for cancer patients who need them" (p. 36).

Guideline 6: Governments should furnish to the INCB annual estimates of the quantities of narcotic drugs needed for medical and scientific purposes for the following year.

Article 19, paragraph 1 of the 1961 Convention *(16)* states:

"The Parties shall furnish to the Board each year for each of their territories, in the manner and form prescribed by the Board, estimates on forms supplied by it in respect of the following matters: (a) Quantities of drugs to be consumed for medical and scientific purposes; (b) Quantities of drugs to be utilized for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention; (c) Stocks of drugs to be held as at 31 December of the year to which the estimates relate..."

Article 12, paragraph 3 of the 1961 Convention *(16)* states:

"If any State fails to furnish estimates in respect of any of its territories by the date specified, the Board shall, as far as possible, establish the estimates. The Board in establishing such estimates shall to the extent practicable do so in co-operation with the Government concerned."

The 1995 INCB report *(3)* recommended that:

"Governments submit annually to the Board official estimates of the next year's requirements for narcotic drugs... In 1989, the Board requested Governments to

critically examine their methods of assessing domestic medical need and to make the changes required to ensure that future estimates would accurately reflect the medical need...If past consumption trends for narcotic drugs are stable, future needs can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. If medical demand for one or more narcotic drugs is increasing in response to unmet needs, the method of estimation should take into account the extent of unmet needs and the potential effects on future demand of efforts to improve the rational use of narcotic drugs" (p. 8).

"*To implement these responsibilities, Governments enact laws and take administrative and enforcement measures. Each Government estimates annually the amount of narcotic drugs that will be needed to satisfy all medical and scientific requirements in the country for the next year. The International Narcotics Control Board evaluates, confirms and publishes the amount of narcotic drugs for each Government. Each Government may then manufacture or import narcotic drugs within that amount, and distribute them to medical facilities for the treatment of patients*" (p. 1).

In assessing their annual estimates for opioids, governments should take into account past consumption trends and anticipate future demand by increasing their estimates as suggested by INCB to sufficiently cover their actual needs. The INCB *(3)* recommends that governments increase their estimates of requirements of narcotic drugs from year to year to allow for the possibility of increased consumption that may be due to education and heightened awareness. In countries or territories where there is rapid economic and social development, or where present consumption is low due to inadequate pain management, or where there is recent expansion of pain relief programmes, subsequent increases in the annual estimate may be expected to be relatively higher than in other countries:

"*Governments should add to their annual estimates of requirements for narcotic drugs a margin of 10 per cent to allow for the possibility of increased consumption... and, if need be, should add an even greater margin in countries or territories where there is rapid economic and social development*" (p. 16).

Guideline 7: Governments should furnish a supplementary estimate to the INCB if it appears that the availability of narcotic drugs will fall short of medical needs, or to meet emergency needs or exceptional medical demand.

In 1995, an INCB survey *(3)* showed that 60% of responding governments had submitted supplementary estimates to the Board because of unforeseen increases in medical need. When furnishing a supplementary estimate, governments should always include an explanation of the circumstances necessitating the increase. Although supplementary estimates should not become a common practice, it is recommended that supplementary estimates be furnished by the Competent Authority and communicated via facsimile to the Board in order to act expeditiously on these requests.

In 1998, the WHO Expert Committee on the Use of Essential Drugs *(7)* stated:

"Following the recommendation of the Committee at its previous meeting, endorsed subsequently by the International Narcotics Control Board, an international consensus was established at the United Nations Commission on Narcotic Drugs in 1996 on the application of simplified control measures to permit the use of morphine in emergency situations. On the basis of this consensus, WHO has developed model guidelines on the simplified control procedures and distributed them to national drug regulatory authorities" (p. 57).

In 1995, the INCB *(3)* stated:

"*If there are unforeseen increases in medical demand, Governments may submit supplementary estimates to the Board at any time. Requests for supplementary estimates are acted on expeditiously*" (p. 1).

"*If medical demand exceeds the estimates, governments may submit supplementary estimates at any time; these are examined and confirmed expeditiously by the Board. In recent years, the number of supplementary estimates has increased significantly*" (p. 8).

Article 12, paragraph 5 of the 1961 Single Convention *(16)* declares:

"*The Board, with a view to limiting the use and distribution of drugs to an adequate amount required for medical and scientific purposes and to ensuring their availability for such purposes, shall as expeditiously as possible confirm the estimates, including supplementary estimates, or, with the consent of the Government concerned, may amend such estimates.*"

Article 21, paragraph 4 (b) of the 1961 Convention *(16)* states that:

"*...Parties shall not during the year in question authorize any further exports of the drug concerned to that country or territory, except: (i) In the event of a supplementary estimate being furnished for that country or territory in respect both of any quantity over-imported and of the additional quantity required, or (ii) In exceptional cases where the export, in the opinion of the Government of the exporting country, is essential for the treatment of the sick.*"

Guideline 8: Governments should submit annual statistical reports to the INCB on the production, manufacture, trade, use and stocks of narcotic drugs.

Article 20, paragraph 1 of the 1961 Convention *(16)* declares:

"*The Parties shall furnish to the Board for each of their territories, in the manner and form prescribed by the Board, statistical returns on forms supplied by it in respect of the following matters: (a) Production or manufacture of drugs; (b) Utilization of drugs for the manufacture of other drugs, of preparations in Schedule III and of substances not covered by this Convention, and utilization of poppy straw for the manufacture of drugs; (c) Consumption of drugs; (d) Imports and exports of drugs and poppy straw; (e) Seizures of drugs and disposal thereof; (f) Stocks of*

drugs as at 31 December of the year to which the returns relate; and (g) Ascertainable area of cultivation of the opium poppy."

Guideline 9: Governments should establish a dialogue with health care professionals about the legal requirements for prescribing and dispensing narcotic drugs.

In 1995, an INCB survey *(3)* of impediments to opioid availability identified health care professionals' fear of legal sanctions as a significant impediment. Specifically, the reluctance to prescribe or stock opiates was attributed to concerns about legal sanctions; this was the third most-frequently ranked impediment (47% of respondents).
In 1989, the INCB *(9)* recommended that:

> *"Health professionals... should be able to...[provide opiates]...without unnecessary fear of sanctions for unintended violations...[including]...legal action for technical violations of the law...[that]...may tend to inhibit the prescribing or dispensing of opiates"* (p. 15).

The INCB report *(3)* further suggested in 1995:

> "*Governments should communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and should provide an opportunity to discuss mutual concerns*" (p. 16).

In 1990, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* recognized that:

> *"Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licenses being suspended or revoked by the governing authority in cases where large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved"* (p. 39).

Then, in 1996, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* stated:

> "*It is understood that regulatory requirements for physicians, nurses and pharmacists to dispense opioids to patients will differ from country to country. However, the following are general guidelines that can be used to develop a practical system.*
>
> *Legal authority: Physicians, nurses and pharmacists should be legally empowered to prescribe, dispense and administer opioids to patients in accordance with local needs.*
>
> *Accountability: They must dispense opioids for medical purposes only and must be held responsible in law if they dispense them for non-medical purposes. Appropriate records must be kept. If physicians are required to keep records other than those associated with good medical practice, the extra work incurred should*

be practicable and should not impede medical activities. Hospitals and pharmacists must be legally responsible for safe storage and the recording of opioids received and dispensed. Reasonable record keeping and accountability provisions should not discourage health care workers from prescribing or stocking adequate supplies of opioids" (p. 57-58).

Likewise, health care professionals are encouraged to establish a dialogue with governments. In 1995, the INCB *(3)* stated:

"Educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives, should establish ongoing communication with Governments about national requirements for the medical use of narcotic drugs, unmet needs for narcotic drugs and impediments to the availability of narcotic drugs for medical purposes" (p. 18).

Guideline 10: National drug control authorities and health care professionals should cooperate to ensure the availability of opioid analgesics for medical and scientific purposes, including for the relief of pain.

The INCB and the WHO have made several recommendations that necessitate exchange of information and communication between regulators and health care professionals. The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* found in 1996 that:

"Communication between health workers and drug regulators is essential in order to ensure that each understands the other's aims. It is important for pain management experts and medical associations to understand about the national estimate of opioid needs, and be aware of the concerns of regulators. Opioid abuse is a reality, and health care workers must cooperate in the campaign to prevent diversion. It is also important for regulators to learn about the importance of pain relief both for individual patients and for public health in general. Information about cancer pain, where and how cancer patients are treated, and the training of health care personnel will help regulators whose job it is to ensure the integrity of the distribution system. The knowledge that opioid use needs to increase will help regulators to make appropriate changes in the annual estimate"(p. 49).

The INCB *(3)* has recommended several subject areas that should be the focus of the communication between regulators and health professionals:

"Governments should establish a system to collect information from medical facilities that care for surgical, cancer and other patients, from organizations that are working to improve the rational use of narcotic drugs and from manufacturers, distributors, exporters and importers and should establish groups of knowledgeable individuals to assist in obtaining information about changing medical needs" (p. 15-16).

"Governments should inform health professionals about the WHO analgesic method for cancer pain relief" (p. 16).

> *"Governments should communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and should provide an opportunity to discuss mutual concerns"* (p. 16).

> *"Educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives, should teach students in health-care professions and licensed practitioners about the rational use of narcotic drugs, their adequate control and the correct use of terms related to dependence...[and]...should establish ongoing communication with Governments about national requirements for the medical use of narcotic drugs, unmet needs for narcotic drugs and impediments to the availability of narcotic drugs for medical purposes"* (p. 18).

From time to time, physicians may be pressured to provide controlled substances for persons who are not their patients, or for other than legitimate medical purposes. Such pressure may pose a threat to the safety and security of medical practitioners. Succumbing to such pressure is also illegal and unethical medical practice. Thus, one area of cooperation between governments and national medical associations should be to recognize such pressures if they exist, address the source of such pressure, and devise ways to support physicians to resist such pressures.

In 1986, the World Medical Association *(17)* declared:

> *"Physicians must have the professional freedom to care for their patients without interference. The exercise of the physician's professional judgement and discretion in making clinical and ethical decisions in the care and treatment of patients must be preserved and protected"* (p. 1).

Guideline 11: Governments should ensure, in cooperation with licensees, that the procurement, manufacture, and distribution of opioid medications are accomplished in a timely manner so that there are no shortages of supply, and that such medications are always available to patients when they are needed.

In some instances, even in the absence of any specific regulatory impediments in national drug control policy, the process by which a country procures and/or distributes opioid medications may prevent an adequate supply of medication from reaching the patient. The WHO and the INCB have addressed this situation.

In 1986, the participants of the WHO Meeting on the Comprehensive Management of Cancer Pain *(6)* found that:

> *"There is a lack of flexibility in existing drug distribution systems that prevents a wider variety of professional health care workers from prescribing and/or distributing drugs for relief of cancer pain"* (p. 29).

> *"The proliferation of national laws and/or administrative measures regulating the prescription and distribution of opioid drugs necessary for cancer pain relief has hindered access by patients to these drugs"* (p. 28).

In 1990, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* declared:

> *"Manufacturers and/or distributors should be empowered to import, manufacture, stock and distribute opioids in keeping with the international drug conventions and good medical practice"* (p. 39).

In 1996, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* stated:

> *"After the estimate has been confirmed by the INCB, a country may either import or manufacture opioids. In both cases, the participants in the distribution chain should endeavour to ensure that the supply is reliable. Interruptions in the distribution of opioids is distressing for both patients and families and must be avoided"* (p. 50).

In 1995, the INCB report *(3)* recommended that:

> *"Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability* ***and distribution*** *for such purposes, and should make the necessary adjustments* (Emphasis added)" (p. 15).

> *"Governments that experience interruptions in supply of narcotic drugs because of delays in importation or for other reasons should examine the situation and develop a system to accomplish in a timely manner the steps involved, such as issuing licences, arranging for payment, carrying out paperwork, transporting the drugs, taking the drugs through customs and distributing the drugs to medical facilities"* (p. 16).

Guideline 12: Governments should permit and encourage the distribution and availability of opioid medications throughout the country, in order to maximize physical access of patients to pain relief medications while maintaining adequate controls to prevent diversion and abuse.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* found in 1990 that:

> *"It is usually in the patient's best interest to return home if adequate health care support is available: discharge from an institution enhances the patient's autonomy and therefore self-esteem"* (p. 56).

In 1996, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* further clarified that:

"Opioids should be available in locations that will be accessible to as many cancer patients as possible" (p. 58).

Guideline 13: Governments should establish and promote a national cancer control programme that includes cancer pain relief and palliative care as a priority for health care resources, including education about the WHO Analgesic Method and provision of pain relief and palliative care.

A 1995 INCB survey *(3)* found that 65% of responding governments reported that they had issued national polices and guidelines to improve the medical use of opioid analgesics for a range of medical conditions, including for pain. In addition, 52% of the governments said that they had sponsored, supported, or endorsed educational programmes in their countries to improve the medical use of opioids. Sixty percent said that they had endorsed the WHO Analgesic Method.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* in 1990 recommended the following:

"Governments should establish national policies and programmes for cancer pain relief and palliative care...[and] ensure that cancer pain relief and palliative care programmes are incorporated into their existing health care systems: separate systems of care are neither necessary nor desirable...[and that] health care workers (physicians, nurses, pharmacists, or other categories appropriate to local needs) are adequately trained in palliative care and the relief of cancer pain...[and] review their national health policies to ensure that equitable support is provided for programmes of palliative care in the home..." (p. 65).

In 1995, the World Health Organization guideline on "National Cancer Control Programmes" *(18)* stated:

"Most cancer in the world is incurable when diagnosed. Even in the developed countries, where prolonged survival has been achieved in a substantial proportion of cases, 50% of cancer patients will die of their disease. Palliative care therefore deserves high priority in cancer therapy, and will be required in 80% of cases in some countries. The relative simplicity and inexpensiveness of palliative care justify considerable attention being given to that aspect of cancer control worldwide" (p. 82).

The 1995 INCB report *(3)* found that:

"Governments should inform health professionals about the WHO analgesic method for cancer pain relief" (p. 16).

Guideline 14: Terminology in national drug control policy should not have the potential to confuse the medical use of opioids for pain with drug abuse or drug dependence.

According to a survey of governments conducted by the INCB *(3)*, the impediment to improving availability and use of opioids most frequently identified by government drug control agencies was concern about drug abuse (72%). Furthermore, 54% of the governments indicated that their narcotic law defined addiction or drug dependence, and 43% required patients who received

opioid prescriptions to be reported to the government. Section V describes terminological problems and clarifies in detail the meaning of these key terms.

Guideline 15: In their efforts to prevent diversion, governments should avoid undue restrictions impacting on patient care decisions which are ordinarily medical in nature. Such decisions as the amount of drug prescribed and duration of treatment should be made by the physician and be based on individual patient needs.

A 1995 INCB survey *(3)* found that, for hospital patients, 60% of the responding governments did not set a maximum amount, and 80% did not set a maximum length of time for which opioids could be prescribed at one time. For patients who live at home, 49% of responding governments did not set a maximum quantity, and 72% did not set a maximum length of time, for which morphine could be prescribed.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(5)* found in 1996 that:

> *"Medical decisions: Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation"* (p. 58).

Guideline 16: National drug control policy should avoid prescription requirements that may unduly restrict physician and patient access to pain relief.

A 1995 INCB survey *(3)* found that 35% of responding governments reported that special government prescription forms were not necessary for a physician to prescribe morphine. For example, some governments require physicians to use complicated prescription forms with several parts that need to be completed separately and which are available in limited quantity and from few places in the country.

Article 30, paragraph 2 (b) of the 1961 Convention *(16)* declares:

> *"[Governments shall]...(i) Require medical prescriptions for the supply or dispensation of drugs to individuals. This requirement need not apply to such drugs as individuals may lawfully obtain, use, dispense or administer in connection with their duly authorized therapeutic functions; and (ii) If the Parties deem these measures necessary or desirable, require that prescriptions for drugs in Schedule I should be written on official forms to be issued in the form of counterfoil books by the competent governmental authorities or by authorized professional associations."*

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care *(4)* recommended in 1990 that:

> *"Record-keeping and authorization requirements should not be such that, for all practical purposes, they eliminate the availability of opioids for medical purposes. Multiple-copy prescription programmes are cited as means of reducing careless prescribing and 'multiple doctoring' (patients registering with several medical*

practitioners in order to obtain several prescriptions for the same, or similar, drugs). There is some justification for this, but the extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should also be questioned" (p. 39).

SECTION X
SELF-ASSESSMENT CHECKLIST

Governments or other interested groups, including health care professionals, may use the following checklist to guide their analysis of national drug control policies. Please note that some inquiry may be needed prior to answering the questions contained on this checklist.

1. Has the government conducted an examination to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments?

, Yes , No , Information not available

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are absolutely necessary for the relief of pain and suffering?

, Yes , No , Information not available

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make adequate provision to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering?

, Yes , No , Information not available

4a. Has the government established administrative authority for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? [11]

, Yes , No , Information not available

4b. Are adequate personnel (employees) available for the implementation of this responsibility?

, Yes , No , Information not available

5a. Does the government have a method to estimate realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care?

, Yes , No , Information not available

[11] **In some cases, the government's policy may be found in either the law or administrative policies, or in both.**

5b. Has the government critically examined its method for assessing medical needs for narcotic drugs, as requested by the INCB?

, Yes , No , Information not available

5c. Has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities?

, Yes , No , Information not available

6. Does the government furnish annual estimates to the INCB of need for narcotic drugs for the next year in a timely way?

, Yes , No , Information not available

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a supplementary estimate?

, Yes , No , Information not available

8. Does the government submit to the INCB in a timely way the required annual statistical reports respecting production, manufacture, trade, use and stocks of narcotic drugs?

, Yes , No , Information not available

9a. Has the government informed health professionals about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns?

, Yes , No , Information not available

9b. Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids?

, Yes , No , Information not available

10. Is there cooperation between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes?

, Yes , No , Information not available

11. Has the government taken steps, in cooperation with licensees, to ensure that there are no shortages of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems?

, Yes , No , Information not available

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will maximize physical access of patients to pain relief medications?

, Yes , No , Information not available

13a. Has the government established a national cancer control programme to which it allocates health care resources?

, Yes , No , Information not available

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing education programmes and by its inclusion in medical, pharmacy and nursing curriculum?

, Yes , No , Information not available

14. Is there terminology in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence?

, Yes , No , Information not available

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment?

, Yes , No , Information not available

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief?

, Yes , No , Information not available

ACKNOWLEDGMENTS

The World Health Organization wishes to acknowledge the assistance of the World Health Organization Collaborating Centre for Policy and Communications in Cancer Care, Pain & Policy Studies Group, University of Wisconsin, Comprehensive Cancer Center (Madison, Wisconsin, USA). The following staff of the Collaborating Centre prepared the initial drafts of this document and hosted the meeting of the working group to review the document: Mr D.E. Joranson, Senior Scientist and Director; Dr A.M. Gilson, Researcher for Policy Studies; Ms K.M. Ryan, Policy Analyst; and Ms M.A. Maurer, Associate Research Specialist. For more information on this WHO Collaborating Centre, refer to the Pain & Policy Studies Group website at http://www.medsch.wisc.edu/painpolicy.

Listed below are the participants in the WHO Working Group, held in Madison, Wisconsin, USA, 22-24 November 1999:

Mr R. Bhattacharji, Narcotics Commissioner of India, Gwalior, India
Dr C. Blengini, General Practitioner; Member, Special Committees of Italian Ministry of Health on Pain and Palliative Care, Cuneo, Italy
Dra. L. De Lima, Consultant, Pan American Health Organization, Houston, Texas, USA
Dr P. Emafo, Expert, World Health Organization Expert Advisory Panel for Drug Dependence; Member-elect, International Narcotics Control Board, Benin City, Nigeria
Ms Gu Weiping, Director, Department of Drug Safety and Inspections, State Drug Administration, Beijing, China
Mr D. Joranson, Director, World Health Organization Collaborating Centre for Policy and Communications in Cancer Care, Pain & Policy Studies Group, University of Wisconsin, Madison, Wisconsin, USA *(Chair)*
Dr A. Nixon, Head of Palliative Care Medicine, King Faisal Specialist Hospital & Research Centre, Riyadh, Saudi Arabia
Ms C. Selva, Chief, Estimates Unit, International Narcotics Control Board secretariat, United Nations, Vienna, Austria

WHO Secretariat

Mr T. Yoshida, Quality Assurance & Safety: Medicines, Essential Drugs and Medicines Policy

REFERENCES

1. World Health Organization Programme on Cancer Control. *Developing a global strategy for cancer*. Editor: Karol Sikora, March 1998.

2. International Narcotics Control Board. *Report of the International Narcotics Control Board for 1998*. New York, NY: UN, 1999.

3. International Narcotics Control Board. Availability of opiates for medical needs. In: *Report of the International Narcotics Control Board for 1995*. New York, NY: UN, 1996.

4. World Health Organization. *Cancer pain relief and palliative care: Report of a WHO expert committee* (Technical Report Series 804). Geneva, Switzerland: WHO, 1990.

5. World Health Organization. *Cancer pain relief with a guide to opioid availability* (Second edition). Geneva, Switzerland: WHO, 1996.

6. World Health Organization. *Cancer pain relief*. Geneva, Switzerland: WHO, 1986.

7. World Health Organization. *The use of essential drugs: Report of a WHO Expert Committee* (Technical Report Series 882). Geneva, Switzerland: WHO, 1998.

8. World Health Organization. *WHO Expert Committee on Drug Dependence. Twenty-eighth report*. (Technical Report Series 836). Geneva, Switzerland: WHO, 1993.

9. International Narcotics Control Board. Demand for and supply of opiates for medical and scientific needs. In: *Report of the International Narcotics Control Board for 1989*. New York, NY: UN, 1989.

10. Joranson DE. Availability of opioids for cancer pain: Recent trends, assessment of system barriers, new World Health Organization guidelines, and the risk of diversion. *Journal of Pain and Symptom Management,* 8(6):353-360, 1993.

11. Joranson DE. New international efforts to ensure availability of opioids for medical purposes. *Journal of Pain and Symptom Management,* 12(2):85-86, 1996.

12. United Nations International Drug Control Programme. *Format and guidelines for the preparation of national drug control master plans*. Vienna, Austria: UN, 1994.

13. Patton CV, Sawicki DS. *Basic methods of policy analysis and planning* (Second edition). Englewood Cliffs, NJ: Prentice Hall, 1993.

14. Weimer DL, Vining AR. *Policy analysis: Concepts and practice* (Second edition). Englewood Cliffs, NJ: Prentice Hall, 1992.

15. United Nations International Drug Control Programme. *National laws and regulations relating to the control of narcotic drugs and psychotropic substances: Cumulative index 1994*. Vienna, Austria: UN, 1994.

16. United Nations. *Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961*. New York, NY: UN, 1977.

17. World Medical Association. *World Medical Association declaration on physician independence and professional freedom.* Adopted by the 38th World Medical Assembly. Rancho Mirage, CA, USA, October 1986.

18. World Health Organization. *National cancer control programmes: Policies and managerial guidelines.* Geneva, Switzerland: WHO, 1995.

19. World Health Organization. *WHO Expert Committee on Drug Dependence. Sixteenth report*. (Technical Report Series 407). Geneva, Switzerland: WHO, 1969.

20. World Health Organization. *WHO Expert Committee on Addiction-Producing Drugs. Thirteenth report*. (Technical report Series 273). Geneva, Switzerland: WHO, 1964.

21. World Health Organization. *The ICD-10 Classification of Mental and Behavioural Disorders. Clinical descriptions and diagnostic guidelines.* Geneva, Switzerland: WHO, 1992.

22. WHO Collaborating Centre for International Drug Monitoring. *Print-out from the Adverse Drug Reaction database*. Uppsala, Sweden: 1999.

ANNEX 1

USE OF TERMS IN THIS DOCUMENT

WHO Analgesic Method (also called the "Three-Step Analgesic Ladder") was developed to promote the sequential use of drugs to achieve effective pain relief. The first step is a non-opioid medication (such as aspirin, paracetamol, or ibuprofen). If this does not relieve the pain, an opioid for mild to moderate pain (such as codeine) should be added. When an opioid for mild to moderate pain in combination with a non-opioid medication does not provide effective analgesia, then an opioid for moderate to severe pain (such as morphine or one in the therapeutic group of morphine) should be substituted. Adjuvant drugs should be given at any point during drug treatment to relieve adverse effects of analgesics, to enhance pain relief, and to treat concomitant psychological disturbances such as insomnia, anxiety, and depression.

Consumption statistics are reported by governments to the INCB annually and represent the amounts of narcotic drugs that are distributed in a country to the retail level, i.e. to hospitals, pharmacies and practitioners.

DDD or "defined daily dose" is the assumed average maintenance dose per day for a drug used on its main indication in adults. Drug consumption figures are presented as numbers of DDDs per population per day for comparative purposes in drug utilization studies. In the INCB technical publications, DDD figures were calculated as the annual average daily dose of drug consumed, computed over five years, per million inhabitants in a given country.

Diversion refers to the movement of controlled drugs from licit to illicit channels of distribution or use.

Drug dependence is a cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour.

Law refers to rules of conduct having binding legal force adopted by a sovereign authority, legislative or other governmental body at the national, state or local level.

Narcotic drug is a legal term that refers to all those substances covered by the Single Convention on Narcotic Drugs, 1961 and the 1972 Protocol amending that Convention, including opiates, opioids, as well as cocaine and marihuana.

National policy should be interpreted broadly. There are different *levels* of "national policy," including law (sometimes referred to as codes or statutes), regulations (issued by governmental agencies to interpret or implement laws), and other policy (governmental directives, budgets or policy documents). For example, some provisions and administrative practices should be in law, while others are a more appropriate function of administrative activities of governments. In some cases, the authoritative sources specify the level. There are also different *types* of national policies that may be relevant to the subject of these Guidelines. For example, some of the relevant provisions and administrative practices may be found in governmental policies on public health, drugs, drug abuse and cancer control. "National policy" also refers to the government policies of states, provinces, territories, and other governmental subdivisions especially where this level of government is deemed to have responsibilities relevant to the subject of the guidelines. For example, some states adopt policies that are relevant to narcotics control.

Opiate refers to substances that are produced from the poppy plant, such as codeine and morphine.

Opioid is a scientific term that refers to both natural and synthetic drugs whose effects are mediated by specific receptors in the central and peripheral nervous systems, including codeine, morphine, oxycodone and fentanyl.

Regulation is an official ruling by government having the force of law and issued for the purpose of implementing or interpreting laws.

The 1961 Convention refers to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961.

Tolerance refers to a reduction in the sensitivity to a drug following repeated administration, in which increased doses are required to produce the same magnitude of effect previously produced by a smaller dose.

Withdrawal syndrome refers to the consequences of repeated administration of certain drugs, whose abstinence can increase the intensity of drug-seeking behaviour because of the need to avoid or relieve withdrawal discomfort and/or produce physiological changes of sufficient severity to require medical treatment.

ANNEX 2

ORDERING INFORMATION FOR KEY RESOURCES (WHO PUBLICATIONS)

Title:	**Cancer pain relief and palliative care. Report of a WHO expert committee. Technical report series, No. 804**	**Cancer pain relief: With a guide to opioid availability**
Author:	World Health Organization	World Health Organization
Date:	1990	1996
Language:	Available directly from WHO in: English, French, Spanish Also available in: Chinese, Indonesian, Italian, Japanese, Polish, Russian and Turkish.	Available directly from WHO in: English, French, Spanish Also available in: Bengali, Chinese, German, Indonesian, Italian, Japanese, Portugese, Russian, Serbian, and Vietnamese.
Internet:		See: www.medsch.wisc.edu/painpolicy/publicat/cprguid.htm for Part 2 of the book (English only)
Cost:	Sw.fr. 9.-/US $7.20	Sw.fr. 17.-/US $15.30
Order No.:	1100804	1152247
Abstract:	This report considers what can and should be done to comfort patients suffering from the distressing symptoms of advanced cancer. Although methods for the relief of pain are emphasized, other physical, psychological, and spiritual needs for comfort are also included. The concept of palliative care is explained in terms of its concern with quality of life and comfort before death, emphasis on the family as the unit of care, dependence on teamwork, and relationship to curative interventions. Subsequent sections concentrate on measures for the relief of pain and other physical symptoms, the psychosocial needs of the patient and family, and the need for spiritual comfort. A section on ethics provides important statements concerning the legal and ethical distinction between killing the pain and killing the patient.	This new edition of WHO guidelines to cancer pain relief presents a simple and practical method to relieve the pain syndromes unique to cancer. After a brief explanation of the physiological and psychological causes of cancer pain, part one presents a nine-step procedure for pain assessment, including questions clinicians should ask. The most extensive section details how to select and prescribe opioid and non-opioid analgesics, drugs for neuropathic pain, and adjuvant drugs for the treatment of side effects, the enhancement of pain relief and the management of psychological disturbances. Part two describes the international system by which morphine and other opioids are made available for medical purposes. It concludes with the criteria that can be used to regulate the dispensing of opioids by physicians, nurses, and pharmacists.
Order Information:	To order directly from WHO: WHO Distribution and Sales 1211 Geneva 27, Switzerland Telephone: 41 22 791 2476 Fax: 41 22 791 4857 Email to place orders: bookorders@who.ch To order from publishers in most countries, a list of sales agents is available on the internet at: www.who.int/dsa	

ORDERING INFORMATION FOR KEY RESOURCES
(UN PUBLICATIONS)

Title:	**Availability of opiates for medical needs**	**Competent National Authorities under the International Drug Control Treaties**	**Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961**	
Author:	United Nations – International Narcotics Control Board	United Nations	United Nations	
Date:	1996	1999	1972	
Language:	Available directly from UN in: English, French, Spanish	English, French, Spanish, Arabic, Russian	English	English, French
Internet:	See: www.incb.org under AAnnual Report, 1995 Special Report@ for English, French and Spanish versions (PDF format)		www.incb.org/e/ind_conv.htm	untreaty.un.org
Cost:				
Order No.:	E.96.XI.6	E.99XI.p	E.77.XI.3	
Abstract:	This report, based on a survey of governments in the world, shows that opioids are still widely unavailable for medical needs. INCB recommends steps that governments and health professionals should take to address this problem.			
Order info:	Order exclusively from UN Publications Sales Office and Bookshop CH-1211, Geneva 10 Switzerland Telephone: 41-22-917-2614 Fax: 41-22-917-0027 Email: unpubli@unog.ch Or UN Publications Rm. DC2-853, 2 UN Plaza New York, NY 10017 USA Telephone: 212-963-8302 or 1-800-253-9646 Fax: 212-963-3489 Email: publications@un.org			

ANNEX 3

SUMMARY OF THE GUIDELINES

Number	Title of Guideline
1	Governments should examine their drug control policies for the presence of overly restrictive provisions that may impact their health care system in the delivery of pain relief, and take corrective action as needed.
2	National drug control policies should recognize that opioids are absolutely necessary for medical care, in particular for relief of pain and suffering.
3	National drug control policies should recognize the obligation of governments to ensure adequate opioid availability for all medical and scientific needs.
4	Governments should designate an authority for ensuring adequate availability of opioids for medical care.
5	Governments should develop, using information from relevant sources, a practical method to estimate realistically the medical and scientific needs for opioids.
6	Governments should furnish to the INCB annual estimates of the quantities of narcotic drugs needed for medical and scientific purposes for the following year.
7	Governments should furnish a supplementary estimate to the INCB if it appears that the availability of narcotic drugs will fall short of medical needs, or to meet emergency needs or exceptional medical demand.
8	Governments should submit annual statistical reports to the INCB on the production, manufacture, trade, use and stocks of narcotic drugs.
9	Governments should establish a dialogue with health care professionals about the legal requirements for prescribing and dispensing narcotic drugs.
10	National drug control authorities and health care professionals should cooperate to ensure the availability of opioid analgesics for medical and scientific purposes, including for the relief of pain.
11	Governments should ensure, in cooperation with licensees, that the procurement, manufacture, and distribution of opioid medications is accomplished in a timely manner so that there are no shortages of supply, and that such medications are always available to patients when they are needed.
12	Governments should permit and encourage the distribution and availability of opioid medications throughout the country, in order to maximize physical access of patients to pain relief medications while maintaining adequate controls to prevent diversion and abuse.
13	Governments should establish and promote a national cancer control programme that includes cancer pain relief and palliative care as a priority for health care resources, including education about the WHO Analgesic Method and provision of pain relief and palliative care.
14	Terminology in national drug control policy should not have the potential to confuse the medical use of opioids for pain with drug abuse or drug dependence.
15	In their efforts to prevent diversion, governments should avoid undue restrictions impacting on patient care decisions which are ordinarily medical in nature. Such decisions as the amount of drug prescribed and duration of treatment should be made by the physician and be based on individual patient needs.
16	National drug control policy should avoid prescription requirements that may unduly restrict physician and patient access to pain relief.