

# A Compendium of INCB Statements on Access to Medicines

**DCAM: Drug Control and Access to Medicines**



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## Drug Control and Access to Medicines (DCAM)

Tens of millions suffer annually from severe untreated pain cause by cancer, HIV, accidents and chronic conditions. Fewer than 5% of the estimated 13 million people suffering heroin dependency have access to effective, medication-assisted treatment. On paper, international treaties and national law allow, indeed oblige, access to opioid medicines for pain and drug dependency. BUT IN PRACTICE, at the government level, cumbersome regulations have combined with training deficits and fear of opioids to perpetuate untreated pain and addiction in most countries of the world.

The International Narcotics Control Board recognizes that *“the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs.”* (INCB. Report of the International Narcotics Control Board for 1995: Availability of opiates for medical needs. New York, NY: United Nations, 1996)

The Drug Control and Access to Medicines (DCAM) Consortium was established in 2008 to assist national governments and international organizations to fulfil these dual drug control obligations. DCAM is the **Center for Health Law, Policy and Practice** at Temple University; **AIDS Projects Management Group**; and the **Pain and Policy Studies Group**, University of Wisconsin.

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Any candid review of the INCB's statements over the past decade must conclude that the Board strongly supports and works to facilitate access to controlled drugs for medical and scientific purposes. It is paradoxical, then, that many stakeholders criticize the INCB and see it as a barrier. An important theme coming out of our interviews of well-informed champions in the pain, palliative care and drug treatment domains was that national officials in drug control and health care perceive the INCB to be against improving access. ***This document refutes these perceptions by collecting and organizing INCB statements on a range of specific issues related to medical and scientific access (up to and including the 2008 Annual Report).***

# **THE INTERNATIONAL NARCOTICS CONTROL BOARD: STATEMENTS AND POSITIONS ON THE AVAILABILITY OF OPIOID MEDICINES UNDER INTERNATIONAL CONTROL**

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## **1. Introduction: International Drug Control is Intended to Promote Public Health\***

The Single Convention on Narcotic Drugs, 1961, is the central policy that guides international and national narcotic control policy and activities. It is “Concerned with the health and welfare of mankind.” (U.N. Single Convention, Preamble)

The Single Convention originated with a 1958 United Nations resolution (U.N. ECOSOC Resolution 689, 1958) to convene a plenipotentiary conference for the purpose of replacing numerous multilateral treaties with one convention on narcotic drugs; it is firmly rooted in concern for the public health and welfare of mankind. The conference and subsequent adoption of the Single Convention in 1961 were done pursuant to the Charter of the U.N. which grants powers to the Economic and Social Council with respect to matters of international economic, social, cultural, educational and health.

“The Economic and Social Council may make or initiate studies and reports with respect to international economic, social, cultural, educational, health and related matters and may make recommendations with respect to any such matters to the General Assembly to the members of the United Nations, and to the specialized agencies concerned.... It may make recommendations for the purpose of promoting respect for, and observance of, human rights and fundamental freedoms for all...It may prepare draft conventions for submission to the General Assembly, with respect to matters falling within its competence.” (United Nations Charter, Chapter 10: The Economic and Social Council Functions and Powers. Article 62)

The Single Convention was amended in 1972 to respond to increased cultivation, manufacture and trafficking of illicit drugs and to the need to increase demand reduction activities, specifically to provide treatment and rehabilitation services for drug abusers. The 1972 amendments also strengthened the purpose of the Single Convention which had been to limit the availability of narcotic drugs to medical and scientific purposes, by establishing an “obligation of parties to ensure the availability of those drugs for such purposes.” (Bayer and Ghodse, 1999)

“The international drug control conventions...oblige parties to take steps to protect the health and welfare of their populations.” (INCB 2008 Annual Report, ¶17)

“For years, the Board has called on Governments to fulfil that treaty obligation [ensuring the availability of narcotic drugs used for medical purposes] and make the availability of drugs a priority public health issue. Nevertheless, large discrepancies in the consumption of those medicines remain.” (INCB 2008 Annual Report, Foreword by Dr. Hamid Ghodse, page iii)

Furthermore, “Access to narcotic drugs such as morphine and codeine, both on the WHO Model List of Essential Medicines, is considered by WHO to be a human right as defined by the International Covenant on Economic, Social and Cultural Rights (General Assembly resolution 2200 A (XXI).” (INCB 2008 Annual Report, ¶20)

“The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of

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\* All direct quotes in this document are in quotation marks. Underlining is added to call attention to the most relevant statements. Complete citations of all authoritative sources appear at the end of the document.

mankind, as well as of the fact that drug addiction is a worldwide social and economic threat. . Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts.”(INCB Training Materials for the Single Convention, Part 1, 2005, ¶2)

## **2. Opioid Medicines are Indispensable for Good Health and Health Care**

The INCB has often called public attention to the importance of opioids to health.

“International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotic drugs, but they also recognize that they are indispensable for the relief of pain and suffering. Narcotic drugs, including opiates, have a variety of medical uses. They are used as an anaesthetic or analgesic, and to treat diarrhoea, cough or narcotic addiction, as well as for veterinary, dental and laboratory purposes. The International Narcotics Control Board, in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use.” (INCB 1995 Special Report, Summary, p. iii)

“One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances.” (INCB 2008 Annual Report, ¶770)

“The international drug control conventions...obliges parties to take steps to protect the health and welfare of their populations. Governments must ensure the provision of narcotic drugs and of psychotropic substances for medical and scientific purposes; they must...provide services for the treatment and rehabilitation of drug abusers...” (INCB 2008 Annual Report, ¶17)

“Several developing countries need to strengthen their capacity to provide treatment for drug addicts. The Board encourages WHO to increase its support to Governments in their efforts to strengthen their drug abuse treatment capacity and to ensure that the treatment is of high quality.” (INCB 2008 Annual Report, ¶772, Recommendation 46)

“According to WHO projections, two thirds of the estimated 15 million new cancer cases per year will occur in developing countries by the year 2015. Some 70-80 per cent of cancer patients suffer severe pain, whether acute or chronic, in the late stages of the disease. There is broad consensus today that, for the treatment of severe pain related to cancer, opioids, above all morphine, are indispensable due to their affordability and analgesic efficacy.” (INCB 1999 Annual Report, ¶9)

“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.” (INCB 1989 Annual Report, ¶1)

### **3. The Single Convention on Narcotic Drugs, 1961, has the Twin Objectives of Controlling Illicit Use and Assuring Availability of Controlled Drugs for Medical and Scientific Purposes**

“The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs.” (INCB 1995 Special Report, ¶1)

“The primary objective of the 1961 and 1971 Conventions is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs.” (INCB 2008 Annual Report, ¶20)

“The Board believes that 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. ... Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (INCB 1995 Special Report, ¶48)

“The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. Guided by a similar principle, States recognized in the Convention on Psychotropic Substances of 1971 that the availability of psychotropic substances for medical and scientific purposes should not be unduly restricted. Adequate availability and limitation were considered by the State parties to the 1961 Convention and the 1971 Convention as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.” (INCB 1999 Annual Report, ¶1)

“If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance.” (INCB 1999 Annual Report, ¶38)

“A well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances has to fulfil, inter alia, the following functions:

- (a) To provide for relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of drugs for the purpose of abuse;” (INCB 1999 Annual Report, ¶41)

“The 1972 Protocol amending the 1961 Convention can be considered the first response to the increased illicit cultivation of the opium poppy and the cannabis plant, the increased illicit production of cannabis, cannabis resin and opium, the increased illicit manufacture of heroin, and the increased illicit traffic in all of those drugs. It was expected that strengthening the respective obligations of parties and expanding the role of the Board would lead to a greater efficacy of national efforts in the suppression of such illicit activities and to better cooperation among national authorities, with the assistance of the Board in preventing the international expansion in trafficking. The provisions of the Protocol were, however, unable to counteract the further increase in the illicit cultivation, production and manufacturing trends. It was only in 1988 that the international community realized the necessity of undertaking more concentrated action and the importance of developing new methods of combating the activities of organized criminal cartels.

There are two other elements in the 1972 Protocol which should be mentioned:

(a)The 1961 Convention was amended by demand reduction provisions which were patterned after the respective provisions of the 1971 Convention;

(b)The provisions of the 1961 Convention, intended to limit the availability of narcotic drugs to medical and scientific purposes, were supplemented by the obligation of parties to ensure the availability of those drugs for such purposes.

Both amendments are very important. First, because they reflect the realization that without the reduction of illicit demand, supply reduction measures will bring temporary results only, and, second, one of the basic principles of international drug control is that reduction in the availability of drugs for non-medical purposes should not affect and limit their therapeutic use.” (Bayer and Ghodse, Bulletin on Narcotics, 1999, p. 12)

“The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of mankind, as well as of the fact that drug addiction is a worldwide social and economic threat. Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶2)

“Broadly speaking, it [INCB] deals with two aspects of drug control: with regard to licit manufacture, commerce and sale of drugs, the Board endeavours to ensure that adequate supplies are available for medical and scientific uses, and that leakage from licit sources to illicit traffic do not occur.” (Conversation with Dr. Ghodse, Addiction, 2007, p. 202)

#### **4. Low Opioid Consumption Indicates Inadequate Medical Availability**

“For years, the Board has called on Governments to fulfil that treaty obligation [ensuring the availability of narcotic drugs used for medical purposes] and make the availability of drugs a priority public health issue. Nevertheless, large discrepancies in the consumption of those medicines remain. As a result of the underutilization of these drugs in many

countries, the World Health Organization (WHO) estimates that perhaps as many as 86 million persons suffer from untreated moderate-to-severe pain each year.” (INCB 2008 Annual Report, Foreword by Dr. Hamid Ghodse, page iii)

“The low levels of consumption of opioid analgesics for the treatment of pain in many countries, in particular in developing countries, continue to be a matter of serious concern to the Board. The Board again urges all Governments concerned to identify the impediments in their countries to adequate use of opioid analgesics for the treatment of pain and to take steps to improve the availability of those narcotic drugs for medical purposes, in accordance with the pertinent recommendations of WHO. (INCB 2007 Annual Report, ¶97)

“The discrepancies in consumption levels of narcotic drugs and psychotropic substances continue to be very significant in different regions. Some of those differences can be explained by cultural differences in medical treatment and by varieties in prescription patterns. However, excessively high or low levels in drug consumption require special attention.” (INCB 2008 Annual Report, ¶770, Recommendation 35)

“The Board has brought to the attention of the international community the fact that the levels of consumption of opioid analgesics for the treatment of moderate to severe pain were low in a number of countries. The Board welcomed the adoption of Economic and Social Council resolution 2005/25 of 22 July 2005, entitled ‘Treatment of pain using opioid analgesics’, in which the Council called upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use.” (INCB 2007 Annual Report, ¶208)

“The consumption of opiates, morphine in particular, was low and relatively stable until the mid-1980s. In the last 10 years consumption of morphine and certain other narcotic drugs has increased significantly in some countries and is beginning to increase in others. This is largely the result of efforts by Governments, WHO and health professionals to improve relief of pain due to cancer. Nevertheless, the Board believes that the medical need for opiates is far from being fully satisfied in both less developed and developed countries.” (INCB 1995 Special Report, Summary, page iii)

“Pursuant to Economic and Social Council resolution 1989/15, the Board, in cooperation with the World Health Organization (WHO), prepared in 1989 a special report entitled Demand for and Supply of Opiates for Medical and Scientific Needs. In that special report, the Board stated that there was evidence suggesting that the medical need for opiates, particularly for the treatment of cancer pain, was not being fully met. There were a number of reasons, including inadequate government systems for assessing medical need; fear of drug abuse, which had led to laws that unduly impeded the availability of opiates; insufficient health-care infrastructure, personnel and financial resources; and public and professionals' fears of opiate addiction. Professional medical practice in different countries and attitudes of health professionals had similarly affected the availability of opiates. Global consumption of morphine, one of the opiates essential for cancer pain management, had begun to increase significantly in the mid-1980s. However, only small number of developed countries, representing a small part of the world's population, had accounted for the increase. Most countries, particularly those in the developing world, used small amounts of morphine or none at all. The Board made a number of recommendations to Governments, WHO and professional associations to improve the situation.” (INCB 1995 Special Report, ¶4)

“The development of medicines of higher quality and the better management of their availability could make the relief of pain and suffering more universal and qualitatively better. Unfortunately, there continue to be shortfalls in the availability of such medicines, and certain recent global trends seem to be undermining the positive developments. There is evidence in many countries that opioids, like all drugs intended for medical use, do not necessarily reach those who need them most. Thus, the objective of the 1961 Convention—ensuring adequate supply of narcotic drugs, especially opioids, for medical purposes—is still far from being achieved. Also, in many countries, there is virtually no reliable and regulated licit supply of important psychotropic substances.” (INCB 1999 Annual Report, ¶18)

## **5. The INCB is Committed to Ensuring Adequate Availability of Opioids for Medical and Scientific Needs**

“Some of the challenges discussed in this chapter fall under the explicit authority of the conventions; other challenges were not envisaged at the time the conventions were being drawn up, yet they affect the capacity of Governments to implement the conventions. Those challenges include:

(a) Health-related challenges: how to ensure adequate availability of narcotic drugs and psychotropic substances to meet medical and scientific requirements for pain relief and for the treatment of drug-related health problems” (INCB 2008 Annual Report, ¶3)

“To ensure more effective implementation of the international drug control conventions, the Board:...

(d) Encourages Governments of countries where the consumption of opioid analgesics is low to stimulate rational use of those drugs through measures promoted by the Access to Controlled Medications Programme...” (INCB 2008 Annual Report, ¶55)

“The Board again urges all Governments concerned to identify the impediments in their countries to adequate use of opioid analgesics for the treatment of pain and to take steps to improve the availability of those narcotic drugs for medical purposes, in accordance with the pertinent recommendations of WHO.” (INCB 2008 Annual Report, ¶102)

“The Board trusts that the Access to Controlled Medications Programme, the framework of which was prepared by WHO in cooperation with the Board, will provide effective assistance to Governments in that regard. Activities of the programme are expected to address various impediments to adequate availability of opioids, focusing on regulatory, attitude and knowledge impediments. The Board will provide expertise to WHO in those areas of the programme related to its mandate. The Board urges all Governments and the international entities concerned, such as UNODC, to cooperate with WHO in the implementation of the programme. The Board again calls upon Governments to provide resources to WHO for the implementation of the programme.” (INCB 2008 Annual Report, ¶103)

“The International Narcotics Control Board is the independent and quasi-judicial control organ for the implementation of the United Nations drug control treaties, established in 1968 by the Single Convention and replacing preceding international treaty bodies that had monitored earlier conventions. INCB works to ensure that adequate supplies of drugs are available for medical and scientific uses and that diversion from licit sources to illicit traffic does not occur. To this end, the Board administers an estimates system and a statistical returns system for narcotic drugs, which are explained in Part 2 and Part 3 of this training material, respectively.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶9)

Following its survey of governments in 1995, the INCB published a list of activities that it would undertake according to the Single Convention, to improve availability of opioids for medical and scientific purposes:

“The Board will:

- (a) Increase monitoring of annual estimates submitted by Governments and initiate dialogue as necessary to identify unmet needs and ensure that annual estimates of requirements for narcotic drugs are neither overestimated nor underestimated;
- (b) Continue to ensure expeditious confirmation of supplementary estimates submitted by Governments to assist them in coping with unforeseeable needs;
- (c) Encourage Governments to use information from a variety of sources to improve their capability to estimate foreseeable medical needs for narcotics drugs;
- (d) Encourage Governments to develop drug distribution systems that are well controlled and that will ensure availability of narcotic drugs to patients in medical facilities and in the community;
- (e) Convene seminars in selected regions or areas for government narcotic control authorities and health-care representatives to facilitate the exchange of information about legal requirements, unmet medical needs, methods of estimating future needs, and ways to improve the availability of narcotic drugs for medical needs;
- (f) Review on a regular basis national and international developments relevant to improving the availability of narcotic drugs for medical purposes, incorporating updated information and observations into its annual report;
- (g) Re-evaluate in the year 2000 the world situation and the progress of Governments and other organizations in implementing the recommendations below, issuing new findings, conclusions and recommendations.” (INCB 1995 Special Report, ¶50)

## **6. Governments are Obligated to Ensure Adequate Opioid Availability for Medical and Scientific Needs**

“Governments must ensure the provision of narcotic drugs and of psychotropic substances for medical and scientific purposes.” (INCB 2008 Annual Report, ¶17)

“For years, the Board has called on Governments to fulfil that treaty obligation [ensuring the availability of narcotic drugs used for medical purposes] and make the availability of drugs a priority public health issue.” (INCB 2008 Annual Report, Foreword by Dr. Hamid Ghodse, page iii)

“The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. Guided by a similar

principle, States recognized in the Convention on Psychotropic Substances of 1971 that the availability of psychotropic substances for medical and scientific purposes should not be unduly restricted. Adequate availability and limitation were considered by the State parties to the 1961 Convention and the 1971 Convention as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.” (INCB 1999 Annual Report, ¶1)

“If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance. (INCB 1999 Annual Report, ¶38)

“The availability of narcotic drugs is guided by national policy that should be consistent with the international conventions on narcotic drugs. Thirty (48 per cent) of the governments indicated that their laws recognized that narcotic drugs were indispensable, and forty-one (63 per cent) of the governments said that there was a provision recognizing the obligation to ensure availability of narcotic drugs for medical purposes.” (INCB 1995 Special Report, ¶17)

“Governments are invited to consider the following recommendations:

(f) 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 and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws” (INCB 1995 Special Report, ¶51)

“The Board believes that 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. A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licences, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (INCB 1995 Special Report, ¶48)

## **7. Efforts to Control Abuse and Prevent Diversion of Opioids are Vital but Must Not Interfere in their Medical Availability**

“The Board is responsible for ensuring that the supply of narcotic drugs for licit purposes is limited exclusively to the amount needed for medical and scientific needs. To prevent and detect diversion of narcotic drugs from licit to illicit channels, the Board monitors the cultivation, manufacture, import, export and consumption of such drugs in the world. If the treaty requirements for drug control are implemented consistently, the potential for diverting narcotic drugs to illicit channels is reduced to a minimum without interfering in their availability for medical treatment of patients who need them. 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 levels.” (INCB 1995 Special Report, ¶2)

“There are two other elements in the 1972 Protocol which should be mentioned:

(a)The 1961 Convention was amended by demand reduction provisions which were patterned after the respective provisions of the 1971 Convention;

(b)The provisions of the 1961 Convention, intended to limit the availability of narcotic drugs to medical and scientific purposes, were supplemented by the obligation of parties to ensure the availability of those drugs for such purposes.

Both amendments are very important. First, because they reflect the realization that without the reduction of illicit demand, supply reduction measures will bring temporary results only, and, second, one of the basic principles of international drug control is that reduction in the availability of drugs for non-medical purposes should not affect and limit their therapeutic use.” (Bayer and Ghodse, Bulletin on Narcotics, 1999, p. 12)

“The Board believes that 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. A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licences, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (INCB 1995 Special Report, ¶48)

“The Board attaches great importance to the fact that there has been no sign of an increase in the number of cases involving the diversion of morphine or other pure opioids into illicit channels at any stage of the manufacturing and distribution chain, despite increases in consumption. That is an indication that improvements in the licit drug supply are possible within the present drug control framework.” (INCB 1999 Annual Report, ¶16)

“The system of control measures laid down in the 1961 Convention provides effective protection of international trade in narcotic drugs against attempts at their diversion into illicit channels. In

2008, as in recent years, no cases of diversion of narcotic drugs from licit international trade into the illicit traffic were detected.” (INCB 2008 Annual Report, ¶69)

## **8. Governments Must Ensure that Medical Needs are Satisfied by Implementing Single Convention Obligations: Estimates and Statistics**

### **a. Governments Must Adopt Law to Implement the Single Convention**

“The Single Convention has universal application, which means that all countries are subject to some of its provisions whether or not they are Parties to the Convention. The preamble of the Single Convention alludes at its universal character, as it is motivated by the Parties’ concern over the health and welfare of mankind and their consideration that effective measures against abuse of narcotic drugs require coordinated and universal action. All countries must play a part in the implementation of the Single Convention in order to ensure the adequate availability of narcotic drugs for medical and scientific purposes, while at the same time limiting such availability to their legitimate needs. This is ensured, in particular, through the universal application of the system of estimates of drug requirements, which is explained in Part 2 of this training material.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶4)

### **b. Governments Must Designate a National Competent Authority to Administer the Estimates and Statistics System**

“Pursuant to article 17 of the Single Convention, Parties shall maintain a special administration for the purpose of applying the provisions of the Convention. Such an administration must coordinate the work of the various ministries and Government offices relating to the implementation of the treaty provisions, in the fields of health, social welfare, justice, law enforcement, etc. This may include, among other things, the competent national authorities empowered to issue certificates and authorizations for the import and export of narcotic drugs, the authorities that control domestic production/manufacture of narcotic drugs, state enterprises that produce/manufacture narcotic drugs, the institutions dealing with prevention and treatment of drug abuse, and the law enforcement authorities charged with preventive and repressive action against illicit traffic in narcotic drugs.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶25)

“It should be noted that a special administration does not necessarily mean a single authority, although a single authority may be designated as the interlocutor, on behalf of the Government, with the international drug control organs, such as the Ministry of Foreign Affairs. A special administration may simply consist of a mechanism of coordinated and effective cooperation between the different authorities and institutions involved in implementing the Single Convention.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶26)

“The most important provisions of article 31 are those that require a license regime for the authorization of export and import of substances under the control of the Convention, also defining the manner in which such a regime shall function. Each country must have a competent authority empowered to issue export/import authorizations for narcotic drugs, and the name and address of that authority must be communicated to the Secretary-General (c/o the Executive Director of UNODC).” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶42)

**c. The Estimates System is Flexible and Must Be Used To Ensure Adequate Availability**

“The Board notes that some Governments did not submit their estimates of requirements for narcotic drugs for 2009; therefore, the estimates for those countries were established by the Board. The Board urges the Governments concerned to examine their requirements for narcotic drugs for 2009 and provide their own estimates to the Board for confirmation, in order to prevent any possible difficulties with the availability of narcotic drugs required for medical and scientific purposes in their countries.” (INCB 2008 Annual Report, ¶767-Recommendation 5)

“Some Governments have submitted the same estimates of requirements for narcotic drugs for several years. The Board requests the Governments concerned to regularly assess their requirements for narcotic drugs to ensure that the estimates furnished to the Board for confirmation reflect their actual needs for narcotic drugs during the year in question.” (INCB 2008 Annual Report, ¶767-Recommendation 6)

“Several developing countries need to make additional efforts in order to establish estimates and/or assessments for the medical and scientific use of narcotic drugs, psychotropic substances and some precursors reflecting actual requirements for the adequate treatment of their populations. The Board requests WHO to increase support to Governments in their efforts to establish adequate estimates and/or assessments for the medical and scientific use of controlled substances. The Board encourages WHO to join the Board in an initiative to identify methods to be applied in developing countries in order to arrive at adequate estimates for narcotic drugs, assessments for psychotropic substances and estimates for some precursors.” (INCB 2008 Annual Report, ¶772 - Recommendation 45)

“In order for a country to have enough narcotic drugs or opiate raw materials to meet the demand for medical treatment of its population and for scientific research, it must be able to adequately determine its needs for those purposes. The Single Convention, in articles 12 and 19, provides for a system of estimates of drug requirements in order to determine those needs in an opportune manner. The drug regulatory authority of each country is responsible for determining these estimates.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶27)

“The purpose of the estimate system is to limit the supply of narcotic drugs of each country to the quantities which it needs for legitimate uses, for the maintenance of adequate stocks, and for legitimate exports, and thus to minimize the risk of diversion into the illicit drug trade. If the needs are underestimated, a country may not be able to meet the requirements of narcotic drugs for the medical treatment of its population in a given year. This is because a country may not manufacture or import narcotic drugs in excess of the estimates that have been confirmed by the Board for that country, nor is an exporting country allowed to export narcotic drugs in excess of the importing country’s corresponding estimates. The estimates system for narcotic drugs is thoroughly explained in Part 2 of this training material.” (INCB Training Materials for the Single Convention - Part 1, 2005, ¶28)

“The Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (referred to further in the text as “Single Convention”) established a dual obligation for Governments: Governments should ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes. At the same time they should limit the availability of narcotic drugs to the medical and scientific needs of the countries. In order to achieve this objective, it is the responsibility of each Government, inter alia, to determine the legitimate requirements for

narcotic drugs in its own country and to submit the estimates of those requirements to the International Narcotics Control Board (INCB) every year. After the estimates have been determined by the Government and confirmed by INCB, a country may legally manufacture or import narcotic drugs.” (INCB Training Materials for the Single Convention - Part 2, 2005, ¶1)

“In a well established drug supply system the determination of drug requirements is usually a matter of systematically monitoring drug supplies and regularly replenishing them as they are utilized. But when a new drug supply programme is being established, when an existing programme is being reorganized, or when current consumption patterns suggest inefficient or irrational drug use, then a more methodical approach to determine drug requirements is needed. Based on the main source of information used, there are three basic methods for estimating drug quantities. As can be seen below, all these methods have advantages and disadvantages; therefore, it is recommended to use a combination of them:” (INCB Training Materials for the Single Convention - Part 2, 2005, ¶29)

“Primarily, the Board recommends using past demand as a base to determine estimates, in the absence of circumstances that might warrant a change. If past consumption trends for narcotic drugs are stable, future needs can be estimated by averaging the amounts consumed in recent years and adding a margin for unforeseeable increases. Governments should add to their annual estimates of requirements for narcotic drugs a margin of 10 per cent for narcotic drugs included in Schedule I of the Single Convention, and 20 per cent for the narcotic drugs included in Schedule II, to allow for the possibility of increased consumption because of population growth, evolution of health services and trends in the incidence of diseases and their treatment.” (INCB Training Materials for the Single Convention - Part 2, 2005, ¶31)

“If on the other hand medical needs for one or more narcotic drugs are increasing in response to unmet needs, the method of estimation should take into account the extent of unmet needs and the potential effects on future demand of efforts to improve the rational use of narcotic drugs. To that purpose Governments should establish a system to collect information from medical facilities that care for surgical, cancer and other patients, and from organizations that are working to improve the rational use of narcotic drugs. Also they should consult regularly manufacturers, distributors, exporters and importers to assist in obtaining information about changing medical needs. Governments might also use past consumption figures in countries with a comparable social and economic development. They should add a margin even greater than 10 percent when there is rapid economic and social development or rapid expansion of the medical use of drugs, or in the case of introduction of new formulations or drugs.” (INCB Training Materials for the Single Convention - Part 2, 2005, ¶32)

“Governments are invited to consider the following recommendations:

(c) 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;

(f) 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 and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been

established and that personnel are available for the implementation of those laws” (INCB 1995 Special Report, ¶51)

“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.” (U.N. Single Convention, Article 12, ¶3)

“When computing the estimates, the Board will of course be guided by the interests of public health in the country or territory concerned. It will ensure that the estimates which it establishes enables the country or territory involved to import sufficient quantities of drugs for its medical needs. The Board will be guided by the same considerations as the Government in question would be if it has prepared its own estimates.” (U.N. Commentary on the Single Convention, 1962, ¶4, regarding Article 12, ¶3 of the U.N. Single Convention)

“The Board shall examine the estimates, including supplementary estimates, and, except as regards requirements for special purposes, may require such information as it considers necessary in respect of any country or territory on behalf of which an estimate has been furnished, in order to complete the estimate or to explain any statement contained therein.” (U.N. Single Convention, Article 12, ¶4)

“In carrying out its functions, the Board must ensure that its administration of the estimate system does not cause Governments undue difficulties in providing themselves with drugs which they need for medical purposes. It is for this reason also that the Board must try to prevent underestimates, which may create such problems for countries or territories which furnish them. In determining the figures the Board should, in the case of countries and territories which import their narcotic drugs, allow a wider margin for those of them which are distant from sources of supply than for those which are near to these sources.” (U.N. Commentary on the Single Convention, 1962, ¶2 regarding Article 12, ¶4 of the U.N. Single Convention)

“The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs. 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. 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.” (INCB 1995 Special Report, ¶1)

“Governments and the 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.” (INCB 1995 Special Report, ¶3)

“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...” (INCB 1995 Special Report, ¶28)

“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...” (INCB 1995 Special Report, ¶29)

#### **d. Supplementary Estimates May be Submitted at Any Time**

“The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs. 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. 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.” (INCB 1995 Special Report, ¶1)

“Even the most carefully calculated estimates based on sound methods may prove inadequate in the course of the year to which the estimates apply. This may happen, in particular, since Governments furnish to the Board their annual estimates of narcotic drug requirements as far as six months in advance of the year to which these estimates relate. The Single Convention provides therefore for the furnishing of supplementary estimates by which the original estimates can be modified to respond to changing circumstances and situations.” (INCB Training Materials for the Single Convention - Part 2, 2005, ¶85)

“Secondly, supplementary estimates are those furnished by Governments to revise estimates that were established by the Board. In accordance with article 12, paragraph 3, the Board establishes estimates for countries that have failed to furnish their own estimates. Governments are encouraged, however, to revise these estimates and communicate the revised estimates to the Board, preferably using Form B. The revised estimates will replace those established by the Board. Those amended estimates are considered also as supplementary estimates when they are received during the year to which they pertain.” (INCB Training Materials for the Single Convention - Part 2, 2005, ¶87)

**e. The Statistics System Enables Monitoring for Potential Diversion and Progress to Ensure Adequate Availability**

“By analysis of the estimates and the statistical returns submitted by Governments, the Board may identify possible deficiencies in the implementation of the control provisions in the respective countries. For example, the Board may identify whether imports or exports of a narcotic drug are in excess of the total of estimates for the importing country for a given year. The Board may also identify whether the manufacture of a narcotic drug exceeded the total of estimates of the manufacturing country.” (INCB Training Materials for the Single Convention - Part 3, 2005, ¶91)

“Upon reception of annual statistics and comparison with the trade statistics of a given year, the Board may identify whether there are any annual imbalances in the movement of narcotic drugs in a country; that is, whether quantities of narcotic drugs available to a country in a given year do not tally with their disposal. These imbalances are brought to the attention of the countries for clarification, since they may indicate a possible diversion at the national distribution level, or shortcomings in the national control system for narcotic drugs.” (INCB Training Materials for the Single Convention - Part 3, 2005, ¶97)

“By analyzing the statistical information on the licit movement of narcotic drugs throughout several years, the Board may identify important trends in such movement. The Board also analyzes the statistical information it receives in order to identify trends in the worldwide availability of narcotic drugs for medical needs. A summary of the trends in the licit movement of narcotic drugs worldwide is published annually by INCB in its technical publication on ‘Narcotic Drugs: Estimated World Requirements for (year) - Statistics for (year)’. The statistical data on which such trends are based is published in tables contained in the same document.” (INCB Training Materials for the Single Convention - Part 3, 2005, ¶99)

“The Board analyzes the statistical information received regarding the production/ manufacture of opiate raw materials and the consumption of opiates, in order to aid its work in maintaining the global balance of the supply of, and demand for, opiates for medical and scientific needs. The results of this analysis are also published in the technical publication on ‘Narcotic Drugs: Estimated World Requirements for (year) - Statistics for (year)’. ” (INCB Training Materials for the Single Convention - Part 3, 2005, ¶100)

“The timely submission to the Board of information required under the international drug control conventions is one of the key elements of the international drug control system. The Board reiterates its request to all Governments to furnish in a timely manner all statistical reports required under the conventions. Governments are encouraged to seek from the Board any information that will help them in meeting their reporting obligations under the conventions.” (INCB 2008 Annual Report, ¶767-Recommendation 2)

**9. The Global Supply of Opioids is Sufficient to Meet Medical Demand**

“As the Board has emphasized over the years in its technical report on narcotic drugs, global demand for opiate raw materials for medical and scientific purposes as requested by Governments has been fully met. Currently, global stocks of opiate raw materials are sufficient to cover global demand for more than one year. The often expressed view that there is a global shortage of opiates for medical and scientific purposes,... is not based on hard facts.” (INCB 2007 Annual Report, ¶205)

“Global stocks of opiate raw materials should cover global demand for about one year to ensure the availability of opiates for medical and scientific purposes. At the end of 2007, total stocks of opiate raw materials rich in morphine were sufficient to cover global demand for more than 15 months.” (INCB 2008 Annual Report, ¶91)

“The Board considers it important that the total volume of the global licit opioid manufacturing has stabilized in recent years at a level close to that of global medical consumption. Such a balanced situation, while necessary to minimize the risk of opioids being diverted into illicit channels, often proved difficult to achieve in the past. This positive development should be seen as a result of continued efforts by the Board and the Governments involved. The Board is of the view that, with this achievement in opioid supply, more emphasis can now be given to making further improvements in the use of opioids for medical purposes worldwide.” (INCB 1999 Annual Report, ¶13)

## **10. Governments Must Address Impediments at the National Level that Impede Opioid Availability**

### **a. Some Governments Have Adopted Unduly Strict Drug Control Policies**

“...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.” (INCB 1989 Annual Report, Summary)

“The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession.” (INCB 1999 Annual Report, ¶31)

“The Board and WHO reviewed documents and studies on the availability of opioid analgesics at the national level and examined the activities undertaken and planned by various bodies to assist Governments in ensuring the availability of those drugs for medical use. The Board and WHO observed that, although there was no shortage of licitly produced opioid analgesic raw materials worldwide and there had been a substantial increase in the global consumption of opioids in the past two decades, access to opioid analgesics continued to be difficult in some countries. The difficulties in having access to opioid analgesics are due to various interrelated factors, such as inadequate medical education and lack of knowledge and skills in pain management, public attitude, regulatory impediments and economic constraints.” (INCB 2007 Annual Report, ¶210)

### **b. The Imperative to Evaluate National Drug Control Policy and Administration**

“The Board again urges all Governments concerned to identify the impediments in their countries to adequate use of opioid analgesics for the treatment of pain and to take steps to improve the availability of those narcotic drugs for medical purposes, in accordance with the pertinent recommendations of WHO.” (INCB 2008 Annual Report, ¶102 and ¶770 - Recommendation 36)

“WHO, in consultation with the Board, prepared an assistance programme called Access to Controlled Medications Programme. The programme is designed to address impediments to the rational use of opioid analgesics, focusing on regulatory, attitude and knowledge impediments. The Board encourages UNODC to cooperate with WHO in the implementation of the Access to Controlled Medications Programme, with a view to promoting rational use of opioid analgesics by health-care professionals.” (INCB 2008 Annual Report, ¶772 - Recommendation 44)

“...The Board welcomed the adoption of Economic and Social Council resolution 2005/25 of 22 July 2005, entitled ‘Treatment of pain using opioid analgesics’, in which the Council called upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use.” (INCB 2007 Annual Report, ¶208)

“The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession.” (INCB 1999 Annual Report, ¶31)

“(c) 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;” (INCB 1989 Annual Report, ¶49)

“In its 1989 special report, the Board mentioned a number of factors that, if present in narcotics control laws and health-care systems, could limit availability of narcotic drugs for medical and scientific purposes. The Board requested every government to conduct an examination to determine if such impediments existed and, if they did, to take corrective action. In the questionnaire, governments were asked if, in the preceding five years, they had examined whether there were factors in their health-care systems and laws and regulations that impeded the use of opiates for medical purposes. Thirty-six (57 per cent) of the responding governments reported having done so. Of the 27 governments that had not, 12 stated that they had made plans to do so.” (INCB 1995 Special Report, ¶13)

“The availability of narcotic drugs is guided by national policy that should be consistent with the international conventions on narcotic drugs. Thirty (48 per cent) of the governments indicated that their laws recognized that narcotic drugs were indispensable, and forty-one (63 per cent) of the governments said that there was a provision recognizing the obligation to ensure availability of narcotic drugs for medical purposes.” (INCB 1995 Special Report, ¶17)

“Governments are invited to consider the following recommendations:

(a) 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; (INCB 1995 Special Report, ¶51)

### **c. Some Laws and Practices Reflect Misunderstanding of Drug Abuse and Dependence**

“The impediment to opiate availability most frequently reported by governments was concern about opiate addiction. In 1969, WHO replaced the terms ‘habituation’ and ‘addiction’ with the term ‘dependence,’ which WHO has characterized primarily as a compulsion to take a drug for its psychic effects. Furthermore, WHO has clarified that cancer patients who are physically dependent (the manifestation of which would be a withdrawal syndrome if the opiate medication was stopped) are not considered to fulfil the criteria for drug dependence. Therefore, it is of interest for further study that 54 per cent of the governments indicated that their narcotic law defined addiction or drug dependence and that 43 per cent of the governments required patients who received opiate prescriptions to be reported to the government.” (INCB 1995 Special Report, ¶34)

“In reaction to an increase in illicit traffic, 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 the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes.” (INCB 1989 Annual Report, ¶42)

“Of the 36 governments that had made efforts to identify such impediments [whose presence could limit availability of narcotic drugs for medical and scientific purposes], only 4 indicated that no impediments had been found. From a list of 13 potential impediments, each of the remaining 32 governments identified an average of 4.8 impediments. The impediments that the 32 governments identified are presented in rank order in table 1. The most common single impediment to the medical use of opiates was concern about addiction to opiates, identified by 23 (72 per cent) of the 32 governments...” (INCB 1995 Special Report, ¶14)

“A quite distinct group of problems in the management of drug availability and use is directly related to inadequate medical practice, improper diagnosis and therapy, lax prescribing or the absence of prescribing. A doctor’s willingness or reluctance to prescribe a particular type of medicine is but one small part of a complex relationship between the patient, the doctor and the drug. The relationship may assume quite different characteristics in different regions and countries. The main underlying causes of inappropriate prescribing appear to be the following: inadequate knowledge and information; incorrect interpretation of existing legal, regulatory and medical restrictions; unethical, lenient behaviour and sometimes direct financial interest or iatrogenic drug abuse.” (INCB 1999 Annual Report, ¶20)

### **d. Health Care Professionals Too Often Fear Legal Sanctions**

“While sanctions are necessary to deal with persons who transgress the law, they should not, as such, constitute an impediment to the prescription or dispensation of opiates in accordance with existing regulations. The vast majority of health professionals exercise their activity within the law and should be able to do so without unnecessary fear of sanctions for unintended violations. Occasions may still arise when a health professional could nevertheless be exposed to legal action for technical violations of the law. This possibility may tend to inhibit the prescribing or dispensing of opiates.” (INCB 1989 Annual Report, ¶43)

“Forty-seven per cent of the governments that examined for impediments indicated that health professionals were reluctant to prescribe or dispense opiates out of concern about the possibility of legal sanctions. Governments reported that the maximum sentence for a physician failing to comply with the laws and regulations governing opiate prescribing was 22 years in prison; the maximum reported fine was 1 million dollars. In addition, 48 per cent of the responding governments reported having mandatory minimum penalties, some as high as 10 years in prison.” (INCB 1995 Special Report, ¶36)

## **11. Governments Need Adequate Resources to Implement Treaty Obligations**

“The Board calls again upon the Governments concerned to provide adequate resources to ensure the compliance of those authorities with all their control functions, including reporting obligations under the 1961 Convention.” (INCB 2008 Annual Report, ¶60)

“Difficulties experienced by some Governments in submitting the required statistical data to the Board have different reasons, including the inadequate resources and inadequate training provided to the authorities responsible for the control of licit activities related to narcotic drugs and psychotropic substances. The Board again calls upon the Governments concerned to allocate adequate resources to their national competent authorities to ensure the compliance of those authorities with all their control functions, including reporting obligations under the conventions.” (INCB 2008 Annual Report, ¶767-Recommendation 3)

“The Board is aware that drug control authorities have other tasks besides reporting to the Board. The Board is also aware that the duties of drug regulatory agencies are manifold and include licensing and inspection of manufacturers and traders, issuing export and import authorizations and ensuring adequate drug supply. The Board recognizes that, without the cooperation of the different agencies, the competent national authorities would not be able to report adequately and in a timely manner to the Board. Such internal cooperation may require adequate funding.” (INCB 2007 Annual Report, ¶237)

## **12. Assistance May be Needed to Increase National Capacity to Comply with Treaty Obligations**

“Efforts are under way to develop practical and reliable methods for correctly assessing national requirements for narcotic drugs and psychotropic substances, based on actual medical needs. Such assessment tools are urgently needed by the Governments of many developed and developing countries that are currently not in a position to assess their national requirements correctly. The Board and WHO have been encouraging and assisting Governments in these efforts. The Board has noted in recent years several useful national and international initiatives to promote professionally sound medical prescription practices, inter alia, through training for health personnel in those areas.” (INCB 1999 Annual Report, ¶17)

“The Board is always ready to assist Governments in complying with their reporting obligations under the 1961 Convention. In 2007, as in previous years, the Board provided to several Governments, at their request, explanations on issues regarding reporting requirements.” (INCB 2007 Annual Report, ¶68)

“The Board prepared detailed training material on the control of narcotic drugs and guidelines on reporting on those drugs for use by national competent authorities. Those training materials are available on the website of the Board ([www.incb.org](http://www.incb.org)). The methods of reporting were included

in the training of national drug control administrators (see paragraph 185 below) and were dealt with during an informal consultation on reporting, organized for selected Governments by the Board during the fiftieth session of the Commission on Narcotic Drugs, in March 2007.” (INCB 2007 Annual Report, ¶69)

“All Governments are encouraged to seek from the Board any information that they may require regarding the control of narcotic drugs under the 1961 Convention, including reporting requirements.” (INCB 2007 Annual Report, ¶70)

#### Ongoing training opportunities

“At the request of Governments, the secretariat of the Board organizes in Vienna training for national drug control administrators to improve the functioning of national drug control administrations. During 2007, the Board offered such training to national drug control administrators from a number of countries, including Canada, Cuba, Ghana, Jordan and the United States, as well as to representatives of the United Nations Interim Administration Mission in Kosovo.” (INCB 2007 Annual Report, ¶185)

“The training provided national drug control administrators with an opportunity to obtain a better understanding of the functioning of the international drug control system and to discuss some of the problems and difficulties encountered in the implementation of the international drug control treaties. The Board trusts that the training will enhance the capacity of the national drug control administrations to comply with the provisions of the treaties in those countries.” (INCB 2007 Annual Report, ¶186)

“The Board also used various opportunities to provide ad hoc advice to national drug control administrators on treaty requirements for reporting on narcotic drugs, psychotropic substances and precursors. Such advice was provided through communications, individual meetings, during the country missions of the Board and in an informal consultation on reporting organized by the Board during the fiftieth session of the Commission on Narcotic Drugs.” (INCB 2007 Annual Report, ¶187)

“To facilitate full compliance with reporting obligations as required under the international drug control treaties, the Board has also made available online, detailed training material on the control of narcotic drugs, psychotropic substances and precursors, as well as guidelines for reporting on those substances.” (INCB 2007 Annual Report, ¶188)

“The following recommendations are for consideration by the United Nations International Drug Control Programme (UNDCP):

(a) The UNDCP model national legislation on the control of narcotic drugs should contain provisions that recognize the obligation to ensure the availability of narcotic drugs for medical and scientific purposes;

(b) The UNDCP national drug control master plan should include policies, strategies and administrative measures for accomplishing the responsibilities associated with the obligation to ensure the availability of narcotic drugs for medical and scientific purposes;

(c) UNDCP should assist Governments in improving legislation and administrative capabilities to implement the obligation to ensure the availability of narcotic drugs for medical and scientific purposes;

(d) UNDCP should review situations where lack of resources prevents a Government from ensuring the availability of narcotic drugs for medical and scientific purposes and should identify sources of assistance.” (INCB 1995 Special Report, ¶52)

### **13. Communication between Governments and Health Care Professionals is Vital**

“Governments are invited to consider the following recommendations:

(c) 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;

(g) Governments should inform health professionals about the WHO analgesic method for cancer pain relief;

(h) 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;” (INCB 1995 Special Report, ¶51)

“Educational institutions and non-governmental health-care organizations are encouraged to consider the following recommendations:

(a) 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;

(b) 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.” (INCB 1995 Special Report, ¶56)

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