



INTERNATIONAL NARCOTICS CONTROL BOARD

2010

**Report of the
International Narcotics Control Board on the
Availability of
Internationally Controlled Drugs:
Ensuring Adequate Access for
Medical and Scientific Purposes**



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Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes (E/INCB/2010/1/Supp.1)

Narcotic Drugs: Estimated World Requirements for 2011 — Statistics for 2009 (E/INCB/2010/2)

Psychotropic Substances: Statistics for 2009 — Assessments of Annual Medical and Scientific Requirements for Substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971 (E/INCB/2010/3)

Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances: Report of the International Narcotics Control Board for 2010 on the Implementation of Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (E/INCB/2010/4)

The updated lists of substances under international control, comprising narcotic drugs, psychotropic substances and substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances, are contained in the latest editions of the annexes to the statistical forms (“Yellow List”, “Green List” and “Red List”), which are also issued by the Board.

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Introduction

1. Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention),¹ as amended by the 1972 Protocol,² and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention)³ is a mandate of the International Narcotics Control Board.

2. By becoming parties to the international drug control conventions, Governments have accepted the obligation to introduce the provisions of those treaties into their national legislation and to implement them. The International Narcotics Control Board is the body established by the 1961 Convention that is responsible for monitoring the compliance of Governments with the international drug control treaties and for providing support to Governments in this respect.

3. The conventions established a control regime to serve a dual purpose: to ensure the availability of controlled substances for medical and scientific ends while preventing the illicit production of, trafficking in and abuse of such substances. The 1961 Convention, while recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to humankind, affirms 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. Equally, the 1971 Convention recognizes that, while the parties to the Convention were determined to prevent and combat abuse of and trafficking in psychotropic substances, their use for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted. The implementation of the international drug control treaties by parties is monitored by the Board, whose responsibilities under article 9 of the 1961 Convention expressly include the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes.

4. The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. However, despite numerous efforts by the Board and the World Health Organization (WHO), as well as non-governmental organizations, their availability in much of the world remains very limited, depriving many patients of essential medicines. The Board continues to monitor the worldwide availability of narcotic drugs and psychotropic substances and has made their availability one of the main topics of its dialogue with Governments on adequate treaty implementation.

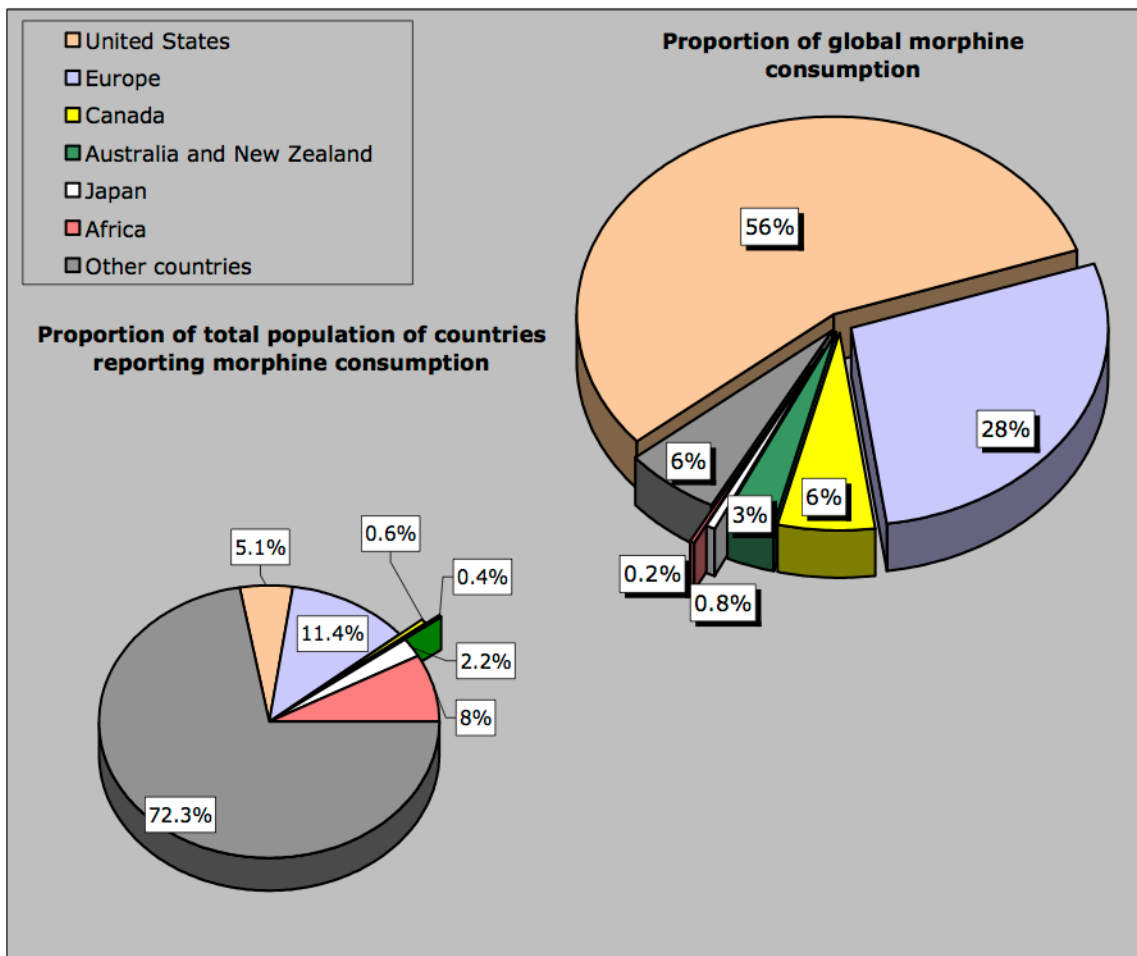
¹ United Nations, *Treaty Series*, vol. 520, No. 7515.

² *Ibid.*, vol. 976, No. 14152.

³ *Ibid.*, vol. 1019, No. 14956.

5. Narcotic drugs such as morphine, fentanyl and oxycodone are opioid analgesics effective for the treatment of moderate and severe pain. Data from 2009 show that more than 90 per cent of the global consumption of these opioid analgesics occurred in Australia, Canada, New Zealand, the United States of America and several European countries. This means that their availability was very limited in many countries and in entire regions. Although medical science has the capacity to provide relief for most forms of moderate to severe pain, over 80 per cent of the world population will have insufficient analgesia, or no analgesia at all, if they suffer from such pain.⁴

Figure 1. Distribution of morphine consumption, 2009



6. Similar disparities exist for the consumption levels of psychotropic substances, although their identification is more difficult, as the 1971 Convention does not require Governments to provide consumption data on such substances to the Board.

7. Taking into account that the global supply of opiate raw materials is sufficient for the production of opioid analgesics such as morphine, codeine and other alkaloids, and does not

⁴ There are a number of safe and effective methods to treat pain. Opioid analgesics continue to be the mainstay for the relief of moderate to severe pain.

constitute a barrier to the availability of narcotic drugs, it should be possible to significantly improve this situation through appropriate action by Governments. However, many other barriers to adequate availability, identified and highlighted by the Board in the past, continue to exist. The present supplement to the report of the Board for 2010 focuses on efforts undertaken to ensure adequate availability, developments over recent years and the current levels of availability of narcotic drugs and psychotropic substances, and provides recommendations for action to be taken at the international and national levels.

Action taken by the Board to ensure adequate availability

8. The Board, acting under the mandate assigned to it by the Conventions, was among the first to issue a warning that availability of narcotic drugs was not ensured in a majority of countries. More than 20 years ago the Board became aware of this problem, being in a singular position to assess consumption in various countries. The 1961 Convention requires Governments to submit to the Board annual statistical data, including data on the consumption of narcotic drugs. Consumption data submitted by Governments are analysed by the Board and then published in its annual technical publication on narcotic drugs. While reporting on consumption of psychotropic substances is not required by the 1971 Convention, consumption is calculated on the basis of other statistical data provided to the Board⁵ and is published in the annual technical publication on psychotropic substances.

9. The regular analysis of consumption data, particularly regarding narcotic drugs, convinced the Board that the level of consumption of narcotic drugs was very low in a number of countries. Therefore, in 1989, the Board, in cooperation with WHO, assessed the medical need for opiates in the world. They found that medical needs for opiates were not being fully satisfied, in particular for the treatment of cancer pain.

10. The Board found that only a few countries had established effective systems for assessing medical needs. A number of interrelated factors were identified as important impediments. Laws and regulations, and their administration or interpretation, unduly impeded the availability of opiates. Lack of resources in the health-care system prevented the optimal availability and use of opiates. Fear of addiction among professionals and the public was also a deterrent to the appropriate medical prescription of opiates. In addition, lack of up-to-date professional training impeded the adequate use of opioids to treat pain.

11. The findings of this study were published in the Board's special report for 1989 on the demand for and supply of opiates for medical and scientific needs.⁶ The Board made a number of recommendations to Governments to help them to minimize or overcome many of the impediments to making opiates available for medical needs. Governments were requested to examine their methods of assessing medical needs for opiates; evaluate their health-care systems and laws and regulations for impediments to opiate availability; develop plans of action to facilitate the availability of opiates for all appropriate conditions; and establish national policies, guidelines and professional education on the rational medical use of opiates.

⁵ Data on manufacture, imports, exports and stocks of psychotropic substances.

⁶ United Nations publication, Sales No. E.89.XI.5.

12. Five years later, in 1994, the Board examined the effectiveness of the international drug control treaties in a supplement to its annual report, entitled *Effectiveness of the International Drug Control Treaties*.⁷ In its evaluation the Board concluded that the treaty objective of ensuring an adequate supply of narcotic drugs, especially opiates used for medical purposes, had not been universally achieved.

13. Therefore, in 1995, the Board published another special report, entitled *Availability of Opiates for Medical Needs*,⁸ which included specific recommendations to Governments, the United Nations International Drug Control Programme, the Commission on Narcotic Drugs, WHO, international and regional drug control, health and humanitarian organizations and educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain, and other health-care representatives. The recommendations of the special report are still valid. Furthermore, chapter I of the report of the Board for 1999⁹ was dedicated to the issue of availability of narcotic analgesics. The Board identified in that chapter, inter alia, constraints and impediments to the adequate availability of opioids for the treatment of pain and made recommendations to Governments for corrective action. As internationally controlled drugs were overused in some countries, leading to prescription drug abuse and related problems, chapter I of the report of the Board for 2000¹⁰ dealt with overconsumption of internationally controlled drugs and recommended a balanced approach in their use.

14. One tool to assess whether countries improve availability levels, or at least are aware of the problem and show the intention to improve, is the analysis of the estimates for narcotic drugs, which all countries submit to the Board. The Board regularly contacts countries with missing or particularly low estimates in order to ensure adequate availability of opioids for the treatment of pain. This practice was formalized in November 1999, when the Board started selecting certain groups of countries with low levels of consumption of opioid analgesics (mainly morphine) and with common characteristics.¹¹ In 2004 the Board contacted four countries¹² that had significantly increased their consumption levels and requested information on the policies and activities they considered the main causes for their growing consumption of opioid analgesics, in particular morphine, in order to make this information available to countries that needed to improve their consumption levels.

15. The matter was repeatedly brought to the attention of Governments in circular letters to all countries and specific letters to individual countries. In August 2001, a joint letter from the President of the Board and the Chair of the United Nations Development Group was sent to all resident coordinators of the United Nations system at the country level, urging them, inter alia, to be aware of underconsumption and the lack of medicaments available for the treatment of severe pain in many developing countries (see annex II). This request was confirmed in February 2005, in a follow-up joint letter from the President of the Board and the Chair of the United Nations Development Group (see annex III). In April 2006, the President of the Board emphasized in a letter to all

⁷ United Nations publication, Sales No. E.95.XI.5.

⁸ United Nations publication, Sales No. E.96.XI.6.

⁹ United Nations publication, Sales No. E.00.XI.1.

¹⁰ United Nations publication, Sales No. E.01.XI.1.

¹¹ Main characteristics for selection: no estimates for morphine; large population and very low level of consumption of morphine; very high cancer rate and low level of consumption of analgesics; functioning control administration but low level of availability; high-income countries outside Europe and North America with inadequate availability.

¹² Brazil, Canada, France, United States of America.

countries the difficulties of access to narcotic drugs and psychotropic substances for needy patients and encouraged Governments to take measures to ensure the inclusion of the subject of rational use of drugs in the curricula of the appropriate university faculties (see annex IV).¹³

16. The subject of availability of opioids for the treatment of pain is discussed with individual Governments during all missions of the Board. The letters of recommendation sent to Governments after the missions include, if appropriate, specific recommendations on the availability of opioids for the treatment of pain. Equally, the WHO guidelines on achieving balance in national opioids control policy¹⁴ are always included in the information material provided to competent authorities during Board missions.

17. The Board regularly includes the subject of the availability of narcotic drugs in speeches at meetings of intergovernmental bodies, such as the twentieth special session of the General Assembly, sessions of the Commission on Narcotic Drugs, the Economic and Social Council and World Health Assembly, and regional meetings of international organizations. In March 2010, at the fifty-third session of the Commission on Narcotic Drugs, the discussion of availability resulted in Commission resolution 53/4, entitled “Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse”.

18. WHO is the main partner of the Board in activities to increase the availability of opioids for the treatment of pain. Specific cooperative activities between the Board and WHO include the promotion by the Board of the WHO guidelines on achieving balance in national opioids control policy; the establishment of a working group on availability in 2003, which prepared a proposal for strengthening working relationships between the Board and WHO with regard to the availability of narcotic medicines and promoting rational use of psychotropic medicines; and cooperating in the WHO global strategy against pain, aimed at providing assistance to countries in, inter alia, building capacity and raising awareness in the area of using opioids in pain treatment.

19. The World Health Assembly, in its resolution WHA58.22, and the Economic and Social Council, in its resolution 2005/25, invited WHO and the Board to examine the feasibility of an assistance mechanism to facilitate the adequate treatment of pain using opioid analgesics. WHO and the Board reviewed documents and studies on the availability of opioid analgesics at the country level and examined activities conducted and planned by various bodies to assist Governments to ensure the availability of those medicines for legitimate medical use. They concluded that although there was no shortage of licitly produced opioid analgesic raw material worldwide and global licit consumption of opioids had increased substantially in the past two decades, access to opioid analgesics continued to be difficult in many countries, owing to several constraints.

20. WHO and the Board found that an assistance mechanism to facilitate adequate treatment of pain using opioid analgesics was feasible. Therefore, WHO started the preparation of the Access to Controlled Medications Programme and developed the framework of that Programme in consultation with the Board. The Programme is implemented by WHO. The Board actively promotes

¹³ Those three letters are also posted on the Board’s website at www.incb.org/incb/en/other-issues_correspondence.html.

¹⁴ World Health Organization, document WHO/EDM/QSM/2000.4.

the Programme during its missions, in speeches on the subject of availability and through specific references and recommendations in its annual reports.

21. However, while consumption of narcotic drugs for medical purposes had increased significantly in some countries, owing inter alia, to the efforts of the Board, the level of availability of substances controlled under international conventions remained low and inadequate in most countries. The Board therefore concluded that the promotion of a better understanding of the provisions of the international drug control treaties was required. One major part of this effort is the provision of assistance to Governments in establishing more realistic estimates of requirements for medications containing controlled substances. The Board and WHO are at present jointly developing guidelines on estimating requirements for substances under international control. This initiative is intended to identify methods to be applied by countries to arrive at adequate estimates for narcotic drugs, assessments for psychotropic substances and estimates for some precursors for medical purposes.



Achieving a balance between ensuring availability of internationally controlled substances for medical and scientific purposes and preventing their diversion and abuse

92. As affirmed in Commission on Narcotic Drugs resolution 53/4, on promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse, the balance between adequate availability of these drugs and prevention of their diversion and abuse is at the core of the international drug control conventions. While in the absence of indicators of appropriate use it is at present not possible to determine what appropriate consumption levels would be in individual countries, let alone at the global level, it is possible to identify consumption levels that appear to be much too low or disproportionately high.

93. In the case of countries with nil or practically nil consumption levels, such indicators for adequate levels are not required, as there can be no doubt as to the inadequacy of availability. The Board considers all levels of consumption of narcotic drugs below 200 S-DDD per million inhabitants per day inadequate. However, this does not imply that levels above 200 S-DDD can be considered adequate as the determination of whether availability of internationally controlled substances required for treatment is sufficient depends on the specific morbidity data.

94. It may be of help to compare consumption levels between countries with similar levels of socio-economic development to determine whether a country's per capita consumption of certain drugs is in line with the levels prevalent in comparable countries. However, this method has two shortcomings. Low levels of consumption of internationally controlled substances are prevalent in certain regions. The fact that the majority of countries in a region record the same inadequately low levels of consumption does not make those levels adequate, but only indicates that most of the countries in the region face the same problem. On the other hand, disproportionately high levels of consumption of certain substances in a number of countries with comparable levels of socio-economic development do not make these consumption levels adequate. They could also indicate that prescription levels in all of those countries may be too high, and there could be a variety of reasons for this.

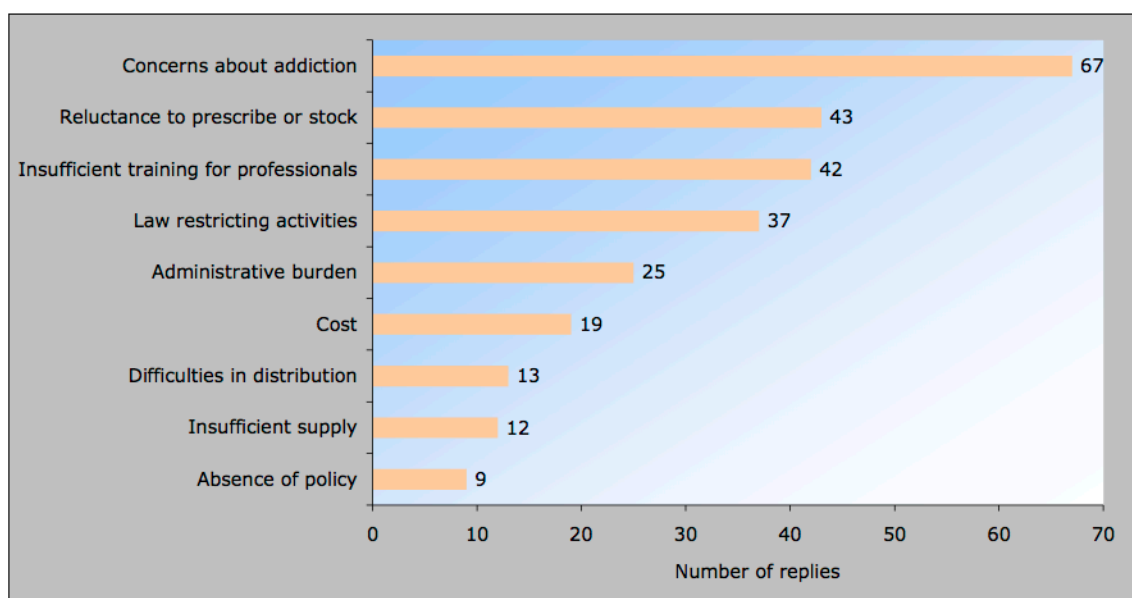
95. At present, therefore, circumstantial indicators are used to support other indicators of whether consumption levels are too low or too high. Reports on untreated patients and on difficulties in obtaining required medications indicate serious impediments to availability. Reports on diversion of internationally controlled substances from domestic distribution channels, on large-scale smuggling of such substances, on trafficking and on significant abuse might indicate availability of internationally controlled substances above levels required for sound medical practice.

A. Impediments to availability of opioid analgesics

96. The level of consumption of opioid analgesics in a country is generally correlated with its level of socio-economic development. There are a variety of factors determining why specific countries are found to have the highest levels of consumption of opioid analgesics in their region, including good reporting to and cooperation with the Board.

97. The Board has on a number of occasions drawn the attention of Governments to the causes of limited availability of opioids under international control. The causes include regulatory, attitudinal, knowledge-related, economic and procurement-related problems that adversely affect availability. In a recent survey conducted by the Board²⁴ on impediments to the availability of opioids for medical needs,²⁵ a majority of Governments reported that attitude- and knowledge-related impediments — namely, addiction-related concerns among health-care professionals and patients and insufficient training for health-care professionals — continued to be the main factors contributing to the underuse of opioids. Unduly restrictive laws and burdensome regulations were also commonly perceived as playing a significant role in limiting the availability of opioids. A smaller number of Governments reported that difficulties involving distribution and supply and the high cost of opioids were major obstacles to making opioids adequately available. The most important impediments listed by countries were concerns about addiction, reluctance to prescribe or stock and insufficient training for professionals. The ranking of importance of the various impediments as indicated by countries responding to the survey is shown in figure 29.

Figure 29. Main factors affecting the availability of opioids for medical needs



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

²⁴ The survey was carried out by means of the questionnaire on which figure 29 is based.

²⁵ Report of the International Narcotics Control Board on Follow-up to the Twentieth Special Session of the General Assembly (United Nations publication, Sales No. E.09.XI.7).

98. In many countries with low consumption levels for opioids, the availability of opioids is influenced by a combination of regulatory, knowledge-related and economic factors. Those factors are clearly not independent of one another; for example, it may be more difficult to bring about regulatory reforms in a country where concerns about drug addiction are pervasive among policymakers and health-care professionals. Overcoming those impediments therefore requires a multifaceted approach and the participation of a broad range of stakeholders from the relevant governmental regulatory bodies, health-care professionals and non-governmental organizations active in the field of health care.

99. France has successfully developed and implemented a multifaceted programme to ensure the adequate availability of opioid analgesics for the treatment of pain. Over the past decade, per capita consumption of opioid analgesics used in the treatment of moderate and severe pain has increased more than fivefold in France, making it one of the countries with apparently adequate and appropriate levels of consumption of opioid analgesics under international control.

100. After it was recognized that in France the level of consumption of analgesics was too low and pain was not being adequately treated in the health-care system, legislative and policy changes were introduced to promote the implementation of successive national action plans to combat pain, starting in 1989. Ensuring that health-care professionals are adequately educated about the treatment of pain has been an important element of each action plan. To that end, modules on pain treatment and palliative care were introduced into the curricula of medical and nursing schools, and programmes about pain treatment were developed to provide continuous training for personnel in health-care facilities. At the same time, a number of regulatory reforms made it less difficult for opioids to be procured, prescribed and dispensed. Examples of such reform measures that have had a significant impact on the effective treatment of pain include extending the validity of prescriptions for opioid analgesics from 7 to 28 days and allowing nurses to administer opioids in the absence of a doctor. While promoting the consumption of opioids for the treatment of pain, the Government of France has, at the same time, established mechanisms to monitor and prevent the abuse and diversion of those substances. All of the above activities remained within the frame of the international conventions.

101. While increases in consumption levels for opioid analgesics may be easier to achieve in countries that, like France, have adequate resources for health care, such improvements are also possible in countries with more limited resources, such as Uganda. Over the past 10 years, morphine consumption in Uganda has increased steadily, as a result of the expansion of a programme that provides home-based palliative care to patients throughout the country. In Uganda, as in France, key factors in the successful implementation of this approach include the commitment of the Government to making relief from pain a health-care priority and the education of health-care professionals about the use of opioids and palliative care. Another important step towards ensuring access to morphine for patients in a range of health-care settings has been the introduction of legal reforms allowing nurses to prescribe morphine. That is an example of the kind of task-shifting recommended by WHO²⁶ to increase access to health-care services in situations where there is a shortage of health-care workers. Developing systems for the reliable procurement of morphine and

²⁶ World Health Organization, *Task Shifting: Rational Redistribution of Tasks among Health Workforce Teams — Global Recommendations and Guidelines* (Geneva, 2008).

making it available for oral administration, at a low cost, have also been essential to efforts to broaden access to that drug. Again all of the activities remained within the frame of the international conventions.

102. The examples of France and Uganda show that increased consumption of opioid analgesics can be achieved with strong governmental support through a multipronged strategy to remove impediments to their availability. Although many countries in Europe have consumption levels for opioids under international control that are comparable to that of France, a number of countries, including many in Eastern Europe, currently have levels of opioid consumption that are much lower than the level reported by France 10 years ago. For the majority of the people in many countries in Africa, access to low-cost oral morphine is practically non-existent. Unfortunately, inadequate access to opioids remains a reality in a large number of countries not only in Africa and Eastern Europe but in all regions. The Board calls upon the Governments of those countries to take determined steps to ensure adequate access to opioid analgesics and to reinforce the regulatory agencies, which is a key to adequate access to controlled drugs and their appropriate use. To that end, Governments should consider the recommendations contained in the 1995 special report of the Board on the availability of opiates for medical needs,²⁷ and in chapter I of the Board's report for 1999.

103. The Board notes with appreciation that in the past few years, the Governments of a number of countries, including Georgia, Guatemala, Panama, Serbia and Viet Nam, have introduced policy reforms aimed at ensuring adequate access to opioid analgesics. The Governments of those countries and others that are in the initial stages of developing strategies for improving the availability of opioids should provide strong support for the implementation of those strategies. Mechanisms should be in place for monitoring the implementation and the long-term effectiveness of policies to improve access to opioids.

104. The Board is of the opinion that there is an urgent need for some Governments to take specific measures to ensure that their populations have adequate access to opioid-based medications in accordance with the international drug control conventions. In particular, Governments of countries in which opioid consumption is below 100 S-DDD per million inhabitants per day and Governments of countries with no opioid consumption at all should immediately take appropriate action to ensure access to such medications. The key element is an effective regulatory body. It is not admissible that large parts of the world remain seriously undersupplied with medicines that are necessary to alleviate the pain and suffering of patients.

105. The Board calls the attention of Governments to the fact that accurate estimation of requirements for internationally controlled substances is essential to ensure the adequate availability of those substances for medical and scientific purposes. Poor estimation of those requirements can lead to many problems in the use of controlled substances in the health-care system, such as shortages, irrational prescribing, distortion of demand and low cost-effectiveness; it can also lead to surpluses and increased risk of diversion of controlled substances. Proper use of the system of estimates for narcotic drugs and the system of assessments for psychotropic substances is important to ensure adequate availability of internationally controlled substances. For this purpose, national

²⁷ Availability of Opiates for Medical Needs (see footnote 8 above).

competent authorities need to ensure that health-service providers can easily communicate their requirements to them.

B. Availability of internationally controlled substances above levels required for sound medical practice

106. Lack of availability of narcotic drugs and psychotropic substances may deprive patients of their fundamental rights and the opportunity to have relief from physical pain and from suffering due to mental illness. On the other hand, excessive availability of these drugs can lead to diversion and abuse and subsequently to drug dependence. Over recent years the Board has noted with increasing concern that the abuse of internationally controlled substances, diverted into illicit channels at various stages of their distribution, continues to be widespread in many countries and has in some countries reached or overtaken the levels of abuse of illicit drugs.

107. In a number of countries, the abuse of pharmaceuticals containing controlled substances is second only to the abuse of cannabis. The pharmaceutical preparations diverted and abused contain various opioids, benzodiazepines and amphetamine-type stimulants. Among opioids, diversion of preparations containing buprenorphine, codeine, dextropropoxyphene, fentanyl, hydrocodone, methadone, morphine, oxycodone and trimeperidine account for the largest quantities diverted. Among the psychotropic substances, alprazolam, buprenorphine, diazepam, flunitrazepam, phenobarbital and phentermine are the most often diverted and abused substances.

108. Data collected by Governments suggest that abuse patterns are related to excessive overall availability of the pharmaceutical preparations containing these substances. In particular, countries with already elevated levels of consumption of narcotic drugs and psychotropic substances that experience further significant increases should be vigilant to determine whether these increases are related to actual medical requirements or to their misuse and abuse. Changing drug prescription and drug consumption patterns is usually a slow process, and new drug consumption habits develop over a period of years. New fashions in drug abuse, on the other hand, develop quite fast, in particular when the drugs of abuse show the same effect as previously abused illicit drugs but are easier to obtain. A culture of widespread and excessive availability of pharmaceuticals that have effects similar to those created by illicit drugs will result in the increasing substitution of these pharmaceuticals for illicit drugs. Reversing such a trend is difficult and requires efforts, as the abused pharmaceuticals will remain available. This explains why, in countries with excessive availability, the non-medical use of pain relievers, tranquillizers, stimulants or sedatives has become the fastest-growing drug problem.

109. In most countries the problem of abuse of prescription drugs has received less attention from drug control regulators than abuse of illicit drugs. The systematic collection of data on prescription drug abuse in household surveys is at present carried out only in the United States, which means that reliable data on the extent of such abuse are limited to that country. The problem is, however, not restricted to the United States. Abuse of prescription drugs is reported from all regions in the world.

110. Abuse of prescription drugs can be as dangerous as abuse of illicit drugs. In particular, the share of prescription opioids in cases of death related to overdose has significantly increased. This has, unfortunately, been overlooked by the general public for a long time. Over the last decade the number of cases of death related to prescription drug abuse has risen significantly, overtaking in some countries the number of cases of death from overdose related to illicit drugs. However, it was only because the deaths of several prominent entertainers were related to abuse of prescription drugs that the media and the broader public have taken note of the dangers of prescription drug abuse. Action should be taken, however, before such high levels of abuse of prescription drugs are reached. Since excessive availability is often the first step towards increasing abuse of prescription drugs, drug control regulators need to be vigilant with regard to high consumption levels of narcotic drugs and psychotropic substances.

111. Increasing abuse of prescription drugs has led to rising levels of poly-drug addiction, combining licitly manufactured medicines and illicit drugs or several medicines containing internationally controlled substances. Equally, the abuse of combination products manufactured by the pharmaceutical industry or prescription formulas prepared in pharmacies combining several internationally controlled substances is increasing.

112. The Board encourages all Governments to identify unusual trends in consumption levels for narcotic drugs and psychotropic substances and to take remedial action, if required. In the absence of accepted norms for adequate consumption, Governments may wish to analyse past trends and compare their national consumption levels with those of other countries at a similar level of socio-economic development.

113. Such comparisons could be carried out on the basis of the tables on the consumption of opioid analgesics and the various groups of psychotropic substances published by the Board in its technical report on narcotic drugs and its technical report on psychotropic substances. The Governments of countries with particularly high or rising levels of consumption of narcotic drugs and psychotropic substances should monitor the situation closely, determine whether their territories are being used for illegally operating Internet pharmacies, identify possible overprescribing or any other unprofessional practices among medical professionals and ensure that domestic distribution channels are adequately controlled. All Governments should implement the recommendations of WHO on the rational prescribing of drugs and take measures to promote sound medical practices.²⁸

114. To prevent substances under international control from being diverted in one country and subsequently smuggled into another, Governments should harmonize at the regional and subregional levels measures taken to reduce excessive consumption levels, so that the efforts made in one country will not result in problematic consumption patterns shifting to neighbouring countries.

115. However, the use of certain groups of substances may not differ only between countries with comparable levels of socio-economic development in different regions, but also between countries in

²⁸ "Promoting rational use of medicines: core components", *WHO Policy Perspectives on Medicines*, No. 5, September 2002. Available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.3.pdf.

the same region, owing to cultural and demographic factors. For example, significant cross-national and country-specific variations indicate considerable variances in medical practice between otherwise similar countries, and sometimes even within countries.

116. A persistent difference in consumption of internationally controlled substances is seen in the regional preferences for groups of psychotropic substances in Europe and in North America, two regions with similar levels of socio-economic development. While Europe records the world's top use of benzodiazepines, North America records the top consumption of performance-enhancing stimulants. This may imply cultural differences, but may also be related to demographics, as benzodiazepines are taken mostly by the older segments of the population, while performance- and body shape-enhancing drugs are consumed to a larger extent by adolescents and younger adults.

117. The channels of supply of abused prescription drugs vary, but, in principle, once they have left the officially controlled supply channels they are to be found in a "parallel market" of sometimes significant dimensions. In many countries, unregulated drug markets called "street markets" operate in parallel to or often in the absence of licensed pharmacies. The reasons for purchasing medications on such street markets are often related to economic factors or to an insufficient supply through official channels. Illegally operating Internet pharmacies are another kind of parallel market. As in street markets, customers can obtain internationally controlled drugs such as benzodiazepines, opioids, stimulants and barbiturates without a prescription. The supplies for these markets are often diverted or stolen products, or unregistered, substandard or counterfeit medications.

118. Depending on the country, the reasons for utilizing unregulated markets vary. They include limited access to health-care facilities, lower cost of drugs, which is often related to the fact that they are substandard or counterfeit products, overly stringent prescription requirements, the desire to obtain drugs without medical records to preserve privacy or demand for prescription drugs for abuse purposes.

119. All Governments should apply the International Narcotics Control Board guidelines for the control of Internet pharmacies,²⁹ because in some countries such pharmacies represent the principal channel for the illicit distribution of internationally controlled substances.

C. Ensuring adequate availability in emergency situations

120. Emergency situations in the wake of natural or man-made disasters may lead to a sudden and acute need for medicines containing controlled substances. Such a situation arose following the devastating earthquake in Haiti in January 2010. Controlled substances such as morphine and pentazocine were urgently required to provide medical care for the large number of people who had been injured in the earthquake.

²⁹ Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet (United Nations publication, Sales No. E.09.XI.6).

121. Humanitarian relief agencies have often found it difficult to rapidly obtain medicines containing controlled substances for medical care in emergency situations, in part because of the control measures exerted over the international movement of such medicines. The administrative requirements that must be fulfilled under normal circumstances to authorize the import and export of controlled substances slow down the supply of urgently needed medicines to disaster areas. This problem is compounded if competent national authorities in the importing countries are no longer functioning.

122. To address that issue, WHO, in consultation with the Board, prepared the Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care.³⁰ The Guidelines provide a simplified procedure for the export of medicines containing controlled substances to be handled by reputable humanitarian relief agencies. Soon after the earthquake in Haiti, the Board sent letters to all Governments and selected humanitarian relief agencies to remind them about the simplified procedures contained in the Guidelines.

123. Because emergency situations come about suddenly, competent authorities should be prepared to use the simplified procedures contained in the Guidelines to expedite the supply of controlled medicines as soon as the need arises. The Board invites Governments and humanitarian relief agencies to bring to its attention any problems encountered in making deliveries of controlled medicines in emergency situations. Governments may wish to include in their special stocks of narcotic drugs and psychotropic substances quantities to meet the need for such substances in the event of an emergency situation.

³⁰ World Health Organization, document WHO/PSA/96.17.

VI

Conclusions and recommendations

124. The International Narcotics Control Board has frequently confirmed that the underlying principles of the international drug control treaties provide the mechanism to ensure availability of narcotic drugs and psychotropic substances for medical and scientific requirements while at the same time preventing their inappropriate use and abuse. Ensuring availability of narcotic drugs and psychotropic substances and preventing their diversion are not contradictory goals; in fact, action to achieve these two objectives can be in synergy if measures are correctly and fully implemented. The proper interpretation of these two complementary aims is accepted by an ever-wider range of countries. However, substantial progress is still required in a number of countries.

125. The Board notes that, in response to previous recommendations on availability of narcotic drugs, a significant number of Governments have increased their estimates to meet medical demand, issued national policies to improve medical use of narcotic drugs, supported educational programmes and examined their health-care systems, laws and regulations for impediments. There have been improvements in the adequacy of supply of certain narcotic drugs and psychotropic substances in many countries, but there have been setbacks in others. While the most significant improvements are recorded in highly developed countries, the setbacks, unfortunately, have occurred mostly in the regions that 20 years ago had the lowest levels of availability of internationally controlled substances.

126. As shown in the Board's analysis, a large number of countries in many regions continue to record inadequate levels of availability of internationally controlled substances. Africa remains the region with the largest number of countries recording little or no availability. Other regions where the situation has not improved, and in certain cases worsened, are Central America and the Caribbean and South Asia. However, even in regions with overall increasing levels of availability, countries remaining at the lower margin in terms of consumption of controlled substances record inadequately low levels of availability.

127. Among the countries with particularly low levels of availability are a number of countries with large populations; thus, large parts of the world population have no access to narcotic drugs and psychotropic substances. Also, even if countries have recorded improvements, the improvements may not have led to levels that could be considered adequate, because of low starting levels. In spite of the progress made towards meeting treaty objectives, relatively few countries in the world have an adequate drug supply management system and working mechanisms that ensure reliable, needs-based assessments, equitable availability and cost-effectiveness.

128. According to the analysis of the Board, deficiencies in drug supply management remain attributable to lack of financial resources, inadequate infrastructure, the low priority given to health

care, weak government authority, inadequate education and professional training, and outdated knowledge, which together affect the availability of not only controlled drugs but all medicines.

129. Substantial improvement in the availability of narcotic drugs and psychotropic substances is linked to progress in the availability of medicines in general, particularly in countries with limited resources for health, where growing economic disparities, pressing basic needs and poor infrastructure are the principal barriers to any lasting improvement. During recent years international awareness has increased, and efforts to facilitate the supply of licit drugs to underdeveloped areas are carried out by intergovernmental and non-governmental organizations. However, despite growing global awareness of the prevailing unsatisfactory situation, a considerable number of countries continue to show no appreciation of the problem itself or of the relative ease with which efficient treatment can be provided.

130. It appears that a number of countries have not yet recognized that adequate availability of medicines, including narcotic drugs and psychotropic substances, is an essential part of their responsibility towards their populations. Negligence towards this responsibility is shown when countries do not even estimate their requirements and appear to have no knowledge about the quantities of certain drugs their populations would require for medical treatment. In other countries, where such negligence is not observed, other obstacles continue to prevail, including outdated restrictive regulations and, more frequently, uninformed interpretations of otherwise correct regulations, misguided fears and ingrained prejudices about using opioids for medical purposes.

131. The Board has always emphasized that the efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes must not adversely affect their availability for such purposes. On the other hand, increasing the use of certain controlled drugs for legitimate medical purposes needs thorough monitoring. Careful attention has to be given to ensuring the legitimate absorption capacity of countries and the proper functioning of safeguard mechanisms in order to minimize misuse and leaks in the system. The Board is of the opinion that a well-educated and functioning control-system administration is a prerequisite for ensuring availability, as it will be able to determine the quantities required and will identify shortages and problems in distribution. A functioning control-system administration will also be a responsible partner for cooperation with professional and consumer associations.

132. The overall goal of a well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances should be to provide 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, to prevent the diversion of drugs for the purpose of abuse. To ensure this, Governments need to fulfil the following essential tasks:

Recommendations on availability of narcotic drugs and psychotropic substances

(a) Governments should assess the actual requirements of the national health systems for internationally controlled substances; calculate their annual requirements for such substances and furnish the Board with timely estimates for narcotic drugs and assessments for psychotropic

substances. In case national requirements are at the lower margin of levels of requirements in the region, Governments may need to critically examine their methods for assessing their medical requirements for narcotic drugs and psychotropic substances;

(b) Governments should identify impediments to availability of narcotic drugs and psychotropic substances (policy, regulatory, administrative) and take detailed, step-by-step measures to remove those impediments;

(c) Governments should establish a system to collect information from medical facilities that provide care for the mentally ill, addicts and surgery, cancer and other patients, from organizations that are working to improve the appropriate use of narcotic drugs and psychotropic substances, and should establish groups of knowledgeable individuals to assist in obtaining information about changing medical needs; they should also make use of available guidelines on assessing the actual requirements for narcotic drugs and psychotropic substances for their country;

(d) Once a country has reached an appropriate level of consumption of narcotic drugs and psychotropic substances, Governments should add to their annual estimates of requirements for narcotic drugs and assessments for psychotropic substances a margin to allow for the possibility of increased consumption from such general causes as population growth, evolution of health services and trends in the incidence of diseases and their treatment and, if need be, should add an even greater margin in countries or territories where there is rapid economic and social development or rapid expansion of the medical use of drugs, including the introduction of new formulations or drugs;

(e) Governments that experience interruptions in the supply of narcotic drugs and psychotropic substances 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;

(f) Governments should determine whether their national narcotics laws contain elements of the 1961 Convention as amended by 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;

(g) Governments should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede the prescribing or dispensing of, or needed medical treatment of patients with, narcotic drugs or psychotropic substances, or their availability and distribution for such purposes, and, should this be the case, make the necessary adjustments;

(h) To promote adequate availability of psychotropic substances globally and in specific countries pursuant to Commission on Narcotic Drugs resolution 53/4, Governments should collect the most reliable statistical data on the consumption of psychotropic substances and submit that information to the Board in timely fashion;

(i) Governments should fully cooperate with the Board in ensuring adequate availability of narcotic drugs and psychotropic substances; they should examine their medical needs for narcotic drugs and psychotropic substances, as well as the impediments to their availability, advise the Board of the results of those efforts and inform the Board if it can be of assistance; they should also inform the Board about progress and needs concerning implementation of the present recommendations;

Recommendations on appropriate use

(j) Governments should ensure the correct education and training of health professionals and should inform health professionals about the WHO analgesic method for cancer pain relief; they should communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and psychotropic substances and should provide an opportunity to discuss mutual concerns;

(k) Governments should ensure that comprehensive curricula on substance abuse and rational use of psychoactive drugs are used in relevant faculties of universities, medical, pharmaceutical and nursing schools and other health-care institutes;

(l) Governments should stimulate, through regulation and monitoring, ethical behaviour in drug marketing; they should ensure high professional standards in therapy (diagnosis, deciding on therapy, prescribing);

(m) Governments should educate the public in the appropriate use of narcotic drugs and psychotropic substances and in the correct use of pharmacotherapy with other therapeutic options, and should enlist in this effort the active participation of professional organizations and consumer associations;

(n) Governments should establish a comprehensive registration and authorization system and select carefully and support safer and more cost-effective drugs and reliable alternative treatment modalities;

(o) Governments should also encourage the development and use of better and safer therapeutic agents (with little or no dependence potential) to replace medicines with limited efficacy and safety. Countries experiencing abuse problems with regard to combination products or prescription formulas have a responsibility to make sure that action is taken to prevent such abuse;

Recommendations on national control systems

(p) Governments should endeavour to keep the supply and consumption of internationally controlled substances under close supervision. Experience has shown that particular attention needs to be given to adequate legislation and correct administrative arrangements, adapted, as required, to new trends and developments;

(q) Governments should establish a sufficient degree of government authority and regulatory control over the national drug supply, including the control of narcotic drugs and psychotropic substances;

(r) Governments should conduct inspections of manufacturers, exporters, importers and wholesale and retail distributors, as well as of stocks and records, and take appropriate action against those who fail to comply with applicable legal requirements and professional codes of conduct. Activities of market intermediaries such as brokers must be regulated, as appropriate;

(s) Governments need to ensure adequate financial and human resources for their drug regulatory authorities and other agencies and provide capacity-building to their staff;

(t) Governments need to implement effective policies to combat counterfeit drugs and provide a comprehensive legal framework to make trading in counterfeit products a serious criminal offence; exporting countries must regulate the process with a view to preventing the export of drugs that are counterfeit or of poor quality;

(u) Governments should be aware and make the best use of the Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care;

Recommendations on prevention of diversion and abuse

(v) Governments should enforce existing legislation to ensure that narcotic drugs and psychotropic substances are not illegally manufactured, imported or exported and are not diverted to the unregulated market;

(w) Governments should collect data on the abuse of prescription drugs in a more systematic manner and include in their national surveys on drug abuse, as far as possible, pharmaceuticals containing narcotic drugs and psychotropic substances, by including either specific groups of substances or specific narcotic drugs and psychotropic substances, as required;

(x) Considering the international nature of the problem and to complement the efforts of law enforcement in individual countries in the above-mentioned areas, Governments, as well as regional and international organizations, should develop intergovernmental agreements for effective joint operations and arrangements and standards to be applied at the regional level;

(y) Governments should take prompt and effective action to implement previous recommendations of the Board on Internet trading and on the misuse of the mail for smuggling of internationally controlled substances.

133. To achieve the goal of adequate availability of narcotic drugs and psychotropic substances globally, support from the world community is required. Progress in countries with low levels of consumption of such drugs is usually gradual. Prevailing market conditions and the present supply system do not make it possible to ensure the availability of needed medicines in low-income

countries. Economic and financial conditions in such countries and insufficient health-care infrastructure are impediments that cannot be overcome by those countries alone. Progress can be achieved only on the basis of a more humanitarian approach that is in line with the treaty system. Such an approach in selected countries may include the provision of assistance in establishing more reliable baseline estimates and assessments of medical needs and consultations with potential suppliers under preferential conditions.

134. The Board concludes that if the above recommendations are implemented, there will be significant additional progress towards ensuring adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes. The Board will continue its examination of the situation and will monitor responses to its recommendations. To support progress the Board will continue to:

(a) Monitor annual estimates for narcotic drugs and assessments for psychotropic substances submitted by Governments and initiate dialogue as necessary to identify unmet needs and ensure that annual estimates or assessments of requirements for narcotic drugs and psychotropic substances are neither overestimated nor underestimated;

(b) Ensure expeditious confirmation of supplementary estimates and processing of modified assessments for psychotropic substances submitted by Governments to assist them in coping with unforeseeable needs;

(c) Review on a regular basis national and international developments relevant to improving the availability of narcotic drugs and psychotropic substances for medical purposes, incorporating updated information and observations into its annual report;

(d) Encourage Governments to develop drug distribution systems that are well controlled and that will ensure availability of narcotic drugs and psychotropic substances to patients in medical facilities and in the community;

(e) Cooperate with UNODC to include in the model national legislation on the control of narcotic drugs and psychotropic substances provisions that recognize the obligation to ensure the adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes;

(f) Respond to the call of the Commission on Narcotic Drugs in the area of availability of internationally controlled substances and support the Commission in its efforts to remind parties to the 1961 Convention and the 1971 Convention of their obligations in this respect;

(g) Cooperate with WHO to assist Governments in developing adequately controlled drug distribution systems that are capable of providing narcotic drugs and psychotropic substances to patients in hospitals and in the community;

(h) Alert the international community to new trends in abuse of pharmaceutical preparations containing narcotic drugs and psychotropic substances;

(i) Alert the international community to emerging new methods of trafficking of internationally controlled substances;

(j) Support Governments in implementing the provisions of the international drug control treaties and additional control measures, as requested by the Economic and Social Council, as well as the relevant guidelines of the Board.

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