INTERNATIONAL NARCOTICS CONTROL BOARD
Vienna

Report of the International
Narcotics Control Board for 1995

Availability of Opiates for Medical Needs

Special report
prepared pursuant to Economic and Social Council
resolutions 1990/31 and 1991/43

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Summary

International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotics 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.

The Economic and Social Council, in its resolution 1989/15, requested the Board to pursue the early finalization and implementation of a project to assess legitimate needs for opiates in various regions of the world, hitherto unmet because of insufficient health care, difficult economic situations or other conditions. In 1989, the Board, in cooperation with the World Health Organization (WHO), issued a special report entitled *Demand for and Supply of Opiates for Medical and Scientific Needs*. In that special report, the Board concluded that the medical need for opiates, particularly that related to the treatment of cancer pain, was not being fully satisfied. It recommended that Governments should critically examine their methods of assessing domestic medical needs for opiates and of collecting and analysing data, so as to make the changes required to ensure that future estimates would accurately reflect the actual need. It also recommended that Governments should examine the extent to which their health-care systems and laws and regulations permitted the use of opiates for medical purposes, should identify possible impediments to such use and should develop plans of action to facilitate the supply and availability of opiates for all appropriate indications. Subsequently, the Council, in its resolutions 1990/31 and 1991/43, requested the Board to accord priority to monitoring the implementation of the recommendations contained in its special report.

In response, the Board has prepared the present special report, again in cooperation with WHO, to ascertain whether Governments have fully implemented the recommendations contained in its special report of 1989, to identify Governments that have not yet fully implemented the recommendations, as well as their reasons, and to propose measures to improve the availability of opiates for medical purposes. The present special report includes a survey of all Governments, as well as inquiries to WHO and professional organizations. Sixty-five (31 per cent) of 209 Governments responded to the survey.

A review of trends in the consumption of selected narcotic drugs was also conducted. 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. The Board presents its findings, conclusions and recommendations to Governments, the United Nations International Drug Control Programme, the Commission on Narcotic Drugs, WHO, international and regional organizations and professional associations.

CONTENTS

Tables

Figures

EXPLANATORY NOTES

The following symbol has been used in tables throughout the report:

A dash (--) indicates that the amount is nil or negligible.

The following abbreviations have been used in this report:

AIDS	acquired immunodeficiency syndrome
INCB	International Narcotics Control Board
UNDCP	United Nations International Drug Control Programme
WHO	World Health Organization

INTRODUCTION

1. The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol[1] 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 unforseen increases in medical demand, Governments may submit supplementary estimates to the Board at any time. Requests for supplementary estimates are acted on expeditiously.

2. 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.

3. 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.

4. 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*.[2] 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.[3] 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 a 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

*The term "opiates" is used in reference to substances produced from the poppy plant, such as codeine and morphine. It is recognized that the term "opioid" is a scientific term that can also be used to refer to both natural and synthetic drugs whose effects are mediated by specific receptors in the nervous system.

**"Narcotic drugs" is a legal term that refers to all those substances covered by the Single Convention on Narcotic Drugs of 1961 (United Nations, *Treaty Series*, vol. 520, No. 7515) and the 1972 Protocol amending that Convention, including opiates as well as cocaine and synthetic substances such as pethidine and fentanyl.

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.[3]

5. The consumption of narcotic drugs, particularly those used for the treatment of pain due to cancer, is increasing. Cancer can be painful, especially but not only in the late stages of the disease. In many less developed countries, cancer patients die without treatment, and many are incurable when they enter the hospital. Pain management and palliative care are the most humane responses in such situations. Projections show that causes of death involving cancer will increase, in part as a result of the ageing of the population and increased use of tobacco. By 2015, it is estimated that there will be 15 million new cancer cases annually and approximately 9 million cancer deaths, of which 6 million will occur in the developing world. The prevalence rate of acquired immunodeficiency syndrome (AIDS), which can involve tumours and pain, is also increasing in some countries. The projected cumulative total of adult AIDS cases for the year 2000 is approximately 10 million, of which nearly 90 per cent will be in the developing world. Lung cancer and AIDS will be the two most common causes of death in the early part of the twenty-first century. Published reports from developed countries show that inadequate use of narcotic analgesics for the relief of cancer pain is common.

6. In 1986, WHO and its Expert Committee on Cancer Pain Relief and Active Supportive Care developed an effective analgesic method for relief of cancer pain. The method is based on important advances in medicine and relies on the availability of non-narcotic as well as narcotic drugs, including morphine, codeine and others. Morphine and other strong narcotic analgesics are essential to the treatment of severe cancer pain. The objective of WHO is to increase the number of cancer patients who benefit from a relatively simple method. WHO established a vigorous global programme to educate Governments, health professionals and the public about how to bring the relief that is possible to cancer patients in hospitals and in the community. WHO recommended that Governments should (a) ensure the availability of non-opiate and opiate analgesics, particularly low-cost morphine for oral administration, make realistic determinations of their opiate requirements and ensure that annual estimates submitted to the Board reflect actual needs; (b) ensure that their narcotic control legislation allows sufficient manufacture, import, stocking, prescribing and dispensing; (c) ensure that the appropriate health professionals are legally authorized to handle opiates; and (d) review and simplify the legal controls over opiates to ensure that they are available in necessary quantities. The WHO Expert Committee also noted that, with pressure for the legalization of euthanasia likely to increase, Governments should make efforts to keep fully informed of all developments in the field of cancer pain relief, palliative care and management of terminally ill cancer patients. The WHO Expert Committee indicated that the principles of pain management in cancer also applied to patients with AIDS.[4]

7. Since 1986, over 60 countries have established or have made plans to establish national cancer control programmes that include an emphasis on pain management. In addition, a network of WHO collaborating centres, professional organizations and individuals have been designated to develop the international programme. The result has been increasing attention to cancer pain relief worldwide, resulting in increasing consumption of morphine and other narcotic analgesics.

I. SURVEY OF GOVERNMENTS

8. The Board conducted a study in 1995 to evaluate the extent to which the recommendations made in its special report in 1989 had been implemented. The Board requested information from governments, WHO (see annex I) and professional organizations (see annex II). That information, together with other information available to the Board, provided the basis for the conclusions and recommendations contained in the present special report.

A. Description of the survey

9. A questionnaire was developed by the Board to collect information on implementation of the 1989 recommendations of the Board, availability of narcotic drugs including opiates, impediments to availability, national policies and guidelines, Governments' methods of assessing medical needs, anticipated changes in consumption and legal requirements for prescribing.

10. The questionnaire was sent to the governments of 209 countries and territories. Sixty-five* (or approximately one third) of those governments returned the completed questionnaire in time for their replies to be included in the analysis (annex III); only those replies are discussed in the present special report. Twenty-three governments** sent their replies too late to be included in the analysis. Fifty-four (83 per cent)*** of the responding governments included in the analysis were parties to the 1961 Convention or to that Convention as amended by the 1972 Protocol; seven**** were not. The 65 governments (including the Government of China) together accounted for 50 per cent of the world's population. Fifty-five per cent of the governments represented developing countries or areas and 40 per cent represented developed countries or areas. Only 3 of the replies were from governments of least developed countries.***** Additional data were included for each country or area for purposes of analysis: per capita consumption of morphine for 1993, development status and the human development index.

11. The remaining two thirds of governments in the analysis represented 144 countries accounting for the other one half of the world's population. Most of the least developed countries were in that group, including most of the 52 governments that had not submitted any estimates of narcotic drugs for medical purposes to the Board for the period 1994-1996.

12. Some caution should be used in interpreting the data from this survey for the following reasons: governments with an interest in the subject or with progress to report may have been more likely to respond to the questionnaire; few Governments of least developed countries responded; the questions

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*Algeria, Andorra, Argentina, Armenia, Australia, Bahrain, Belarus, Belgium, Benin, Bhutan, Brunei Darussalam, Burkina Faso, Cape Verde, Cayman Islands, Central African Republic, China, Colombia, Cyprus, Czech Republic, Eritrea, Fiji, Finland, France, Germany, Greece, Hong Kong, Iran (Islamic Republic of), Ireland, Italy, Japan, Kenya, Lao People's Democratic Republic, Latvia, Lithuania, Malaysia, Maldives, Malta, Mexico, Mongolia, Morocco, Myanmar, Namibia, Netherlands, Oman, Peru, Philippines, Poland, Republic of Moldova, Russian Federation, Saint Lucia, Samoa, Slovakia, Spain, Sri Lanka, Switzerland, Thailand, Tunisia, Turkey, Turks and Caicos Islands, United Arab Emirates, United States of America, Venezuela, Yugoslavia, Zaire and Zimbabwe.

**Benin, Botswana, Bulgaria, Burundi, Chile, Cuba, Denmark, Djibouti, Falkland Islands (Malvinas), Iraq, Luxembourg, Macao, Madagascar, Mozambique, Niger, Portugal, Saint Kitts and Nevis, Suriname, Swaziland, Syrian Arab Republic, Trinidad and Tobago, Tunisia and Uruguay.

***Percentages in the present report do not include missing data and may not total 100 per cent due to rounding.

****Andorra, Bhutan, Central African Republic, Eritrea, Maldives, Namibia and Samoa.

*****Several island States have not been categorized according to development status.

were not pre-tested with governments; some questions may not have been interpreted in the same way by all respondents; many but not all governments collected information from other sources to provide complete answers to the questions; the responses were from governments only (health-care groups might have replied differently to the questions) and some governments did not provide answers to some questions.

B. Impediments to availability

13. 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.

14. Of the 36 governments that had made efforts to identify such impediments, 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. Insufficient education of health-care professionals and restrictive narcotic laws and regulations tied for second (59 per cent each). Reluctance to prescribe or stock opiates owing to concerns about legal sanctions ranked third (47 per cent), followed by reluctance to stock opiates for fear of theft or robbery (38 per cent). Thirty-eight per cent of the governments cited as an impeding factor the administrative burden of regulatory requirement for opiates; 34 per cent cited insufficient import or domestic manufacture of needed opiates. The potential for diversion was mentioned by 34 per cent of the governments. Thirty-one per cent of the governments that had identified impediments indicated that the cost of opiate medications was an impediment. Issues in the health-care system, such as insufficient resources, training, personnel and facilities, problems in the opiate distribution system and absence of national policy, were cited less frequently. The Board also wanted to know whether governments perceived that the requirements for import and export of narcotics impeded the use of opiates for medical purposes; 6 (19 per cent) of the 32 governments indicated that that was the case. Almost all (92 per cent) of the responding governments said that they had taken steps to address the impediments that had been identified.

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*Andorra, Argentina, Belgium, Benin, Brunei Darussalam, Cape Verde, China, Colombia, Cyprus, Eritrea, Fiji, France, Germany, Iran (Islamic Republic of), Italy, Japan, Kenya, Malaysia, Malta, Mexico, Mongolia, Morocco, Myanmar, Philippines, Poland, Republic of Moldova, Russian Federation, Spain, Switzerland, Thailand, Tunisia, Turks and Caicos Islands, United States of America, Venezuela, Zaire and Zimbabwe.

**Algeria, Armenia, Australia, Bahrain, Belarus, Bhutan, Cayman Islands, Central African Republic, Czech Republic, Finland, Hong Kong, Ireland, Lao People's Democratic Republic, Latvia, Lithuania, Maldives, Namibia, Netherlands, Oman, Peru, Saint Lucia, Samoa, Slovakia, Sri Lanka, Turkey, United Arab Emirates, and Yugoslavia.

***Belarus, Bhutan, Central African Republic, Lao People's Democratic Republic, Lithuania, Maldives, Namibia, Peru, Saint Lucia, Samoa, Turkey and Yugoslavia.

****Andorra, Cyprus, Italy and Tunisia.

Table 1. Factors that impede the medical use of opiates

Number of reporting governments	*Response rate (percentage)*	*Impediment*
23	72	Concerns about addiction to opiates
19	59	Insufficient training of health-care professionals about opiates
19	59	Laws or regulations that restrict opiate manufacture, distribution, prescription or dispensing
15	47	Reluctance to prescribe or stock opiates because of concerns about legal sanctions
12	38	Reluctance to stock opiates because of concerns about theft or robbery
12	38	Administrative burden of regulatory requirements for opiates
11	34	Insufficient import or manufacture of needed opiates
11	34	Potential for opiate diversion
10	31	Cost of opiate medications
7	22	Insufficient health-care resources, personnel and facilities
6	19	Administrative burden of import-export requirements
5	16	Problems in the opiate distribution system
4	13	Absence of national policy or guidelines

15. Forty-two (65 per cent) of the 65 governments that responded to the survey indicated that they had issued national policies or guidelines to improve the medical use of opiates for a range of medical conditions. The most frequent medical condition for which policies or guidelines had been issued was cancer pain (56 per cent), followed by acute pain (46 per cent), chronic pain (29 per cent), pain in general (26 per cent), pain due to AIDS (25 per cent) and pain in children (20 per cent). It appears that the policies for chronic pain, pain due to AIDS and pain in children may be part of a policy concerning pain in general. Fifty-two per cent of the governments said that they had sponsored, supported or endorsed educational programmes in their countries or areas to improve the medical use of opiates. In most cases, the programmes were sponsored by the governments that had issued policies or guidelines. Governments that had examined for impediments were more likely to have issued national policies. Little is known about the nature of those policies.

16. Additional information on educational programmes was provided by non-governmental organizations in response to inquiries by the Board (see annex II). The Board appreciates the efforts of non-governmental organizations to provide it with relevant information; the International Association for the Study of Pain surveyed its national chapters throughout the world. The replies from Canada, Chile, Colombia, Hungary, Japan, Kenya, Malaysia, New Zealand, Philippines, Republic of Korea, Russian Federation, Singapore, Slovakia, United Kingdom of Great Britain and Northern Ireland and United States of America are summarized in annex III.

C. Availability for medical needs

17. 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.

18. The availability of drugs for patient care is influenced by national policies that provide for the approval of their medical uses. In the survey, governments were asked to indicate acceptable medical uses of opiates in their countries or areas. Most (98 per cent) of the governments reported that the use of opiates as an analgesic was acceptable, followed by their use as an anaesthetic (91 per cent) and to treat cough (80 per cent). Other uses, such as to treat diarrhoea or addiction or veterinary or for dental purposes, were less frequently mentioned (see table 2). For some governments there were fewer acceptable medical uses of opiates than for other governments. Governments having a provision in their legislation to ensure the availability of opiates were more likely to have issued a policy to improve the use of opiates.

Table 2. Acceptable medical uses of opiates

Number of reporting governments	*Response rate (percentage)*	*Use*
64	98	As an analgesic
59	91	As an anaesthetic
52	80	To treat cough
41	63	To treat diarrhoea
35	54	For veterinary purposes
31	48	For dental purposes
29	45	To treat opiate addiction
--	--	None

19. WHO recommends that Governments, especially those with limited health-care resources, should adopt policies to ensure the availability of reasonably priced "essential drugs" that are safe and effective for the treatment of diseases and conditions. When such policies are formulated, it is important that they take into account the needs of cancer pain relief programmes. Approximately three fourths (72 per cent) of the governments that responded to the survey said that they had an essential drug list. Seventy-one per cent of the governments had morphine on their essential drug lists, followed by pethidine,* codeine, fentanyl, methadone, buprenorphine and others (see table 3). It appears that not all narcotic drugs recommended by WHO are on such lists. It should be noted that the questionnaire did not elicit replies about drug formularies.

20. The WHO analgesic method requires the use of opiates, in particular codeine and morphine. Sixty per cent of the responding governments said that they had endorsed the method, 18 per cent indicated that they had not endorsed it and 23 per cent were not aware of the WHO method.

21. Forty-six per cent of governments promoted non-opiates for pain relief in lieu of opiates.

22. Governments reported that narcotic drugs were available in their countries or areas to varying degrees. The injectable narcotic drugs reported to be available were morphine (79 per cent), pethidine (72 per cent), fentanyl (69 per cent), pentazocine (45 per cent), alfentanil (43 per cent), naloxone (42 per cent), buprenorphine (39 per cent), nalbuphine (31 per cent), tramadol (31 per cent), nalorphine (22 per cent) and methadone (19 per cent). Oral immediate-release preparations were less available: codeine tablets, 65 per cent; morphine powder or solution, 40 per cent; dextropropoxyphene tablets,

*According to WHO, pethidine is not preferred to relieve chronic cancer pain because of the accumulation of a toxic metabolite that has been associated with seizures in patients.

35 per cent; buprenorphine tablets, 31 per cent; pentazocine tablets, 31 per cent; morphine tablets, 29 per cent; tramadol tablets, 29 per cent; methadone tablets, 26 per cent; and pethidine tablets, 25 per cent. Also available were the slow-release formulations of morphine (45 per cent) and fentanyl (14 per cent). The preparations recommended by WHO were considerably less available than those in injectable form.

Table 3. Substances appearing on essential drug lists of the reporting governments

Number of reporting governments	*Response rate (percentage)*	*Substance*
30	46	Morphine
27	42	Pethidine
27	42	Codeine
20	31	Fentanyl
7	11	Methadone
7	11	Buprenorphine
3	5	Pentazocine
3	5	Dextromoramide
3	4	Alfentanyl
2	3	Omnopon
2	3	Tilidine
2	3	Trimeperidine
2	3	Tramadol
2	3	Cocaine
2	3	Diphenoxylate
1	2	Butorphanol
1	2	Dextropropoxyphene
1	2	Hydromorphone
1	2	Nalbuphine
1	2	Normethadone
1	2	Naloxone
1	2	Oxycodone
1	2	Phenoperidine
1	2	Pholcodine

23. A patient's ability to obtain opiates such as morphine depends on whether his or her health-care facility stocks it. Only 48 per cent of governments reported that morphine in any dosage form was stocked in all hospitals with cancer programmes, 46 per cent reported that it was stocked in all general and community hospitals and 19 per cent reported that it was stocked in all community pharmacies. The preparations recommended by WHO for cancer pain appear not to be sufficiently available in hospitals that treat cancer patients.

24. Increasingly, hospice is becoming a form of care used to improve access to pain management and palliative care for people who are dying with diseases such as cancer and AIDS. Fifty-nine per cent of the responding governments said that such programmes are present in their countries or areas. The vast majority of governments said that opiates such as morphine were available to treat patients in those programmes. The extent to which opiates were actually used is not known. Seven Governments indicated that opiates such as morphine were not used in hospice programmes: Cape Verde, Eritrea, Kenya, Lao People's Democratic Republic, Myanmar, Samoa and Zaire.

25. Consistent availability of pain medications to patients is essential; shortages cause severe hardship for patients. Although 43 per cent of responding governments reported that they never had shortages, 54 per cent reported that there had been shortages of opiates in hospitals or pharmacies in their countries or areas, either seldom (26 per cent), occasionally (25 per cent) or often (3 per cent). Shortages were the result of insufficient importation (29 per cent), delays in shipping and distribution (23 per cent), increased medical demand (20 per cent), delays due to paperwork and administrative procedures (19 per cent) and insufficient domestic manufacture (6 per cent). Governments that reported no shortages were more likely to have a high human development index.

D. Governments' methods for estimating medical need

26. Governments submit annually to the Board official estimates of the next year's requirements for narcotic drugs. If medical demand exceeds the estimates, governments may submit supplementary estimates at any time; these are examined and confirmed expeditiously by the Board. In recent years, the number of supplementary estimates has increased significantly; there have been increases in requests for morphine, fentanyl and pethidine. Sixty per cent of the responding governments reported that in the preceding five years they had submitted supplementary estimates to the Board because of unforeseen increases in medical needs. Governments that had submitted supplementary estimates in the preceding five years were more likely to be developed countries with a high human development index and high per capita consumption of morphine.

27. While most governments reported they were able to obtain additional supplies expeditiously, 15 governments (34 per cent) indicated that that was not the case. This could be because of the time needed to arrange for importation, transportation and distribution of an additional unanticipated amount. Governments with high per capita consumption of morphine were more likely to obtain supplies expeditiously.

28. 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. More than one half of the responding governments (59 per cent) said that they had not critically examined their methods for assessing medical need for opiates in the last five years. Governments that had critically examined their methods of assessment were more likely to have submitted supplementary estimates; governments that had not conducted an examination were also less likely to report consumption statistics to the Board.

29. 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. Ninety-two per cent of the 65 responding governments indicated they used previous years' consumption to estimate future needs for narcotic drugs; 60 per cent used trends in importation from previous years. Other methods included information from health-care professionals (62 per cent) and consultation with pharmaceutical manufacturers (48 per cent). To a lesser extent, governments used information about currently unmet needs in medical institutions (25 per cent) and the incidence and prevalence of pain (14 per cent). Seventy-two per cent of the responding governments indicated that their method for estimating future consumption reflected actual medical needs for opiates. Forty-five per cent of governments indicated they were satisfied with the method they used, while 47 per cent were only somewhat satisfied; 8 per cent said they were not satisfied.

30. In 1989, the Board recommended that Governments should monitor changing medical needs so that the national estimate of future need could be adjusted.[3] Fifty-nine per cent of the responding governments indicated that they had a procedure to monitor changes in the consumption of opiates in

their countries or areas. Governments having such procedures were more likely to be satisfied with their methods for estimating future medical needs.

E. Legal requirements for prescribing

31. Narcotic control laws of individual countries or areas also establish a regulatory framework that governs medical availability of narcotic drugs. Of the 65 governments that responded to the survey, 14 (22 per cent) also had provincial, state or territorial narcotic control laws. Such laws were more restrictive than the national law in six countries: Armenia, Australia, Benin, China, Oman and United States.

32. WHO has published guidelines for the regulation of health professionals who prescribe, dispense and administer narcotic drugs. The guidelines recommend that narcotic drugs should be available for patients in hospital, as well as for those who can live in the community, and that physicians should be able to decide the dose and duration of treatment based on the individual needs of each patient. All governments surveyed reported that physicians could prescribe opiates such as morphine to a patient in a hospital. Forty per cent of the governments set a maximum amount of morphine that could be prescribed at one time to a hospitalized patient, with some as low as 30 milligrams. Twenty per cent of the governments said that there was a maximum length of time that a hospitalized patient could receive morphine; in some cases it was as low as three days.

33. All but six (9 per cent) of the governments reported that physicians could prescribe morphine for patients who lived at home. Governments had a number of requirements for a physician to prescribe morphine to such patients: special government prescription form (65 per cent of the governments); permission of the hospital or medical supervisor (22 per cent); special licence (12 per cent); and special training (5 per cent). Fifty-one per cent of the governments also set a maximum quantity of morphine that could be prescribed at one time for a patient who lived at home; in some cases it was as low as 15 milligrams. Twenty-eight per cent of the governments indicated that there was a maximum length of time for which a patient who lived at home could receive morphine; in some cases it was as low as 3-7 days, although that appeared to be renewable in some cases. It is likely that such limitations were established many years ago when the main use of narcotic drugs for pain was in injections for post-surgical pain in hospitals.

34. 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.

35. Twenty-six (40 per cent) of the responding governments allowed or required narcotic medication such as morphine that had been left over following the death of a patient to be returned to the hospital or pharmacy. Such provisions not only maintain control over narcotic drugs, but also reduce waste if the medication is returned unopened and unexpired.

36. 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

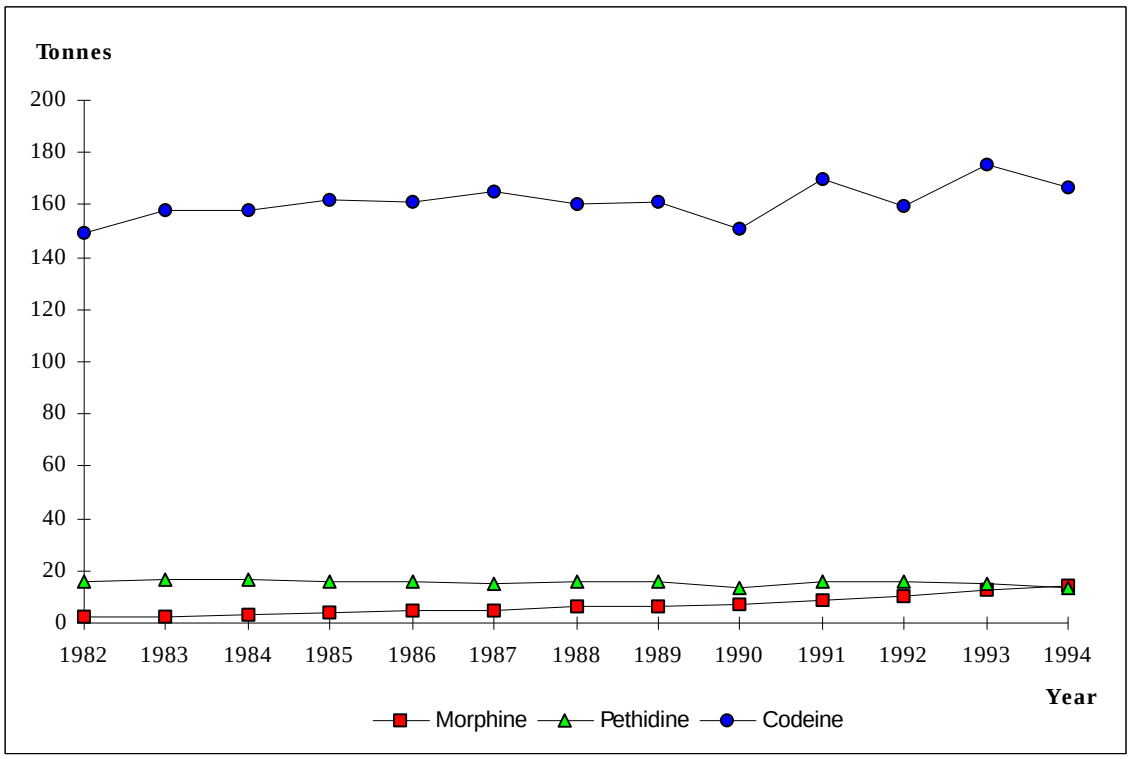
was 1 million dollars. In addition, 48 per cent of the responding governments reported having mandatory minimum penalties, some as high as 10 years in prison.

37. Governments had little or no concern about diversion (in 37 per cent of the responses) or were moderately concerned (19 per cent), very concerned (26 per cent) or extremely concerned (11 per cent). Governments that were least concerned about diversion were more likely not to have shortages and to have morphine available in most community pharmacies.

II. TRENDS IN OPIATE CONSUMPTION

38. Figure I shows the global consumption trends of selected narcotic drugs from 1982 to 1994. Codeine, a natural opiate derived from the poppy plant, has several major medical uses, such as the treatment of pain, cough and diarrhoea. Codeine is widely distributed throughout the world and represents the bulk of all opiate consumption. Global consumption is expected to continue increasing, led by major consumer countries, including Australia, Canada, France, India, Switzerland, Turkey and United Kingdom. A number of governments that responded to the survey said that they anticipated increases in consumption of up to 25 per cent in the next several years; several indicated increases of 25-50 per cent; and a few predicted increases of greater than 50 per cent. The United States was the only major consumer of codeine that predicted a decrease of over 25 per cent in the next several years.

Figure I. Global consumption of morphine, pethidine and codeine, 1982-1994



39. Pethidine is a synthetic narcotic traditionally used, often in injectable form, to treat surgical pain. Total consumption of pethidine is gradually decreasing. The major consumers of pethidine are Australia, Canada, China, Germany, India, Poland, United Kingdom and United States. Pethidine consumption is likely to continue decreasing as a result of declining use in some major user countries and increasing use of other narcotic drugs. However, some of the decrease may be offset by increases in those countries that are encouraging better pain management. A number of governments responding to the survey anticipated increases of up to 25 per cent in the next several years; several indicated increases of 26-50 per cent; and a few small countries predicted increases of greater than 50 per cent. Several countries, including Argentina, China, France and the Netherlands, predicted a decrease of 11-25 per cent.

40. Globally, morphine has been used in injectable form to treat surgical pain and, more recently, in oral form to treat pain due to cancer and other conditions. The predominant feature in the use of morphine since the second half of the 1980s has been the rapid increase in quantities used for the treatment of pain.* Figure II presents the consumption of morphine from 1972 to 1994. The large increase in morphine consumption is attributable to worldwide efforts by Governments, WHO and other organizations to improve the management of pain, in particular pain due to cancer. The Board noted in its annual report for 1995 that the upward trend was particularly noticeable in France, Germany, Japan, United Kingdom and United States.[5] Consumption of morphine and other narcotic drugs is likely to continue increasing because of anticipated increases in most major user countries, as well as in countries that are starting or expanding cancer pain relief programmes, such as China, France, Germany, India, Indonesia, Japan, Mexico, Poland, Spain and Zimbabwe. Many governments that responded to the survey said that they anticipated increases in consumption of up to 25 per cent in the next several years; even more indicated increases of 26-50 per cent; and several predicted increases of greater than 50 per cent.

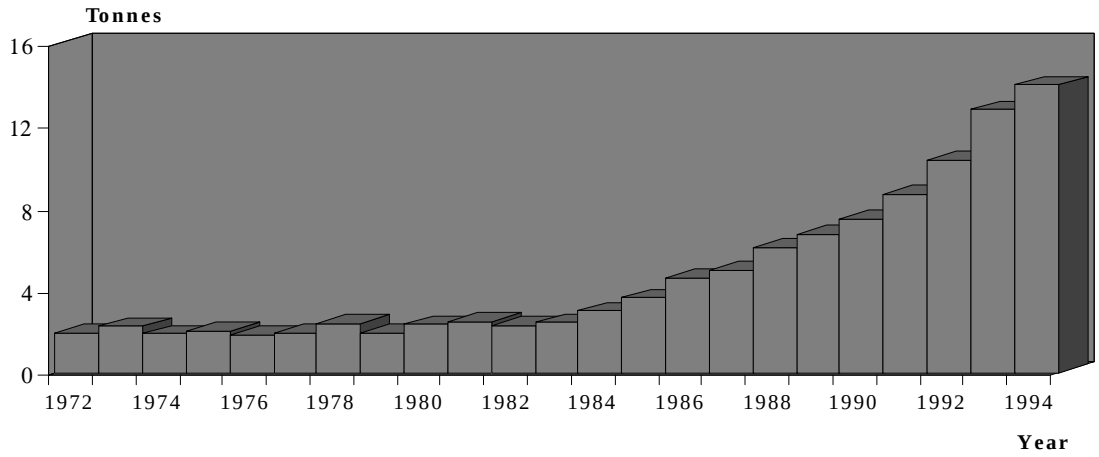


Figure II. Global consumption of morphine, 1972-1994

41. For buprenorphine, dextropropoxyphene and pentazocine, most governments anticipated increases or decreases in consumption of up to 10 per cent and some anticipated increases of up to 25 per cent. For alfentanil and methadone, some governments anticipated increases of 25-50 per cent. A number of governments anticipated increases of up to 25 per cent for fentanyl, with several anticipating increases of between 26 and over 50 per cent in consumption in the next several years. With the introduction of fentanyl plasters, further demand for fentanyl is expected.

*The statistics of the Board for morphine consumption include a small percentage that is used for manufacturing combination products that contain a small amount of morphine that are subject to less control. Some countries may consume a large amount of morphine for this purpose, resulting in a significant overstatement of morphine consumption for a particular year.

42. Several trends are likely to increase the medical use of narcotic drugs:

(a) A number of governments, including major consumers, have indicated they anticipate significant increases in consumption of morphine and other narcotic drugs;

(b) Expected increases in the population of older people, cancer patients and AIDS patients will increase the number of patients who will need pain relief;

(c) The growth of palliative and hospice care in national health systems will increase the numbers of patients who are treated;

(d) Continued efforts by Governments, WHO and other health organizations to improve pain relief and deal with impediments will likely increase medical demand;

(e) New efforts to relieve cancer pain are beginning in countries that have traditionally consumed small amounts of narcotic drugs;

(f) In some countries, the practice of medicine is broadening to include the use of narcotic drugs to relieve pain in certain selected patients with chronic non-cancer pain, in particular when pain has not responded to other treatments, thereby expanding the numbers of patients that may be treated with narcotic drugs;

(g) The shift from injectable to oral dosage forms of morphine requires 3-6 times the amount to obtain the same effect;

(h) Pharmaceutical companies are developing and marketing new products in new dosage forms throughout the world.

43. There are also factors that may retard increases in consumption:

(a) Some impediments, such as limitations in resources for basic health care, as well as cultural beliefs and attitudes about pain and suffering and narcotic drugs, may not change or may be slow to change;

(b) The incorporation of advances in pain medicine and the rational use of narcotic drugs into mainstream medicine and public awareness in the world will take time.

III. CONCLUSIONS AND RECOMMENDATIONS

44. The Board wishes to express its appreciation to the governments that responded to its 1995 survey. The Board notes with satisfaction that a significant number of governments are making efforts to respond to its recommendations; they are increasing their estimates to meet medical demand, issuing national policies to improve medical use of narcotic drugs, supporting educational programmes and examining their health-care systems and laws and regulations for impediments, or are planning to do so.

45. Governments reported a number of problems with the availability of narcotic drugs that must be dealt with. Those problems included lack of availability of drugs recommended by WHO, such as oral morphine, in many countries and particularly in hospitals with cancer programmes; insufficient importation; periodic shortages; problems with estimating future medical needs; and national narcotic laws that did not ensure medical availability of narcotic drugs and restricted availability. Although 36 governments reported having examined their health-care systems and laws and regulations for impediments to availability, they represented only 17 per cent of the governments in the world. Those that did so identified numerous impediments, most of which were linked not only to concerns about drug addiction, drug diversion and restrictive national laws, but also to insufficient import or manufacture, as well as problems in national health-care delivery systems, including insufficient training, personnel and facilities and the cost of medication.

46. The Board notes that most governments in the world did not respond to its questionnaire; thus, the Board did not have sufficient information concerning approximately one half of the world's population. Among those governments that did not respond were most of the developing and least developed countries, as well as those governments that had frequently failed to submit annual estimates of narcotic drug requirements as required by the 1961 Convention. The Board is cognizant that less developed countries have more difficulty meeting basic health-care needs. Nevertheless, the Board encourages governments of such countries to make efforts to examine their medical needs for narcotic drugs as well as the impediments to their availability, to advise the Board of the results of those efforts and to inform the Board if it can be of assistance. The governments that did not respond included a number of developed countries that the Board believes should also concentrate their attention on identifying unmet medical needs.

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

48. 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.

49. Therefore, bearing in mind the conditions prevailing in individual countries and the availability of resources, the Board concludes that if the recommendations below are implemented there will be significant additional progress towards ensuring adequate availability of narcotic drugs for medical and

scientific purposes. The Board will continue its examination of the situation and will monitor responses to its recommendations.

50. 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.

A. Recommendations for consideration by Governments

51. 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 medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments;

(b) Governments that have not done so should, in response to the recommendations contained in the 1989 special report of the Board,[3] critically examine their methods for assessing medical needs for narcotic drugs and should make suitable arrangements for ensuring their availability;

(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;

(d) Governments should add to their annual estimates of requirements for narcotic drugs a margin of 10 per cent to allow for the possibility of increased consumption 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 supply of narcotic drugs because of delays in importation or for other reasons should examine the situation and develop a system to accomplish in a timely manner the steps involved, such as issuing licences, arranging for payment, carrying out paperwork, transporting the drugs, taking the drugs through customs and distributing the drugs to medical facilities;

(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;

(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;

(i) Governments should inform the Board about progress and needs concerning implementation of the present recommendations;

(j) Governments that did not reply to the 1995 questionnaire of the Board should do so.

B. Recommendations for consideration by the United Nations International Drug Control Programme

52. 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.

C. Recommendations for consideration by the Commission on Narcotic Drugs

53. The Commission on Narcotic Drugs should call on Member States to give full consideration to the present special report and the recommendations contained in it, in the light of the following:

(a) The worldwide extent of unrelieved pain and suffering associated with diseases such as cancer and AIDS;

(b) The relatively recent medical advances that make pain relief possible;

(c) The fact that morphine and other narcotic analgesics must be available to provide such relief;

(d) The fact that there continues to be unmet medical needs for narcotic drugs particularly but not only in less developed countries;

(e) The obligation of parties to the 1961 Convention or to that Convention as amended by the 1972 Protocol to ensure the availability of narcotic drugs for medical and scientific purposes.

D. Recommendations for consideration by the World Health Organization

54. WHO is encouraged to consider the following recommendations:

(a) WHO should expand its efforts to provide Governments with information about its analgesic method for the relief of cancer pain and to educate the public, health professionals and policy makers about the rational medical use of narcotic drugs, including the analgesic method for the relief of cancer pain;

(b) WHO should continue to inform the public, health professionals, competent authorities and policy makers about the correct definition of terms regarding dependence, as well as their significance or lack of significance when narcotic analgesics are used to treat cancer pain under medical supervision;

(c) WHO should, in cooperation with the Board, assist Governments in developing adequately controlled drug distribution systems that are capable of providing narcotic drugs to patients in hospitals and in the community;

(d) WHO should encourage health-care organizations to communicate with national narcotic control authorities about the rational use of narcotic drugs, legal requirements, unmet medical needs and impediments to availability;

(e) WHO should expand its efforts to develop methods that can be used by governmental and non-governmental organizations to identify impediments to the appropriate medical availability of narcotic drugs;

(f) WHO should continue to evaluate whether national essential drug lists and formularies contain the narcotic drugs that are needed for cancer pain relief;

(g) WHO should inquire into the extent to which and the reasons why non-narcotic drugs are used in lieu of narcotic drugs for the treatment of severe pain, including the medical and regulatory factors behind that approach.

E. Recommendations for consideration by international and regional drug control, health and humanitarian organizations

55. International and regional drug control, health and humanitarian organizations are encouraged to consider the following recommendation: international and regional organizations that assist Governments with drug control, health and humanitarian aid should consider ways in which they can promote the WHO analgesic method for the relief of pain and support making narcotic analgesics available under adequate control.

F. Recommendations for consideration by educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives

56. 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.

Notes

[1]United Nations, *Treaty Series*, vol. 976, No. 14152.

[2]*Demand for and Supply of Opiates for Medical and Scientific Needs* (United Nations publication, Sales No. E.89.XI.5).

[3]Ibid., para. 49.

[4]*Cancer Pain Relief and Palliative Care: Report of a WHO Expert Committee* (World Health Organization Technical Report Series, No. 804 (Geneva, 1990).

[5]*Report of the International Narcotics Control Board for 1995* (United Nations publication, Sales No. E.96.XI.1), para. 69.

Annex I

RESPONSE FROM THE WORLD HEALTH ORGANIZATION: STATUS OF IMPLEMENTATION OF THE ECONOMIC AND SOCIAL COUNCIL RESOLUTIONS ON THE MEDICAL USE OF OPIATES

I. STATUS OF IMPLEMENTATION OF ECONOMIC AND SOCIAL COUNCIL RESOLUTION 1989/15

A. Interpretation of Economic and Social Council resolution 1989/15

1. For the World Health Organization (WHO), there is some ambiguity regarding the meaning of the recommendation in Economic and Social Council resolution 1989/15. With respect to the meaning of "medical need", it is usual to observe a significant gap between "need" and "effective demand" for any commodity. Since estimates of drug requirements to be submitted to the International Narcotics Control Board (INCB) would have to be close to the actual consumption, [WHO] initially felt that this would refer to "effective demand" rather than "need".

2. However, the background information [in the 1989 special report of INCB][a] seems to suggest that "medical need" for opiates in this recommendation refers to need, or the quantity of opiates that would be consumed medically if ideal systems of drug distribution and medical care were available to all in need.

3. The ... comments [below] are based on this interpretation.

B. Implementation status

4. Conceptually, "medical need" for a drug could be obtained as follows:

(a) Number of patients with a particular disease requiring medication with the drug in question;

(b) Quantity of the drug required to treat one patient having that disease.

Multiply (a) and (b) above for each disease requiring the drug and add them up.

5. The number of patients with a particular disease requiring medication with the drug in question (referred to in paragraph 4 (a) above) concerns health statistics, an area in which WHO has:

(a) Updated and disseminated standards for classification of diseases [International Classification of Diseases];

(b) Implemented activities aimed at strengthening epidemiological capabilities of countries.

6. The quantity of the drug required to treat one patient having the disease in question (referred to in paragraph 4 (b) above) involves drug selection and standard medication with the drug, in areas in which WHO has:

(a) Updated and promoted the use of a guide for the selection of essential drugs, including morphine and codeine;

(b) Promoted ... a medication strategy for the relief of cancer pain, which includes the use of morphine and codeine.

C. Conceptual and practical limitations

7. The theoretical and practical limitations of these approaches should be properly understood:

(a) The selection of a particular drug from among a number of alternative drugs, as well as the quantity and mode of use of the drug, are usually determined by the prescribing physician based on the condition of each patient;

(b) An exception to this is the system-wide application of treatment guidelines specifying the drug, dosage and duration of use, in order to achieve specific public health goals, such as leprosy or tuberculosis control within the framework of the relevant governmental health programmes;

(c) Such a governmental/official standardization of medical practice is not normally considered suitable for common indications of opiates (pain, coughs). Therefore, it would not be appropriate for WHO to direct its limited resources to the preparation of quantitative guidelines for the medical use of opiates;

(d) Offering relevant information to prescribers (model prescribing information) would be the limit of what WHO would do, but such information is also available elsewhere and its influence on the prescribing practices of individual physicians is unknown.

II. INFORMATION ON OTHER TOPICS

A. The unmet medical needs for opiates

8. The INCB document groups impediments into three categories.[b] Activities to address these impediments are well integrated into ongoing activities of WHO, as briefly explained below.

1. Impediments due to inadequacies of health-care systems

9. The development of health-care systems based on primary health care continues to be a high priority programme of WHO. Ensuring the availability of safe and effective drugs at a reasonable cost is an integral component of a health-care system. To help Governments achieve this objective, WHO, through its two programmes concerned with the rational use of drugs, continues to study/develop guidelines and provide support to Governments in such areas as (a) policy including financing; (b) supply and logistics; (c) quality assurance; (d) rational use; and (e) other issues, such as response to emergency situations.

10. However, the problems facing the health sector today, with respect to ensuring access to essential drugs and rational use of drugs, are increasingly complex and take place in a rapidly changing environment. Due to the world economic crisis, the purchasing power of households has decreased in many countries, especially in Africa; this decrease has led in many countries to an aggravation of drug shortages in health-care facilities. The medical use of opiates has, therefore, not been seen as a priority issue.

2. Impediments due to drug control legislation and administration (regulatory impediments)

11. Though not mentioned in the ... INCB document, [WHO is] aware that medical needs for opiates for emergency medical care are unmet, due to regulations hindering the transportation of opiates to sites of emergencies across international borders. WHO has been drawing the attention of INCB to this problem since 1992. As a result INCB's perception has changed to the extent of including a positive suggestion on this matter in its report for 1994.[c]

12. However, since the relevant [report of the Executive Director of the United Nations International Drug Control Programme (UNDCP)] (E/CN.7/1995/14) disregarded this important suggestion, a valuable opportunity to draw the attention of the Commission on Narcotic Drugs to this matter was unfortunately lost. WHO therefore is obliged to revitalize its awareness-building efforts so that a practical solution can be found to this regulatory impediment.

13. Even in normal situations, overly restrictive regulations can result in depriving a majority of the population of access to controlled drugs, simply because the cost of complying with the regulations is added on to the distribution cost of the drug, directly or indirectly.

14. With a view to striking a delicate balance between the need to prevent diversion and the need to minimize regulatory impediments, WHO has promoted the concept of a balanced regulatory approach, taking all available opportunities such as participation in training seminars for national regulatory personnel.

15. The concept of a balanced regulatory approach should apply to additional national control measures over and above the minimum requirements under the 1961 Convention,[d] as well as to mandatory control measures. This advocacy campaign has therefore been directed not only to national regulatory personnel, but also to international regulatory authorities such as INCB and the ... Commission on Narcotic Drugs. The latter includes discussions on such issues as (a) simplified procedures to respond to emergency medical needs, (b) simplified estimates and (c) simplified reporting.

16. In addition to the promotion of this concept, WHO has drawn the attention of national regulatory authorities to concrete examples of control measures that could be viewed as overly restrictive, as appropriate.

3. Impediments associated with professional practice

17. Much effort has been made by WHO to address them. To reduce excessive fear of iatrogenic addiction, WHO clarified and promoted the correct understanding of the concept of drug dependence. It has also promoted the provision of adequate care for the relief from cancer pain, and the use of a treatment regimen including morphine and codeine.

B. The status of barriers to opiate availability and progress to overcome them

18. There has been encouraging progress in some countries in lowering the barriers associated with professional perception and practices.

19. However, little change has been noted with respect to barriers associated with resource constraints at the national level, as well as those associated with regulatory systems (see the comments on paragraph 1 above).

C. The status of implementation of WHO recommendations to Member States concerning national policy, education and training, and drug availability for cancer pain and palliative care

20. Considerable progress has been made in some countries (e.g. China, Japan). Continued dialogue is being held with other countries to promote the recommendations.

D. Other information as may be relevant

21. With regard to regulatory impediments, it may be useful to analyse regulatory costs of complying with the control measures included in UNDCP model legislation.

Notes

[a]*Demand for and Supply of Opiates for Medical and Scientific Needs* (United Nations publication, Sales No. E.89.XI.5), paras. 21-24.

[b]Ibid., paras. 25-48.

[c]*Report of the International Narcotics Control Board for 1994* (United Nations publication, Sales No. E.95.XI.4), para. 21 (i).

[d]United Nations, *Treaty Series*, vol. 520, No. 7515.

Annex II

RESPONSES FROM NON-GOVERNMENTAL ORGANIZATIONS

1. The International Association of Cancer Registries did not have information readily available to answer the inquiry of the International Narcotics Control Board.

2. The International Council of Nurses response highlighted the role of the nurse in the prevention of substance abuse and acknowledged the therapeutic need for opiates.

3. The International League of Dermatological Societies/International Committee of Dermatology commented that the use of opiates in dermatology was relatively slight and peripheral to the use of opiates by other specialties, adding that it was not aware of any unmet medical needs for opiates.

4. The International Union against Cancer indicated that an adequate response would take more time than available because it was an organization of member organizations and offered to explore ways to assist the Board.

5. The World Federation of Anaesthesiologists noted that there were countries in the area of the eastern Mediterranean and the Persian Gulf in which government restrictions on opioids were so irksome that doctors avoided their prescription. It also noted that joint efforts in the United Kingdom of Great Britain and Northern Ireland by the Royal College of Surgeons and the College of Anesthesiologists in 1990 had stimulated introduction of acute pain control teams in many hospitals; in Wales, official goals had been set to reduce patient complaints of pain and the Wales College of Medicine was offering a multidisciplinary distance learning diploma in pain management. The World Federation of Anaesthesiologists stressed that those developments were based on better usage of opioids.

6. The World Psychiatric Association commented that concern about unmet needs applied particularly to developing countries, which accounted for only 20 per cent of the medical use of opioids. It stated that some countries had rigorous restrictions on drugs of abuse, which made it difficult for opioids to be used for medical purposes, such as pain relief, for which there were no suitable substitutes. It offered to provide additional information.

Annex III

SUMMARY OF REPLIES RECEIVED BY THE INTERNATIONAL NARCOTICS CONTROL BOARD FROM NATIONAL CHAPTERS OF THE INTERNATIONAL ASSOCIATION FOR THE STUDY OF PAIN

1. *In Canada*, there is an adequate supply of opiates for medical and scientific needs. A national policy for cancer pain was adopted in 1984. Guidelines are emerging for opiate use in chronic, non-malignant pain. Education for health professionals is inadequate. Under-treatment of cancer pain is common. Transnasal butorphanol and transdermal fentanyl have recently been made available. Triplicate prescription programmes have reduced prescribing of opiates. There is a gross shortage of funding for research on pain management. The National Cancer Institute has new recommendations for cancer pain.

2. *In Chile*, recommendations by the International Narcotics Control Board have been well implemented. Regulatory authorities are sensitive to needs and there are no problems with importing and distributing. Opiates are used spinally. Patient-controlled analgesic pumps are beginning to be used. Consumption of morphine almost doubled from 1993 to 1994 and will continue to increase with the development of the national programme of pain relief and palliative care. There is no diversion. The cost of slow-release morphine is too high and there is a lack of immediate-release preparations. The national chapter of the International Association for the Study of Pain sponsors education and research on the rational use of opiates.

3. *In Colombia*, opiates are used to treat acute and post-operative pain and cancer pain; many dosage forms are available, including slow-release and transdermal. Morphine use is increasing. The narcotic department is willing to improve the regulatory climate for opiates. The national chapter of the International Association for the Study of Pain sponsors seminars for many professionals, patients and the public to improve the rational use of opiates.

4. *In Hungary*, recommendations of the Board are accepted and approved by the Government. There are no restrictions on opiates for intractable pain. The introduction of long-acting opiates revolutionized pain management; such opiates are provided free of charge to cancer patients. The medical needs for opiates are being met. The national chapter of the International Association for the Study of Pain sponsors regular educational programmes for physicians and plans to educate patients and the public in the rational use of opiates.

5. *In Japan*, recommendations of the Board are accepted by the Government. The medical use of opiates has increased yearly, reaching 504 kg in 1993; nevertheless such use is still far less than in other countries such as Canada. The narcotic law has been revised. There are many educational seminars on the rational use of opiates; new textbooks on the subject will be available soon.

6. *In Kenya*, recommendations of the Board are strictly adhered to. Pethidine is the main drug used for medical purposes and morphine is rarely available. The prohibitive cost of opiates is compounded by structural adjustment programmes of the World Bank and the International Monetary Fund. The use of opiates is minimal. Barriers include the regulatory climate for opiates, low family incomes and no foreign exchange with which to import opiates. Pharmacies are unwilling to stock opiates due to government controls, making access difficult for patients. Kenya needs to raise family incomes and to relax government opiate controls and structural adjustment programmes. The national chapter of the International Association for the Study of Pain sponsors seminars on pain management where the use of opiates has been debated.

7. *In Malaysia*, opiates are readily available in the form of morphine hydrochloride tablets, morphine sulfate injections, pethidine injections and fentanyl injections. Oral pethidine is no longer available. The

cost of opiates was reasonable until the Government Medical Store was privatized. Slow-release morphine is expensive compared with immediate-release morphine. Private doctors do not stock opiates due to record-keeping and security requirements. Acute pain is a problem but it is getting better with the dramatic increase in morphine use. The lack of knowledge about treating cancer pain is widespread. Many cancer patients are not receiving optimal pain care because of medical ignorance and the non-availability of aqueous morphine in private practices. The fear of addiction is a big problem even when opiates are used to treat cancer patients. The World Health Organization (WHO) method is not widely known. Hospice programmes are limited. The national chapter of the International Association for the Study of Pain sponsors many workshops and seminars for physicians, nurses and medical students. There is a need for core curriculum in pain management in medical, dental, nursing and pharmacy schools. There is also a need for more recognition of the WHO programme.

8. *In New Zealand*, most recommendations of the Board are implemented but not exclusively by the Government. Insufficient attention is given to the education of professionals, especially at the undergraduate level. There is a wide range of opiates available, including continuous and patient-controlled analgesic infusions. Syringe drivers are not too expensive. Epidural opiates are used widely as an anaesthetic. The medical needs for opiates are being met. There is widespread fear of addiction among professionals. Regulatory restrictions are insignificant, except for limits on prescription quantity and triplicate prescriptions. The national chapter of the International Association for the Study of Pain sponsors educational seminars on the rational use of opiates. The use of opiates to treat chronic non-cancer pain is unsettled as yet; however, new advisory, but not mandatory, guidelines are available.

9. *In the Philippines*, recommendations of the Board are far from being implemented. There is a cancer control programme but there is little implementation of it. The availability of morphine is erratic even in tertiary government cancer hospitals. The use of opiates is generally confined to treating pain due to surgery and cancer; it is rarely used for the relief of chronic, non-malignant pain. Barriers to the use of opiates are the current regulatory climate; limitations on prescription (800 mg per prescription), which is difficult for patients who live far away; and the difficulty in working with government. The national chapter of the International Association for the Study of Pain regularly sponsors symposia to educate professionals about opiate use.

10. *In the Republic of Korea*, recommendations of the Board are currently being implemented. Opiates are used to treat acute pain, cancer pain and, in some cases, chronic non-malignant pain. Most of the medical needs for opiates are being met. The Government can be notified to remedy shortages. An increase in opiate use requires notification of the Government twice a month. There are no barriers in the regulatory climate. Opiates can be prescribed with a correct diagnosis and the address of the patient, but for one week only. There is a good relationship between the national chapter of the International Association for the Study of Pain and the Government. There are few if any barriers to the rational use of opiates. The national chapter sponsors seminars, journals and public education on the rational use of opiates. Hospices are being established.

11. *In the Russian Federation*, recommendations of the Board are generally being implemented. Opiates such as tramadol and buprenorphine are used instead of codeine and morphine, which have been recommended by WHO, because the former have fewer side-effects and a low dependence potential. Due to economic problems, the demand for opiates is not met from time to time, but there are no other obstacles. Training programmes for professionals must be improved. Training plans for patients and professionals are being prepared.

12. *In Singapore*, recommendations of the Board are being implemented. Opiates are used for pre-operative medication for the relief of both acute and chronic pain, and for adjunct therapy in acute pulmonary oedema. There are no unmet medical needs for opiates. Although there are harsh narcotic laws there is no problem with the availability of opiates. There are no insurmountable barriers to the

rational use of opiates. There are plans to hold seminars for the public, professionals and patients on the subject.

13. *In Slovakia*, the Government has accepted recommendations of the Board. There are no restrictions on the prescription or availability of opiates. To improve the relief of cancer pain, it will be necessary for the Minister of Health to openly adopt and implement the WHO cancer pain programme. The national chapter of the International Association for the Study of Pain sponsors many seminars to educate medical students, physicians and the public in the rational use of opiates.

14. *In the United Kingdom of Great Britain and Northern Ireland*, there is no problem with the opiate supply. Large quantity prescriptions can be a problem on weekends due to insufficient pharmacy stocks. The medical needs for opiates are being met. The national chapter of the International Association for the Study of Pain sponsors considerable education for physicians and hospices on the rational use of opiates. Opiates are used to relieve acute and chronic pain, including cancer pain; breathlessness, especially from interstitial lung filtration of cancer; cough; and diarrhoea. Other uses are possible. There are no real barriers to the rational use of opiates, but there is a need for more training programmes for professionals.

15. *In the United States of America*, the supply of opiates for medical purposes is adequate. Federal law recognizes the benefit of controlled substances to public health and the responsibility to ensure the availability of opiates for medical purposes. Physicians cannot prescribe narcotic drugs to treat addiction unless they are separately registered to dispense methadone. Intractable pain is recognized as a legitimate medical purpose for prescribing narcotic drugs. The Government should adjust regulatory policy to reduce restrictions and paperwork related to opiate use. Some state laws are too strict. State medical board investigations of physicians have a chilling effect on prescribing. There are new educational programmes to inform medical regulators. Cancer pain under treatment is still common. There are new state cancer pain initiatives in almost every state. There are new guidelines for opiate use to relieve acute post-surgical and cancer pain, and there is increasing recognition of the benefits of using opiates to relieve chronic, non-malignant pain.

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