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INTERNATIONAL NARCOTICS CONTROL BOARD
Vienna

Report of the International Narcotics Control Board for 1989

Demand for and Supply of Opiates for Medical and Scientific Needs

Special Report
prepared pursuant to Economic and Social Council
resolution 1989/15

UNITED NATIONS

ABBREVIATIONS

The following abbreviations are used, except where the context otherwise requires:

Abbreviation	Full title
Board (or INCB)	International Narcotics Control Board
1961 Convention	Single Convention on Narcotic Drugs, 1961, signed at New York on 30 March 1961
Council	Economic and Social Council of the United Nations
Narcotic drug	Any of the substances in Schedules I and II of the 1961 Convention, whether natural or synthetic
Opiates	The phenanthrene alkaloids of opium and their derivatives which have been placed under international control
1972 Protocol	Protocol amending the Single Convention on Narcotic Drugs, 1961, signed at Geneva on 25 March 1972
WHO	World Health Organization

NOMENCLATURE OF COUNTRIES AND TERRITORIES

In referring to political entities, the Board is guided by the rules governing the practice of the United Nations. The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Board concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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SUMMARY

This report was prepared further to Economic and Social Council resolution 1989/15 of 22 May 1989 which requested the International Narcotics Control Board 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". The assessment in the present supplement to the Board's report for 1989 was prepared in conjunction with the World Health Organization.

The Single Convention on Narcotic Drugs, 1961, limits exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of opiates. Individual countries enact laws and regulations to implement the provisions of the 1961 Convention with adequate controls over the licit distribution of opiates to prevent diversion and to ensure their availability for medical and scientific purposes.

Information available to the Board and WHO suggests, however, that the need for opiates for legitimate medical purposes is not being fully met. Only a few countries have established effective and comprehensive systems for assessing that need and monitoring the extent to which it is met. Moreover, the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented. Limitations within health-care systems, in particular the inadequate development of infrastructure and insufficient personnel and financial resources have, to varying degrees, prevented the optimum use of opiates by patients who need such drugs. Public perception of a potential danger of personal risk of addiction may likewise deter the therapeutic use of opiates. Lastly, professional medical practice in different countries and the attitude of health professionals have similarly affected the supply of opiates.

Ensuring the supply of opiates for medical needs requires an effective assessment and monitoring system. The availability of opiates could also be improved through legislative and administrative measures designed to achieve a better balance between the control of opiates and their supply for medical purposes; easier access to improved health-care services; and the dissemination of up-to-date information to health professionals regarding the rational use of opiates. Any increase in demand for opiates that might be expected to arise from such measures could be met in the short-term from existing opiate stocks and in the long-term by adjusting production to meet the new demand.

INTRODUCTION

1. One of the objectives of the Single Convention on Narcotic Drugs, 1961, 1/ and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, 2/ is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion.

2. It is the responsibility of all countries to estimate their annual requirements of opiates. Taking into account such factors as previous consumption patterns, morbidity and mortality data, emerging medical needs and the method used for quantifying requirements, the estimates are examined and confirmed by the Board for the following year. Supplementary estimates may be submitted at any time and are immediately considered by the Board. The estimates system is thus sufficiently flexible to respond to unforeseen needs for opiates in the light of changing circumstances.

3. During the mid- and late 1970s, in reaction to an earlier shortage, the production and availability of opiates for medical purposes greatly increased resulting in the accumulation of stocks. As of 1974, however, consumption of those drugs levelled off. In order to reduce the widening gap between increasing supply and stable consumption, consultations were held between the Board and producing countries, leading to a drastic reduction in the opium poppy cultivation areas. Two special reports, one published as a supplement to the Board's Report for 1980 3/ and another as a supplement to the Report for 1985, 4/ sought to assist Governments by providing data which threw light on the supply and demand equation. Since 1980, an approximate balance has been achieved between the production of opiate raw materials and consumption of opiates for medical purposes. During the period of over-production, excessive stocks accumulated. They have been the subject of many resolutions by both the Commission on Narcotic Drugs and the Economic and Social Council. Despite the existence of excessive stocks, information available to the Board and to WHO suggests that the need for opiates for legitimate medical purposes is not being fully met. Thus, patients suffering from conditions which might be treated with opiates often cannot obtain them. This situation exists in both developed and developing countries, but is more acute in the latter.

4. It is against such a background that the Economic and Social Council adopted resolutions 1988/10 of 25 May 1988 and 1989/15 of 22 May 1989. Council resolution 1988/10 requested the Board to review available information on the problem of excess stocks in order to develop a practical and effective solution. To comply with that request, the Board sought the assistance of WHO in gathering further information on licit medical needs for opiates in various regions of the world. In resolution 1989/15 of 22 May 1989 the Council commended the efforts of the Board to date and requested it to complete the project.

5. In response to those resolutions, the Board, in conjunction with WHO, undertook to identify possible medical needs for opiates which were currently not being met for a variety of reasons. Information was gathered from various

sources, including drug regulators, health system managers, medical specialists, pharmacists and specialized units within WHO, to determine how countries are assessing their medical needs for opiates, the extent to which those needs are being met, what impediments have arisen, and what short-, medium- and long-term strategies may be deployed to overcome those impediments. A list of documents consulted in the preparation of this study is given in annex III.

6. The term "opiates" is used in this study to designate the phenanthrene alkaloids of opium and their derivatives which have been placed under international control. This report is concerned exclusively with the demand for and supply of opiates for medical and scientific purposes; consequently, whenever reference is made to cultivation, production, manufacture of, trade in, and utilization of drugs, it is to be understood that such reference relates exclusively to licit activities and transactions.

I. AN OVERVIEW OF PRODUCTION OF OPIATE RAW MATERIALS AND CONSUMPTION OF OPIATES

7. The data relating to consumption of opiates for medical and scientific needs, production of opiate raw materials and the balance between production and consumption are shown in the Table.

A. Production of opiate raw materials

8. Since 1980, when the principal producing countries reduced acreage following consultations with the Board, global production has fallen substantially, oscillating around the 200-tonne mark in morphine equivalent. Between 1980 and 1985, total production of opium and of poppy straw, expressed in terms of morphine equivalent, averaged 207 tonnes, representing 56 per cent of the peak reached in 1978, when 367 tonnes were produced. During the three subsequent years, 1986-1988, production remained below the level of consumption at an average of 168 tonnes. Advance statistics and projections show a total harvest of 155 tonnes and 185 tonnes for 1989 and 1990, respectively, both below projected total use. Beginning in 1986, global production below consumption levels allowed for reduction in the stocks of raw materials.

9. The area of poppy cultivation in India has continued to diminish, and opium production has likewise followed a declining trend. The area harvested in 1989 was only about 15,000 hectares, and the country's opium production amounted to 488 tonnes, equivalent to 54 tonnes of morphine, the lowest since 1968 with the exception of the harvest in 1984 when a cold wave destroyed most of the crop. Production in 1989 represented only 30 per cent of the 1978 level of production, the highest ever reached. It is forecast that approximately the same area of cultivation will be maintained in 1990, and that a total of 467 tonnes of opium, or 51 tonnes in morphine equivalent, will be produced.

10. In Turkey, the area actually harvested has been consistently lower than the area estimated. From 1985 to 1987 the area harvested in Turkey was approximately 5,000 to 6,000 hectares, less than 10 per cent of the peak level recorded in 1977, and production of poppy straw was roughly 9 tonnes per annum in terms of morphine equivalent. Whereas in 1988 over 18,000 hectares were actually harvested and production amounted to 25 tonnes, only about 8,000 hectares were harvested in 1989, as a result of drought and frost, with production amounting to 8 tonnes. Although the estimated acreage in 1990 is the same as that for 1989, expected production should be substantially higher, if weather conditions permit, and should amount to 30 tonnes in morphine equivalent.

11. Between 1983 and 1985, the area harvested in Australia averaged 5,300 hectares and poppy straw production reached 49 tonnes in morphine equivalent in 1985. During the three subsequent years, 1986-1988, both the the area harvested and the amount of poppy straw produced were reduced and amounted to, on average, 3,600 hectares and 36 tonnes of morphine. The acreage for 1989 and 1990 is at the 1983-1985 level with expected production of, respectively, 47 and 51 tonnes, which will allow the replenishment of stocks. The yield of morphine extracted from poppy straw reached 1.23 per cent in Australia in 1988, the highest ever recorded by any country.

Table

PRODUCTION AND CONSUMPTION OF OPIATES

Country	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990
India															
Area	1 586	57 224	63 684	52 081	35 166	35 578	31 958	31 359	18 620	25 153	23 811	22 823	19 858	15 019	(15 255)
Production	161.0	138.9	184.6	160.1	106.6	127.8	108.0	115.8	53.4	86.8	75.1	76.8	61.9	53.7	(51.4)
Turkey															
Area	2 000	72 000	50 600	18 000	18 400	15 330	8 534	7 002	12 569	4 902	5 404	6 137	18 760	8 284	(40 000)
Production	51.1	129.6	101.7	45.2	49.4	36.5	15.3	11.5	20.8	9.2	8.4	9.2	24.7	8.4	(29.6)
Australia															
Area	2 799	5 783	6 854	8 774	1 551	3 742	2 459	5 273	5 738	4 851	3 994	3 273	3 462	4 581	(5 700)
Production	9.9	21.3	27.8	52.9	10.0	33.3	20.5	41.4	42.3	49.4	38.5	30.0	38.5	46.8	(51.2)
France															
Area	4 940	5 281	6 778	5 060	4 597	2 615	4 460	3 731	3 705	4 029	3 200	3 300	3 113	2 641	(3 200)
Production	9.3	16.7	24.7	21.0	15.7	11.4	25.0	12.7	23.2	20.7	15.7	13.8	21.4	11.9	(17.2)
Spain															
Area	700	980	1 799	1 790	2 137	67	1 602	5 311	4 567	4 042	3 458	3 252	2 935	(4 500)	(4 500)
Production	0.2	0.5	1.2	2.8	5.0	0.1	2.2	11.4	17.3	11.2	5.6	5.8	8.4	(12.2)	(12.2)
Other countries															
Production	17.8	24.7	26.7	32.8	28.4	19.2	15.5	23.9	28.8	34.6	27.1	21.0	20.6	(22.9)	(22.9)
Totals															
(a) Production	249.3	331.7	366.7	312.8	215.1	228.3	183.5	214.7	185.8	211.9	170.4	156.6	175.5	(155.9)	(184.5)
(b) Consumption	185.1	186.7	196.0	192.2	187.6	197.1	185.6	192.2	194.5	202.4	202.3	205.4	199.2	(202.5)	(202.3)
Balance (a)-(b)	64.2	145.0	170.7	120.6	27.5	31.2	-0.1	22.5	-8.7	9.5	-31.9	-48.8	-23.7	(-46.4)	(-17.8)

Note: Area harvested is indicated in hectares and production and consumption in tonnes of morphine equivalent.
Figures in parentheses are estimates or projections.

12. The area harvested in France has averaged 3,200 hectares in recent years; in 1989, however, because of adverse climatic conditions, poppy straw production amounted to only 12 tonnes in morphine equivalent. The same area of cultivation will be maintained for 1990 and the projected production of 17 tonnes is expected to be at the same level as the average production between 1986 and 1988.

13. In Spain, an area of 4,000 to 5,000 hectares has been authorized for opium poppy cultivation in recent years; the area actually harvested has been around 3,000 hectares. Poppy straw production in the country is projected to be 12 tonnes in morphine equivalent per annum for 1989 and 1990.

14. In addition to those five countries, which cultivate the poppy primarily for alkaloid extraction, some countries cultivate the plant mainly for the production of seeds or edible oil. Some of the straw available is processed to manufacture narcotic drugs. Aggregate production in the latter countries, namely, Bulgaria, Czechoslovakia, Hungary, Poland, Romania, the Union of Soviet Socialist Republics and Yugoslavia, showed a decline from 1986 to 1988, averaging 23 tonnes of morphine. While production in Hungary has been rising, partly as a result of improved industrial yields attained in recent years, that increased production seems to be offset by a decline in the USSR. Although cultivation of Papaver somniferum for the extraction of oil is permitted under licence in the USSR, the state authorities in the republics are reluctant to authorize such cultivation in view of possible abuse. It is assumed that total production of the countries mentioned in this paragraph will remain at the current level.

B. Global consumption of opiates

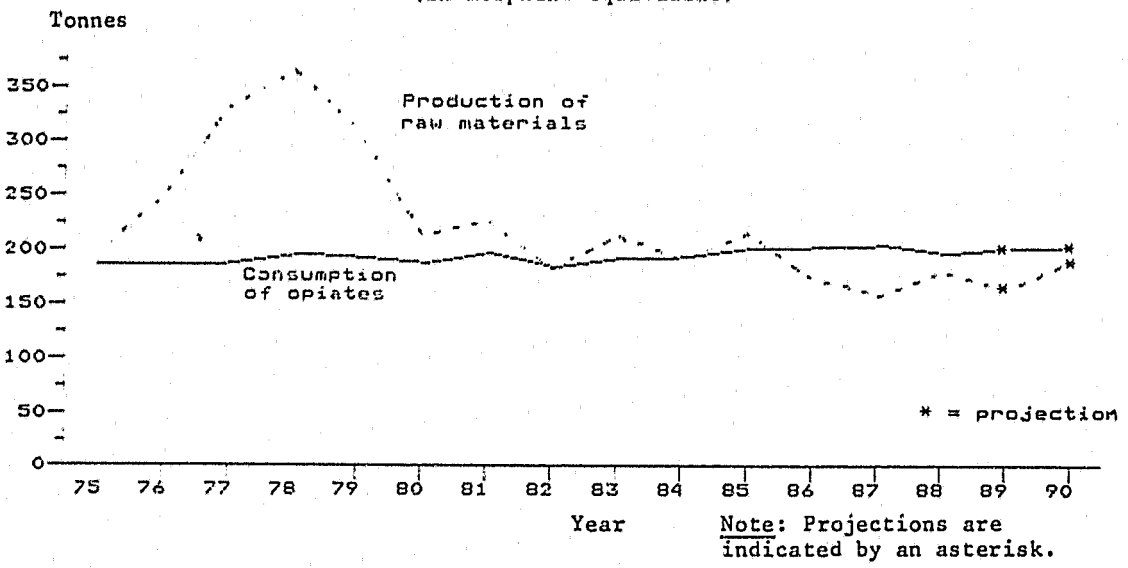
15. As noted in recent annual Reports of the Board, the global consumption of opiates has stabilized during the last 15 years at an annual average of roughly 200 tonnes in terms of morphine equivalent. It is noteworthy that, since 1985, total consumption has somewhat increased and exceeded 200 tonnes per annum between 1985 and 1987, mainly reflecting the level of codeine consumption which accounts for more than 80 per cent of the total. Among other opiates, consumption of dihydrocodeine, which had continued to show a steady and gradual increase, fell substantially in 1988 for the first time during the period under consideration. Having reached a peak in 1986, pholcodine consumption declined for the next two years. A declining trend has also been discerned in global consumption of ethylmorphine. As a result of increasing oral administration of morphine for pain relief, demand for this analgesic has more than doubled in recent years. In the medium term, as was projected by the Board, global consumption of opiates appears to remain at approximately 200 tonnes in morphine equivalent.

C. Balance between production and consumption

16. As reflected in Figure I, total production of opiate raw materials and global consumption of opiates have been in approximate balance since 1980. This is in sharp contrast to the period from 1976 to 1979, when rapid increases in the area of cultivation resulted in over-production of opiate raw materials and accumulation of stocks. Annual production exceeded 300 tonnes in morphine equivalent between 1977 and 1979, with a peak of 367 tonnes in 1978, amounting to over 170 tonnes in excess of total consumption. Between 1980 and 1983, global production was slightly above the consumption level by

an average of 20 tonnes. Since 1986 global production has been on an average about 35 tonnes below total opiate consumption. For 1989 and 1990, the same level of production will be maintained. Those trends have helped reduce the excessive stocks of opiate raw materials.

Figure I. World production and consumption of opiates (in morphine equivalent)

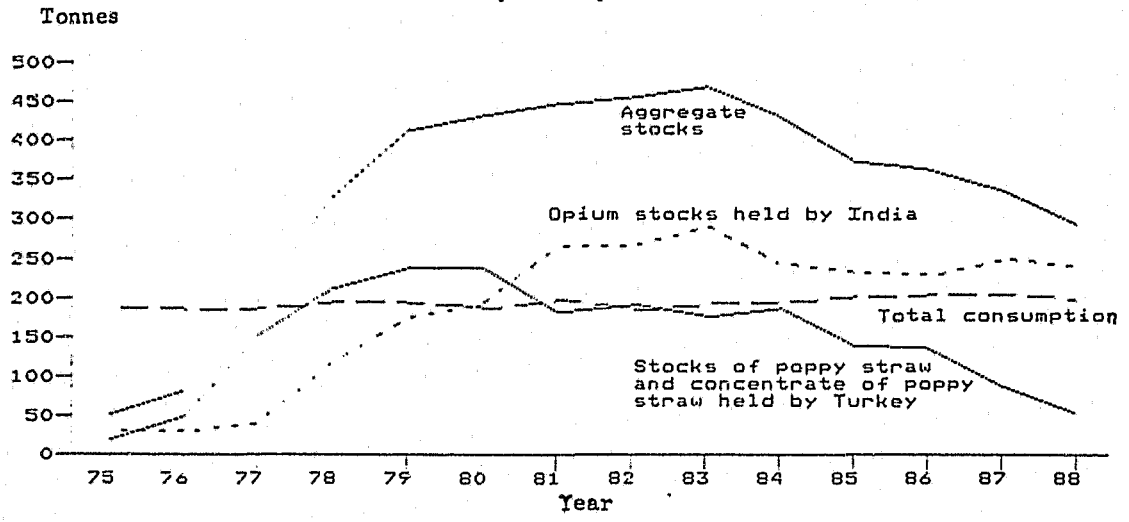


Note: Projections are indicated by an asterisk.

D. Stocks of opiate raw materials

17. Stocks of opiate raw materials are maintained by both producing and manufacturing countries. Most of the stocks are, however, held in India and Turkey; only those stocks are therefore considered here. Figure II shows the stocks of opium held by India and of poppy straw and concentrate of poppy straw held by Turkey, expressed in terms of morphine equivalent, together with world consumption of opiates. Stocks in those two countries are affected by the level of production, exports and, to a lesser extent, domestic use. Between 1976 and 1979, stocks held in India and Turkey began to accumulate rapidly, exceeding the level of global consumption in 1978. From 1980 to 1983, the level of the stocks stabilized with only a slight increase. At the time, the aggregate stocks of opiate raw materials held in India and Turkey alone were sufficient to supply nearly two and a half years of world consumption. Stocks in India have declined since 1983, and those in Turkey since 1984. On the basis of the information available to the Board, the aggregate stocks in those countries amounted to less than 300 tonnes in morphine equivalent at the end of 1988, representing a reduction of about 40 per cent from the peak recorded in 1983.

Figure II. Stocks of opiate raw materials held in India and Turkey (in morphine equivalent)



18. In addition to the factors mentioned in the preceding paragraph, the level of stocks in Turkey was affected by the destruction in 1985 of poppy straw equivalent to more than 40 tonnes of morphine. Stocks held in Turkey in the form of straw and of poppy straw concentrate declined rapidly in 1987 and 1988, as the country's exports rose. In particular, Turkey's exports of poppy straw concentrate, mainly to the United States of America, the United Kingdom of Great Britain and Northern Ireland and the Netherlands, showed a substantial increase, reaching 56 tonnes in morphine equivalent in 1988. As a result, the stocks of straw and concentrate held in Turkey decreased to 35 tonnes of equivalent morphine at the end of 1988. According to information available to the Board, the stocks of raw materials held in Turkey will be depleted by the end of 1989, especially since production has been particularly low during the current year.

19. While the stocks of opium held in India have also shown a decline since 1983, they still amounted to over 200 tonnes in morphine equivalent at the end of 1988, exceeding the world's opiate needs for one year; and the country's opium exports have remained low at an average of 69 tonnes in morphine equivalent between 1983 and 1988. Part of the decline in exports resulted from reduced demand for noscapine, an opium alkaloid not under international control. The level of opium stocks is, however, expected to diminish further, chiefly as a result of drastic reduction in the area of cultivation.

20. Recalling the relevant Council resolutions, which repeatedly emphasized the need for international co-operation and solidarity to overcome the problem of excess stocks, the Board notes that the recent evolution shows that substantial reduction in stocks has been realized. However, stocks of opium still remain excessive and a major burden. The Board therefore wishes to stress the necessity for all producing countries not to increase the level of production of opiate raw materials until the global opium stocks revert to normal levels.

II. ASSESSMENT OF NEEDS

21. All countries are required to provide estimates of their annual requirements for opiates. To fulfil that requirement, countries use various methods and consider a variety of factors to establish estimates for each narcotic drug concerned. In establishing estimates, the method applied usually includes a projection of anticipated trends in drug use, consideration of import statistics in recent years and consultation with the national pharmaceutical industry. The fundamental problem with such methods is that the factors taken into consideration may not adequately reflect the medical need for opiates or ensure the identification of unmet needs. Import or consumption data does not, for example, reflect the quantities inadequately distributed or, for that matter, diverted, misused or over-used.

22. The study of actual licit drug consumption at the regional or national level is a recently introduced discipline which is currently applied in a limited number of developed countries. Available information suggests that few countries use a thorough, comprehensive, systematic approach to assessing their domestic medical need for drugs in general and opiates in particular. Similarly, few have established an effective monitoring system to determine the extent to which medical need is being met and to provide a basis for appropriate corrective measures to respond to unmet needs. At best, countries may have systems which now satisfy unmet needs for opiates merely by recourse to the submission of supplementary estimates to the Board. Such systems may be based partly on the incorrect assumption that import levels correspond to medical needs.

23. To assess and quantify the medical need for a drug at the national level can be a complex and challenging task. A failure to assess properly the medical need for opiates and then to ensure their availability may severely affect the quality of life of those who require such drugs and are not able to obtain them. The assessment should be based on a comprehensive and systematic examination not only of past and anticipated trends in consumption, but also of other relevant data, such as morbidity and mortality patterns, social, cultural and demographic factors, defined daily doses per unit of population, the level of consumption of alternative non-opiate drugs, the pattern of drug selection by medical practitioners in their treatment programmes and data on unmet needs. Such a system depends on the use of reliable and thorough methods of data collection and analysis. It is therefore essential that those responsible for quantifying medical need for opiates should consult with experts in the health-care system to ensure their continued access to the most accurate information possible. Training programmes for drug-regulatory personnel should accordingly emphasize the importance of determining actual medical requirements for opiates, including needs hitherto unidentified, and underline the various factors which must be considered when assessing overall licit needs for drugs. Such programmes should ultimately lead to the establishment of a proper balance between availability and control of opiates.

III. IMPEDIMENTS TO MEDICAL AVAILABILITY OF OPIATES

24. Medicaments in general, and opiates in particular, require special handling. In this connection, the health-care system, drug regulations and health professionals all play a critical role. Even though every endeavour is made by Governments to facilitate access to drugs which are needed for therapeutic purposes, impediments occasionally arise, making it difficult to make certain drugs available. Impediments within the health-care system, and those arising from or relating to legislation, administration and professional practice are identified in this chapter by way of example of some of the problems and issues which Governments may have to address in order to improve drug supply systems and facilitate access to opiates.

A. Impediments in health-care systems

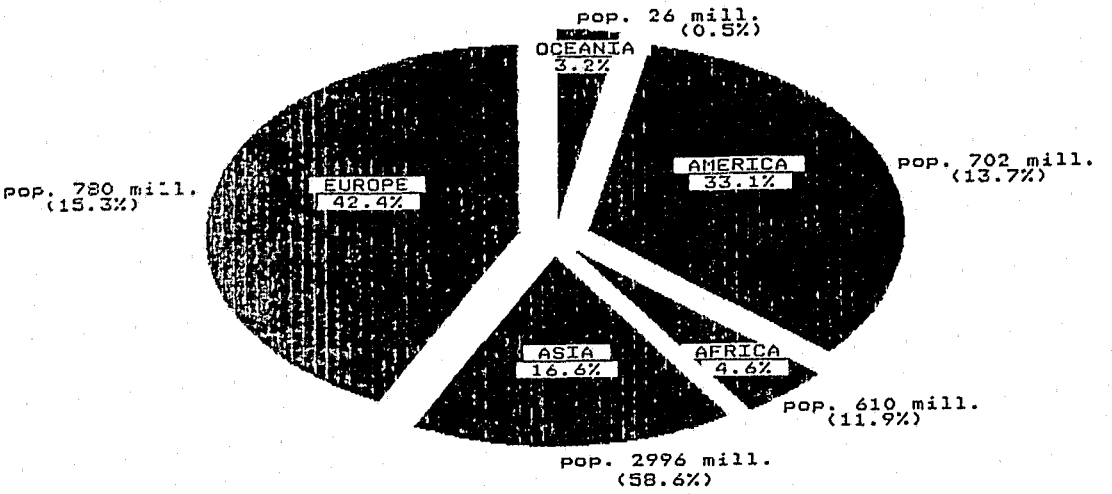
25. In many parts of the world, health-care delivery services are provided within a complex system characterized by manpower and financial constraints and by scarcities of drugs. Infrastructure developments in some cases have not kept pace with the demand for services.

26. One of the global indicators used by WHO to monitor progress in implementing strategies of health for all is the number of countries that spend at least 5 per cent of their gross national product (GNP) on health. In WHO member States for which the relevant information is available, the percentage of GNP spent on health ranges from a low of 0.4 per cent to a high of 12.6 per cent. Developed countries spend, on the average, 6.8 per cent, as against 2.2 per cent by the least developed countries, and 3.6 per cent by other developing countries. Moreover, resources in some countries are devoted to expensive and highly sophisticated technologies serving a small urban minority, further exacerbating existing inequalities.

27. Priority is increasingly being accorded by developing countries to the provision of essential drugs - those needed for the most common illnesses and which should be readily available at all times. More than 100 countries have developed lists of such drugs. The WHO Model List of Essential Drugs, which usually serves as a guide for the selection of drugs for national lists, includes codeine, morphine and pethidine.

28. Because of financial constraints and other limitations in health-care systems, there are significant disparities between countries in the consumption of medicaments. In 1987, 10 countries with less than one third of the world population accounted for 71 per cent of total world sales of medicaments. The uneven consumption pattern exists for both opiates and other medicaments. For instance, in 1987, five countries with a total population of approximately 620 million (12 per cent of the world population) accounted for 71 per cent of total global consumption of morphine. Disparities in consumption of opiates are further exemplified by Figure III.

Figure III. World consumption of opiates in 1988 by region



29. Disparity in national income among countries is the major factor for the uneven access to drugs. In 1985, per capita drug consumption in developed countries amounted to US$62.1, as against US$5.4 in developing countries. Average figures for those country groups can, however, be artificial, because of differences between countries within each group. Among developed countries, for instance, the value of drug consumption per capita in one country in 1985 was US$116.2, while it amounted to US$41.4 in another. Such differences exist even among developing countries, though within a narrower range. In some developed and in most developing countries, there is a significant difference in the availability of drugs in urban as compared with rural areas.

30. According to WHO estimates, between 1.3 and 2.5 billion people in the world have little or no regular access to essential drugs. In 24 out of 104 developing countries, more than 70 per cent of the population have no access to such drugs. Inefficient drug procurement systems, poor distribution procedures and injudicious prescription and consumption patterns have exacerbated the problems arising from inadequate infrastructure, lack of resources and bad management. Some developing countries already spend as much as 35 per cent of their public health budget to purchase medicaments, and their resources have been stretched to the limit.

31. In the context of prescribing, dispensing and administering opiates, three types of health personnel, namely medical practitioners, pharmacists and nurses, play a particularly important role. Health personnel costs in some health-care systems account for almost 75 per cent of the total health budget. The training of health professionals and their legal status, role and functions vary from one country to another. In addition, their respective roles in prescribing, dispensing and administering opiates have been delimited in some countries through special control measures.

32. Considering the other disparities in national health-care systems, it is not surprising that there are significant differences in the availability of health personnel. In some countries, there is only one physician for every 100,000 inhabitants, while in others one doctor serves a population of 400 people. Nursing personnel range from a low of 4 per 100,000 in population to a high of 830. The pharmacist-to-population ratio, which is about 1:1,200 in certain developed countries, is 1:700,000 in some rural areas in developing countries. Despite the staggering shortages of health personnel in certain parts of the world, some countries have an excess of personnel, particularly medical practitioners. The imbalance in health personnel has been growing since the mid-1970s, though it has taken time for countries to devote attention to it and take steps to redress it.

33. In specialized activities or in geographical locations where there is a shortage of health personnel, countries may have to consider various measures to ensure that such shortages do not adversely affect access to opiates. With regard to primary health care and rural health posts staffed by personnel who are not medically qualified, problems might arise in the handling and dispensing of certain types of opiates included in the category of essential drugs. In such instances, countries need to develop appropriate reporting and accountability systems so that such opiates can still be used without contravening the provisions of the international drug control treaties.

34. Health-care systems around the world have recourse to a variety of approaches to health-care financing and cost-recovery methods. In some countries, health care is provided within the context of a social security scheme, and the percentage of the population covered by such a scheme may be as low as 4 per cent or as high as 96 per cent. According to WHO estimates, the cost of providing essential drugs in primary health care is less than US$1 per person per year. Information is not readily available as to how the cost factor influences decisions on the prescription of opiates in the different contexts in which health care is provided. Where opiates are not supplied free of charge or their costs are not subject to reimbursement, it is not yet known what factors influence medical practitioners to prescribe opiates or not.

35. In many countries there exist one or more informal systems of health care outside, but parallel to, the formal system of health services. Some patients have recourse to traditional forms of treatment when access to modern treatment is costly, limited or inconvenient. Social, cultural and psychological considerations also have a bearing on the choice of treatment methods. The role of informal systems, such as community-based support systems, and of officially recognized systems of medicine, such as acupuncture, need to be studied more closely to identify how those systems influence the use of drugs, in particular opiates. One country has enacted legislation recommending the use of acupuncture as an alternative to the use of opiates to avoid, or alleviate, pain.

36. The non-availability of drugs and the inaccessibility to health-care facilities and resources are problems essentially arising from the level of development of a country. Given the magnitude of the problems that need to be dealt with to redress the existing imbalances and to make access to health care more equitable, acceptable and affordable, it is not surprising that the medical use of opiates has not received much attention. Nor have many countries attempted to facilitate their use by making health personnel sensitive to the issues involved and by developing mechanisms to quantify needs and overcome supply and distribution problems.

B. Impediments in legislation and administration

37. The past century and a half has seen rapid advances in medical science, among which the development of more and more potent analgesics is an important element. The appropriate medical use of alkaloids derived from the opium poppy has brought relief from pain to large numbers of sufferers. On the other hand, opiates were, from a historical perspective, among the first substances to be extensively abused outside legitimate medical applications. Because of such abuse, opiates were also among the first substances to be subjected to legal controls.

38. Beginning almost 80 years ago, a succession of international treaties have recognized the dual role played by opiates and certain other substances which have varying degrees of therapeutic usefulness but may also lead to individual and public health problems when abused. The treaties have aimed at establishing a balance between availability and control of such substances so that the latter need not impede the former. That delicate balance is clearly expressed in the preamble to the 1961 Convention which, on the one hand, recognizes "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", and, on the other hand, also recognized "that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind".

39. It was in the context of the need to ensure proper balance between supply and licit demand that the 1961 Convention entrusted the Board with the task of limiting availability of drugs to an "adequate amount required for medical and scientific purposes" while preventing illicit supply of, illicit trafficking in and use of, drugs. Naturally, the provisions of the 1961 Convention must be translated into appropriate national legislation in order for the control system to function. Both Parties to the Convention and non-parties have introduced, to varying extents, domestic legislation to control opiates and administrative and other measures to enforce the legislative requirements.

40. In enacting such domestic legislation, as well as carrying out its provisions, either the legislator or the official entrusted with implementing the legislation may lose sight of or encounter difficulties in ensuring the need for balance between availability of opiates and prevention of their abuse. In this connection, it should be recalled that prevention of availability of many opiates for licit use does not necessarily guarantee the prevention of the abuse of illicitly procured opiates. Thus, an overly restrictive approach to the licit availability of opiates may, in the end, merely result in depriving a majority of the population of access to opiate medication for licit purposes.

41. In some situations, the difficulty arises from the relevant law or regulation itself, or the manner in which it is being implemented or not being implemented; in others, it is due to the attitude of administrators, health professionals or the public. Several situations in which this problem frequently occurs are examined in the following paragraphs.

42. In reaction to an increase in illicit traffic, legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes.

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

44. Occasions may also arise where the regulatory requirements are perceived by legitimate importers, distributors or practitioners as too cumbersome, inconvenient or time consuming. They accordingly tend to avoid any handling of opiates so as not to have to comply with what they consider as complicated procedures. It is necessary to change that perception if proper health care is to be made available to the population at large.

C. Impediments associated with professional practice

45. WHO estimates that at least 3.5 million cancer patients currently suffer needlessly from pain. Effective analgesics and proven therapeutic methods are available but are not being used to full advantage by physicians. Studies undertaken in a number of developed countries indicate that patients surveyed were not always receiving satisfactory relief from pain. Health professionals, in particular physicians, clearly have a major impact on the treatment programme of a patient. The therapeutic approach pursued by a physician depends on a variety of factors, including training, experience and attitude of the health-care professional and the availability of appropriate drugs and facilities. Some countries have chosen to promote the use of non-narcotic drugs with lower efficacy that do not require a complex infrastructure for their distribution, and are not subject to the strict controls required for opiates.

46. The use of certain drugs may be directly or indirectly limited by policies or guidelines adopted by Governments or medical associations. The prohibition of the use of a drug to treat one part of the population (for example children) or a particular condition may deter use of the drug under any circumstances. The lack of specific guidelines on the use of drugs such as opiates, and on the treatment of certain conditions for which those drugs may be indicated, may contribute to practitioners' reluctance to use such drugs for legitimate medical purposes. To deal with the problem, some Governments, in consultation with experts in the field, have drawn up, for health practitioners, guidelines on the use of specific drugs and on the accepted or preferred methodology to be applied when treating particular conditions. WHO has also developed guidelines for the treatment of cancer pain.5/

47. In some countries the use of certain drugs is limited by the need for special authorizations or by the conditions under which the drugs may be made available. Policies or regulations may dictate or specify the conditions under which a drug may be used and therefore may affect the way in which health professionals conduct a treatment programme.

48. Available information suggests that some health professionals may have, to varying degrees, a reluctance to use opiates in the treatment of their patients. There seems to be fear among health professionals (which is shared by certain patients and their families) that the use of opiates will result in iatrogenic addiction. As a result, some practitioners prescribe opiates only in dosages which are insufficient for effective treatment or for periods of time which are too short to produce the desired effect. Others refuse to use any opiates, opting for weaker non-opiate drugs even though the treatment indicated for the condition may be an opiate. It has been suggested that the training or education received by many health professionals does not focus sufficient attention on the treatment of pain, on the proper use of opiates, or on the treatment of chronic or acute conditions for which those drugs are required or indicated.

IV. CONCLUSIONS AND RECOMMENDATIONS

49. Evidence available suggests that medical need for opiates, particularly that related to the treatment of cancer pain, is not being fully satisfied. Factors which may directly or indirectly impede the availability of opiates have been identified. With due consideration to the conditions prevailing in individual countries and to the availability of resources, the implementation of the following recommendations over the short-, medium- and long-term will help to minimize, if not overcome, many of the impediments to making opiates available for medical need:

For consideration by Governments

(a) Governments should critically examine their methods of assessing domestic medical need for opiates and of collecting and analyzing data, so as to make the changes required to ensure that future estimates will accurately reflect the actual need;

(b) Governments should develop and apply a system for monitoring the extent to which medical need for opiates is being met, so that appropriate corrective action may be taken to cover any hitherto unmet needs;

(c) Governments should examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications;

(d) Governments should establish national policies and develop guidelines on the rational use of opiates and on the treatment of conditions for which opiates may be indicated;

(e) Governments should ensure that health professionals receive sufficient education and up-to-date training in the use of opiates and have access to information on drug dependence.

For consideration by the World Health Organization

(f) WHO should develop guidelines and provide assistance to Governments in establishing the most appropriate national system for assessing the domestic medical need for opiates.

For consideration by professional associations and medical instructors

(g) Medical instructors and professional associations of physicians, pharmacists, nurses and pharmaceutical manufacturers should be urged to promote rational use of opiates for medical purposes, bearing in mind their responsibility to ensure that opiates will not be abused.

Notes

1/ Single Convention on Narcotic Drugs, 1961 (United Nations publication, Sales No. 62.XI.1).

2/ Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961 (United Nations publication, Sales No. E.77.XI.3).

3/ Demand and Supply of Opiates for Medical and Scientific Needs (United Nations publication, Sales No. E.82.XI.4).

4/ Demand and Supply of Opiates for Medical and Scientific Needs (United Nations publication, Sales No. E.85.XI.7).

5/ World Health Organization, Cancer Pain Relief (Geneva, 1986).

Annex I

ECONOMIC AND SOCIAL COUNCIL RESOLUTION 1989/15

Demand and supply of opiates for medical and scientific purposes

The Economic and Social Council,

Recalling its resolutions 1979/8 of 9 May 1979, 1980/20 of 30 April 1980, 1981/8 of 6 May 1981, 1982/12 of 30 April 1982, 1983/3 of 24 May 1983, 1984/21 of 24 May 1984, 1985/16 of 28 May 1985, 1986/9 of 21 May 1986, 1987/31 of 26 May 1987 and 1988/10 of 25 May 1988,

Emphasizing once again the central role of the Single Convention on Narcotic Drugs of 1961, a/ in the control of the production of and trade in opiates,

Reaffirming the need to maintain a balance between the supply of and demand for opiate raw materials for medical and scientific purposes which is an important element in the international control strategy and policy on drug abuse control,

Concerned that the traditional supplier countries continue to face financial and other burdens as a result of their large stocks of opiate raw materials,

Emphasizing once again the fundamental need for international co-operation and solidarity to overcome the problem of excess stocks,

Having considered the section of the report of the International Narcotics Control Board for 1988 on the demand for and supply of opiates for medical and scientific needs, b/

1. Urges all Governments to give serious consideration to ways of resolving the problem of excess stocks and bringing about rapid improvement;

2. Commends the International Narcotics Control Board for its efforts and requests it to pursue the early finalization and implementation of the project, referred to in paragraph 40 of its report, which would assess legitimate needs for opiates in various regions of the world hitherto unmet because of insufficient health care, difficult economic situations or other conditions;

3. Requests the Secretary-General to transmit the present resolution to all Governments and appropriate international agencies for consideration and implementation.

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a/ United Nations, Treaty Series, vol. 520, No. 7515, p. 151.

b/ E/INCB/1988/1 (United Nations publication, Sales No. E.88.XI.4), chap. II, sect. C.

Annex II

ECONOMIC AND SOCIAL COUNCIL RESOLUTION 1988/10

Demand and supply of opiates for medical and scientific purposes

The Economic and Social Council,

Recalling its resolutions 1979/8 of 9 May 1979, 1980/20 of 30 April 1980, 1981/8 of 6 May 1981, 1982/12 of 30 April 1982, 1983/3 of 24 May 1983, 1984/21 of 24 May 1984, 1985/16 of 28 May 1985, 1986/9 of 21 May 1986 and 1987/31 of 26 May 1987,

Re-emphasizing the central role in the control of the production of and trade in opiates played by the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs of 1961, a/

Reaffirming the fundamental need for international co-operation and solidarity in all activities relating to the control of narcotic drugs,

Bearing in mind that the maintenance of a world-wide balance between the licit supply of and the legitimate demand for opiates for medical and scientific purposes is an important aspect of an international strategy and policy for drug abuse control,

Concerned that large stocks of opiate raw materials held by traditional supplier countries continue to impose heavy financial and other burdens on them,

Having considered the section of the report of the International Narcotics Control Board for 1987 on the demand for and supply of opiates for medical and scientific purposes, b/ including the observation that world demand and production have been in approximate balance and that, over the next several years, the demand for opiates will remain at the present level,

1. Urges all Governments seriously to consider ways of resolving the problem of excess stocks in order to bring about an expeditious improvement in the current situation;

2. Requests the International Narcotics Control Board to review the available information on the problem and to enter into a dialogue with interested Governments and other parties in order to develop a practical and effective solution, which may involve international development assistance organizations;

3. Requests the Secretary-General to transmit the present resolution to all Governments and appropriate international agencies for consideration and implementation.

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a/ United Nations, Treaty Series, vol. 976, No. 14152.

b/ United Nations publication, Sales No. E.87.XI.3, chap. II, sect. B.

Annex III

LIST OF DOCUMENTS

In addition to legislative texts published in the United Nations E/NL document series and in the WHO quarterly, International Digest of Health Legislation, the documents and publications listed below were consulted in the preparation of this supplement.

Z. Bankowski and A. Mejia, eds., Health Manpower out of Balance (Geneva, Council for International Organizations of Medical Sciences, 1987).

Demand and Supply of Opiates for Medical and Scientific Needs (United Nations publication, Sales No. E.82.XI.4).

Demand and Supply of Opiates for Medical and Scientific Needs (United Nations publication, Sales No. E.85.XI.7).

H. Ghodse and I. Khan, eds. Psychoactive Drugs: Improving Prescribing Practices (Geneva, World Health Organization, 1988).

Report of the International Narcotics Control Board for 1988 (United Nations publication, Sales No. E.88.XI.4).

B. Rexed et al. Guidelines for the control of Narcotic and Psychotropic Substances (Geneva, World Health Organization, 1984).

World Drug Market Manual (London, IMSWORLD Publications Ltd., 1988).

World Health Organization, Cancer Pain Relief (Geneva, 1986).

World Health Organization, The Use of Essential Drugs, Technical Report Series 770 (Geneva, 1988).

World Health Organization, WHO Expert Committee on Drug Dependence, Technical Report Series 761 (Geneva, 1988).

World Health Organization, The World Drug Situation 1988 (Geneva, 1988).

World Health Organization, "The health professions in the 1980s: a statistical update", World Health Statistics Annual, 1988, pp.43-70.