### I. Freedom from pain and suffering

# A. Ensuring an adequate supply of controlled drugs for medical purposes: a principal objective of the international drug control treaties

- The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. 2 Guided by a similar principle, States recognized in the Convention on Psychotropic Substances of 1971 that the availability of psychotropic substances for medical and scientific purposes should not be unduly restricted.<sup>3</sup> Adequate availability and limitation were considered by the States parties to the 1961 Convention and the 1971 Convention complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those conventions. In adopting such aims, Governments were motivated by two complementary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.<sup>4</sup>
- 2. Success in this endeavour depends to a large extent on the degree to which those aims are understood, accepted, supported and implemented by Governments, by the professionals involved in the complex task of operating a national licit drug supply system and, ultimately, by the general public. In developing and implementing national drug control laws and regulations, it is particularly important to maintain an optimal balance between restriction and facilitation efforts.
- 3. Pursuant to article 9 of the Single Convention on Narcotic Drugs as amended by the 1972 Protocol,<sup>5</sup> the International Narcotics Control Board endeavours to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes and to ensure their availability for such purposes and facilitates national action to attain the aims of that

Convention. In discharging its functions, the Board has regularly monitored the status of national compliance with the international drug control treaties and the functioning of the treaty system. In 1994, the Board reviewed the operation and effectiveness of the three main international drug control treaties and highlighted in its report the principal areas where the treaty provisions had not been wholly effective or adequate. Among the identified shortcomings was the fact that the treaty objective of ensuring an adequate supply of narcotic drugs, especially opiates used for medical purposes, had not been universally achieved.<sup>7</sup> The Board suggested specific remedial measures at the national and international levels. At the same time, the Board voiced its concern over the easy availability of psychotropic substances, in particular their indiscriminate and excessive use in many countries and their diversion into illicit channels as a result of inadequate control measures.

#### **B.** Progress and constraints

## The significance of controlled drugs in alleviating pain and suffering

- 4. During the past few decades, significant progress has been made in health care throughout the world. The availability of increasingly effective and safe therapeutic agents has played a large role in this process. Pharmaceutical research and industrial manufacture have led to the discovery and commercialization of many new psychoactive medicines. A better understanding of the working mechanisms of the human body has enabled many new derivatives of already known drugs or entirely new types with even higher specificity, efficacy and safety to become important tools of modern medicine. Older and less effective drugs with lower benefit-risk margins have, in turn, gradually lost their therapeutic significance. Narcotic drugs and psychotropic substances used in medicine are no exception.
- 5. Virtually all new narcotic drugs and psychotropic substances with accepted medical use represented progress in therapy at the time that they were introduced; however, their dependence potential became apparent during their

large-scale therapeutic use. Thus, there was a need for specific administrative restrictions regarding their manufacture, trade and medical use. Growing concern over their abuse potential led to a reassessment of their therapeutic usefulness Most semi-synthetic and synthetic opioids<sup>8</sup> under international control today were developed before the adoption of the 1961 Convention. It was originally hoped that the therapeutic qualities of morphine could be improved desirable (central separating its analgesic, cough-suppressant, anti-diarrhoeal) effects from its undesirable (addictive) properties. Unfortunately, that goal has not been achieved to date; consequently, several opioids initially welcomed as safer alternatives to older drugs have failed to live up to expectations. Some opioids, primarily morphine and codeine, have not only been essential therapeutic tools with a range of applications for more than 100 years, but have also gained in importance in recent times. Both codeine and morphine have been on the Model List of Essential Drugs of the World Health Organization (WHO) since 1977, when the list was first published, and morphine is among the drugs proposed by WHO for the New Emergency Health Kit 1998.

- Expansion and diversification of the licit opioid market have been somewhat slow during the past 20 years; there has been a relatively small increase in the number of scheduled narcotic drugs used for licit purposes. Global licit opioid consumption has therefore continued to grow slowly, the total volume reaching approximately 240 tons in morphine equivalent in 1999.9 This is because the demand for pure opium alkaloids, mainly morphine and codeine, has increased slowly while the consumption of raw opium, its concentrates and opium tincture has gradually decreased. Codeine is now the most widely used natural opioid; it is used as a cough suppressant and as an analgesic. Its average annual consumption has been around 170 tons in recent years, representing about 75 per cent of total opiate consumption. Between 1978 and 1998, global codeine consumption rose at an annual rate of only about 1-2 per cent. Global consumption of morphine for medical purposes was relatively low and stable for many years before 1984, when it amounted to about 2.2 tons, but since then it has risen almost tenfold. Other semi-synthetic or synthetic opioids with significant or increasing consumption levels are buprenorphine, hydrocodone, hydromorphone, oxycodone and fentanyl.
- 8. In the absence of cross-national comparative data, it is difficult to arrive at valid estimates of the aggregate number of people on a global scale affected by any health problem requiring treatment with a narcotic drug or psychotropic substance. Although pain and suffering are difficult to assess quantitatively, national health surveys conducted during the

and actual use. After a few decades, that process led to a number of changes in each category of controlled drugs with medical use.

past 20-30 years, mostly in developed countries, document the fact that such conditions affect large segments of society.

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

#### **Progress**

- 10. There has been notable progress in achieving the aims of the international drug control treaties, including the provision of narcotic drugs and psychotropic substances for medical purposes. The ever-increasing variety of new therapeutic agents and the multitude of preparations on the global pharmaceutical market offer health-care professionals and patients alike a growing number of treatment options. Such new medicines can make the relief of human pain and suffering more universally available and qualitatively better; however, they may also offer new opportunities for misuse.
- 11. Governments have placed substantial groups of psychoactive substances, currently marketed and used as medicines, under international control because of their recognized abuse and dependence potential and the risk that they may pose to public health; that should be acknowledged as a significant achievement. Thus, the scope of international drug control, especially the control of psychotropic substances, has expanded considerably since the 1971 Convention entered into force. The scope of control under the 1961 Convention has evolved much more slowly, reflecting both the more comprehensive initial coverage of that Convention and the slower development of the pharmaceutical opioid market.
- 12. The voluntary implementation of certain regulatory and reporting provisions by many Governments has been a welcome development. The Commission on Narcotic Drugs, in its resolution 7 (XXXIX), endorsed the position of the Board that the distribution of narcotic drugs and psychotropic substances needed for humanitarian aid in acute emergencies justified the application of simplified control procedures. The adoption of that resolution

demonstrates that the international regulatory system can be flexible when required.

- 13. The Board considers it important that the total volume of the global licit opioid manufacturing has stabilized in recent years at a level close to that of global medical consumption. Such a balanced situation, while necessary to minimize the risk of opioids being diverted into illicit channels, often proved difficult to achieve in the past. This positive development should be seen as a result of continued efforts by the Board and the Governments involved. The Board is of the view that, with this achievement in opioid supply, more emphasis can now be given to making further improvements in the use of opioids for medical purposes worldwide.
- As a positive consequence of the joint efforts by the Board and WHO to encourage the use of opioids to relieve cancer-related pain, there has been a sustained increase in the consumption of morphine, global consumption having practically doubled during each five-year period since 1984, reaching a level of 21 tons in 1998. That trend has been attributed mainly to substantial growth in opioid consumption in several developed countries. Opioid consumption has tended to increase in those countries that have implemented programmes for the relief of cancer pain. Several countries have revised their national laws and directives regulating the supply of narcotic drugs. National pain management committees have been created, new education programmes have been initiated and new guidelines for prescribing opioids have been introduced. Some countries are in the process of improving their national supply of opioids.
- 15. Research conducted in several countries has shown that opioid treatment can be effective in 75-90 per cent of patients with cancer-related pain. In addition, more attention has been given in recent years to the use of various opioids to relieve acute or chronic pain not related to cancer. It is now widely accepted that orally administered opioids (morphine, codeine, hydromorphone, oxycodone and pethidine) contribute to the efficient management of severe pain and their availability for the relief of cancer-related pain is considered to be an indicator of the quality of such programmes. Moreover, in recent years, the industry has developed several more advanced modes of administering opioids, such as slow-release tablets and trans-dermal patches, and new devices for the safer application of opioids.
- 16. The Board attaches great importance to the fact that there has been no sign of an increase in the number of cases involving the diversion of morphine or other pure opioids into illicit channels at any stage of the manufacturing and

distribution chain, despite increases in consumption. That is an indication that improvements in the licit drug supply are possible within the present drug control framework.

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

#### **Constraints and impediments**

- 18. The development of medicines of higher quality and the better management of their availability could make the relief of pain and suffering more universal and qualitatively better. Unfortunately, there continue to be shortfalls in the availability of such medicines, and certain recent global trends seem to be undermining the positive developments. There is evidence in many countries that opioids, like all drugs intended for medical use, do not necessarily reach those who need them most. Thus, the objective of the 1961 Convention—ensuring adequate supply of narcotic drugs, especially opioids, for medical purposes—is still far from being achieved. Also, in many countries, there is virtually no reliable and regulated licit supply of important psychotropic substances.
- 19. The availability of a certain type of medicine depends on many general factors, such as the economic development and social structure of a country, the type and quality of health care, the resources available for health care and the social and cultural background, norms and trends. Some of those factors are external to drug distribution systems and adjustments go beyond international drug control. Others operate within the drug distribution system, and those are the focus of the Board's considerations and recommendations for improvement. Some factors are actually the same for both excessive and insufficient availability; others are subject-specific or country-specific.

- A quite distinct group of problems in the management of drug availability and use is directly related to inadequate medical practice, improper diagnosis and therapy, lax prescribing or the absence of prescribing. A doctor's willingness or reluctance to prescribe a particular type of medicine is but one small part of a complex relationship between the patient, the doctor and the drug. The relationship may assume quite different characteristics in different 21. Experience has shown that the absence of an efficient drug regulatory authority and of adequate drug-related information may easily lead to either overconsumption or underconsumption. In its report for 1994, the Board concluded that most weaknesses of national drug control systems derived not from the underlying concepts of the drug control framework but from limited resources and implementation capacity and a lack of determination on the part of Governments and their services. 10 It is usually in those areas that improvements are most needed.
- 22. In the regions where the majority of the world population lives, actual availability of medicines is determined by economic factors rather than by real medical needs. The availability of narcotic drugs and psychotropic substances is no exception. Disparities between their availability in developing countries and their availability in developed countries tend to be even greater because in developing countries the relief of pain and suffering is given much lower priority than other, more urgent health and social problems (infectious diseases, gastroenteral infections, malnutrition etc.).
- 23. Today, the international drug control treaties and the corresponding national laws and regulations have to operate in a quickly changing global political, economic and social environment. Significant changes, such as the regional and global integration of markets, new regional and global economic structures and the expansion of multinational companies, together with the lifting of trade and traffic barriers, and the growing intensity and volume of free trade, while they are welcome developments, pose new challenges to the original aims and practices of drug control. Such developments particularly affect countries with weak economies and vulnerable infrastructure. The Governments of such countries often encounter difficulties in securing adequate drug supplies and, at the same time, establishing and implementing efficient drug regulatory policies.
- 24. Typical signs of inadequate regulations, weak enforcement or non-existent or dysfunctional national drug distribution structures are the appearance on local markets (whether State-run or private, official or street-operated) of medicinal products that are sub-standard, fake or adulterated,

regions and countries. The main underlying causes of inappropriate prescribing appear to be the following: inadequate knowledge and information; incorrect interpretation of existing legal, regulatory and medical restrictions; unethical, lenient behaviour and sometimes direct financial interest or iatrogenic drug abuse.

or whose expiration dates have elapsed. The marketing strategies of some companies have included the manufacture of and trade in sub-standard medicines. In view of the serious potential hazard that such distribution practices pose to public health, concerted international efforts, involving the active participation of bona fide pharmaceutical manufacturers, are needed to put an end to such drug supply channels.

- 25. In countries where the licit drug supply is inadequate, the pharmaceutical manufacturers themselves tend to organize and manage the distribution of medicines and relevant information to medical services and doctors. Where prescription obligations are not properly regulated or supervised, promotion often targets consumers as well. As previously emphasized by the Board, any advertisement of controlled drugs for medicinal purposes that targets the general public is not only contrary to the established ethical norms of the pharmaceutical industry, but also contravenes article 10 of the 1971 Convention. The Board urges Governments to prohibit such advertising.
- 26. In spite of recent progress, the medical use and availability of opioid analgesics continue to be relatively moderate. In a large proportion of the countries and territories in the world, insignificant amounts of these medicines are available for medical purposes and it is generally agreed that the treatment of chronic or acute pain caused by cancer is still inadequate: only about 10-30 per cent of patients suffering from severe cancer-related pain may be receiving adequate treatment, even in many technologically advanced countries. The rate is much lower in developing countries. The Board has requested Governments to pay more attention to this particular problem and to identify and deal with the factors that cause inadequate availability of opioids for medicinal purposes.
- 27. There is no universal consumption standard, one that is applicable to all countries regardless of their social, demographic and economic situations. What constitutes optimal drug availability in one country may not be optimal drug availability in another. In fact, there is no country or region in which the status of the availability of a medicine can be considered a standard for the rest of the world. In

addition, pain relief programmes have to be viewed in the broader context of national drug supply, availability and management. Many other pressing health needs may require It cannot be denied, however, that regional and national comparative data concerning drug consumption provide some indication of emerging consumption trends. A global survey of all countries and territories initiated by the Board in 1995 confirmed both the positive and the negative tendencies mentioned above. Global opioid consumption continued to rise, but disparities among countries remained the same or increased. The 10 largest consumer countries accounted for as much as 80 per cent of analgesic morphine consumption. The average per capita consumption of morphine in 1998 in the 10 countries with the highest morphine consumption levels was 31 grams per 1,000 inhabitants. In the 10 countries with the next highest consumption levels, the corresponding figure was 16 grams per 1,000 inhabitants. In the next 60 countries, with a total morphine consumption of more than 1 kg, it was only 2 grams per 1,000 inhabitants. In the remaining 120 countries, there was little or no opioid consumption. Several African countries reported no morphine consumption. In a limited number of countries that had recently begun or had continued implementing programmes for the relief of cancer pain, the aggregate improvement was attributed to growing consumption; however, there was no such improvement in most developing countries.

The distribution of opioid medicines varies from region to region and from country to country. There are consistently large differences in the annual consumption and in the availability of information on opioid analgesics in countries with similar economic development and social structures. Such differences cannot be attributed exclusively to differences in economic development or to the existence or absence of a regulatory system. Many countries with similar economies continue to show large differences in consumption. Some countries with relatively high per capita income (such as the Bahamas, Italy, Kuwait, the Republic of Korea, Saudi Arabia, Singapore and the United Arab Emirates) continue to have low consumption levels. The same seems to apply to a relatively small group of countries where morphine or other opioids are manufactured: some (such as Australia, France, the Netherlands, the United Kingdom of Great Britain and Northern Ireland and the United States of America) consume substantial amounts of opioids while others (such as India, the Islamic Republic of Iran and Turkey) consume very little. Some countries with a high incidence of cancer (such as the Czech Republic, Estonia, Hungary and Uruguay) have relatively low morphine consumption levels. In some of those countries with low consumption, there appears to be a continuing

the same level of attention, if not more, depending on the situation in the country in question.

preference for using pethidine or other synthetic opiates as analgesics, but the possibility of serious undertreatment of cancer-related (and other) pain cannot be excluded.

- 30. Many Governments have difficulties in assessing their opioid requirements or do not give such assessments the necessary attention. This fact is reflected in their poor reporting performance. The great majority of them are developing or least developed countries, which often lack the resources to carry out such a task. The impediments to opioid availability that are frequently reported by government authorities are:
- (a) Impediments originating in the regulatory and drug control system;
  - (b) Medical/therapeutic impediments;
  - (c) Economic impediments;
  - (d) Social and cultural impediments.
- 31. The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession.

## C. Concern over the continuing excessive availability of psychotropic substances

32. Unlimited or excessive availability of addictive medicines on national or international markets is as much a cause of concern to the Board as insufficient supplies. While the unavailability of such medicines deprives patients of their fundamental right to and opportunities for relief of pain and suffering, the excessive availability of such medicines frequently results in unjustified overconsumption, and dependence, thus causing unnecessary suffering. During the past 20 years, there have been a number of important improvements in the availability of psychotropic medicines,

such as the gradual narrowing of accepted therapeutic uses of several previously well-established unsafe psychotropic substances (for example, various barbiturates, amphetamine, methamphetamine, fenetylline, methaqualone, pemoline, phenmetrazine and phendimetrazine). One equally important development has been that persistent control efforts have 33. At the same time, there is evidence that, for several substances, the trend towards overconsumption has continued in many countries and that new problems have emerged in others. Overconsumption is a frequent phenomenon in many technologically advanced countries; however, it is not restricted to those countries. In some countries there have been incidents involving the overconsumption of almost all psychotropic substances with significant therapeutic use. The extent, characteristics and underlying causes vary and are often country-specific.

- The increasing life expectancy in technologically advanced countries has resulted in higher prevalence rates for insomnia and anxiety, the elderly being the main consumers of many of the sedative and hypnotic medicines available in those countries. This trend itself is a significant factor contributing to the growing consumption in those countries. The same countries have reported high prevalence rates for attention deficit disorder (ADD) and obesity, two health conditions frequently treated today with controlled amphetamine-type substances. The reported prevalence rates for obesity range from 15 to 30 per cent among middle-aged persons in many developed countries and a large proportion of that population group receives treatment with amphetamine-type anorectics, often on a long-term basis. The medical use of amphetamines is increasingly being questioned in many countries. At the same time, justified global demand for other drugs, such as certain benzodiazepines and phenobarbital, continues to be high. In many countries, diazepam continues to be among the 10-20 most prescribed drugs and among the 20-30 medicines with the highest sales figures.
- The Board has repeatedly emphasized in its reports that there continue to be significant differences between the trends in the consumption of certain psychotropic substances in otherwise similar countries; for example, such trends in countries in North America (mainly the United States) differ significantly from such trends in countries in Europe. Many countries in Europe consume relatively high amounts of benzodiazepine-type hypnotics and sedatives benzodiazepine-type anxiolytics, the European average for those drugs being 3 times higher than that of the United States. There are also considerable variations between European countries. A recent study revealed that doctors in France prescribe about four times more sedatives, hypnotics

reduced or stopped the manufacture of and international trade in medically less adequate addictive substances such as methaqualone, secobarbital, fenetylline, pemoline and other amphetamines, as well as the widespread diversion of those substances for non-medical purposes.

and tranquillizers than doctors in Germany and the United Kingdom. In almost all European countries, there are doctors who prescribe benzodiazepines for unnecessarily long periods and for symptoms that may not require the use of such substances. The widespread availability of such substances facilitates drug abuse and dependency and may have other serious consequences for the health of the patients concerned. For amphetamine-type psychostimulants, primarily methylphenidate, amphetamines and various anorectics, the United States and, to a lesser degree, Canada are by far the main consumer countries (measured in terms of defined daily doses (DDD) per capita). The United States has in recent years accounted for 90 per cent of global methylphenidate consumption, and its per capita consumption of anorectics is by far the highest in the world, 10 times more than the average for countries in western Europe. For some of those substances, the trend towards rapidly growing consumption, seen in North America, is now also occurring in other parts of the world such as Latin America and in certain countries in Asia and Europe as well.

- In developed countries, although the assessment of needs is often based on professional evaluation, actual availability tends to be in excess of actual needs and is strongly influenced by the marketing practices of pharmaceutical companies. Those factors, together with new cultural trends, expectations, a weak regulatory system and improper medical practice typically result in excessive availability and unjustified consumption. The Board has regularly assessed national and regional consumption trends and identified crucial factors facilitating or driving excessive availability, such as weak or dysfunctional regulatory control. aggressive pharmaceutical marketing information and improper medical practice.
- 37. Psychotropic substances with addictive potential will continue for quite some time to be important tools in the field of medicine. Reducing the excessive availability of such substances and their potential for overconsumption will continue to be essential to the effective functioning of national and international drug control systems. It is, therefore, imperative that Governments remain vigilant in preventing, monitoring and counteracting such trends.

#### D. Conclusion

- 38. If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance. There has been substantial progress in both directions since the entry into force of the 1971 Convention and the 1961 Convention as amended by the 1972 Protocol. A growing number of States parties to the two conventions have established the national administrative basis required for the implementation of those conventions, and the ultimate aim of universality may be achieved in the near future. The Board notes with satisfaction the growing commitment of Governments to implement not only the conventions, but also supplementary measures on a voluntary basis.
- 39. The global environment in which the international drug control treaties have operated since they came into force has been rapidly changing, often posing challenges to the effective implementation of the treaties at the national level. The treaty system has nevertheless proved its efficacy in and adaptability to such a changing environment. At the same time, it has become more important for the pharmaceutical industry, whose operations are becoming more and more international, to respect the role and policies of national public health authorities. Governments should provide sufficient oversight and a well-functioning regulatory system in the interest of public health. Much the same applies to the powerful role of conventional and electronic media. Frequent misuse of the media has unfortunately not been countered by their proactive use by Governments and relevant government agencies to provide correct, unbiased and much-needed information. The Board considers that, under the conditions of globalization and weakening national powers, intensified regional cooperation is more important than ever before.
- 40. There have been improvements in the adequacy of supply of certain narcotic drugs and psychotropic substances in many countries, and there have been setbacks in others. In spite of the progress made towards meeting treaty objectives, relatively few countries in the world have an adequate drug

- supply management system and working mechanisms that ensure reliable, need-based assessment, equitable availability and cost-effectiveness. Deficiencies in drug supply management are often attributable to lack of financial resources, inadequate infrastructure, the low priority given to health care, weak government authority, inadequate education and professional training, and outdated knowledge, which together affect the availability of not only controlled drugs but all medicines.
- 41. A well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances has to fulfil, *inter alia*, the following functions:
- (a) To provide for relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of drugs for the purpose of abuse;
- (b) To establish a comprehensive registration and authorization system; and to select carefully and support safer and more cost-effective drugs and reliable alternative treatment modalities;
- (c) To stimulate, through regulation and monitoring, ethical behaviour in drug marketing and information; and to ensure high professional standards in therapy (diagnosis, deciding on therapy, prescribing);
- (d) To ensure the correct education and training of health professionals; to educate the public in the rational use of narcotic drugs and psychotropic substances and in the correct use of pharmacotherapy with other therapeutic options; and to enlist the active participation of professional organizations and consumer associations;
- (e) To encourage the development and use of better and safer therapeutic agents (with little or no dependence potential) to replace medicines with limited efficacy and safety.
- 42. The Board is conscious of the fact that substantial improvement cannot be expected in the availability of the relatively few narcotic drugs and psychotropic substances, whatever their therapeutic significance, without progress in the availability of medicines in general. This is of particular relevance to countries with limited resources for health, where growing economic disparities, pressing basic needs and poor infrastructure are the principal barriers to any

lasting improvement. One important lesson learned from a joint initiative of the Board and WHO is that, while efforts to prevent oversupply should be maintained, more emphasis should be put on facilitating the supply of licit drugs to underdeveloped areas. While such efforts are gaining worldwide attention, a considerable number of countries continue to show no appreciation of the problem itself or of 43. The Board has always placed particular emphasis on reminding Governments that the fight against the abuse of narcotic drugs and psychotropic substances and that efforts to limit the use of such drugs strictly to medical (and scientific) purposes must not adversely affect their availability for important medical purposes. The Board, in cooperation with WHO, will continue to deal with those negative factors which are directly related to the regulatory system, such as the reliability of estimates and of assessed requirements, the adequacy of national legislation and the effect of regulatory barriers on availability.

- 44. Increasing the use of certain controlled drugs for legitimate medical purposes is a necessity, but it needs thorough monitoring. Careful attention has to be given to ensuring the legitimate absorption capacity of countries and the proper functioning of safeguard mechanisms in order to minimize misuse and leaks in the system. The close balance between supply and demand, especially in the case of opiates, has to be maintained. Ensuring the adequate availability of opioids requires sustained concerted efforts, including the active participation of professional and consumer associations. The relatively rapid progress of the recent past has given new momentum to such efforts.
- 45. In addition to concerted efforts by WHO and the World Bank to improve the access of developing countries to essential drugs, the Board will continue to focus its attention on those countries. It is evident that, after so many years of stagnation, progress in those countries is likely to be slow, especially considering the prevailing market conditions and the present supply system, which are not in a position to ensure the availability of needed medicines in low-income countries. At present, developing countries account for, at best, only a negligible share of the world's pharmaceutical market, largely because of their economic and financial conditions. Progress can only be achieved on the basis of a more humanitarian approach that is in line with the treaty system. Such an approach in selected countries may include the provision of assistance in establishing more reliable baseline estimates and assessments of medical needs and consultations with potential suppliers under preferential conditions. The development of a new, non-profit mechanism for the use of otherwise unused narcotic products may also offer advantages and should be considered.

the relative ease with which efficient treatment may be provided. Outdated restrictive regulations and, more frequently, uninformed interpretations of otherwise correct regulations, misguided fears, and ingrained prejudices about using opioids for medical purposes continue to prevail in many countries.

- 46. The opioid manufacturing industry should consider making high-quality opioid preparations more affordable in countries with little or no resources and low consumption levels. Organizers of international aid programmes should be invited to consider donating, within the framework of their programmes, essential drugs, including narcotic drugs and psychotropic substances, to countries not in a position to secure such drugs from the international pharmaceutical market. A special programme of cooperation, involving the Board, WHO and the United Nations International Drug Control Programme (UNDCP), should be established to monitor the effects of increased opiate availability in selected countries and to serve as a model for other initiatives.
- 47. Action by Governments to reduce the indiscriminate consumption of controlled drugs has yielded some positive results. Unfortunately, because of a variety of cultural, attitudinal and technological factors, significant negative trends have also emerged. In countries with scarce resources, inappropriate use of narcotic drugs and psychotropic substances often occurs outside formal health-care structures; that problem can be remedied mainly by improving the overall economic, social and health conditions in those countries. In more affluent countries, however, it is within the power and in the interest of Governments to counteract negative trends through direct measures and better information and through professional associations, voluntary groups and pharmaceutical companies.
- 48. In some countries, recently introduced health insurance and reimbursement policies focus on treatment effectiveness and outcome and may contribute to reducing inappropriate drug use. Ideally, a national pharmaceutical market should offer a selection of drugs that corresponds to the existing and emerging new health needs of the population and that realistically reflects the means available to the country in question; that, however, is still a desirable though unattained goal in many countries. The international community is strongly urged to intensify efforts to ensure that that goal is attained in as many countries as possible by actively assisting countries in which resources are scarce.

Some narcotic drugs and psychotropic substances will continue to be important tools in medicine worldwide, offering relief from pain and suffering until safer medicines with less or even no dependence potential become available. The overriding importance of widely available, safe and efficacious medicines, regulatory measures and strict drug registration and quality-control requirements should provide sufficient incentives for the research community and the The Board recognizes that medicines can be of great benefit in relieving pain and suffering, but pharmacotherapy is not a panacea. In addition to pharmacotherapy, there is a wide variety of complementary and/or alternative treatment modalities available in different parts of the world, including counselling and psychotherapy, which may often be more culturally relevant and more effective in relieving many types of human pain and suffering. Such alternative treatment modalities, if proven to be effective, deserve to be promoted, taking into account the cultural and social environment.

pharmaceutical industry to explore new concepts and avenues, resulting in safer drugs with more specific therapeutic effects. Such processes may ultimately lead to a pharmaceutical market in which the therapeutic use of the majority of the currently known addictive drugs will become a part of the past—at present, still a utopian idea.