

## I. Overconsumption of internationally controlled drugs

### A. Ensuring the use of controlled drugs for medical and scientific purposes

1. The introduction as pharmaceuticals of many of the narcotic drugs and psychotropic substances now controlled under the Single Convention on Narcotic Drugs of 1961<sup>1</sup> and the Convention on Psychotropic Substances of 1971<sup>2</sup> was viewed as a sign of progress in pharmacotherapy, in particular in the treatment of pain and certain types of neuropsychiatric disorders. Narcotic drugs such as cocaine, opium and heroin were appreciated and enthusiastically applied worldwide in medicine until their addictive properties and therapeutic limitations in wide-scale application were recognized. It was soon universally accepted that the health and social risks that such drugs posed to individual consumers and society, associated with their uncontrolled or excessive use and easy availability, largely outweighed the benefits derived from their medical use. Manufacture of and international trading in those drugs became subject to national and international regulation.

2. Innovations in science and pharmaceutical development gradually opened the way for safer, more selective and equally potent medicines for alleviating pain and other forms of human suffering and for less reliance on drugs that produce high dependence. As the global regulatory system received wide acceptance, manufacture of and trading in many drugs with a high dependence potential, such as opium and cocaine, for medical purposes quickly diminished. The medical use of many psychotropic drugs such as barbiturates, several non-barbiturate sedative hypnotics and many amphetamines followed a similar pattern. Yet, in the absence of perfect alternatives, many less than ideal narcotic drugs and psychotropic substances continue to be used today as pharmaceuticals for the treatment of diseases and the alleviation of pain and other forms of human suffering. Their actual value in medicine always depends on the availability of safer alternatives for the same purposes. Ensuring adequate availability, under regulated conditions, for medical purposes is an important task of government authorities. Controlled drugs must also be available for scientific purposes to permit research on safer drugs for the same and related purposes.

3. Pain and other forms of suffering may result from disease or from a state of dependence on otherwise beneficial psychoactive drugs following prolonged, excessive use. Although unavailability of drugs may deprive patients of their fundamental rights and the opportunity for relief from pain, excessive availability of drugs may result in the diversion of such drugs to illicit trafficking and in drug abuse, leading to drug dependence, and may thus cause unnecessary suffering.<sup>3</sup> The abuse of controlled drugs such as amphetamines and benzodiazepines, diverted into illicit channels at various stages of their distribution, continues to be widespread in many countries and requires appropriate vigilance and countermeasures.

4. The synergy produced by easy availability, inappropriate use of controlled medicinal drugs and spreading illicit consumption of drugs is well documented. Drug abuse has reached significant levels in the past as a result of unregulated, medically inappropriate consumption of controlled drugs. Such incidents have occurred in many countries, both developed and developing, and have been the main reason that, since 1971, Governments have been extending control to an increasing number of psychotropic substances used for medical purposes.

5. National regulatory controls and the international control system have been applied more consistently and more universally during the last two decades and have thus become more effective. Those achievements have to be maintained and bettered in the future. Other important achievements include the following: the closer matching of the global manufacturing and trade volumes of the opiates and many psychotropic substances (barbiturates, several amphetamines and benzodiazepines) with legitimate requirements; on practically every continent, the considerable reduction in the volume and number of incidents involving diversion; and the gradual improvement in national regulatory controls, including prescription practices.

6. The illicit use of drugs has taken on global dimensions. New patterns of drug abuse can easily develop as a result of excessive availability and inadequate regulatory controls. Governments, in cooperation with the International Narcotics Control Board, therefore, have to monitor closely the supply of and demand for such drugs. In its report for 1999,<sup>4</sup> the

Board, in accordance with its mandate to supervise the national implementation of the principal objectives of the international drug control treaties, reviewed the adequacy of the supply of controlled drugs for the relief of pain and suffering. The Board found that the objectives of the international drug control treaties had not been uniformly achieved throughout the world. It noted with concern the continuing global disparities in the actual availability and the unjustifiable discrepancies in the consumption of important licit narcotic drugs and psychotropic substances in different regions.

7. For the reasons mentioned above, unlimited or excessive availability and inappropriate or non-medical use of controlled drugs are as much of a concern to the Board as insufficient supply. On the basis of its previous reviews, the Board considers that there is sufficient reason to believe that unregulated, excessive drug supply and consumption trends in certain countries may be continuing and that new problems may be developing.

#### **B. Medical requirements and availability: two variables to be assessed and adjusted**

8. The national supply of drugs in general should correspond to medical (and scientific) needs as closely as possible and, therefore, it is important to assess those needs as accurately as possible. For narcotic drugs and psychotropic substances, a close balance is even more important given their abuse potential and the risk that they may be diverted into illicit markets. In previous decades, lack of consistent controls often led to the manufacturing volume of several psychotropic substances being largely in excess of global medical requirements, resulting in frequent incidents involving the large-scale diversion of those substances into illicit channels. With the increasingly universal application of the 1971 Convention, such incidents have become rare, considerably improving the effectiveness of the treaty system in the field of psychotropic substances. For economic and cultural reasons, those improvements have had only a small impact on the disparities between regions and countries in terms of their access to controlled drugs for medical purposes. Figures for global consumption of licit drugs show that the bulk of the medicine continues to be consumed in a handful of countries,<sup>5</sup> and the

proportion is even higher for narcotic drugs and psychotropic substances. Economically weak countries and the poorer segments of society continue to have little or no access to medicines and medical care, and the treaty system can do little in this respect.

9. The extent of the medical use of drugs, including controlled substances, depends on many factors and variables. The economic and social conditions in a country, together with the importance accorded to health care, determine to a large extent the national capacity and ultimately the availability of medicines in general. The effective functioning of regulatory controls is also an important condition.

10. Most developing countries lack the resources and expertise required for determining medical needs and adjusting drug supply to meet those needs. Medical practice shows undesirably large variations attributable to chronic shortage of staff and inadequate training and information. At the same time, experience shows that the actual availability of drugs tends to exceed drug requirements in many developed countries. In such countries, societal, cultural and attitudinal factors that influence consumption distort the perception and measurement of real medical needs.

11. For the above-mentioned reasons, it is desirable that the two variables are not only known but also adjusted in a cost-efficient manner. National drug requirements may be assessed in a number of ways. Figures based on morbidity (that is, on the prevalence rates of specific illnesses—the morbidity method) or on regular surveys of past national consumption of selected drugs (the consumption method) can, in theory, provide a basis for estimating national requirements. Although they are useful under certain conditions, both methods have limitations, especially when making international comparisons. Those limitations include the following:

(a) Cross-national and in-country variations of morbidity prevalence data reported for certain psychiatric conditions tend to be large, indicating, in turn, considerable variance in medical diagnostic criteria;

(b) Treatment practice (the choice of pharmacotherapy, of complementary or of alternative treatment options, the choice of drug, dosage, duration) shows considerable cross-national and in-country variations; for example, considerable differences in medical

practice are reported in member States of the European Union in spite of continued efforts at harmonization;

(c) Patterns of use of controlled drugs in general and, above all, of individual substances change with time as a function of progress in drug development, but also under the effect of regulation and control; such changes tend to be uneven and add to the complexity of assessing cross-national variations;

(d) In many countries, figures reflecting past consumption levels of selected medicines can only give a general indication of real requirements because of the distorting effects of economic conditions and infrastructure.

12. Comparisons of consumption data between countries and regions appear to be the most useful indicators for discerning differences in consumption levels and unusual trends requiring attention. The Board has pointed out in its recent reports the large and consistent differences between the consumption levels of countries in North America and those in Europe.<sup>6</sup> Reported annual figures show that the consumption of amphetamine-type stimulants is considerably higher in the United States of America than in countries in Europe and elsewhere, whereas the consumption of benzodiazepine-type sedative hypnotics and anxiolytics is consistently higher in European countries. Ever since the second half of the 1980s, when Governments started to report to the Board on benzodiazepines, average per capita consumption of benzodiazepines has been much higher in Europe than in any other region, on average three times higher in countries in Europe than in the United States. During the same period, the consumption of amphetamines in Schedule II of the 1971 Convention has been about 10 times higher in the United States than in any country in Europe. Consistently large differences have been recorded in some European countries with otherwise similar economic conditions. In France for example, the consumption level of benzodiazepines was for many years one of the highest in Europe, on average more than twice that in Germany or Norway. In recent years, however, the French authorities have succeeded in significantly reducing the consumption of benzodiazepines through serious efforts to promote a more rational use of such substances (see paragraph 177 below).

13. Largely due to economic limitations, drug consumption levels are considerably lower in

developing countries. The average consumption of benzodiazepine-type sedative hypnotics in the period 1997-1999 was (in defined daily doses (DDD) per 1,000 inhabitants per day) 34 in Europe, 8 in the Americas, 6 in Asia and 1.3 in Africa. The average consumption of benzodiazepine-type anxiolytics was also disproportional: 41 in Europe, 24 in the Americas, 13 in Asia and 6 in Africa. Large inter-country variations are also typical of developing countries; some countries consume considerably higher quantities per capita than the majority, whereas many others report virtually no consumption.<sup>7</sup>

14. Excessive drug consumption that is medically unjustified, predominantly in developed countries, has a number of general and sometimes country-specific causes and driving forces, the most significant of which are the commercial, sociocultural and educational environments in those countries. Similarly, newly gained wealth or affluence appears to be the origin of quickly growing drug consumption in countries and territories experiencing rapid economic growth (for example, in Malaysia, Singapore and Thailand and in the Hong Kong Special Administrative Region of China), especially if such consumption (anorectics) is perceived to be part of a new fashion.

15. In developed countries, the prevalence of anxiety and insomnia and the consumption of sedative hypnotics are growing, the elderly being the main group of consumers. The Board notes with concern the frequent long-term use (beyond one year and sometimes indefinitely) of psychotropic substances for treating psychological reactions to social pressure without a diagnosis for a specific disorder. There are different forms of insomnia, anxiety, obesity and child hyperactivity, as well as various kinds of pain, for which controlled drugs, the opioids, amphetamines, barbiturates and benzodiazepines (in order of their dependence liability) are extensively used in medicine today; these affect large segments of the population in many countries and tend to be of chronic nature. Many surveys show that clinically significant anxiety affects up to 15 per cent of the population in many countries. In some developed countries, the prevalence of obesity is estimated to be as high as 30 per cent, resulting in significant direct and indirect health and economic costs. Similar prevalence figures are reported for insomnia in many countries. It is estimated that up to 4 per cent of the population of many developed countries are regular long-term consumers of

benzodiazepine-type sedative hypnotics. A considerable proportion of those patients (up to 70 per cent) are also reported to be suffering from social pressure rather than from a real mental or physical disease. In some countries, as much as 25-33 per cent of all patients that had been prescribed an anxiolytic or a sedative hypnotic received such treatment without being diagnosed for having a mental disorder.<sup>8</sup> The use of controlled drugs, medicine-taking behaviour and an expanding self-care culture are all becoming more socially acceptable. Recent surveys indicate that 70-95 per cent of illnesses are managed by self-care in many countries and this tendency has an important influence on medical practice and on the clinician-patient relationship in general.<sup>9</sup>

16. Similar tendencies may be seen in many developing countries and in younger age groups. Correcting mood and behaviour through controlled drugs is becoming widespread. This affects the immediate environment of the individual and society and impose a considerable burden on the national economy and infrastructure. Thus, for Governments, keeping the supply and consumption of drugs, especially controlled drugs, in line with medically justified levels is not only an important public health issue but also an economic issue.

### **C. Effects of the drug distribution chain on use**

#### **Impact of the manufacturing industry**

17. Drug manufacture and trade are important dynamic sectors of the global economy, subjected to an elaborate regulatory mechanism for the protection of consumers. This safeguard mechanism is in the hands of Governments. Each participant in the drug supply chain between the manufacturer and the consumer has particular interests, opportunities and obligations. The ultimate beneficiaries should ideally be patients and society at large. Excessive availability occurs when the relative influence of those constituents is out of balance, for example as a result of weak government regulation or unethical or illegal drug promotion.

18. Because of the continuing expansion of free trade, it is of the utmost importance that manufacturers exhibit responsible and ethical behaviour in the promotion of all medicinal products. The regulatory

requirements concerning narcotic drugs and psychotropic substances destined for medical purposes represent additional responsibilities for manufacturers. Many manufacturers are in principle convinced that it is in their interest to accept those responsibilities and comply with national and international regulatory requirements. Experience shows, however, that certain policies in company sales and promotion practices may interfere with sound health policy.<sup>5</sup> Examples include the continuing manufacture of, trade in and promotion of: (a) certain controlled drugs when better treatment options or safer alternative drugs are available (e.g. the continuing promotion of amphetamine-type substances for weight control); and (b) drugs or preparations that have been insufficiently tested on specific target groups of consumers, such as children, pregnant women or the elderly. For ethical reasons, few psychotropic medicines have been adequately tested for safety and efficacy in children, although there are high rates of prescribing. This situation has been the subject of critical review.<sup>10, 11</sup>

19. Scientific progress in understanding the underlying physiological processes of certain health conditions such as obesity and attention deficit disorder (ADD) has been slow in the past few decades. In the absence of effective causal therapies, symptomatic treatment continues, to a large extent using amphetamine and amphetamine-type medicines (amphetamine-type anorectics and methylphenidate). The therapeutic indications and use of those substances had previously fallen to modest levels in recognition of their limited efficacy and safety. Subsequently, they were placed under strict national and international controls. The Board, in its reports, has pointed to the potential problems resulting from the renewed popularity of those substances, as reflected in the unprecedented increases in their manufacture and consumption in some countries. The growing use of those substances for the treatment of school-age and also pre-school children,<sup>10, 11</sup> in the absence of universally accepted and validated definitions, diagnostic criteria and guidelines for such practice, has recently been the subject of concern.

20. In some countries, company sales promotion is often addressed to not only physicians but also the public, circumventing prohibitions on advertising. Direct advertisement frequently portrays drugs as common consumer goods, thus encouraging higher drug consumption. Free promotional samples are

distributed through company representatives and company-owned distributors in developed and developing countries alike. The continuing existence of such aggressive sales methods may be a sign of inadequate government regulations and/or of weak enforcement of existing regulations. Such sales promotion characterizes, for example, the medicine markets of countries with quickly changing market structures, such as countries in central and eastern Europe.

21. The quality and comprehensiveness of drug-related information made available to doctors and patients by pharmaceutical manufacturers often show unacceptable variations.<sup>12, 13</sup> This issue is of crucial importance, since doctors often see company advertising and written information as the prime source of information on drugs. Drug promotion sometimes consists of support, including drug-related information specifically designed and directly addressed to various associations and vocational groups for further dissemination to consumers. Isolated cases of direct financial support to such civil or professional associations and promotional groups have also been reported.

22. Although ethical norms for medicinal drug promotion have been developed by the pharmaceutical industry and by the World Health Organization (WHO),<sup>14</sup> they do not appear to be observed by some companies. Effective but questionable sales promotion methods have often preceded increases in the consumption of psychotropic substances. The Board wishes to reiterate the request to Governments made in its report for 1996<sup>15</sup> to strictly implement the provisions of article 10 of the 1971 Convention, which prohibits the advertisement of psychotropic substances to the general public.

23. Drugs, including prescription medicines, are increasingly being advertised on the Internet by a wide range of companies. The number of Internet-based distributors of controlled drugs operating in many countries is rapidly growing. Some of those companies, operating without licence and/or quality control, are in fact engaging in illegal activities. The potential for misuse is high; in some countries, such activities have continued in spite of state controls, giving rise to serious concern at the national and international levels.<sup>16</sup> Supplying such companies with controlled

drugs raises the question of the responsibility of manufacturers.

24. In many countries, unregulated drug markets called "street markets" continue to operate parallel to and often in the absence of licensed pharmacies. Lack of purchasing power, expensive quality medicines and weak infrastructure are the main factors contributing to their existence. Unethical suppliers of such parallel "street markets" in many developing countries with large quantities of diverted medicines, as well as unregistered, substandard or fake pharmaceuticals, are in obvious contravention of the law. Their existence is proof of inadequate national regulation. There is a need for concerted international efforts in which bona fide pharmaceutical manufacturers take an active part in eradicating such illegal drug supply channels.<sup>17</sup>

#### **Impact of medical practice**

25. The medical profession bears an important responsibility for appropriate drug dispensing in general and for the prescribing of controlled drugs in particular. It is the prescriber who determines the choice of drug, its dosage, duration and termination and, ultimately, the availability of a particular psychoactive drug for a given patient. The clinician enjoys a great degree of professional freedom and discretion in such decisions. A well-founded therapeutic decision is based on a good, trusted clinician-patient relationship, accurate assessment and diagnosis by the clinician and careful consideration of the available therapeutic options, including the expected benefits and risks. The clinician-patient interaction involves responsibilities on the part of both, the extent of which is influenced by the culture of the country in question. In an age of wider access to health-related information, of "concordance" and of joint decision-making, the patient is becoming an increasingly important contributor to the entire therapy process in a "therapeutic alliance".<sup>18</sup> Only in this way can improvements be expected in the poor rates of compliance of patients with therapy (60-75 per cent) reported for various mental and physical disorders treated with psychoactive drugs. Continued education of the public in drug use is indispensable.

26. As discussed in paragraphs 8-16, significant cross-national and country-specific variations in psychiatric morbidity and drug use data indicate, inter alia, that there continue to be considerable variances in

medical practice (density of services, doctor-patient relationship, professional quality and diagnostic and therapeutic attitudes and practices) between otherwise similar countries and sometimes even within countries. Individual choices and preferences of doctors, other health personnel and patients themselves strongly influence drug use and continue to cause great variances. In spite of the recognition of the urgent need for harmonization and standardization, consensus in these areas has developed rather slowly. Consequently, a significant range of problems in the national and international management of drug availability and use can be ascribed to inconsistencies or inadequacy in medical practice.<sup>18</sup>

27. Inappropriate prescription of controlled psychoactive medicines includes uninformed prescribing; inconsistent or lax prescribing; wilful and consistent misprescribing for abuse; and self-prescribing and self-administration. The principal underlying causes of such behaviour appear to be inadequate training; shortage of information; lenient or lax attitudes; lack of a sense of professional responsibility; unethical behaviour; personal drug addiction; and criminal behaviour or direct financial interest.

28. Many detailed studies suggest that excessive reliance on pharmacological treatment of mental disorders and psychiatric conditions, with a preference for finding quick solutions exclusively through the use of pharmaceuticals, is a significant contributing factor in countries with overconsumption. Longer-term negative effects are often disregarded, underestimated, or subordinated to short-term cost savings. There is a wide range of complementary or alternative treatment approaches for many of the mental disorders and painful conditions treated today with pharmaceuticals (psychotherapy, counselling, traditional medicine), and such alternatives may often be culturally more relevant and more effective.<sup>19</sup> Several recent studies, however, show that the use of multiple drugs (polypharmacy), often in irrational combinations, in inadequate dosages and for excessively long treatment periods, continues to be quite common. Such medical practice is contrary to the principles of cost-effectiveness and rational evidence-based therapy and is a waste of resources.

29. The Board has noted in recent years useful national and international initiatives to promote professionally sound medical prescription practices. National medical associations and other professional

bodies have agreed on definitions of syndromes, better diagnostic criteria, adequate therapeutic approaches and good prescribing practices for some previously controversial health conditions for which psychoactive drugs are being used. Regional efforts in these areas, including training for health personnel, appear to be increasing.

30. Electronic communication creates radically new opportunities not only for manufacturers and commerce, but also for the medical profession, together with new ethical and moral responsibilities and new potential risks. Telemedicine and Internet prescribing may greatly facilitate access to medical and pharmaceutical services for large segments of society at lower cost. At the same time, the potential for errors and intentional misuse is considerable. Substituting direct patient-doctor contact by electronic communication is problematic, particularly in relation to the diagnosis of psychiatric disorders and the prescription of controlled drugs. Efforts to regulate this quickly developing technical area, which has just started, require close cooperation among countries and the relevant international bodies.<sup>20</sup>

31. These issues demonstrate the complexity of the problems that need to be addressed in efforts to improve drug-prescribing behaviour. Professional knowledge, personal preferences, interpersonal relationships and the environment in which physicians and patients interact influence such behaviour. Any lasting improvements can only be expected in the long term as a result of coherent and continuing education and training.<sup>9, 18, 21</sup>

#### **D. Effects of national and international regulatory controls**

32. Although difficult to achieve, a fair balance between the supply and consumption of medically used controlled drugs is one of the goals that national health authorities must strive for in their efforts to promote public health. Improving access to medicines in developing countries goes beyond the objectives of regulatory control, but efficient controls can contribute to an improvement in the situation. In countries with weak infrastructure and few professional resources, inappropriate use of controlled drugs often occurs outside formal health-care structures. Such unregulated use is often a health risk or wasteful. The principal task

of Governments in such situations is to improve the efficiency of the entire drug supply and medical systems.

33. While underutilization of drugs often prevails in developing countries, excessive availability of drugs typically occurs in countries with sufficiently developed infrastructure and resources. Such countries should as a rule be in a position to provide adequate regulatory control, and to prevent consumption from becoming too excessive. In the past, however, such objectives have not always been easy to achieve. Certain causes and contributing factors have already been discussed; others that specifically affect the efficiency of regulation include the following:

(a) The large diversity, together with incomplete and frequently biased drug-related information, make it more difficult for Governments and their health services to regulate drug use. The risk is a loss of regulatory and medical overview, insufficient transparency in supply and wasteful use of resources outside the regulated sphere;<sup>21</sup>

(b) In some countries, disrespect for regulatory requirements is a significant factor contributing to frequent incidents involving excessive use of controlled drugs;<sup>22</sup>

(c) There are indications that the expanding misuse of electronic communication in medicine, without adequate regard for professional ethics and standards, may exacerbate the above-mentioned tendencies;

(d) Globalization of the economy has an important impact on the capacity of Governments to monitor the activities of the pharmaceutical industry. The growing intensity and volume of free trade and multinational firms operating across national borders tend to weaken the regulatory power of Governments in respect of public control over trading in and access to drugs, their price and marketing practices. The Board is of the view that, in conditions characterized by globalization and weakening national powers, consistent and harmonious implementation of the international drug control treaties on the basis of intensified regional cooperation is more important than ever.

34. Universal and persistent implementation of the 1971 Convention has considerably improved the worldwide monitoring of, manufacture of, trade in and

medical use of many psychotropic substances. Unfortunately, there are indications that new problems may be developing, resulting from certain deficiencies, typically at the national level. In some cases, the growing popularity of a few substances in Schedule II (and Schedule IV) of the 1971 Convention, substances considered to be moderately safe, and their widening therapeutic use are reasons for concern. The Board wishes to remind Governments that half a century of therapeutic use of narcotic drugs and psychotropic substances has produced a number of noteworthy precedents. In the past, consumption patterns of entire groups of substances, and sometimes single substances, have essentially been similar: growing popularity and widespread consumption, followed by growing abuse rates. Regulatory efforts by Governments have usually yielded a rapid reduction in the licit manufacture of, trade in and medical use of the substances and have often been accompanied by the development and flourishing of illicit manufacture of and trafficking in the same substances. History has also shown that, without more effective and safer drugs for the same health conditions, excessive consumption is likely to occur. All this underlines the importance of pharmaceutical research and development work and the moral obligations of the pharmaceutical industry.

35. The considerable reductions in the consumption of controlled drugs such as amphetamines and barbiturates in several countries during the last two decades indicate that improvement is possible. Large quantities of amphetamine and methamphetamine were manufactured and traded for direct medical use until the early 1970s, the principal manufacturers being France and the United States. Once the undesirable effects of such wide use became known, national controls, followed by international scheduling in 1971, led to major reductions; required controls soon became common practice worldwide. Such change had no negative effect on therapy. On the contrary, pharmaceutical research produced a range of relatively safer drugs for the same purposes, initially amphetamine-type drugs and later entirely different ones, which gradually replaced or complemented the use of amphetamine and methamphetamine. The medical use of barbiturates underwent similar changes in the early 1970s; that was followed by similar trends in the use of certain long-acting benzodiazepines, as a result of the continued efforts of some Governments.

36. During the last 25 years, reports of the Board have shown that licit manufacture of and international trade in many psychotropic substances have declined quickly and significantly, once efficient controls have been introduced. No significant negative effects on therapy have come to the attention of the Board. Such reductions have played a crucial role in curtailing the large-scale diversion of such substances. Examples include the following:

(a) In the beginning of the 1980s, global manufacture of and trade in methaqualone reached 100 tons annually; most of it was diverted into illicit markets in North America and southern Africa. When controls became effective in the main manufacturing and trading countries, manufacture fell to only a few tons annually;

(b) After secobarbital was moved from Schedule III to Schedule II of the 1971 Convention, the licit manufacture of secobarbital dropped from 11 tons in 1988 to less than 3 tons in 1990 and then declined further;

(c) The licit manufacture of fenetylline, a substance that, in the past, had frequently been diverted in large quantities, has completely ceased as a result of persistent control efforts in the 1980s. Marked reductions have been seen in the manufacture of, trade in and diversion of other anorectics and psycho-stimulants, such as amfepramone, fenproporex, phenmetrazine and pemoline.

37. The above-mentioned reductions in the use of certain controlled drugs clearly document that persistent national efforts, complemented by international control, can yield excellent results. It is therefore important for Governments to monitor carefully the manufacture of, trade in and consumption of controlled drugs. Governments are also free to impose stricter controls or to tighten existing ones if the prevailing local situation so requires (as was the case in Argentina, Chile, China, India and Nigeria). Also, the monitoring of adverse drug effects, together with the systematic assessment of trends in drug consumption can provide insight that is useful in preventing or reacting early to undesirable trends.

## E. Conclusions and recommendations

38. Persistent efforts by Governments to reduce excessive availability and indiscriminate consumption of narcotic drugs and psychotropic substances have yielded significant beneficial results. For many controlled drugs, the volume of drugs manufactured and traded, as well as the scope of their medical use, has been reduced to reasonable levels since the adoption of the international drug control treaties. This and previous reviews by the Board have shown that the excessive or inappropriate use of psychoactive substances, once they become strictly controlled, often tend to be replaced by less strictly controlled substitutes. For example, in western Africa, the primary stimulant of abuse, amphetamine, was replaced by fenetylline, pemoline, mesocarb and ephedrine (in that order), in reaction to tightened control measures.

39. The above-mentioned trends are evidence that Governments and their health professionals have to continue to be vigilant in monitoring developments. The Board considers the earlier examples to be the best references for Governments, particularly when a controlled drug with previously limited medical use, safety and efficacy and documented potential for abuse gains rapidly in popularity. The same applies when new psychoactive drugs are introduced into therapy. The safest way for Governments to prevent the emergence of new problems is to react in a timely manner to avoid the potential for overconsumption of such drugs.

40. Each Government should endeavour to keep the supply and consumption of controlled drugs under its close supervision. Experience has shown that the areas that need particular attention in this respect are:

(a) Adequate legislation and correct (non-bureaucratic) administrative arrangements, adapted, as required, to new trends and developments;

(b) Continued education, training and information provided to health personnel and the general public;

(c) Ethical attitude in medical and pharmaceutical practice, company restraint in marketing and promotion of drugs, and a higher degree of consumer awareness.

41. In countries with scarce resources, where the distribution and use of medicines often occur in an entirely unregulated way, outside formal health-care structures, it is difficult to counteract such use without improving the overall economic situation. It is imperative, therefore, that Governments of developing countries that are willing to improve their national drug distribution systems be given effective assistance. While the testing of new policies and approaches proposed in recent years for the improvement of national drug management in some countries continues,<sup>20</sup> Governments of developing countries should make every effort:

(a) To establish a sufficient degree of government authority and regulatory control over the national drug supply, including the control of narcotic drugs and psychotropic substances, and to eliminate parallel systems for drug distribution;

(b) To actively seek bilateral and multilateral assistance in the management of their national drug supply and to guarantee efficient use of such assistance;

(c) To promote the manufacture and/or the import of generic drug substitution of good quality, in order to make better use of available resources;

(d) To enlist the assistance of local pharmacies as an important (and often the only) professional source of information related to health and the use of drugs.<sup>22</sup>

42. As discussed in paragraphs 17-31 above, in an era of increasingly global pharmaceutical trade, the proliferation of transborder drug distribution has made it essential that Governments actively explore new ways for closer intergovernmental cooperation and concerted action to limit or reduce:

(a) The erosion of government authority in the area of national drug regulation;

(b) The increasing influence of the pharmaceutical industry on drug prescribing and use;

(c) Unethical behaviour in the marketing and direct sale of drugs and the dissemination of biased consumer information on drugs.

43. To complement the efforts of individual countries in the above-mentioned areas, Governments, as well as regional and international organizations, should

develop intergovernmental arrangements and standards to be applied at the regional level.

44. Because of the dual nature of controlled drugs, it is important that clinicians and pharmacists perform their professional duties with utmost care. Prior to prescribing a psychotropic substance or a narcotic drug, the clinician should carefully assess the patient's dependence liability by carefully ascertaining whether the patient has had a history of drug use, drug and alcohol abuse and drug-seeking behaviour. Ideally, every single prescription and the resulting drug use should be based on a direct patient-clinician relationship, correct diagnosis and a rational decision concerning the best treatment modality, in line with the principles of evidence-based medicine.

45. Health authorities should promote the use of culturally relevant and proven complementary or alternative treatment modalities, keeping in mind that, by relying on such therapeutic options rather than on pharmacotherapy per se, cost savings can be substantial. At the same time, Governments should ensure that their interventions do not unnecessarily limit the availability of controlled drugs for therapeutic purposes and ultimately deprive patients of legitimate and efficacious treatment. Professional associations should promote the continued education of physicians in these subject areas to reduce variations in diagnosis and therapy between countries and between institutions, to ensure a consistent and adequate therapeutic response to various mental conditions and to reduce the level of polypharmacy without compromising treatment outcome.

46. In view of the rapidly expanding application of electronic communication in medical practice for diagnosing and prescribing:

(a) Governments should fully recognize the tremendous potential offered by the electronic communication network in enhancing their regulatory functions, especially in the dissemination of unbiased, up-to-date health-related information to their citizens;

(b) Health professionals should refrain from using in an unethical manner telemedicine and electronic prescribing;

(c) Governments of countries where the use of electronic communication for health information, telemedicine and "Internet prescribing" is quickly becoming widespread should cooperate with each other

in establishing effective safeguard mechanisms, including national legal, regulatory and enforcement measures. The transborder nature of this problem requires intergovernmental agreements for quick and effective joint operations.

47. The Board has in previous years expressed its concern over the frequent use of the new global electronic information system for unethical drug promotion and the support of illicit drug manufacture and consumption. Both issues continue to be of great concern to many Governments and various international agencies. Therefore, the Board proposes an intergovernmental and inter-agency initiative in which eminent representatives in the field of communication technology and associations and agencies representing those professions of the health sector adversely affected by the misuse of telecommunication will:

(a) Consult with one another on the effects of emerging electronic medicine and prescribing on present national and international drug control concepts and practices;

(b) Review the experience of those Governments, international organizations and professional associations which have already taken or proposed regulatory measures for the same or similar purposes.

48. The Board appeals to the pharmaceutical industry to demonstrate social responsibility and voluntary cooperation in:

(a) Avoiding unethical behaviour in drug sales promotion and accepting the fact that controlled drugs should be promoted ethically, through well-regulated medical channels;

(b) Disclosing and disseminating complete and unbiased information to medical doctors and pharmacists concerning the benefits and potential risks of their products containing controlled substances;

(c) Supporting independent research into the assessment of potential risks derived from the wide-scale and/or chronic use of some psychotropic drugs (amphetamines, benzodiazepines), especially among high-risk segments of the population;

(d) Participating in supporting countries that have limited resources by donating drugs, including important controlled drugs.

49. Influencing drug consumption trends means changing habits, stereotypes, cultures and individual preferences. That is usually a slow and difficult process. In general, new drug consumption habits develop and flourish over a period of years. They can develop relatively quickly, however, when they are intensely promoted by those who stand to benefit from such developments. Reversing such trends is more difficult. It requires concerted efforts, lasting several years and supported by many constituencies of society.<sup>9, 23</sup> Experience has shown that such efforts can and do succeed.