

analogue approach requires the availability of pharmacological data to be able to demonstrate the similarity of psychoactive effects.

276. In seeking to protect the public from potentially harmful substances, States have also made increasing use of “emergency scheduling” procedures that allow them to take swift action to remove a substance from the market while a decision is pending on whether permanent control measures are to be applied to that substance. The adoption of such emergency measures has been highly effective in ensuring that the public is not unnecessarily put at risk before a comprehensive evaluation of the substance can be undertaken by national authorities.

277. Another approach taken by States to limit the public health dangers posed by some new psychoactive substances has been to subject such substances to requirements similar to those imposed upon manufacturers of medications. This has meant that in order for a new psychoactive substance to be deemed to be legal and obtain market authorization, it must have gone through a rigorous approval process backed up by toxicological data, medical trials etc. States having resorted to this type of control measure have reported that the costs associated with the approval process have acted as an effective deterrent for manufacturers of new psychoactive substances.

278. In many countries, recourse has been made to provisions under consumer and health protection laws with respect to requirements for clear disclosure of ingredients, labelling and instructions for use, leading to the confiscation of contravening products, as well as the closure of retail outlets selling them.

279. As noted above, the legal framework established by the international drug control conventions provides the possibility for States to adopt national control measures beyond those mandated at the international level. The choice by each State of what type of measures to apply is informed by the real situation on the ground that such measures are meant to address, and is also governed by the legal and regulatory norms and structures in place. While the Board acknowledges that each State must pursue the adoption of measures tailored to its specific situation, it remains convinced that in identifying appropriate responses to the emergence of new psychoactive substances, States may benefit from an exchange of best practices on the matter.

280. A global problem such as the proliferation of new psychoactive substances requires global solutions. The Board notes the efforts that have been undertaken at the national, regional and international levels to find effective ways to deal with this imposing problem, and encourages

States and international organizations to continue to work together in sharing information, developing common strategies and exchanging best practices. In the pursuit of its mandate, the Board stands ready to assist Governments.

3. Abuse of pharmaceutical preparations containing narcotic drugs or psychotropic substances

281. Over the years, the Board has repeatedly drawn the attention of Governments to the increasing abuse of prescription drugs containing controlled substances. In its annual report for 2009, in particular, the Board devoted a special topic to this problem to highlight the need for Governments to give it increased attention and to introduce countermeasures. Since 2009, the abuse of prescription drugs has continued to spread in all regions of the world, and is posing serious health and social challenges in some countries. In North America and South and South-East Asia, as well as some countries in Europe and South America, prescription drug abuse has increased substantially in recent years. In the United States, for example, prescription drug abuse is more prevalent than the abuse of any other internationally controlled substance except cannabis. In Germany and the Russian Federation, sedatives and tranquillizers containing benzodiazepines ranked the second most commonly abused substance group. The most abused substances that have been reported include opioids containing buprenorphine, codeine, hydrocodone, methadone and oxycodone, sedatives and tranquillizers containing benzodiazepines, barbiturates or GHB, and stimulants.

282. The abuse of prescription drugs by injection, which increases the risk of HIV, hepatitis B and hepatitis C infection, has also been reported by many Governments. This problem is noted particularly in South Asia, where the most commonly injected prescription drugs include a variety of benzodiazepines and buprenorphine. Health-care coverage among injection drug users in the region is low; this increases the likelihood of drug abusers sharing their injection equipment.

283. One particular concern of the Board is the increase in recent years in the reported abuse of prescription drugs containing psychotropic substances. According to a recent CICAD report on drug abuse in the Americas, the past year prevalence of the abuse of tranquillizers obtained without a prescription among secondary school students was higher than 6 per cent in Bolivia (Plurinational State of), Paraguay and Colombia. In Singapore, the Government has reported a large increase in the abuse of sedatives and tranquillizers containing benzodiazepines. Increased deaths related to the

abuse of psychotropic substances have been reported by a number of countries.

284. While more and more Governments have become aware of the increased abuse of prescription drugs containing psychotropic substances, the problem remains largely underreported worldwide, compared to the abuse of prescription drugs containing narcotic drugs. Furthermore, the Board is concerned that the general public, in particular youth, are not adequately informed about the damaging effects of such abuse.

285. As with the abuse of prescription drugs in general, the abuse of prescription drugs containing psychotropic substances has gained popularity, owing mainly to the fact that such abuse is less stigmatized than the abuse of illicitly manufactured drugs, the perception that such medications can be obtained legally (for example, from health-care professionals) and the mistaken belief that the abuse of such substances is not damaging to health.

286. Another concern of the Board relates to the role of health-care professionals: they may intentionally or unintentionally contribute to the problem of prescription drug abuse in different ways. According to the latest United States National Survey on Drug Use and Health, the majority of prescription drug abusers who obtained such preparations from a friend or relative indicated that the friend or relative had obtained them using a legitimate prescription. Research has indicated that the training that health-care professionals have received in prescribing and dispensing controlled substances and identifying substance abuse was insufficient in many countries. In addition, the dispensing of prescription drugs by pharmacists without the required prescriptions is a factor in sustaining the illicit use of prescription drugs in some regions, such as South Asia.

287. In response to the challenges posed by prescription drug abuse, many Governments have taken action to address this growing problem. For instance, the Government of Singapore requires medical practitioners to report information such as the duration of treatment periods and the dosage and quantities of prescription drugs that are prescribed to suspected drug addicts. The Governments of Germany and the United States have formulated targeted action plans to monitor and reduce prescription drug abuse. However, more needs to be done.

288. The crucial first step is to improve knowledge about the nature and extent of the abuse of prescription drugs, so as to devise a targeted response. Although a number of studies and research papers regarding prescription drug abuse have become available recently, knowledge about this problem in most countries remains extremely limited. The lack of information on the extent of abuse is a particular

concern in Africa, where the availability of prescription drugs on unregulated markets outside the control of the health authorities appears to be a serious problem. As the Board outlined in its annual report for 2009, Governments should include prescription drugs containing controlled substances in national drug abuse surveys to obtain information on the nature and extent of the abuse. In some countries where this has already been done, the questions on the abuse of prescription drugs in the surveys tend to be unspecific and do not lead to sound conclusions. In some other countries, queries about the abuse of psychotropic substances have been omitted in such surveys, perhaps owing to the perception that the high abuse of opioid analgesics is a greater concern. In all such cases, national surveys should be improved by making the questions comprehensive as well as specific regarding the type of substance abused.

289. Secondly, although there has been significant improvement in some countries in raising awareness about the harmful effects of prescription drug abuse, many people, including from the medical profession, are still not aware that the abuse of prescription drugs containing controlled substances can be as dangerous as the illicit use of other drugs such as heroin and cocaine. Therefore, it is necessary for Governments to formulate and implement effective prevention strategies; such strategies should target the general public and medical professionals, who need to be better educated about the dangers associated with prescription drug abuse. Health authorities and professional organizations should develop guidelines and codes of conduct and enhance training programmes for health-care professions, with the aim of promoting rational prescription and dispensation and reducing abuse of prescription drugs.

290. In some countries, prescription drugs that have high rates of abuse have been removed from the market or replaced with variants less prone to abuse. While such approaches can be part of an effective strategy to tackle the abuse of certain prescription drugs over the longer term, care needs to be taken when applying such approaches because they might limit the availability of those substances on the licit market. In addition, dependent abusers can switch to other forms of abuse to substitute for the substance or substances they were abusing previously, and the substitutes may be even more harmful. Therefore, a balanced approach is needed to prevent abuse while at the same time ensuring the availability of prescription drugs for licit purposes.

291. Last but not least, to tackle the problem of prescription drug abuse, measures need to be taken to prevent the illicit supply of prescription drugs. In addition to diversion from licit channels, the clandestine

manufacture of pharmaceutical preparations containing controlled substances has been uncovered in some countries. This suggests that the abuse of certain prescription drugs has become so widespread that traffickers are seeking new methods to meet the demand. Therefore, the Board urges all Governments to take measures to prevent the diversion and illicit manufacture of prescription drugs, as an effective way to prevent abuse.

292. Some psychotropic substances, all of them central nervous system stimulants, are used mainly in the treatment of attention deficit hyperactivity disorder (ADHD), a mental and behavioural disorder that usually results in learning problems, among many others. Methylphenidate is the most widely known and prescribed substance, and in some countries the only substance, used for such treatment. Dexmethylphenidate, the more potent stereoisomeric form of methylphenidate (which is controlled under the 1971 Convention), is now increasingly imported and used in some countries. Furthermore, amphetamine and dexamphetamine, alone or in combination products, are used for the treatment of ADHD. All three substances mentioned above are included in Schedule II of the 1971 Convention, since they are considered to be of little to moderate therapeutic usefulness and their liability to abuse constitutes a substantial risk to public health. On a much smaller scale, pemoline, a substance included in Schedule IV of the 1971 Convention, has also been used in the treatment of ADHD. More recently, lisdexamfetamine, a prodrug of dexamphetamine (after consumption it metabolizes in the body to dexamphetamine) that is not under international control, has been developed. That substance is considered to be less liable to abuse than amphetamines and methylphenidate, and its use in the treatment of ADHD is spreading in some countries. A number of other substances that are not under international control are also used in the treatment of ADHD.

293. The diagnosis of ADHD, in particular in children, is time-consuming and should follow complex assessments of medical, developmental and educational parameters to exclude the possibility that the behavioural and learning problems are caused by other disorders or by family and environmental circumstances. Diagnosis of ADHD and its treatment with the help of central nervous system stimulants, primarily in children, started to grow substantially in North America about two decades ago, and that growth has subsequently spread to many countries and regions. Since consumption of the substances used to treat ADHD improves academic performance and alleviates behavioural problems, there have been reports of pressure

from schools or parents to prescribe such substances to pupils and students without a proper diagnosis of ADHD. ADHD was previously considered to be mainly a problem of schoolchildren; however, ADHD in pre-school children and in adults has also been increasingly diagnosed and treated with stimulants such as methylphenidate.

294. Partly as a consequence of the developments described above, global use of the substances used in the treatment of ADHD has increased during the past two decades, although there have been changes in the use levels of the various substances mentioned above. Whereas global manufacture and use levels of amphetamines increased in the 1990s, when they were consistently much higher than the manufacture and use of methylphenidate, they have followed a downward trend since about 2000. The manufacture and use of pemoline were also much higher in the 1990s and have declined since. In contrast, the global manufacture of methylphenidate, which increased more than tenfold, from 4.2 tons in 1992 to 45.2 tons in 2011, and in 2009 surpassed the combined global manufacture of all amphetamines, continues to grow. The calculated global consumption increased during the same period from 4.2 tons (139 million defined daily doses for statistical purposes (S-DDD)) to 51 tons (1.5 billion S-DDD). While the Board has no direct information on the levels of use of many stimulants such as lisdexamfetamine that are not internationally controlled, there are signs that the total manufacture and use of central nervous system stimulants for the treatment of ADHD are not levelling off.

295. The high demand in the United States, where the use of methylphenidate and other substances for the treatment of ADHD is heavily advertised, including directly to potential consumers, and is promoted at schools, has been the major driving force for the manufacture and use of methylphenidate. The United States has traditionally been the major manufacturer and user of methylphenidate, in addition to being the major importer of amphetamines used in the manufacture of preparations to treat ADHD. In that country, the levels of calculated consumption²⁵ of methylphenidate increased steadily and sharply

²⁵ The 1971 Convention does not require that Governments furnish to the Board statistics on the consumption of psychotropic substances. In 2011, the Commission on Narcotic Drugs, in its resolution 54/6, requested Governments to submit consumption statistics for psychotropic substances to the Board to enable it to evaluate the availability of psychotropic substances in countries and regions. Some Governments have started to submit such statistics; however, so far the data received are not sufficient for the comparison of statistics between countries and years.

from 1.5 S-DDD per 1,000 inhabitants per day in 1992 to 10.8 S-DDD per 1,000 inhabitants per day²⁶ in 2011.

296. The use of methylphenidate for the treatment of ADHD has spread to a number of other countries. In 1992, the share of the United States in the total calculated use of methylphenidate was 86 per cent; in 2011, that figure dropped to 69 per cent. Whereas in 1992 a total of 63 countries and territories reported use of methylphenidate, in recent years over 100 Governments have reported such use. In 2011, Canada and Iceland, for the second consecutive year, showed higher calculated per capita consumption levels than the United States. Other countries in Europe and Oceania²⁷ that show very high rates of per capita consumption of methylphenidate are also among the countries with very high per capita consumption levels of amphetamines.

297. It should be noted that about half of the countries and territories in the world do not report any use of the psychotropic substances that are typically used in the treatment of ADHD. In particular, many countries where the population is much younger than in the countries reporting high consumption levels of stimulants used in ADHD, and that presumably would have a high rate of ADHD, hardly use such stimulants.

298. The increase in the availability and use of the substances used to treat ADHD, in particular methylphenidate, has been accompanied by frequent reports of diversion and abuse of the pharmaceutical preparations containing those substances from licit distribution into illicit channels, in particular in countries where consumption levels have been high. The preparations are typically abused by two groups: (a) students and pupils who want to improve their academic performance and who seem to ignore the health risks involved in the use of such substances without medical supervision, and (b) abusers of amphetamine-type stimulants who crush and subsequently snort, dissolve or inject the substances in question, such as methylphenidate, or mix them with street drugs to create what is called a "speedball". In the United States in the mid-1990s, the levels of abuse of substances that are used to treat ADHD were not less than the abuse levels of stimulants that were illicitly manufactured.²⁸ Whereas most other amphetamine-type stimulants have been obtained from illicit manufacture, all

the methylphenidate found in illicit markets is believed to be diverted from domestic distribution channels.

299. Many methods for the diversion of those preparations were identified. For example, methylphenidate is among the substances most often obtained through illegal Internet pharmacies. In several countries adolescents and young adults reported little difficulty in obtaining preparations containing methylphenidate or amphetamines from friends or schoolmates. Furthermore, schools have been broken into and medication supplies stolen. In some countries there were reports that methylphenidate could be obtained without a prescription, in contravention of the provisions of the 1971 Convention. At least one criminal network was identified that was involved in falsifying orders for preparations containing methylphenidate.²⁹

300. The Board recognizes the usefulness of stimulants in the treatment of ADHD when prescribed on the basis of careful and appropriate diagnosis and proper treatment evaluation. Nevertheless, the Board has repeatedly expressed its concern about the high level of consumption of methylphenidate and the other substances used in the treatment of ADHD, which has led to the widespread diversion and abuse of pharmaceutical preparations containing those substances. The Board has requested the countries concerned to ensure that the control measures foreseen in the 1971 Convention are applied to the stimulants listed in Schedule II of that Convention and to take additional measures, as necessary, to prevent both the diversion from licit distribution channels and the abuse of preparations containing that substance.³⁰ The Board has also stressed on numerous occasions the importance of education and training for health professionals on the rational use of psychoactive drugs, to prevent the abuse of prescription drugs. In this connection, the Board noted that the significant increase in the use of stimulants for ADHD treatment in many countries could be attributed to possible overdiagnosis and overprescription.

301. Diversions of methylphenidate and other substances used in the treatment of ADHD, direct advertising to the general public to promote their use and wide public dissemination of information about the misuse and abuse of such substances, as well as the sources where they can be obtained, have helped to create an illicit market for preparations containing such substances. The Board is therefore concerned about the unabated increase in consumption of methylphenidate in a number of countries.

²⁶ Since 2010, statistical data on consumption were reported by the United States. The reported data confirm excessively high consumption levels.

²⁷ Namely, Australia, Belgium, Denmark, the Netherlands, New Zealand, Norway, Spain and Sweden.

²⁸ *Report of the International Narcotics Control Board for 2006* (United Nations publication, Sales No. E.07.XI.11), para. 87.

²⁹ *Report of the International Narcotics Control Board for 2009* (United Nations publication, Sales No. E.10.XI.1), para. 98.

³⁰ For example, in recommendation 24 of the *Report of the International Narcotics Control Board for 2009*.

Inadequately controlled supplies of those substances at sites such as schools, private homes and illegal Internet pharmacies, as well as the continued lack of awareness on the part of potential abusers about the health risks associated with the abuse of those stimulants, may lead to increased diversion and abuse.

302. The Board therefore reiterates that Governments should closely monitor the consumption levels of all stimulants that are used in the treatment of ADHD and ensure that they are prescribed in accordance with sound medical practice, as required under article 9, paragraph 2, of the 1971 Convention and in line with the rational use of psychoactive drugs, as recommended by WHO. The competent authorities of the countries concerned should further increase their vigilance with regard to the diversion of, trafficking in and abuse of stimulants in Schedule II used for the treatment of ADHD. Where necessary — for example, at schools — safety measures for storage and distribution should be enforced. Health professionals prescribing substances for the treatment of ADHD and health authorities should advise the general public, students and, in particular, parents of young patients of the risks and consequences of the abuse of such substances. The Board calls further on all Governments to inform it of any new development with regard to the diversion of, trafficking in and abuse of those substances.

4. Diversion of pharmaceutical preparations containing narcotic drugs or psychotropic substances

303. Reported seizures of pharmaceutical preparations containing controlled substances and the reports of increasing abuse in many countries and regions (see paras. 281-302 above) prove that these preparations continue to be readily available on the illicit market. Unlike the case of heroin, cocaine and amphetamine-type stimulants, which are well known to be clandestinely manufactured, the illicit manufacture of pharmaceutical preparations containing controlled substances has rarely been reported, indicating that their supply has been originating primarily from diversion from licit domestic distribution channels.

304. The most commonly diverted pharmaceutical preparations contain the following:

- Strong analgesics such as fentanyl, hydrocodone, morphine and oxycodone
- The substances buprenorphine and methadone which are mainly diverted from substitution treatment

- Stimulants such as methylphenidate and phentermine
- Many sedatives and tranquillizers (certain benzodiazepines and barbiturates, and GHB).

Diverted pharmaceutical preparations containing narcotic drugs and psychotropic substances are frequently abused in the countries of diversion. However, they are also often smuggled from the countries where they were diverted to other countries and regions where they are abused, as reported by a number of countries. For instance, diverted preparations containing buprenorphine were smuggled from France into Mauritius, where the abuse of buprenorphine is a significant concern.

305. Governments are increasingly aware that pharmaceutical preparations continue to be diverted to feed the illicit market, yet knowledge about how those drugs are being diverted remains limited. Of the 65 Governments that have returned the 2011 annual report questionnaire, 25 Governments indicated that they had seized pharmaceutical preparations containing narcotic drugs and psychotropic substances; however, only 7 Governments could identify the source of supply or methods of diversion. Lack of knowledge about the diversion methods makes it difficult to devise targeted countermeasures.

306. On the basis of information available to the Board, the diversion of pharmaceutical preparations containing controlled substances continues to occur mainly in the domestic supply chain. While such diversion appears to be a problem in many countries, it is most prominent in countries where either the national legislation or its implementation is weak.

307. Diversion is often facilitated knowingly or unknowingly in the health-care sector, for instance, through unethical practices of health-care professionals, such as prescribing controlled substances in a manner that is not medically appropriate. The role of some pharmaceutical companies is also important in this regard when they boost sales by offering incentives to medical practitioners for promoting their products. Pharmacies are another important source of diversion for pharmaceutical preparations containing controlled substances. Preparations that require a prescription are obtained in many countries illicitly from pharmacies with or without prescriptions, sometimes owing to a lack of qualified pharmacists in those pharmacies. For example, according to a report of UNODC, in South Asia significant quantities of pharmaceutical preparations are diverted from licensed and unlicensed pharmacies both with and without prescription.