

for Availability and Accessibility of Controlled Medicines. After each mission, it sends the Governments a letter with recommendations that may, if appropriate, include specific passages on ensuring the availability of opioids for the treatment of pain. The Board regularly addresses the availability of narcotic drugs in speeches at meetings of intergovernmental bodies, such as the twentieth special session of the General Assembly, sessions of the Commission on Narcotic Drugs, the Economic and Social Council and the World Health Assembly, and regional meetings of various international organizations.

232. Simplified control measures are in place for the provision of internationally controlled medicines for emergency medical care. Emergencies are defined as “any acute situation (e.g. earthquakes, floods, hurricanes, epidemics, conflicts, displacement of populations) in which the health conditions of a group of individuals are seriously threatened unless immediate and appropriate action is taken, and which demands an extraordinary response and exceptional measures”.³⁵ They occur in the wake of natural or man-made disasters that may lead to a sudden and acute need for medicines containing controlled substances. In 1996, the Board, together with WHO, devised simplified control procedures for the export, transport and import of controlled medicines for emergency medical care. The simplified regulations would remove the need for import authorizations, provided that the import and delivery were handled by established international, governmental and/or non-governmental organizations engaged in the provision of humanitarian assistance in health matters recognized by the control authorities of the exporting countries. Those simplified procedures are available to all States in the Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care.

233. Such an emergency situation arose following the devastating typhoon in the Philippines in November 2013. The need to provide treatment to the many victims led to an acute shortage of medicines. Many of those needed medicines contained narcotic drugs, such as morphine, and psychotropic substances, such as pentazocine, both of which are under international control. Under normal circumstances, the import and transport of those medications are subject to strict regulatory requirements. However, in catastrophic situations compliance may delay the urgent delivery of medications for emergency humanitarian relief, as national authorities may be unable to take the administrative steps required.

³⁵World Health Organization, *Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care* (document WHO/PSA/96.17).

234. Responding to the humanitarian crisis caused by the typhoon, the Board took steps to hasten the supply of controlled medicines. As in earlier emergencies, it reminded all exporting countries that clear guidelines were in place for the international provision of controlled medicines for emergency medical care. Soon after the typhoon struck the Philippines, the Board sent a letter to all countries to remind them that they could apply those simplified control procedures to hasten the supply of urgently needed medicines. The Board also informed providers of humanitarian assistance about the simplified regulations, including the International Federation of Red Cross and Red Crescent Societies, Médecins Sans Frontières, Merlin/Save the Children and Oxfam International.

235. This solution has been available for a number of years. The Board invites Governments and humanitarian relief agencies to bring to its attention any problems encountered in making deliveries of controlled medicines in emergency situations.

236. The Board would like to remind all Governments that, in acute emergencies, such as the situation following the devastating typhoon in the Philippines, they can apply simplified control procedures for the export, transportation and delivery of medicines containing controlled narcotic drugs or psychotropic substances, and competent authorities may allow their export to the affected country even in the absence of import authorizations or estimated requirements for substances under international control. Emergency deliveries need not be included in the estimates of the receiving country, and exporting Governments may wish to use parts of their special stocks of narcotic drugs and psychotropic substances for this purpose.

237. The Board also reminds all States that, under international humanitarian law, parties to armed conflicts have an obligation not to impede the provision of medical care to civilian populations located in territories under their effective control. This includes access to necessary narcotic drugs and psychotropic substances.

238. The Guidelines are available on the websites of INCB (www.incb.org) and WHO (www.who.int).

3. Use of methylphenidate

239. Methylphenidate, a central nervous stimulant listed in Schedule II of the 1971 Convention, is used for the treatment of various mental and behavioural

disorders, in particular attention deficit and hyperactivity disorder (ADHD) and narcolepsy.³⁶

240. During the 1980s, use of methylphenidate was limited and at stable levels, but it started to increase noticeably at the beginning of the 1990s. In 1994, for example, global use amounted to more than five times the consumption level of the early 1980s. That development was mainly a result of increasing consumption in the United States, although increasing consumption levels were also observed in several other countries and parts of the world. Since then, growth of global consumption of methylphenidate has continued unabated. In 2013, a new record of 71.8 tons (2.4 billion S-DDD) was attained, as can be seen in figure I below. The growing medical consumption of methylphenidate can be attributed mainly to the increasing numbers of diagnoses of ADHD.

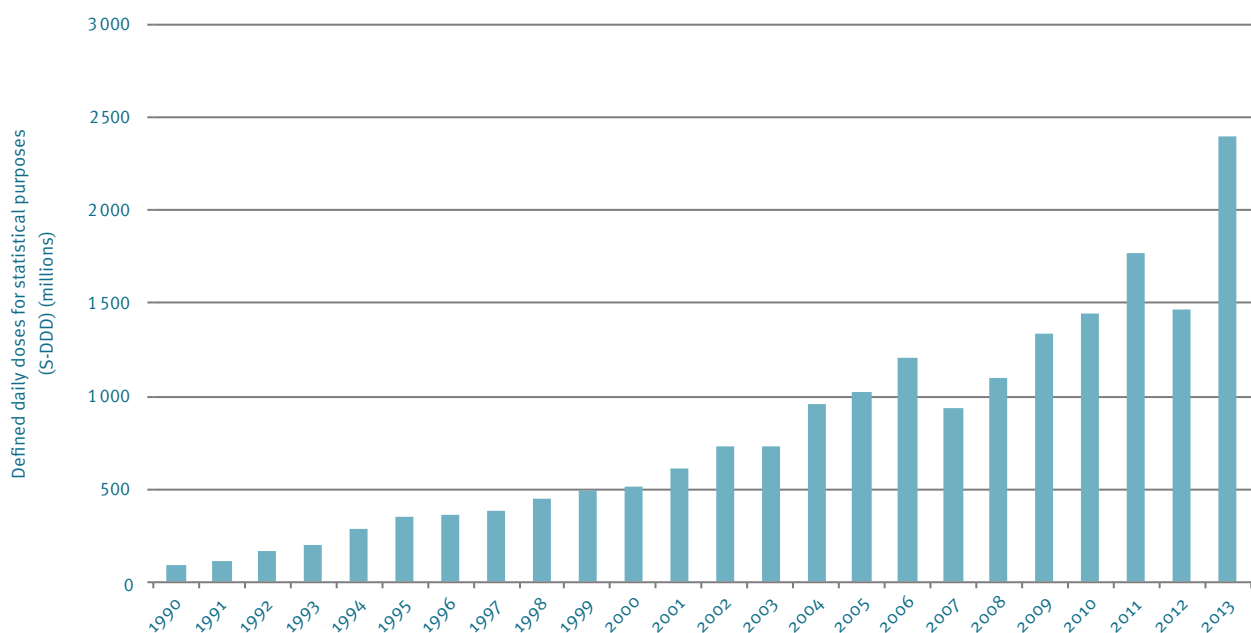
241. Since the mid-1990s, the Board, in its annual reports, has frequently brought to the attention of Governments the growing levels of consumption of methylphenidate and has expressed concern about diversion and abuse of the substance. In its report for 2009, the Board advised against promotional campaigns through various communication channels, including in advertisements directed at potential

³⁶See World Health Organization, *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines* (Geneva, 1992, version 2010); and American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. (Arlington, Virginia, 2013).

consumers, such as those prevalent in the United States, the main consumer of methylphenidate. In that same year, the Board called upon the Governments concerned to ensure that the control measures foreseen by the 1971 Convention were fully applied to methylphenidate and to take additional measures to prevent both the diversion from licit distribution channels and the abuse of preparations containing that substance. The Board also encouraged all Governments to promote the rational use of internationally controlled substances, in accordance with the pertinent recommendations of WHO.

242. Traditionally, methylphenidate has been prescribed to people between the ages of 6 and 14 years, and predominantly for boys. As of 2011 in the United States, about 11 per cent of individuals aged between 4 and 17 years had been diagnosed with ADHD, according to the Centers for Disease Control. Furthermore, a growing number of younger children (as young as 2 and 3 years of age) were also being prescribed methylphenidate. In Australia, 2-year-old children are increasingly being prescribed medication containing methylphenidate, with more than 2,000 children under 6 receiving the treatment. In addition to the increasing number of children treated, the treatment period has been extended, in many cases to several years. Furthermore, there has been an increase not only in the number of young patients but also in the number of adult patients. In Iceland, most ADHD patients taking methylphenidate are over 20 years of age. In Germany, the number of

Figure I. Global consumption of methylphenidate, 1990-2013



Source: Statistical data submitted by Governments in form P.

diagnosed ADHD cases increased by 42 per cent in children and adolescents under the age of 19 between 2006 and 2011.

243. Although the United States continues to account for more than 80 per cent of the calculated global consumption of methylphenidate, the use of that substance in other countries has also significantly increased during the past decade. The countries reporting such an increase include Iceland, which has had the highest per capita consumption of methylphenidate in the world for the past several years, as well as (in descending order by per capita consumption) Norway, Sweden, Australia, Belgium, Germany and Canada.

244. Increased consumption may be attributable to various causes such as: (a) an increase in the number of patients who are diagnosed with ADHD; (b) a widening of the age group of patients likely to be prescribed methylphenidate; (c) increased use among adults; (d) misdiagnosis of ADHD and random prescription of methylphenidate; (e) a lack of appropriate medical guidelines for the prescription of methylphenidate; (f) growing market supply in many countries; (g) influential commercial and/or aggressive marketing practices of the manufacturers of pharmaceutical preparations containing methylphenidate; and (h) public pressure, such as parents' associations lobbying for their children's right to access to ADHD medication.

245. Overmedication and overprescribing of medicines containing methylphenidate may fuel illegal activities such as "doctor shopping", trafficking and abuse, particularly in school settings. Students are misleadingly tempted, particularly during exam periods, to use the substance in order to improve their ability to concentrate and study longer, and thus improve their performance. Hence, this substance is abused by a growing number of teenagers and young adults. Prescription drugs containing methylphenidate are also often obtained from students who are under treatment for ADHD.

246. The Board notes that some Governments have already taken measures to limit the use of methylphenidate to actual medical needs, in conformity with sound medical practice. The authorities of Iceland, concerned about the high level of use of methylphenidate in their country, have taken specific measures aimed at curbing its increasing use, in particular, among adults. These measures include an update of existing clinical guidelines for ADHD treatment and the limitation to specialists in psychiatry of authorization to prescribe it. Prescribers are urged to prescribe, as a first choice, "safer" pharmaceutical preparations containing methylphenidate (i.e.,

preparations that are less prone to misuse). Furthermore, new and more restrictive rules for the reimbursement of the costs of methylphenidate have been introduced, under which only specialists in psychiatry are allowed to initiate treatment with methylphenidate and apply to the health insurance scheme for reimbursement, by submitting observations based on a detailed medical history of the patient, research and diagnosis, as well as a follow-up programme. In Thailand, where overprescribing of methylphenidate had also been of concern, the following preventive measures were taken: (a) prohibition of the sale of methylphenidate in drugstores; (b) limitation of authorization to prescribe methylphenidate, so that only psychiatrists, including child psychiatrists, are allowed to prescribe it; (c) limitations on the formulation of pharmaceutical preparations containing methylphenidate to prohibit them from containing more than two dosages; (d) restriction on the procurement of methylphenidate by hospitals and clinics so that it can only be obtained from a central governmental office; and (e) inclusion of a standard drug information leaflet in all packages.

247. The Board wishes to encourage the Governments of all countries with high consumption rates of methylphenidate to identify the reasons for such elevated consumption and to take action to limit consumption to actual medical needs. Such actions could include adequate education of doctors and other health-care professionals on the rational use of psychoactive drugs. In particular, Governments must exercise vigilance to prevent possible misdiagnosis of ADHD and inappropriate prescribing of methylphenidate. Governments are encouraged to monitor developments in the diagnosis of ADHD, as well as other behavioural disorders, and the extent to which methylphenidate is prescribed for their treatment. The Board requests Governments to ensure that methylphenidate is prescribed in accordance with sound medical practice, as set forth in the 1971 Convention (article 9, paragraph 2). The Board will continue to carefully monitor future developments in countries with high consumption levels of methylphenidate and encourages Governments concerned to share with it and WHO information concerning the use of methylphenidate, prescription practices and misuse, as well as trafficking and abuse in their countries.

4. New psychoactive substances

248. Since the publication of its annual report for 2010, the Board has been warning the international community about the growing problem of trafficking in and abuse of new psychoactive substances. New psychoactive substances are substances of abuse, either in a pure form