

# Chapter III.

## Psychotropic substances

156. There are currently 125 psychotropic substances<sup>54</sup> under international control pursuant to the 1971 Convention. Most of them are contained in pharmaceutical preparations of medicines that act on the central nervous system, which include stimulants, depressants, analgesics and antidepressants.

157. Psychotropic substances are grouped into four schedules according to their therapeutic usefulness, potential for dependence, and liability to abuse and public health risk. The 1971 Convention provides a different control regime for each schedule. The scope of the controls applied to the substances in the four schedules varies according to their level of hazard or risk.

158. Five psychotropic substances<sup>55</sup> currently under international control are included in the latest WHO Model List of Essential Medicines.<sup>56</sup> The list comprises a core and a complementary list.

159. The World Health Organization defines the core Model List as a list of minimum medicines needed for a basic health-care system. The list includes the most efficacious, safe and cost-effective medicines for priority conditions, which are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. Diazepam, lorazepam, midazolam and phenobarbital are included in the core

list. Furthermore, the complementary list presents essential medicines for the treatment of priority diseases for which specialized diagnostic or monitoring facilities and/or specialist training are needed. Buprenorphine is included in the complementary list.

160. The framework of control that the 1971 Convention requires Governments to establish is directed at protecting public health and welfare. The international community, in enacting the Convention, recognized that the abuse of psychotropic substances posed a serious health hazard to the individual and threatened the social and economic fabric of normal life. Only through coordinated national and international measures could the dangers of drug addiction and illicit trafficking be overcome. Disparities in levels of consumption of psychotropic substances among countries and regions are still observed. Inadequate availability and poor access to necessary medical treatments, as well as excessive availability and medically unsound use of psychotropic substances, represent the threats related to the control and use of such substances.

### A. Supply of psychotropic substances controlled under the 1971 Convention

161. The World Health Organization definition of rational use of medicines emphasizes that patients need to “receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them

<sup>54</sup>Nine substances were brought under international control (in Schedules I and II of the 1971 Convention) during the fifty-eighth session of the Commission on Narcotic Drugs, in March 2015.

<sup>55</sup>Buprenorphine, diazepam, lorazepam, midazolam and phenobarbital.

<sup>56</sup>World Health Organization, Model List of Essential Medicines, 19th list (April 2015, amended June 2015). Available from [www.who.int/medicines/publications/essentialmedicines](http://www.who.int/medicines/publications/essentialmedicines).

and their community". According to this definition, irrational use of medicines may refer to lack of access to essential medications or to inappropriate use of medications that are accessible and available. Health-care delivery around the world depends heavily on national health-care systems and the availability of adequate resources. According to WHO, 14 per cent of the global burden of diseases is attributable to mental, neurological and substance use disorders, with almost three quarters of this burden occurring in low- and middle-income countries. In those countries, about four out of five people who need services do not receive them. Available resources are insufficient.

162. At the same time, the risk of oversupply and excessive availability of psychotropic substances under international control, combined with weak and/or inadequate regulatory control measures, may result in their misuse and abuse. Excessive availability of psychotropic substances resulting from unregulated supply and inappropriate or non-medical use of controlled drugs is as much of a concern to the Board as inadequate supply.

163. Particularly well-targeted marketing strategies and heavy advertising campaigns by specific companies, and the pharmaceutical industry as a whole, along with the introduction of more competitive products into the market (generics), can contribute to the excessive supply and availability of psychotropic substances. This occurs mainly in developed countries but can also be observed in developing ones. Excess availability often leads to over-consumption, which leads in turn to dependence and to the illicit trafficking of substances.

164. Insufficient resources and expertise required for determining medical needs and adjusting drug supply to meet those needs jeopardize the balance between availability and consumption. Moreover, 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.

## 1. Supply of analgesics

165. Buprenorphine, lefetamine and pentazocine are the analgesics controlled under the 1971 Convention. Global manufacture of buprenorphine, an opioid analgesic listed in Schedule III of the 1971 Convention, started to increase gradually in the late 1990s, as the substance began to be

used in higher doses for the treatment of pain and opioid addiction. In 2013, global manufacture reached a new record, with almost 9 tons (1.1 billion S-DDD) reported by nine countries. The volume of international trade has increased as well, with over 60 countries reporting imports of the substance in 2013.

166. There was less manufacture of and trade in pentazocine. Global manufacture of that substance fluctuated between a high of 8 tons and a low of 1 ton per year during the past decade. No steady rate of increase in manufacture and trade was discernible.

167. Lefetamine is both a stimulant and an analgesic, with effects similar to codeine. In the 1990s, lefetamine was found to be less effective than buprenorphine in the detoxification of methadone patients. Consequently, manufacture and consumption of lefetamine ceased in the 1990s.

## 2. Supply of stimulants

168. In contrast to some other psychotropic substances, none of the central nervous system stimulants controlled under the 1971 Convention are recognized by WHO as part of the minimum requirements for a basic health-care system; therefore, none of them are included in the WHO Model List of Essential Medicines. This would largely explain the quasi-absence of these substances in the markets of low-income and developing countries.

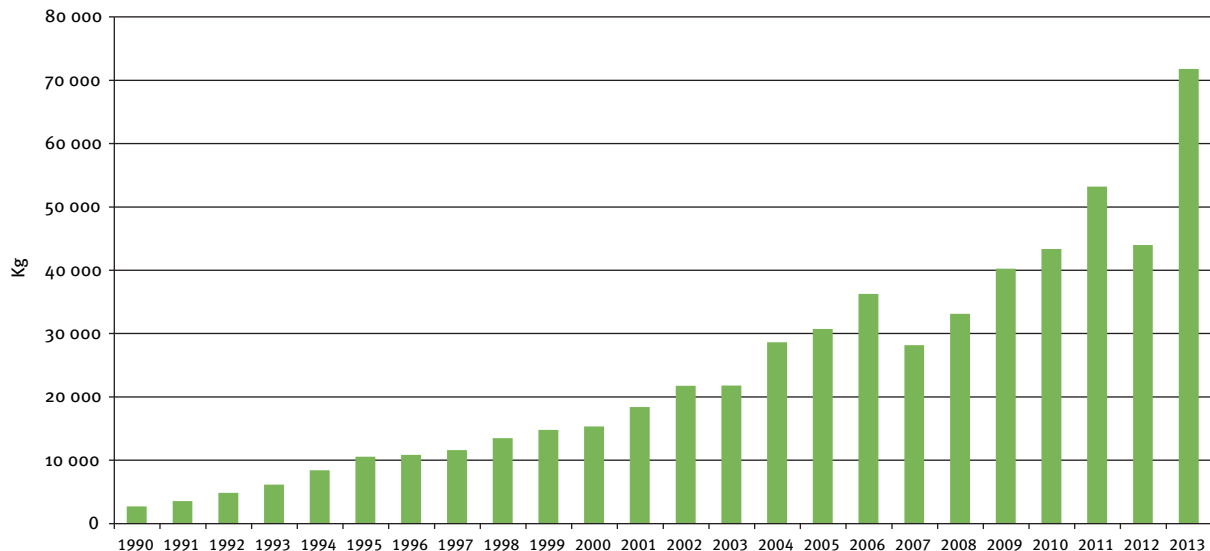
169. Amphetamines and methylphenidate are the only stimulants in Schedule II that are manufactured and traded in large quantities. In particular, they are manufactured in very large quantities in the United States and a few European countries. These substances are mostly used for the treatment of attention-deficit hyperactivity disorder (ADHD) and, in the case of amphetamines, also for industrial processes. During the past 20 years, continual and significant increases in the manufacture of three major substances of the group, namely amphetamine, dexamphetamine and methylphenidate, were observed.

170. While the United States has always been the leading manufacturer of this group of substances, manufacture to meet growing domestic needs also occurs in some European countries, including France, Germany, Hungary and the United Kingdom. Manufacture of amphetamines amounted to 47 tons in 2013, and three countries (United States, Canada and Australia) accounted for 88 per cent of global imports.

171. Global manufacture of methylphenidate has progressively increased in the past 20 years, as shown in figure 39. In 2013, global output of that substance reached a record of nearly 72 tons. The number of countries importing methylphenidate during the past decade was

stable, with about 100 reporting imports in quantities ranging from a few grams to a few tons. In 2013, seven countries<sup>57</sup> in Europe and the Americas accounted for more than 70 per cent of global imports.

Figure 39. Quantities of global manufacture of methylphenidate, 1990-2013



Source: International Narcotics Control Board.

172. Global output of the stimulants listed in Schedule IV, which are mainly used in the treatment of obesity as anorectics, remained stable during the past 10 years, averaging 90 tons per year. During the same period, total imports averaged 21 tons yearly. In 2013, five countries in three regions (Americas, Europe and Oceania) accounted for more than 80 per cent of global imports.

### 3. Supply of benzodiazepines

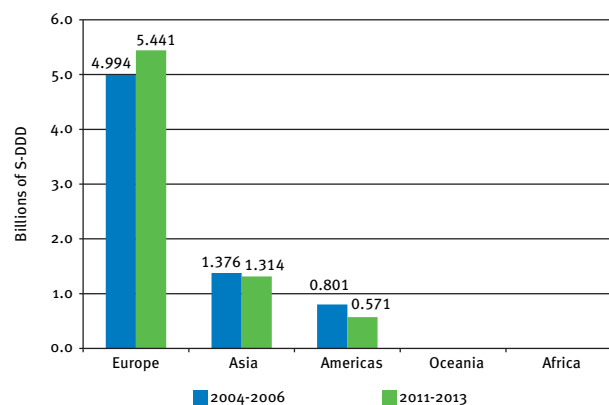
173. The 35 benzodiazepines currently under international control are classified as anxiolytics and sedative-hypnotics and are used in medical practice for the short-term management of insomnia and for pre-medication and the induction of general anaesthesia.

#### (a) Supply of benzodiazepine-type sedative-hypnotics

174. In the past 10 years, manufacture of benzodiazepine-type sedative-hypnotics was reported by between 11 and 16 countries, mainly in Europe (Germany, Italy and Switzerland, which jointly accounted for two thirds of global stocks in 2013), while countries in Asia (China, India and Japan) and in the Americas (Brazil, Canada and the United States) jointly supplied one quarter of global

output. Figure 40 demonstrates that, in the past 10 years, the share of this group of substances supplied by Europe has increased, while the share supplied by Asia and the Americas has decreased. Countries in Africa and Oceania did not supply benzodiazepine-type sedative-hypnotics during that period (except for 6 kg of nitrazepam manufactured by New Zealand in 2012).

Figure 40. Total reported manufacture of benzodiazepine-type sedative-hypnotics, by region, 2004-2006 and 2011-2013

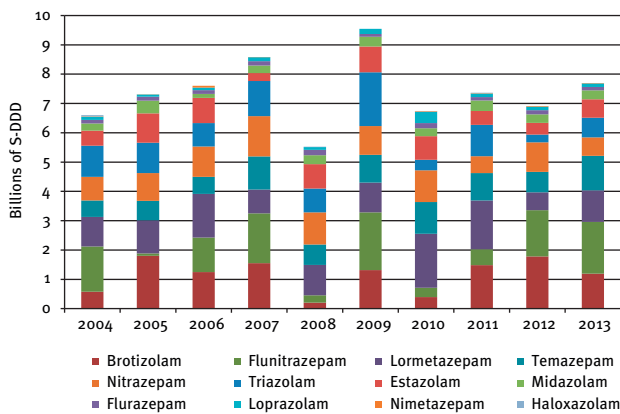


Source: International Narcotics Control Board.

<sup>57</sup>Switzerland, Germany, Spain, Canada, Brazil, the Netherlands and the United Kingdom (in descending order of amounts imported).

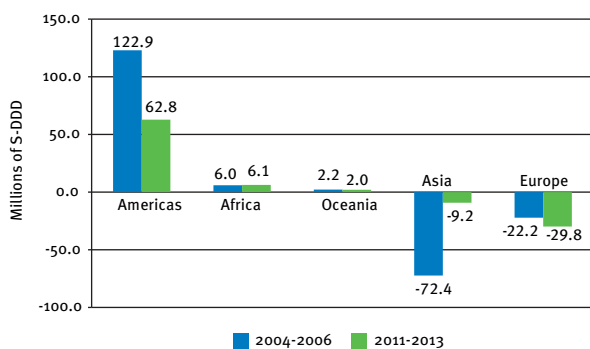
175. In the past 10 years, global reported manufacture of benzodiazepine-type sedative-hypnotics fluctuated around an annual average of 7.4 billion S-DDD (see figure 41). Out of the 12 substances in this group (brotizolam, estazolam, flunitrazepam, flurazepam, haloxazolam, loprazolam, lormetazepam, midazolam, nitrazepam, temazepam and triazolam), only midazolam is included in the WHO Model List of Essential Medicines. Although midazolam accounted for only 4 per cent of total supply of this group of substances in 2013 (see figure 42), it was the most widely traded and most widely available substance geographically, as 134 countries reported imports of this substance. As demonstrated in figure 43, Europe and Asia remain the net suppliers of midazolam.

Figure 41. Total reported manufacture of benzodiazepine-type sedative-hypnotics, by substance, 2004-2013



Source: International Narcotics Control Board.

Figure 43. Average annual net imports of midazolam, by region, 2004-2006 and 2011-2013



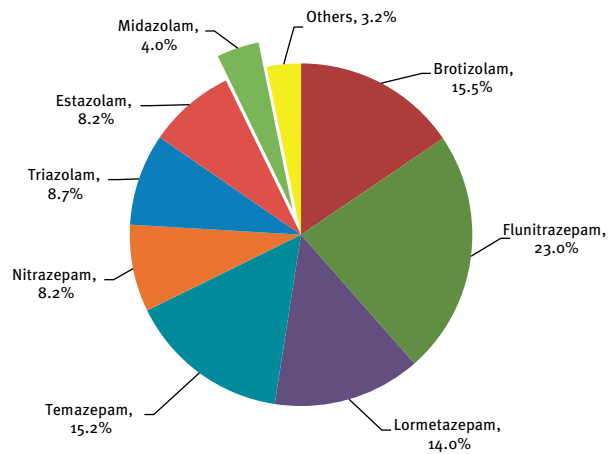
Source: International Narcotics Control Board.

(b) Supply of benzodiazepine-type anxiolytics

176. In the past 10 years, between 16 and 20 countries reported manufacture of benzodiazepine-type anxiolytics. Similar to benzodiazepine-type sedative-hypnotics, the supply of this group of substances originated in Europe, Asia and the Americas (see figure 44), with Italy remaining the main manufacturer, accounting for 44 per cent of global output in 2013.

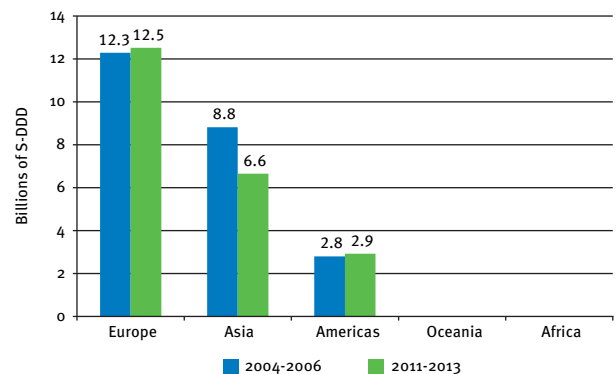
177. In the past 10 years, global reported manufacture of benzodiazepine-type anxiolytics fluctuated between 18.3 and 29.9 billion S-DDD, around an annual average of 22 billion (see figure 45). Twenty-two benzodiazepines

Figure 42. Share of total reported manufacture of benzodiazepine-type sedative-hypnotics, by substance, 2013



Source: International Narcotics Control Board.

Figure 44. Total reported manufacture of benzodiazepine-type anxiolytics, by region, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

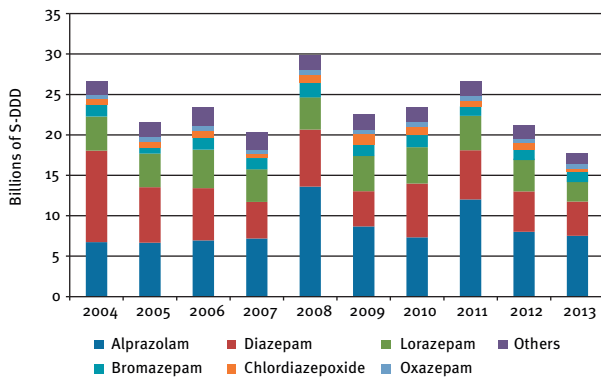
are generally classified as anxiolytics; two of them, diazepam and lorazepam, are included in the WHO Model List of Essential Medicines. During the 2004-2013 period, diazepam and lorazepam accounted for 26 and 18 per cent, respectively, of global supply of this group of substances. The shares of total reported manufacture in 2013 are presented in figure 46. Diazepam, alprazolam and lorazepam are the most widely available substances of this group, as 137, 118 and 102 countries, respectively, report on imports of these substances. The trends in net imports (imports minus exports) of diazepam and lorazepam are presented in figures 47 and 48. Countries in Europe and Asia remain the main suppliers of these two substances. The main changes during the past decade included a

notable increase in net imports of diazepam by African countries, and an increase in net imports of lorazepam by countries in the Americas.

#### 4. Supply of anti-epileptics

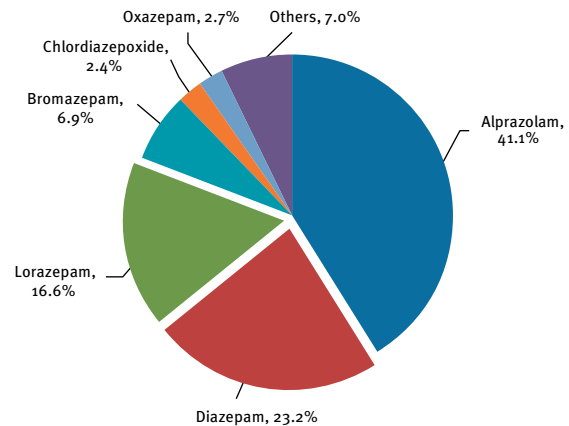
178. There have been divergent patterns in the manufacture and trade of barbiturate-type anti-epileptics (phenobarbital and methylphenobarbital) and benzodiazepine-type anti-epileptics (clonazepam) included in Schedule IV during the past 10 years. Phenobarbital is included in the WHO Model List of Essential Medicines.

Figure 45. Total reported manufacture of benzodiazepine-type anxiolytics, by substance, 2004-2013



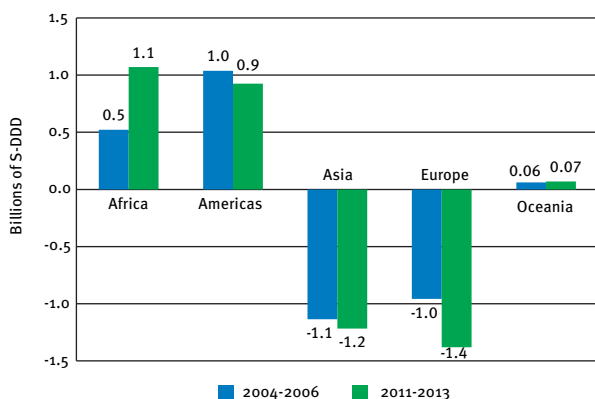
Source: International Narcotics Control Board.

Figure 46. Share of total reported manufacture of benzodiazepine-type anxiolytics, by substance, 2013



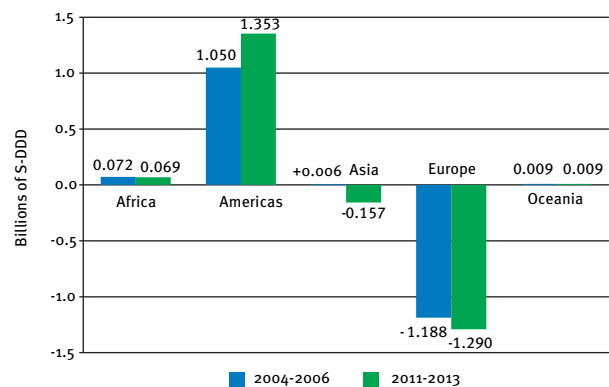
Source: International Narcotics Control Board.

Figure 47. Average annual net imports of diazepam, by region, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

Figure 48. Average annual net imports of lorazepam, by region, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

179. Global manufacture of phenobarbital, which had fluctuated between 7.1 billion S-DDD and 9.7 billion S-DDD during the period 2004-2012, fell to a record low of 3.0 billion S-DDD in 2013. That decrease can be attributed mainly to a substantial decrease in the output of China, the world's leading manufacturer of phenobarbital. Furthermore, the lack of production and production data for 2013 for Hungary and India (two other major manufacturing countries) further exerted downward pressure on reported global supply. As one of the most widely traded psychotropic substances, phenobarbital is traded in an average of 140 countries every year. In 2013, China, Hungary, India and Switzerland (in descending order) together accounted for 89 per cent of total exports, and more than 120 countries reported imports. Major importers included the Russian Federation, Ukraine and the United States.

180. The manufacture of methylphenobarbital, compared with that of phenobarbital, has remained rather limited. During the 2004-2012 period, global manufacture of methylphenobarbital fluctuated considerably, ranging between 0.2 million S-DDD and 438 million S-DDD, mainly because of significant changes in the output reported by India, Switzerland and the United States. In 2013, no manufacture of the substance was reported, and the total volume of international trade remained stable (28.2 million S-DDD).

181. The manufacture and trade of clonazepam, a benzodiazepine that is used mainly as an anti-epileptic, has shown a similar upward pattern over the past 10 years. Global reported manufacture of clonazepam gradually increased from 1.3 billion S-DDD in 2004 to a new record of 3.4 billion S-DDD in 2012, but decreased thereafter to 2.2 billion S-DDD in 2013. That decrease was attributable mainly to the non-reporting of manufacture data for 2013 by India, traditionally a major manufacturer of the substance. While Switzerland was the world's leading manufacturer of clonazepam during the two decades leading up to 2010, Italy took the lead in 2011 and 2012. In 2013, Brazil became the largest manufacturer of the substance, followed by Italy and Switzerland. About 120 countries reported imports of clonazepam in 2013.

## B. Availability of psychotropic substances

182. Conclusions based on the calculated consumption of psychotropic substances should be drawn with caution, as data on manufacture, industrial use, stocks and trade

reported by Governments may not be complete or may not cover all substances. High levels of consumption may, however, indicate overprescription and/or diversion into illicit channels. The system of control provided for in the 1971 Convention is based largely on the system devised for the control of narcotic drugs under the 1961 Convention. The control measures and obligations set out in the 1971 Convention represent the minimum control requirements that Governments must implement and maintain.

183. The degree of availability of psychotropic substances is approximated in the present report by using measures of calculated consumption of individual substances and groups of substances. The 1971 Convention does not foresee reporting on consumption of psychotropic substances to the Board. Therefore, based on statistics reported by Governments on manufacture, industrial use, stocks and international trade, the rates of consumption, measured in S-DDD per 1,000 inhabitants per day, are calculated by the Board every year. For the purposes of the present report, three-year averages were used, in order to account for the occasional non-submission of annual statistics and in view of the practice by some Governments of intermittent manufacture and importing of psychotropic substances when stocks cover domestic requirements for several years.

184. In addition, instances of elevated calculated use of psychotropic substances could relate to increasing manufacture for export, accompanied by a possible lack of reporting of exports and/or a non-reporting of stocks of manufacturers and/or elevated stocks kept by wholesalers.

185. Pursuant to Commission on Narcotic Drugs resolutions 53/4 and 54/6, on promoting adequate availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes while preventing their diversion and abuse, Member States are strongly encouraged to provide the Board, on a voluntary basis, with data on the consumption of psychotropic substances, in the same manner as for narcotic drugs. Those data would be essential in enabling the Board to better analyse trends relating to the consumption of psychotropic substances and, ultimately, to promote the adequate availability of such substances for medical and scientific purposes while preventing their diversion and abuse.

186. Since the adoption of the above-mentioned resolutions, a growing number of Governments have started to submit data on the consumption of psychotropic substances to the Board. However, the total number of Governments supplying the requested information is still too low to be used in lieu of the consumption data as calculated by the Board.