

IV. Psychotropic substances¹¹

A. Supply of psychotropic substances controlled under the 1971 Convention

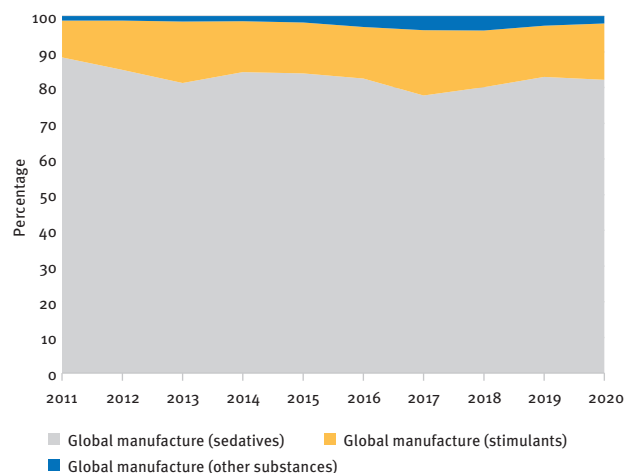
97. The licit international market for internationally controlled psychotropic substances comprises many drugs used to treat a variety of health conditions and disorders. Broadly, the two primary types of substances are sedatives and stimulants. Sedatives is the larger group, comprising sedative-hypnotics, anti-epileptics and anxiolytics, which account for a large number of psychotropic substances under international control and contains the substances most extensively manufactured, traded and consumed. Stimulants is the smaller of the primary categories and comprises amphetamine-type stimulants and other stimulants which are manufactured, traded and consumed in smaller quantities and in fewer countries than sedatives.

98. A number of hallucinogens and psychedelics are also under international control but, as they are included in Schedule I of the 1971 Convention, they are deemed to have limited medical use. Presently, these substances are used in very limited quantities only for scientific and medical research. As such, no hallucinogens or psychedelics are reflected in the analysis of this report.

99. The licit market for internationally controlled psychotropic substances has historically been and continues to be dominated, in terms of gross weight, by sedatives, in particular those from the benzodiazepine and barbiturate substance families. As can be seen in figure 27, sedatives comprised more than 80 per cent of the manufacture of all internationally controlled psychotropic substances from 2011 to 2020, except in 2017, when it dipped to 77.8 per cent. In the same period, stimulants comprised 10 to 18 per cent of all manufacture. Other psychotropic substances have

never exceeded a 4 per cent share of total global manufacture in that time frame.

Figure 27. Proportion of total manufacture of internationally controlled psychotropic substances, by substance type, 2011–2020

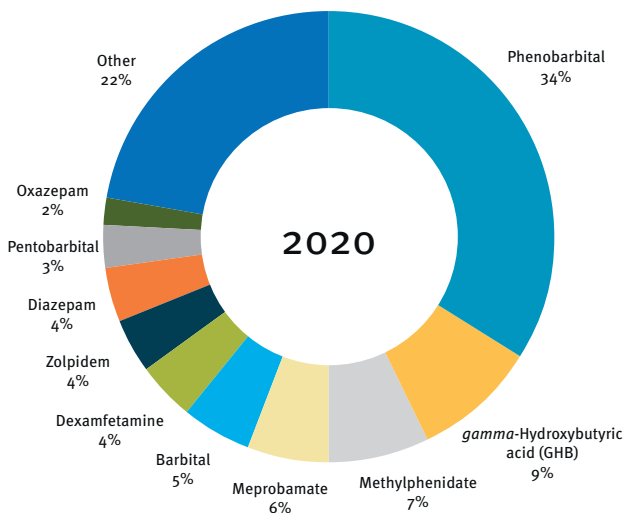


Source: International Narcotics Control Board.

100. A deeper look into manufacture data for the period 2011–2020 reveals that 10 psychotropic substances accounted for a large majority of all manufacture during that period. For 2020, phenobarbital, *gamma*-hydroxybutyric acid (GHB), methylphenidate, meprobamate, barbital, dexamphetamine, zolpidem, diazepam, pentobarbital and oxazepam accounted for 78 per cent of all global manufacture of internationally controlled psychotropic substances, in terms of gross weight, with all other substances (as contained in all four schedules of the 1971 Convention), accounting for 22 per cent of manufacture (see figure 28). Phenobarbital alone accounted for 34 per cent of all manufacture, by gross weight, of psychotropic substances.

¹¹ The latest data available at the time of writing of this report were for 2020. Since then, data for 2021 have been received and are available in the technical report of the Board for 2022 on psychotropic substances (E/INCB/2022/3).

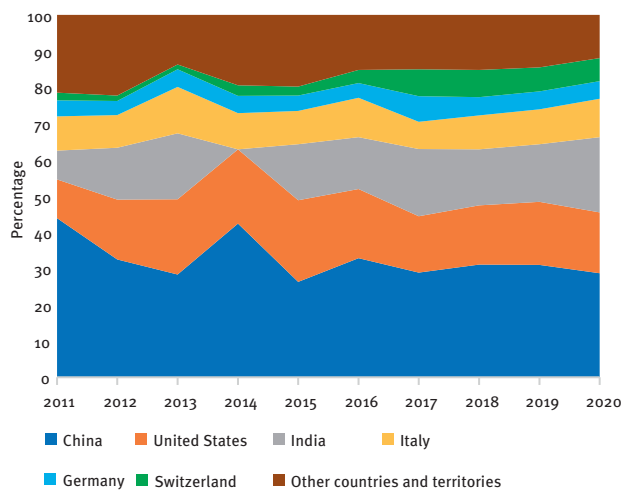
Figure 28. Proportion of manufacture, for select psychotropic substances, 2020



Source: International Narcotics Control Board.

101. Most of the global supply of internationally controlled psychotropic substances comes from a handful of countries. Since 2010, the manufacture of psychotropic substances, in terms of gross weight, has been led by China, Germany, India, Italy, Switzerland and the United States. In 2020, those countries manufactured over 831 tons of internationally controlled psychotropic substances, approximately 88 per cent of the 943.4 tons of psychotropic substances manufactured that year (see figure 29). Consequently, these countries are also the lead exporters of psychotropic substances providing a majority of the world's supply of these substances. For 2020, these countries exported 546.1 tons of psychotropic substances, approximately 72 per cent of the 762.2 tons exported globally.

Figure 29. Proportion of total manufacture of internationally controlled psychotropic substances among top manufacturers, 2011–2020



Source: International Narcotics Control Board.

102. Among the top six manufacturing countries, the specific psychotropic substances predominantly being manufactured varies significantly by country. Between 2011 and 2020, China led global manufacture of phenobarbital and other barbiturates, and India being the other main manufacturer of phenobarbital. In that same period, the United States led in the manufacture of methylphenidate, amphetamine and dexamphetamine, while India and Italy led in overall manufacture of many benzodiazepines. Switzerland led in the manufacture of GHB, while Germany led in the manufacture of phentermine and pentobarbital.

B. Determining adequate needs for psychotropic substances

103. Unlike the 1961 Convention as amended, the 1971 Convention does not include a system of estimates whereby countries provide data on their annual medical and scientific requirements for an internationally controlled psychotropic substance. It was only after the 1971 Convention had entered into force that the international community determined that a global system was necessary for countries to indicate their annual needs for psychotropic substances.

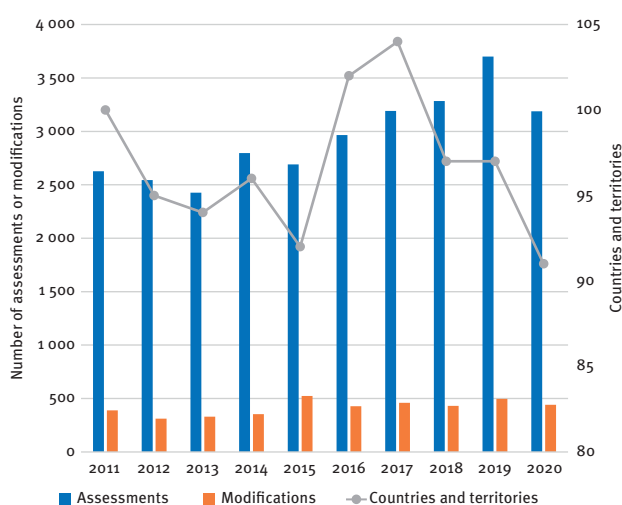
104. In its resolutions 1981/7 and 1991/44, the Economic and Social Council invited countries to communicate to the Board from time to time their assessments of annual and medical scientific requirements for substances listed in Schedules II, III and IV of the 1971 Convention. Like estimates with internationally controlled narcotic drugs, the Board disseminates the information regarding assessments on psychotropic substances to countries on a regular basis.

105. Since the adoption of the assessment system, the Board has been advising countries that they should provide to the Board updated assessments of their annual licit requirements for psychotropic substances at least every three years. Additionally, countries are invited to submit modifications of their assessment for a specific substance as required, for example, if their need for a substance exceeds a previously established assessment. Once set, the assessed quantity of a psychotropic substance does not expire and carries over from year to year unless updated by the respective country or territory.

106. Broadly speaking, nearly all countries and territories regularly provide updated assessments to the Board within the suggested three-year time frame or modify existing assessments. Between 2011 and 2020, at least 91 countries and territories provided updated assessments or modifications to assessments each year with a high of 104 countries in 2017 (see figure 30). One hundred and

ninety-seven countries and territories have provided assessments for psychotropic substances at least once during that 10-year period, which reflects near universal adherence by countries and territories to the assessment system. Not reflected in the figure is that in 2011 the Board established assessments for psychotropic substances on behalf of South Sudan following that country's independence.

Figure 30. Annual number of assessments and modifications submitted compared with number of countries and territories submitting at least one modification or assessment, 2011–2020



Source: International Narcotics Control Board.

107. It must be underscored that the assessment system is flexible. Modifications to existing assessments do not require approval of the Board before being published. This allows countries and territories to rapidly respond to changes in their domestic needs for psychotropic substances. This is reflected in figure 30, which shows how countries and territories submit several hundred modifications to their assessments each year.

108. The quantity of a specific psychotropic substance that a country assesses is, in fact, an aggregate value relating to several specific needs. For example, a country that assesses that it needs 1,000 kg of phenobarbital annually may have determined that quantity because it intends to manufacture that entire quantity to meet domestic demand. Conversely, another country may assess that it needs 500 kg of methylphenidate because it intends to import that full quantity for

domestic consumption as it is unable to manufacture the substance itself. It is important to underscore that the assessment system does not take into account consumption.

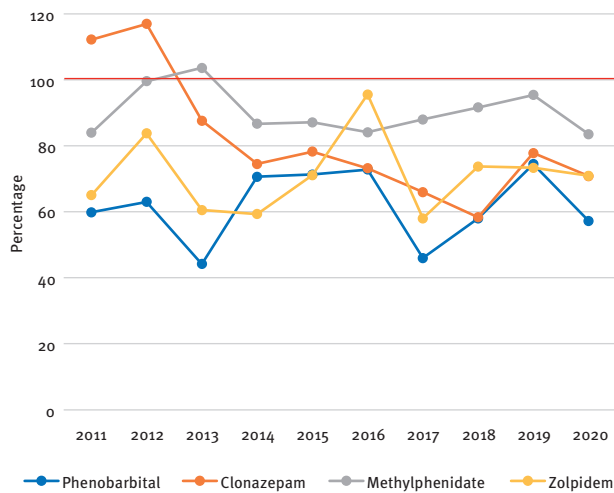
Assessments and licit use of select psychotropic substances (2011–2020)

109. As there are 167 psychotropic substances under international control, an extensive analysis of a decade's worth of data is not practicable in this publication. However, a select few psychotropic substances, with different therapeutic uses, account for a large portion of licit activity in the international market and are generally representative of assessment trends for psychotropic substances. Phenobarbital, a barbiturate, is one of the most extensively manufactured and traded internationally controlled psychotropic substances and is used to treat several types of epilepsy and seizures. Clonazepam, a benzodiazepine, is another widely traded substance mostly used for the treatment of seizures. Methylphenidate is the most widely traded internationally controlled psychotropic stimulant and used for the treatment of attention deficit hyperactivity disorder (ADHD) and, in some cases, narcolepsy. Zolpidem is a non-barbiturate non-benzodiazepine sedative-hypnotic that is widely used for the treatment of insomnia.

110. Determining if the assessed quantity of a particular psychotropic substance meets the actual need of countries is challenging given how the assessment system functions and the lack of consumption data to gauge how much of a substance is actually used. The quantity being assessed for a substance is calculated by countries based on their specific needs for a substance, including manufacture, imports and utilization for the manufacture of other psychotropic and non-psychotropic substances. In principle, the total quantity of those needs for a substance, based on reported statistical data, should not exceed the established assessment.

111. For the four select psychotropic substances, their gross annual assessment is represented by the red line designating 100 per cent in figure 31 below. As can be seen, the aggregate licit use – manufacture, imports and utilization for manufacture of non-psychotropic and other psychotropic substances – reported by countries of clonazepam exceeded its global assessment in 2011 and 2012, which was also the case for methylphenidate in 2012 and 2013.

Figure 31. Proportion of total licit use of select psychotropic substances relative to their aggregate global assessments, 2011–2020



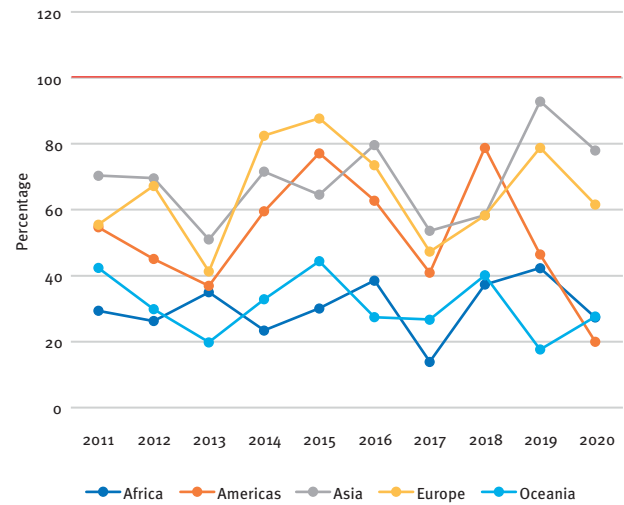
Source: International Narcotics Control Board.

112. Since 2014, the total licit use of the four select psychotropic substances did not exceed their respective aggregate global assessment. In fact, countries have used no less than 84 per cent of the aggregate global assessment for methylphenidate from 2011 to 2020. Usage levels of clonazepam, phenobarbital and zolpidem have varied significantly during the same time period. The highest rate of use of phenobarbital relative to its aggregate global assessment was 74 per cent in 2019 but under 50 per cent in 2013 and 2017.

113. With respect to phenobarbital in particular, a regional breakdown on the proportion of the assessment used reveals some additional trends. Although the proportion of the amount assessed used fluctuates for all regions from 2011 to 2020 (see figure 32), both Africa and Oceania are consistently around 40 per cent or lower. This difference between regions regarding the proportion of how much an assessment is used also extends to clonazepam, methylphenidate and zolpidem.

114. It is difficult to draw conclusions based on these data. As the calculation of an assessment is not based directly on the consumption of a specific substance, it is difficult to know if an assessment reflects a country's actual need. In any case, the ideal assessment use rate should track as close to 100 per cent as possible without going over. Using less than the entire amount in the assessment for a psychotropic substance does not necessarily indicate that the needs in the region or a particular country are not being met. In some cases, it may simply be necessary for countries to more

Figure 32. Proportion of total licit use of phenobarbital relative to its aggregate regional assessment, 2011–2020



Source: International Narcotics Control Board.

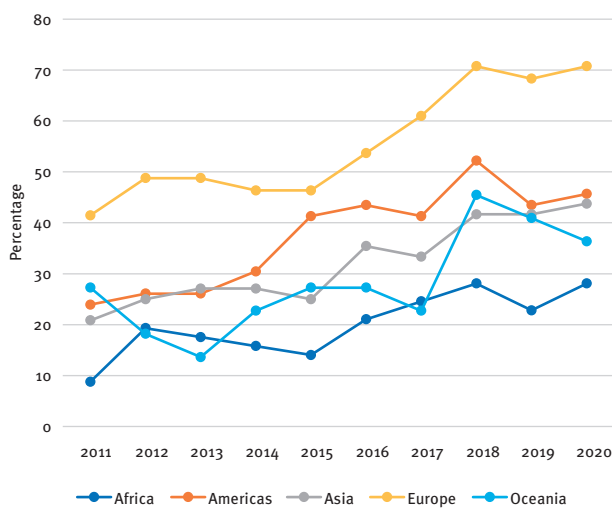
carefully evaluate their assessments and update the Board as necessary. On the other hand, a lack of statistical reporting by countries adversely affects the accuracy of what quantity of an assessment is used. For example, the sharp decline in use for the Americas in 2020, as seen in figure 32, is due to key countries in the region not having provided their statistical reports for that year.

C. Availability of psychotropic substances

1. Consumption data and psychotropic substances

115. A key challenge in determining the availability of psychotropic substances for medical and scientific purposes is that the 1971 Convention does not mandate the States parties to provide consumption data as part of their annual statistical reports. Acknowledging that this data gap hinders the ability of the Board and the international community to determine adequate levels of availability for psychotropic substances, the Commission on Narcotic Drugs adopted resolution 54/6 of 2011, in which it encouraged Member States to provide consumption data in their annual statistical reports on psychotropic substances. Since the adoption of that resolution, a growing number of countries have been providing those data, reaching a high of 99 countries and territories in 2018. Ever since, nearly half of all countries and territories include consumption data on psychotropic substances as part of their annual statistical report.

Figure 33. Percentage of countries and territories reporting consumption data, by region, 2011–2020



Source: International Narcotics Control Board.

116. The growing number of countries and territories providing consumption data is encouraging, but the lack of data, in particular from less developed countries, makes it difficult to have a complete picture at the global level regarding the availability of psychotropic substances for medical and scientific purposes. This can be seen when looking at submissions by region. From 2011 to 2020, Europe has led in having the highest proportion of countries and territories that submit consumption data, as 71 per cent of all countries and territories in the region provide consumption data (see figure 33). With the exception of the Americas in 2018, no other region has had more than half of their countries and territories provide consumption data as part of their annual statistical report during the same time period.

117. Despite the reporting gap between regions, consumption data provide the most accurate picture regarding the medical and scientific use of psychotropic substances in a country or territory.

2. Availability of select psychotropic substances (2011–2020)

118. While considerable progress has been made since 2018 in quantifying the level of availability of psychotropic medicines, much less has been done in identifying the

underlying reasons for low or high availability and measuring the impact of different levels of availability. Regulatory control is often cited as a factor contributing to the low availability of psychotropic medicines, but more studies are required to determine whether regulatory control does in fact hamper the availability of psychotropic medicines (and if it does, to what extent), alongside other factors such as the low rate of diagnosis of the corresponding mental health conditions and the stigma associated with use of psychotropic substances.

119. Focusing on the changes in the availability of psychotropic medicines over time and comparing such changes in countries with varying income levels, Brauer and others, in their 2021 study,¹² gathered and analysed the pharmaceutical sales data for psychotropic medicines from 65 countries over a 12-year period (2008–2019). The study concluded that sales of psychotropic medicines increased from 28.54 defined daily doses (DDD) per 1,000 inhabitants per day in 2008 to 34.77 DDD per 1,000 inhabitants per day in 2019, representing a 4.08 per cent relative average annual increase. While the absolute annual increase was greater in higher-income countries than in upper-middle-income and low-middle-income countries, the relative average annual increase was greater in upper-middle-income countries (7.88 per cent) than in lower-middle-income countries (2.90 per cent) and high-income countries (1.02 per cent). In 2019, the highest volume of sales per capita of all classes of psychotropic medicines was in North America (167.54 DDD per 1,000 inhabitants per day), and the lowest volume of sales was in Asia (5.59 DDD per 1,000 inhabitants per day). Among 65 countries included in the study, 17 countries had very low consumption of psychotropic medicines in 2019, including some high-income countries and countries with a high prevalence of mental disorders.

120. Other studies have focused on measuring the level of availability of different psychotropic medicines in low-income settings. Sengxeu and others, in their 2020 study,¹³ assessed the availability, affordability and quality of long-term anti-epileptic drugs in Lao People's Democratic Republic. Of all the outlets that researchers visited in the three main provinces, only one in every five had at least one anti-epileptic drug available, and the level of availability in urban areas (24.9 per cent) was considerably different from rural areas (10.0 per cent). Phenobarbital (in tablets of 100 mg) was the most available medication (14.3 per cent), followed by non-controlled substances such as sodium valproate in 200 mg tablets (9.7 per cent), phenytoin in 100 mg tablets (9.7 per cent) and carbamazepine in 200 mg

¹² Brauer and others, "Psychotropic medicine consumption in 65 countries and regions, 2008–19: a longitudinal study", *The Lancet Psychiatry*, vol. 8, No. 12 (December 2021), pp. 1071–1082.

¹³ Sengxeu and others, "Availability, affordability, and quality of essential antiepileptic drugs in Lao PDR", *Epilepsia Open*, vol. 5, No. 4 (December 2020), pp. 550–561.

tablets (8.9 per cent). Possible reasons for the low availability of anti-epileptic drugs include the strict regulatory control of psychotropic and narcotic substances at the national and international levels, the lack of regular assessment of the current need for anti-epileptic drugs, low rates of diagnosis and the uneven distribution of delivery structures between urban and rural areas.

121. Ongarora and others, in their 2019 study,¹⁴ assessed the retail pricing, availability and affordability of medicines in private health-care facilities in low-income settlements in Nairobi County, Kenya. Based on data on the availability of medicine from 45 private health-care facilities in 14 low-income settlements of Nairobi covering the period from September to December 2016, it was found that medicine availability in the facilities ranged between 2 per cent and 76 per cent. Among all medicines, two non-controlled anti-depressants, fluoxetine and amitriptyline, had very low availability.

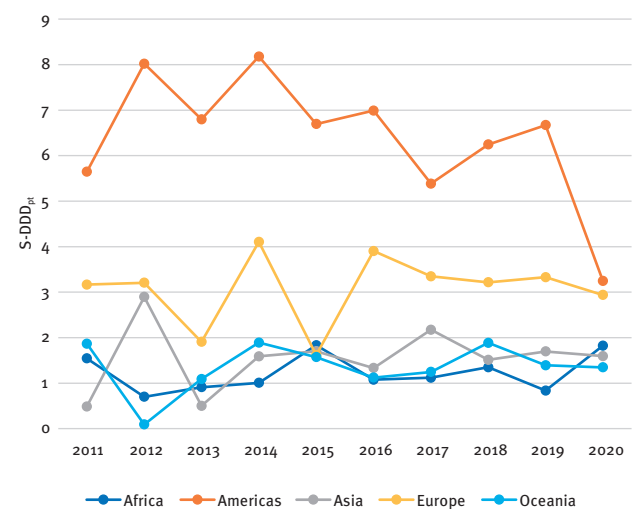
122. As for the data presented below, they are as reported by countries in their annual statistical report to the Board and converted to S-DDD per 1,000 inhabitants per day (S-DDD_{pt}). As a point of reference, an S-DDD_{pt} value of 1 indicates that 0.1 per cent of the population of a country is able to receive a dose of the substance in question each day. It should be noted that the defined daily dose (DDD) values for psychotropic substances are solely for analytical purposes and do not necessarily represent the actual clinical dose for a substance administered to a patient.¹⁵ Regional consumption averages are based only on the data and number of countries that reported consumption data from the given region for that year.

Anti-epileptics (clonazepam and phenobarbital)

123. As clonazepam and phenobarbital are commonly used for the treatment of persons with epilepsy or seizures a combined analysis of their consumption as anti-epileptics can be done. A regional comparison of the consumption trends of these substances – from countries that provided consumption data – for the period 2011–2020 is presented in figure 34. A few trends become immediately apparent, the first being the difference between the level of consumption in the Americas and the level in the other regions. The sharp drop in consumption for the Americas in 2020 is due

to a lack of data from Brazil, which is generally a very high per capita consumer of phenobarbital. European consumption fluctuated in the earlier part of the decade but has been consistent in the last several years, staying around 3.0 S-DDD_{pt}. Finally, consumption levels in Africa, Asia and Oceania are consistently low, relative to the other regions, with only Asia exceeding 2.0 S-DDD_{pt} in 2012 and 2017.

Figure 34. Consumption of select anti-epileptics (clonazepam and phenobarbital) in defined daily doses for statistical purposes per thousand inhabitants per day, by region, 2011–2020



Source: International Narcotics Control Board.

124. According to WHO, more than 50 million people worldwide have epilepsy, and nearly 80 per cent of those people live in low- and middle-income countries. Three quarters of those that live in low-income countries do not receive the treatment they need.¹⁶ This correlates to the comparatively low levels of consumption of clonazepam and phenobarbital in Africa and Oceania as seen in figure 34. However, as there is no benchmark for the adequate consumption of clonazepam or phenobarbital, it is not possible to determine how much these regions are falling short in terms of how much of these substances is needed to treat patients with epilepsy.

125. Within the regions, there are also significant disparities in the consumption of clonazepam and phenobarbital. For example, in Africa, Burkina Faso reported 11.84 S-DDD_{pt} consumed in 2020, the highest value worldwide for that year, with Kenya reporting

¹⁴Ongarora and others, "Medicine prices, availability, and affordability in private health facilities in low-income settlements in Nairobi County, Kenya", *Pharmacy*, vol. 7, No. 2 (April 2019), p. 40.

¹⁵DDD values for internationally controlled psychotropic substances can be found in Table III of the Board's technical report *Psychotropic Substances: Statistics for 2020 – Assessments of Annual Medical and Scientific Requirements for Substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971 (E/INCB/2021/3)*.

¹⁶WHO, Newsroom, Fact sheets, "Epilepsy", 9 February 2022. Available at www.who.int/en/news-room/fact-sheets/detail/epilepsy.

2.1 S-DDD_{pt}. Four other countries in Africa reported between 1 and 2 S-DDD_{pt} consumed and nine other countries less than 1 S-DDD_{pt}. Similar ranges of disparity occur in the Americas, Asia and Oceania. In Europe, there is less disparity among countries regarding the consumption of clonazepam and phenobarbital in 2020, with most countries reporting consumption above 2 S-DDD_{pt}.

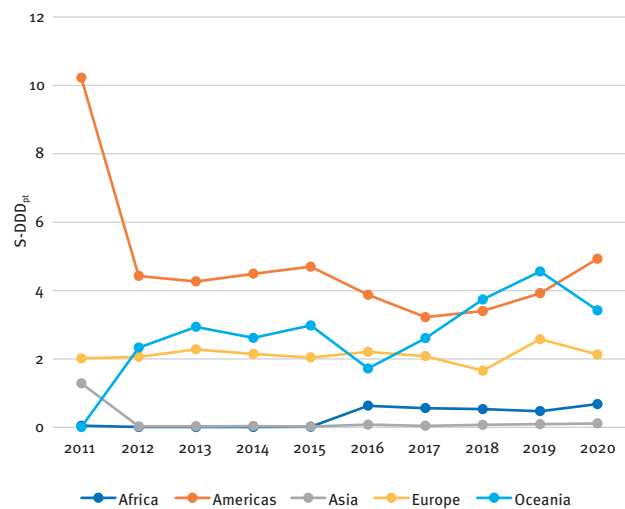
126. It should also be noted that epilepsy can be treated with substances other than clonazepam and phenobarbital. Diazepam, lorazepam and midazolam are also used to treat epilepsy and seizure-related disorders but have much broader applications, and in some countries, they are not considered as a first-line treatment for the management of epilepsy. The low levels of consumption in some regions as shown in figure 34 do not necessarily point to a lack of medication for people affected by epilepsy. Conversely, a higher rate of consumption does not necessarily mean that needs for medication to treat epilepsy in a particular region or country are being met.

Methylphenidate

127. Although there are several international psychotropic substances under international control that are used to treat ADHD, methylphenidate is the most widely traded. Some amphetamine-type stimulants are also used to treat ADHD, but the licit market for those substances is limited to a small group of countries. Figure 35 presents the regional trends in consumption of methylphenidate, among countries that provided consumption data, from 2011 to 2020.

128. Consumption of methylphenidate has been the highest in the Americas, with Canada and the United States accounting for most of the consumption in the region. For 2020, Canada reported consumption of 9.26 S-DDD_{pt}, while the United States reported 7.5 S-DDD_{pt}. Consumption in Oceania has risen since 2016 because consumption has grown in New Zealand: that country reported 3.58 S-DDD_{pt} consumed in 2020. Consumption levels in Europe have been the most stable, typically around 2 S-DDD_{pt}, although Iceland has consistently had the world's highest per capita consumption of methylphenidate for many years, varying between 20.9 S-DDD_{pt} and 34.2 S-DDD_{pt} since 2016. Consumption in Asia is very low, with Israel accounting for

Figure 35. Consumption of methylphenidate in defined daily doses for statistical purposes per thousand inhabitants per day, by region, 2011–2020



Source: International Narcotics Control Board.

most consumption in the region. Similarly, in Africa, consumption is also very low, with South Africa accounting for nearly all consumption.

129. Sufficiently granular prevalence data regarding the number of people affected by ADD and ADHD are not readily available in order to determine if consumption levels in each region are sufficient to treat people with that condition. A 2020 study estimated an ADHD prevalence rate of 7.47 per cent in children and adolescents in Africa.¹⁷ A 2013 study estimated a prevalence rate of ADHD of 4.6 per cent among children and adolescents in Europe and a 5.3 to 5.9 per cent prevalence rate globally.¹⁸ A 2018 study found that the prevalence of ADHD among children in China and Hong Kong, China, to be 6.5 per cent and 6.4 per cent, respectively,¹⁹ while the United States Centers for Disease Control and Prevention estimated an ADHD prevalence rate for 2018 of 9.8 per cent in 2018 among children and adolescents in that country.²⁰

130. As with other conditions, a number of treatment protocols, aside from methylphenidate, are available for people with ADD and ADHD. Nonetheless, because many regions and countries have comparable prevalence rates of

¹⁷ Ayano Getinet, Yohannes Kalkidan and Mebratu Abraha, "Epidemiology of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents in Africa: a systematic review and meta-analysis", *Annals of General Psychiatry*, vol. 19 (2020).

¹⁸ Hoa H. Le and others, "Economic impact of childhood/adolescent ADHD in a European setting: the Netherlands as a reference case", *European Child and Adolescent Psychiatry*, vol. 23, No. 7 (July 2014), pp. 587–598.

¹⁹ Anni Liu and others, "The prevalence of attention deficit/hyperactivity disorder among Chinese children and adolescents", *Scientific Reports*, vol. 8, art. 11169 (August 2018).

²⁰ United States, Centers for Disease Control and Prevention, Data and statistics, "ADHD throughout the years". Available at www.cdc.gov/ncbddd/adhd/timeline.html.

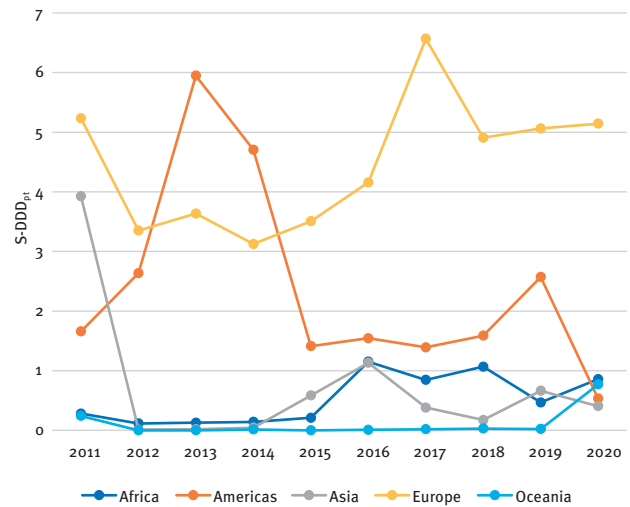
ADD and ADHD, the differences between regions in consumption levels reflect either gaps in treatment, alternative treatment protocols or other inhibitors to access of methylphenidate. For example, some countries have invoked article 13 of the 1971 Convention banning the importation of methylphenidate into their territory.

Zolpidem

131. Zolpidem is one of the most widely traded and used psychotropic substances under international control. In 2020, over 120 countries and territories in all regions report importing the substance. Zolpidem is used for the short-term treatment of insomnia or other sleeping problems when cognitive behavioural therapy and other non-pharmaceutical approaches have been tried. Flunitrazepam and GHB, both psychotropic substances under international control, are also used for treatment of sleeping disorders in some cases but are manufactured and traded among a much smaller number of countries than zolpidem. Figure 36 presents the regional trends in consumption of zolpidem, among countries that provided consumption data, from 2011 to 2020.

132. Levels of consumption of zolpidem vary widely between the regions. Europe has led in consumption since 2015, sustaining rates well above 4 S-DDD_{pt}. Consumption in the Americas has been on the decline, particularly in 2015 as consumption levels in Canada dropped significantly. The sharp drop in consumption for the Americas in 2020 is due

Figure 36. Consumption of zolpidem in defined daily doses for statistical purposes per thousand inhabitants per day, by region, 2011–2020



Source: International Narcotics Control Board.

to a lack of data from Brazil, another major consumer of the drug in the region. Consumption in Africa and Asia has grown since 2014 although neither region has reported more than 1.15 S-DDD_{pt}. Consumption in Oceania has been very low and for many years never exceeded 0.02 S-DDD_{pt}. Australia and New Zealand do not report consumption of zolpidem. Consumption rose in 2020 owing to consumption data on zolpidem being reported in New Caledonia for the first time.