



INTERNATIONAL NARCOTICS CONTROL BOARD



Availability of Internationally Controlled Drugs:
**Ensuring Adequate Access for
Medical and Scientific Purposes**

*Indispensable, adequately available
and not unduly restricted*



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Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes. Indispensable, adequately available and not unduly restricted (E/INCB/2015/1/Supp.1)

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Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances: Report of the International Narcotics Control Board for 2014 on the Implementation of Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (E/INCB/2015/4)

The updated lists of substances under international control, comprising narcotic drugs, psychotropic substances and substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances, are contained in the latest editions of the annexes to the statistical forms (“Yellow List”, “Green List” and “Red List”), which are also issued by the Board.

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Preface

Several decades ago, the international community made a solemn commitment with the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol¹ and the Convention on Psychotropic Substances of 1971:² to make adequate provision to ensure, and not to unduly restrict, the availability of drugs that were considered indispensable for medical and scientific purposes. In recent decades, that promise has not been completely fulfilled. Too many people still suffer or die in pain or do not have access to the medications they need. Unnecessary suffering resulting from a lack of appropriate medication due to inaction and excessive administrative requirements is a situation that shames us all.

Around 5.5 billion people still have limited or no access to medicines containing narcotic drugs, such as codeine or morphine, leaving 75 per cent of the world population without access to proper pain relief treatment. Around 92 per cent of morphine used worldwide is consumed in countries in which only 17 per cent of the world population lives: primarily the United States of America, Canada, Western Europe, Australia and New Zealand. Inadequate access contradicts the notion of article 25 of the Universal Declaration of Human Rights,³ including the right to medical care, which also encompasses palliative care.

The imbalance in the availability of opioid analgesics is particularly worrying, as the latest data show that many of the conditions that require pain management, particularly cancer, are prevalent and increasing in low- and middle-income countries.⁴ At the same time, in recent years there has been an increase in the abuse of prescription drugs and related overdose deaths in countries with high per capita levels of consumption of opioid analgesics.

Apart from the needs related to cancer, pain treatment is required for many other health conditions. In several regions of the world, pain relief drugs are not commonly prescribed. Other internationally controlled drugs such as methadone and buprenorphine are used in the management of drug dependence, but their use is also limited in some countries despite a considerable prevalence of heroin abuse.

In addition to narcotic drugs, the present report also discusses the availability of psychotropic substances controlled under the 1971 Convention. There are significant concerns regarding the consumption and accessibility of these substances, which are necessary in the treatment of a range of serious health conditions. According to the World Health Organization (WHO), mental disorders afflict hundreds of millions of people and their families, but the resources available in most countries to treat such conditions are insufficient. The vast majority of countries allocate less than 2 per cent of their health budgets to mental health, leaving more than 75 per cent of the population in many low- and middle-income countries with no access to such treatment. Insufficient attention has been devoted to this problem. Levels of consumption of psychotropic substances, which are used for the treatment of mental and neurological disorders, such as anxiety, insomnia and epilepsy, continue to vary widely among countries and regions. This reflects on the one hand a diversity in medical practice and related variations in prescription patterns, and on the other hand a lack of accurate data, both quantitative and qualitative, on the consumption of such substances.

Addressing the discrepancy in the availability of narcotic drugs and psychotropic substances for medical and scientific purposes is one of the obligations of Governments in complying with the international drug control conventions. In 1961, the international community committed to

¹United Nations, *Treaty Series*, vol. 976, No. 14152.

²*Ibid.*, vol. 1019, No. 14956.

³General Assembly resolution 217 A (III).

⁴World Health Organization and Worldwide Palliative Care Alliance, *Global Atlas of Palliative Care at the End of Life* (Worldwide Palliative Care Alliance, 2014).

making adequate provision to ensure the availability of narcotic drugs for the relief of pain and suffering. At the same time, parties to that Convention recognized the problem of addiction to narcotic drugs. Both of those principles were set forth in the preamble to the Single Convention. This dual responsibility is at the centre of the discussion that Member States are currently having on the achievements and future prospects of the international drug control system.

Equally, the parties to the 1971 Convention, while expressing a determination to prevent and combat abuse of and trafficking in psychotropic substances, recognized that the use of such substances for medical and scientific purposes was indispensable and that their availability for such purposes should not be unduly restricted.

The Board has raised the issue of availability on various occasions in its history. It devoted special reports to that topic in 1989, 1995 and 2010. The 2010 report⁵ contained a number of recommendations based on the information provided by Member States. These recommendations focused on the availability of narcotic drugs and psychotropic substances, appropriate use, national control systems and the prevention of diversion and abuse.

The inequitable use of opioid analgesics does not seem to be attributable to a lack of raw materials. Global production of opiate raw materials has exceeded global demand for many years. As a result, stocks have been increasing, albeit with some fluctuation. Over the past 20 years, global consumption of opioids has more than tripled. Available data indicate that the amount of opiate raw material that is available for the manufacture of narcotic drugs for pain relief is more than sufficient to satisfy the current level of demand as estimated by Governments. For psychotropic substances, the issue of supply is more complex. That topic is addressed in detail in the chapter devoted to those substances.

Impediments and barriers that can adversely affect availability include regulatory, attitudinal, knowledge-related, economic and procurement-related factors. In 2010, the impediments most often cited by countries were concerns about addiction, reluctance to prescribe or stock, and insufficient training for health professionals. Unduly restrictive laws and burdensome regulations were also commonly perceived as playing a significant role in limiting the availability of opioids. A smaller number of Governments reported that difficulties involving distribution, supply and the cost of opioids were major obstacles to making opioids adequately available.

To assist Governments, INCB decided to prepare the present report on availability five years after the one published in 2010. It has been prepared with inputs from various stakeholders. Member States received a questionnaire in 2014, and more than 100 countries responded, providing valuable information on policies and practices at the national level. Intergovernmental organizations such as WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the United Nations Office on Drugs and Crime (UNODC) have been consulted and have offered relevant data and information to complement those available to INCB. Various civil society organizations representing patients, families, health professionals and other stakeholders have also contributed data and information, and offered their views. In addition, a number of researchers have provided relevant analyses and insights.

The analysis of the latest data on consumption of narcotic drugs shows that, despite the persistence of serious inequalities, there has been significant progress with regard to the availability of opioid analgesics for medical purposes. The data show measurable increases in the average amount of opioid analgesics consumed during the 2011-2013 period compared with the 2000-2003 period. In addition, in comparing the responses provided by Member States in the surveys that were carried out in 1995, 2010 and 2014, it emerges that concerns about the risk of addiction and legislative

⁵*Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes* (E/INCB/2010/1/Supp. 1).

impediments are becoming less relevant and that countries believe that it is necessary to address other key impediments such as lack of training and education, streamlining of supply, costs and limited financial resources.

These data confirm that it is possible, within the framework of the international conventions, to improve the availability of internationally controlled drugs. To achieve this, it is important to have sensible and rational national legislation that both ensures that medicines are available to patients and also protects their health, with health professionals trained in responsible and rational prescribing and aware of the risk of overprescription and abuse.

The data related to psychotropic substances show disparities among countries and regions in the levels of consumption of such substances. Inadequate availability and poor access to necessary medical treatment, as well as excessive availability and medically unsound use of psychotropic substances, all pose challenges to their control and use.

The Board is presenting this special report to Member States in the hope that the analysis and recommendations presented therein may assist them in the development of national policies and control systems that are capable of achieving the goals of the international drug control conventions in relation to ensuring availability of narcotic drugs and psychotropic substances. Member States have already underlined the importance of this issue in a number of resolutions and political declarations adopted by the Commission on Narcotic Drugs. They also referred to it in the Political Declaration of the High-Level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases⁶ and in resolution WHA67.19 of the World Health Assembly, on strengthening of palliative care as a component of comprehensive care throughout the life course.⁷ Furthermore, the present report is being offered to the international community ahead of the special session of the General Assembly on the world drug problem to be held in 2016, and the Board hopes that this contribution will help Member States in their deliberations. At a time when countries are discussing the achievements of the international drug control system, the Board would like to offer a reminder that the overall goal of the international drug control conventions is a well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances by ensuring the safe and rational delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of such drugs for the purpose of abuse.



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International Narcotics Control Board

⁶General Assembly resolution 66/2.

⁷Available from http://apps.who.int/gb/e/e_wha67.html.

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*The annex is not included in the printed version of the present report but is available on the website of the International Narcotics Control Board (www.incb.org).

Executive summary

Indispensable and adequately available for medical and scientific purposes: those two fundamental principles were set forth in the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Later, psychotropic substances were also recognized as being indispensable for medical and scientific purposes. In the Convention on Psychotropic Substances of 1971, Parties further recognized that the availability of such substances should not be unduly restricted.

The present supplement to the annual report of the International Narcotics Control Board (INCB) for 2015 analyses global access to narcotic drugs and psychotropic substances. It also reviews patterns and trends relating to consumption, as well as information provided by Member States on the policies and practices at the country level for ensuring the availability of these controlled substances, and the impediments thereto.

The 1961 and 1971 Conventions indicate the primary interest of the international community in protecting the health and welfare of humankind by making these indispensable substances available for medical and scientific purposes while ensuring that there is no diversion or abuse. The conventions established a control regime to serve this dual purpose. After several decades since their entry into force, this essential element of the conventions is far from being achieved globally. The importance of making these substances available for those who need them is also highlighted in international human rights instruments and in a series of resolutions of the Commission on Narcotic Drugs, the World Health Assembly and regional intergovernmental organizations.

Over the years, INCB has pointed out to Member States the importance of this significant aspect of the international drug control system. In 2010, INCB launched a report entitled *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*, which analysed the global situation with regard to the consumption of internationally controlled substances. Similar reports had been produced in 1989 and 1995. In 2010, the scope of the report was broadened to include psychotropic substances. Five years on, the Board is reviewing the situation and providing Member States and the international community with an update and a series of recommendations to address the problem of availability of narcotic drugs and psychotropic substances.

Narcotic drugs

Opioid analgesics like morphine are indispensable for the treatment of pain caused by cancer, HIV/AIDS, cardiovascular disease, chronic respiratory disease, diabetes, childbirth, surgery, injuries and other conditions or situations. INCB estimates that 92 per cent of morphine is consumed in countries in which only 17 per cent of the world population lives (United States, Canada, countries in Western Europe, Australia and New Zealand). At the same time, 75 per cent of the world population, predominantly in lower-income countries, is left with limited or no access to proper pain relief. The increase in global consumption of opioid analgesics since 1991 seems to have been driven mainly by North America, Europe, Australia and New Zealand, where there has been growing concern about prescription drug abuse.

Low levels of consumption of opioid analgesics in some countries and regions does not seem to be the result of a lack of supply of opiate raw materials and opioids. Data available to INCB indicate that global demand is fully met—and, based on submitted estimates, is expected to continue to be met—by the global production of opiate raw materials, the increasing manufacture of narcotic drugs, and growing stocks.

Despite some progress, levels of opioid consumption continue to be low in Africa, Asia, Central America and the Caribbean, and parts of South America, Eastern and South-Eastern Europe and some small island States in Oceania. Looking at the prevalence of health conditions requiring

palliative care, it becomes apparent that these widespread conditions are often not matched by an adequate opioid treatment and palliative care infrastructure. Measuring the levels of consumption of opioid analgesics against cancer rates reveals insufficient consumption in parts of Africa, Asia, Central America and the Caribbean, Eastern and South-Eastern Europe and some small island States in Oceania. Inadequate opioid availability to treat pain related to AIDS seems to be pronounced in sub-Saharan African and Asian countries. In addition, even in the presence of high levels of national consumption, access for some sectors of the population (rural and poor communities) may be impaired by the limited provision of palliative care services.

The impediments to availability that were most frequently identified by Member States included a lack of training/awareness among medical professionals, fear of addiction, limited financial resources, problems in sourcing, cultural attitudes and fear of diversion. A comparison with data from previous INCB surveys reveals that mentions of fear of addiction and onerous regulations as barriers had declined considerably since 1995.

Inadequate awareness and training of health-care professionals with regard to pain and pain relief, rational prescribing and the safe use of opioid analgesics can lead to such substances being insufficiently prescribed and administered. Fear of addiction seems to be related to a lack of awareness and training, and cultural attitudes. Access is determined not only by physical availability and practical accessibility, but also by affordability. Limited resources can impair the capacity of Governments to provide or subsidize drugs and of patients to afford them. Also, drug prices might be high due to costs arising from regulation, licensing, taxation, import, poor distribution systems, lack of public reimbursement and insufficient availability of inexpensive formulations. Manufacturers and importers/exporters may not produce or trade affordable formulations of internationally controlled drugs when they perceive such formulations to be insufficiently profitable. Finally, inadequate estimates, lengthy and burdensome regulatory requirements, and delays in the supply chain can also cause shortages.

Access to internationally controlled substances might also be unduly restricted out of fear of their diversion into illicit channels, as well as fear of prosecution or sanction. The latter might be exacerbated in the context of unclear, stigmatizing legislation, insufficient legal knowledge among health professionals, or harsh penalties for unintentional violations. Among regulations that are well beyond the provisions of the drug control treaties and that might discourage the prescription, dispensing and use of narcotic drugs are the following: short prescription validities, special multiple-copy prescription forms, onerous record-keeping requirements, and overly restricted access to prescription forms, prescribing/dispensing agents and narcotic drugs (which are often especially limited in rural areas). In addition, most countries or territories do not permit nurses to prescribe narcotic drugs and do not allow drug refills without a new prescription. Such regulations may impede access in areas with an insufficient health-care infrastructure.

Psychotropic substances

Insufficient or inadequate access to psychotropic substances seems to be particularly pronounced in low- and middle-income countries, where it is estimated that about four out of five people who need mental, neurological or substance abuse treatment do not receive such treatment. Regarding the supply and consumption of substances controlled under the 1971 Convention that the World Health Organization lists as essential drugs (buprenorphine, diazepam, lorazepam, midazolam and phenobarbital), diverse patterns emerge. The reported global manufacture and calculated levels of consumption of buprenorphine used for pain relief and opioid dependence treatment have increased significantly in the past decade. While some countries (especially in Europe) show very high levels of consumption, the calculated level of consumption of the majority of countries and regions still remains below 0.1 S-DDD⁸ per 1,000 population per day, indicating insufficient access to this medicine.

⁸Defined daily doses for statistical purposes.

Between 2004 and 2013, reported manufacture of benzodiazepines fluctuated for the sedative-hypnotic midazolam and the anxiolytic diazepam, while it remained relatively stable for the anxiolytic lorazepam. During that period, the global average rate of consumption of diazepam, lorazepam and midazolam decreased by 20, 13.4, and 0.4 per cent, respectively, with levels below the global average in Africa and Asia, and Oceania in the case of lorazepam and midazolam. The reported manufacture of the anti-epileptic phenobarbital fluctuated between 2004 and 2013, falling sharply near the end of the period. Global consumption of phenobarbital declined by 12 per cent, with Europe and the Americas remaining the regions with highest average consumption and Asia, Africa and Oceania showing levels that were below the global average.

As was the case for narcotic drugs, Member States identified a lack of awareness and training as the major impediment to the availability of psychotropic substances. Problems in sourcing, fear of diversion and fear of prosecution or sanction were mentioned as barriers relatively more often with regard to psychotropic substances than they were for narcotic drugs. Among policymakers, mental health care may not be given the priority it deserves, especially in the context of limited resources and stigma associated with mental health conditions and the related use of psychotropic substances. In addition, some countries have identified financial issues as impediments to the availability of psychotropic substances. Furthermore, overly stringent regulations can unduly restrict the availability of such substances.

Availability of internationally controlled drugs for the treatment of opioid dependence

An analysis of levels of consumption of methadone and buprenorphine, as well as opiate substitution treatment services, indicates that access to these services is either not available, or not sufficiently available, in all countries where there is a significant prevalence of people who inject drugs. This can be due to the non-recognition of the effectiveness of such services, cultural resistance, economic or structural incapacity and/or political inaction.

Ensuring adequate availability of internationally controlled drugs in emergency situations

Most narcotic drugs and a large number of psychotropic substances controlled under the international treaties are indispensable in medical practice. Simplified control measures are in place for the provision of internationally controlled medicines for emergency medical care. Competent national authorities may allow the export of internationally controlled substances to affected countries even in the absence of import authorizations or estimated requirements.

Recommendations

Inadequate and insufficient access to internationally controlled substances seems to be the result of limited training and awareness of health-care professionals, policymakers and the general public (reflected in underuse, fear and overregulation), problems in sourcing, limited resources and inadequate infrastructure. Ensuring access does not mean an increase in abuse and diversion, but it is necessary to maintain a balance between control on the one hand, and availability and accessibility on the other hand.

To this end, international cooperation and assistance, the involvement of the entire community, and the commitment of Governments and organizations are required. INCB recommends reviewing legislation and regulatory systems with the aim of removing unduly restrictive provisions while preventing diversion and facilitating access by, for example, allowing a larger base of health-care

professionals to prescribe medications containing substances under international control, where required. An adequate and well-resourced infrastructure needs to ensure the provision and distribution of narcotic drugs and psychotropic substances, including in rural areas. Public funding and reimbursement schemes, in addition to the supply of affordable formulations by pharmaceutical companies, can help overcome financial barriers. Improved training of health-care professionals and heightened awareness can reduce fear, misconceptions, stigma and prejudices that hinder access to and use of internationally controlled substances, while curbing diversion and abuse. Finally, the capacity of competent national authorities to adequately estimate and assess the need for these substances has to be further developed and strengthened.

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The present members of the Board are:

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Chapter I.

Introduction

1. “Pharmakon” is the ancient Greek word for drug. It has been commonly translated as “remedy” or “poison”,⁹ even though it has other meanings that do not correspond exactly with the two main ones.

2. This double meaning represents well the problem that many cultures and societies have faced in the course of history in relation to drugs. Several substances that are available in nature, or that more recently have been synthesized from natural substances or artificially produced, have the capacity to treat or alleviate certain health conditions. For this reason, they are widely used. If taken beyond certain limits, however, they can have negative effects and can damage the health of the persons using them. In addition, there may also be negative consequences for the families of such persons and the broader community.

3. Dealing with the difficult balance between “remedy” and “poison” has been a longstanding problem in many societies. It was at the heart of the development of the international drug control system as outlined in the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol¹⁰ and the Convention on Psychotropic Substances of 1971.¹¹ In the preambles to those conventions, Parties indicated the primary interest of the international community in protecting the health and welfare of humankind by making such indispensable substances available for medical and scientific purposes while ensuring that there was no diversion or abuse. The conventions established a control regime to serve this dual purpose.

⁹Michael Rinella, *Pharmakon: Plato, Drug Culture, and Identity in Ancient Athens* (Lexington Books, 2010).

¹⁰United Nations, *Treaty Series*, vol. 976, No. 14152.

¹¹*Ibid.*, vol. 1019, No. 14956.

A. Role of the international drug control conventions

4. In particular, parties to the 1961 Convention, while recognizing that addiction to narcotic drugs constituted a serious evil for the individual and was fraught with social and economic danger to humankind, also recognized “that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes”.

5. Similarly, parties to the 1971 Convention, while noting with concern the public health and social problems resulting from the abuse of certain psychotropic substances and expressing their determination to prevent and combat abuse of and trafficking in psychotropic substances, recognized “that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted”.

6. Since the entry into force of the three international drug control conventions,¹² these principles have been reiterated in a number of resolutions adopted by the Commission on Narcotic Drugs and then by the Economic and Social Council. More recently, the Commission adopted resolutions 53/4 and 54/6,¹³ with a view to promoting adequate availability of internationally controlled

¹²Including the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (United Nations, *Treaty Series*, vol. 1582, No. 27627), which focuses more on measures related to illicit trafficking.

¹³See E/2010/28-E/CN.7/2018, chap. I, sect. C; and E/2011/28-E/CN.7/2011/15, chap. I, sect. C, respectively.

substances for medical and scientific purposes while preventing their diversion and abuse. In its resolution 53/4, the Commission decided, among other things, to establish a specific agenda item to examine impediments to adequate availability and efforts to prevent the diversion and abuse of narcotic drugs and psychotropic substances.

7. The importance of making internationally controlled drugs available for medical and scientific purposes is also mentioned in the 2009 Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem¹⁴ and in the Joint Ministerial Statement of the 2014 High-Level Review by the Commission on Narcotic Drugs of the Implementation by Member States of the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem.¹⁵

B. Availability of and access to internationally controlled drugs as a health and human right

8. The need to have access to essential drugs is also prominent in other international legal instruments¹⁶ under the concept of the right to health set out in article 25 of the Universal Declaration of Human Rights:¹⁷

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

9. The preamble to the Universal Declaration of Human Rights refers also to the “recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family”. An earlier formulation of the right to health as a fundamental part of human rights was first articulated in the 1946 Constitution of the World Health Organization (WHO), the preamble to which defines health as “a state of complete physical, mental and

social well-being and not merely the absence of disease or infirmity”. The preamble further states that:

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

10. Additionally, the right to health was recognized as a human right in the 1966 International Covenant on Economic, Social and Cultural Rights.¹⁸

11. In his report to the Human Rights Council at its seventh session, the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment stated that:

The de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment.

Further, he added that:

Given that lack of access to pain treatment and opioid analgesics for patients in need might amount to cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome current regulatory, educational and attitudinal obstacles to ensure full access to palliative care.¹⁹

12. Similarly, in a report published in 2011,²⁰ Human Rights Watch argued that under international human rights law, “Governments have an obligation to address the widespread and unnecessary suffering caused by the poor availability of palliative care worldwide.”

13. In addition to the international drug control conventions and the international human rights instruments, the international community has developed a series of legal instruments in the context of the World Health Assembly.

14. Furthermore, WHO has compiled a list of essential medicines that are designed to “satisfy the priority health-care needs of the population” and are selected “with due regard to disease prevalence, evidence on efficacy and

¹⁴See *Official Records of the Economic and Social Council, 2009, Supplement No. 8 (E/2009/28)*, chap. I, sect. C.

¹⁵See *Ibid.*, 2014, *Supplement No. 8 (E/2014/28)*, chap. I, sect. C.

¹⁶Christopher Hallam, “The international drug control regime and access to controlled medicines”, Series on Legislative Reform of Drug Policies No. 26, Transnational Institute and International Drug Policy Consortium (December 2014).

¹⁷General Assembly resolution 217 A (III).

¹⁸General Assembly resolution 2200 A (XXI), annex.

¹⁹A/HRC/10/44, paras. 72 and 74 (e).

²⁰Human Rights Watch, *Global State of Pain Treatment: Access to Palliative Care as a Human Right* (2011).

safety, and comparative cost-effectiveness”.²¹ Several narcotic drugs and psychotropic substances under international control are part of the list and are therefore considered essential to satisfying the priority health-care needs of the population.

15. In its resolution WHA55.14 of 2002, on ensuring accessibility to essential medicines, the World Health Assembly urged Member States:

to reaffirm their commitment to increasing access to medicines, and to translate such commitment into specific regulation within countries, especially enactment of national drug policies and establishment of lists of essential medicines based on evidence and with reference to WHO’s Model List, and into actions designed to promote policy for, access to, and quality and rational use of, medicines within national health systems [and] to reaffirm, within the national drug policies, WHO’s concept of essential medicines as those medicines that satisfy the priority health-care needs of the population, reflecting also availability, quality, price and feasibility of delivery, and re-emphasizing the evidence base for overall national discussions.

16. Also in that resolution, the World Health Assembly requested the Director-General of WHO “to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicines, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them”.

17. In its resolution WHA58.22 of 2005, on cancer prevention and control, the World Health Assembly urged Member States “to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system”. In addition, it requested the Director-General of WHO “to examine jointly with the International Narcotics Control Board the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics”.

18. More recently, on 24 May 2014, the World Health Assembly adopted resolution WHA67.19, on strengthening of palliative care as a component of comprehensive

care throughout the life course.²² In that resolution, it emphasized that the need for palliative care services would continue to grow, partly because of the rising prevalence of non-communicable diseases and the ageing of populations everywhere.

19. In relation to palliative care services, Human Rights Watch, in *Global State of Pain Treatment*, stated that:

Under international human rights law, Governments must ensure equal access to the right to health and take reasonable steps to protect all against inhuman and degrading treatment. This should mean that health policies address the needs of people who require palliative care services; that healthcare workers have at least basic palliative care knowledge and skills; that medications like morphine are available throughout the country; and that drug regulations do not impede the ability of patients facing severe pain to get appropriate treatment. Failure to take such steps will likely result in a violation of the right to health.

20. Furthermore, the WHO Global Action Plan for the Prevention and Control of Non-Communicable Diseases 2013-2020, endorsed by the World Health Assembly in May 2013, includes palliative care among the policy options proposed to Member States as a means of reducing the suffering caused by non-communicable diseases.

21. The World Cancer Declaration of 2013, elaborated by the global cancer community under the leadership of the Union for International Cancer Control, which is building on the Global Action Plan, is aimed at achieving major reductions in premature deaths from cancer, as well as improvements in quality of life and cancer survival rates. The Declaration contains nine targets to be achieved by 2025. One of them is to make effective pain control and distress management services universally available.

22. The Declaration also identifies a series of actions for all stakeholders, in particular Governments, to advance progress towards the targets. The Declaration urges them to:

²¹World Health Organization, definition of “essential medicines”. Available from www.who.int/medicines/services/essmedicines_def (accessed 22/09/2014).

²²The World Health Organization defines palliative care as “an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”. Available from www.who.int/cancer/palliative/definition (accessed 22/09/2014).

- Take steps to remove the many barriers to optimal pain control.
- Work with all stakeholders, including Governments, civil society and relevant private sector players, to address the overregulation of pain medicines.
- Cooperate with international agencies, including WHO, the United Nations Office on Drugs and Crime (UNODC) and the International Narcotics Control Board, to ensure that global implementation of the international drug control conventions strikes an appropriate balance between ensuring availability of pain medicines for cancer patients in pain and preventing their misuse.

23. A number of regional organizations have also emphasized the importance of the availability of internationally controlled drugs for medical purposes. The European Union Drugs Strategy for the 2013-2020 period highlighted the need to ensure and improve access to prescribed controlled medications as one challenge that had been identified in recent years.²³ In 2012, the African Union Conference of Ministers of Drug Control adopted the African common position on controlled substances and access to pain management drugs. That position was translated into the African Union Plan of Action on Drug Control (2013-2017), which lists among its key objectives capacity-building to facilitate the licit movement of narcotic drugs and psychotropic substances for medical and scientific purposes. It also describes some outputs related to this objective, such as the removal of barriers limiting availability of internationally controlled drugs for medical and scientific purposes.²⁴ The Inter-American Drug Abuse Control Commission of the Organization of American States, at its forty-seventh session, adopted a hemispheric drug strategy that states the following:

In applying control measures to limit the use of narcotic drugs exclusively to medical and scientific purposes, the availability of adequate supplies should be ensured. Availability exists when sufficient quantities are on hand and are accessible in accordance with international treaties.²⁵

²³European Union Drugs Strategy (2013-20), *Official Journal of the European Union*, C 402/1, 29 December 2012.

²⁴African Union Plan of Action on Drug Control (2013-2017), submitted for consideration by the African Union Conference of Ministers of Drug Control at its fifth session.

²⁵Inter-American Drug Abuse Control Commission of the Organization of American States, Hemispheric Drug Strategy (adopted on 3 May 2009), para. 37.

C. Action taken by the Board to ensure adequate availability

24. The goal of ensuring adequate, not unduly restricted, availability of internationally controlled drugs for medical purposes has been pursued for over 50 years. It is fair to say that not all countries, in implementing the provisions of the 1961 and 1971 Conventions at the national level, have been able to ensure that this fundamental goal has informed the development of policies and administrative procedures for the distribution of narcotic drugs and psychotropic substances.

25. By becoming parties to the international drug control conventions, Governments have accepted the obligation to introduce the provisions of those treaties into their national legislation and to implement them. The International Narcotics Control Board (INCB) is the body established by the 1961 Convention that is responsible for monitoring the compliance of Governments with the international drug control treaties and for providing support to Governments in that regard.

26. The Board, under article 9 of the 1961 Convention, has the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes. It is in a unique position to monitor the cultivation, production, manufacture, import, export and consumption of narcotic drugs and psychotropic substances.

27. Over the years, the Board has reminded Governments of their obligations in this regard. It has repeatedly voiced its concern about the disparate and inadequate levels of access to controlled substances for medical and scientific purposes worldwide. It has raised this problem repeatedly in its annual reports and devoted a number of special reports to the topic.

28. The Economic and Social Council, in its resolution 1989/15 of 22 May 1989, requested the International Narcotics Control Board to “assess legitimate needs for opiates in various regions of the world, hitherto unmet because of insufficient health care, difficult economic situations or other conditions”. Pursuant to that resolution, INCB prepared a special report entitled *Demand for and Supply of Opiates for Medical and Scientific Needs*.²⁶

29. In that report, the Board concluded that the medical need for opiates, particularly those related to the treatment of cancer pain, were not being fully satisfied. The report further recommended that Governments should:

²⁶E/INCB/1989/1/Supp.

- Critically examine their methods for assessing domestic medical needs for opiates and collecting and analysing data to ensure that estimates reflected actual needs.
- Examine the extent to which their health-care systems and laws and regulations permitted the use of opiates for medical use.
- Identify impediments to such use.
- Develop plans of action to facilitate the supply and availability of opiates for all appropriate indications.

30. The Economic and Social Council, in its resolutions 1990/31 and 1991/43, requested the Board to give priority to monitoring the implementation of those recommendations. In 1994, the Board examined the effectiveness of the international drug control treaties in a supplement to its annual report, entitled *Effectiveness of the International Drug Control Treaties*.²⁷ In its evaluation, the Board concluded that the treaty objective of ensuring an adequate supply of narcotic drugs, especially opiates used for medical purposes, had not been universally achieved.

31. In 1995, the Board prepared another special report, entitled *Availability of Opiates for Medical Needs*.²⁸ In that report, the Board noted that most Governments had not responded to its questionnaire aimed at determining the progress made in the implementation of the recommendations, but concluded that the recommendations of 1989 were far from being implemented, although there had been efforts by some Governments. The Board provided a new set of recommendations for the consideration of Governments; the United Nations Drug Control Programme; the Commission on Narcotic Drugs; WHO; international and regional drug control, health and humanitarian organizations; and educational institutions, as well as non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives.

32. Furthermore, chapter I of the annual report of the Board for 1999 was dedicated to the issue of the availability of narcotic analgesics. As internationally controlled drugs were overused in some countries, leading to prescription drug abuse and related problems, chapter I of the annual report of the Board for 2000 dealt with overconsumption of internationally controlled drugs and recommended a balanced approach in their use.

33. One tool to determine whether countries improve availability levels, or at least are aware of the problem and show the intention to improve, is an analysis of their assessments of annual estimated requirements for narcotic drugs, which all countries are required to submit to the Board. The Board regularly contacts countries with missing or particularly low estimates in order to ensure adequate availability of opioids for the treatment of pain. This practice was formalized in November 1999, when the Board started selecting certain groups of countries with low levels of consumption of opioid analgesics (mainly morphine) and with common characteristics. The matter was repeatedly brought to the attention of Governments in circular letters to all countries and specific letters to individual countries. In August 2001, a joint letter from the President of the Board and the Chair of the United Nations Development Group was sent to all resident coordinators of the United Nations system at the country level, urging them, inter alia, to be aware of underconsumption and the lack of medicaments available for the treatment of severe pain in many developing countries.

34. This request was confirmed in February 2005, in a follow-up joint letter from the President of the Board and the Chair of the United Nations Development Group. In April 2006, in a letter to all countries, the President of the Board emphasized the difficulties regarding access to narcotic drugs and psychotropic substances for patients in need, and encouraged Governments to take measures to ensure the inclusion of the subject of rational use of drugs in the curricula of the appropriate university faculties.

35. In 2010, INCB launched its report entitled *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*, which analysed the global situation with regard to the consumption of internationally controlled substances, broadening the scope of the report to include also psychotropic substances.

36. The 2010 report identified once more the main impediments to adequate availability and provided detailed recommendations to various stakeholders. INCB noted that, in response to previous recommendations concerning the availability of narcotic drugs, a significant number of Governments had increased their annual estimated requirements to meet medical demand, issued national policies to improve medical use of narcotic drugs, supported educational programmes and examined their health-care systems, laws and regulations to see if they created impediments to availability.

37. INCB noted improvements in the adequacy of supply of certain narcotic drugs and psychotropic substances in many countries, but expressed concern about setbacks in

²⁷E/INCB/1994/1/Supp. 1.

²⁸E/INCB/1995/Supp. 1.

others. While the most significant improvements were recorded in highly developed countries, the setbacks had occurred mostly in the regions with the lowest levels of availability of internationally controlled substances. The report concluded that, in spite of the progress made towards meeting treaty objectives, relatively few countries had an adequate drug supply management system and working mechanisms that ensured reliable, needs-based assessments, equitable availability and cost-effectiveness.

38. The report pointed to the deficiencies in drug supply management that remained attributable to a lack of financial resources, inadequate infrastructure, the low priority given to health care, weak government authority, inadequate education and professional training, and outdated knowledge, which together affected the availability of not only controlled drugs but all medicines.

39. In 2012, a publication entitled *Guide on Estimating Requirements for Substances under International Control*²⁹ was launched with the aim of providing competent national authorities with concrete tools to improve the assessment of their national needs.

40. At its 108th session, in November 2013, the Board decided to prepare a special report to be published in 2016 as a supplement to the INCB annual report for 2015. The Board decided that the report should focus on the implementation by Governments of the recommendations contained in its 2010 report on *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*.

41. Pursuant to that decision, the present report is aimed at providing an updated overview of the situation with regard to the availability of narcotic drugs and psychotropic substances for medical and scientific purposes as compared with the situation presented in 2010.

D. Methodology

1. Data on consumption

42. The data provided by countries to INCB show one aspect of the issue of availability, i.e. the amounts that the competent national authorities estimate and report as consumed. This information is available for a large number of countries for several years. However, since the

quality of reporting varies from country to country, such information is not always reliable, even though INCB has the ability to verify reported consumption by using data from export and import notifications. The Board evaluates these consumption data in terms of “defined daily doses for statistical purposes” to ascertain the degree of overprescription or underprescription.

43. The term “defined daily doses for statistical purposes” (S-DDD) has replaced the term “defined daily doses”, which had previously been used by the Board. The defined daily doses for statistical purposes is used by INCB as a technical unit of measurement for the purpose of statistical analysis and is not a recommended prescription dose. This definition, which is not free of a certain degree of arbitrariness, recognizes that there are no internationally agreed standard dosages for narcotic drugs and psychotropic substances, that they are used in certain countries for different treatments or in accordance with different medical practices, and that therefore S-DDD should be considered an approximate measure to rank consumption in different countries. For narcotic drugs, levels of consumption, expressed in S-DDD per million inhabitants per day, are calculated by using the following formula: annual consumption, excluding the manufacture of the preparations in Schedule III of the 1961 Convention, divided by 365 days. The result obtained is divided successively by the population, in millions, of the country or territory during the year in question, and then by the defined daily dose of each substance.³⁰

44. Since the 1971 Convention does not foresee reporting on consumption of psychotropic substances to the Board, the rates of consumption are calculated by the Board every year, based on statistics reported by Governments on manufacture, industrial use, stocks and international trade. The rate of consumption of psychotropic substances is measured in S-DDD per 1,000 inhabitants per day. In addition, 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 import of psychotropic substances when stocks cover domestic requirements for several years.

45. The analysis of the availability of psychotropic substances contained in the present report is based on the levels of consumption of groups of psychotropic substances.

²⁹International Narcotics Control Board and World Health Organization, *Guide on Estimating Requirements for Substances under International Control* (New York, 2012).

³⁰For some countries, the S-DDD calculated for the period 2001-2003 may be higher than the successive periods because of the difficulty at that time of distinguishing the quantities of opioids consumed for pain relief and the opioids utilized for the manufacture of preparations, listed in Schedule III of the 1961 Convention.

Levels of consumption of psychotropic substances expressed in S-DDD are calculated by using the following formula: manufacture plus imports plus stocks at the end of the previous year, minus exports minus quantities used for industrial purposes, minus stocks at the end of the current year, divided by 365 days. The result obtained is divided by the population, in thousands, of the country or territory during the year in question and by the defined daily dose. Some cases of high calculated use of psychotropic substances could be related to increasing manufacture for exports, with a possible lack of reporting of exports and/or a non-reporting of stocks of manufacturers and/or elevated stocks kept by wholesalers.

46. The Board has identified levels of consumption that it considers to be inadequate (consumption of opioid analgesics in quantities between 100 and 200 S-DDD per million inhabitants per day) or very inadequate (consumption of opioid analgesics in quantities equal to or less than 100 S-DDD). However, the Board has not yet defined comparable levels of adequate or inadequate consumption for psychotropic substances.

47. In the analysis of consumption of opioid analgesics expressed in S-DDD, the Board did not include methadone and buprenorphine because of the impossibility of distinguishing their use for pain relief from their use for the treatment of drug dependence.

2. Survey of Member States

48. In the summer of 2014, the Board sent questionnaires to competent national authorities asking for information on the availability of controlled drugs for medical and scientific purposes. One questionnaire was devoted to narcotic drugs, and a separate one to psychotropic substances. A total of 107 countries and territories,³¹ with

³¹ Algeria, Armenia, Australia, Austria, Azerbaijan, Bahrain, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Brunei Darussalam, Bulgaria, Burundi, Cabo Verde, Canada, Chile, China, Colombia, Costa Rica, Côte d'Ivoire, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Georgia, Germany, Ghana, Guatemala, Guinea-Bissau, Haiti, Honduras, Hungary, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Jamaica, Jordan, Kazakhstan, Kuwait, Kyrgyzstan, Latvia, Lebanon, Liberia, Lithuania, Malaysia, Malta, Mexico, Micronesia (Federated States of), Morocco, Myanmar, Namibia, Netherlands, New Zealand, Nicaragua, Oman, Palau, Peru, Philippines, Poland, Qatar, Republic of Korea, Republic of Moldova, Russian Federation, Saint Lucia, Senegal, Serbia, Sierra Leone, Slovakia, South Africa, Spain, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Togo, Tunisia, Turkey, Turkmenistan, Uganda, Ukraine, United Kingdom of Great Britain and Northern Ireland, United States of America, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of) and Zimbabwe, along with Bermuda; Hong Kong, China; Macao, China; Montserrat; New Caledonia; and Saint Helena.

75 per cent of the world's population, responded, providing important information that is discussed in the present report.

3. Other sources of information

49. While INCB data are important in measuring (through S-DDD) the performance of countries in ensuring the availability of internationally controlled drugs for medical use, it is important to also consider other sources of information when evaluating the situation. To that end, the Board also analysed information on health conditions for which internationally controlled drugs are required in order to compare reported consumption against the prevalence of the specific health conditions.

50. The World Health Organization and the Worldwide Palliative Care Alliance provided information on health conditions requiring palliative care and the level of palliative care development. The International Agency for Research on Cancer of WHO provided fundamental information on the prevalence of cancer through its GLOBOCAN database. Information on the prevalence of AIDS was made available by the Joint United Nations Programme on HIV/AIDS (UNAIDS). The United Nations Office on Drugs and Crime provided information on the number of people who inject drugs, which was then used to measure the specific availability of internationally controlled drugs (methadone and buprenorphine) used in the treatment of opioid dependence in relation to the prevalence of people who would be in need of such treatment.

51. In addition, various civil society organizations representing patients, families, health professionals and other stakeholders have also contributed data and information, and offered their views. A number of researchers have provided relevant analyses and insights.

Chapter II.

Narcotic drugs

A. Supply of and demand for opiate raw materials and opioids

52. Inadequate distribution of consumption of opioid analgesics is not the result of a lack of supply of raw materials and opioids. To the contrary, the Board has been concerned by an increase in the production of such substances without a corresponding increase in consumption, leading to a consequent increase in stocks.

53. Opiates consumed by patients for medical treatment are obtained from opiate raw materials (opium, poppy straw and concentrate of poppy straw). Adequate availability of opiate raw materials for the manufacture of opiates is therefore a precondition for ensuring the adequate availability of opiates used for medical and scientific purposes.

54. Pursuant to the 1961 Convention and the relevant resolutions of the Commission on Narcotic Drugs and the Economic and Social Council, the Board examines on a regular basis developments affecting the supply of and demand for opiate raw materials. The Board endeavours, in cooperation with Governments, to maintain a lasting balance between supply and demand. Global stocks of opiate raw materials should cover global demand for

about one year to ensure the availability of opiates used for medical and scientific purposes in the event of an unexpected decline in production resulting from, for example, adverse weather conditions in producing countries.³²

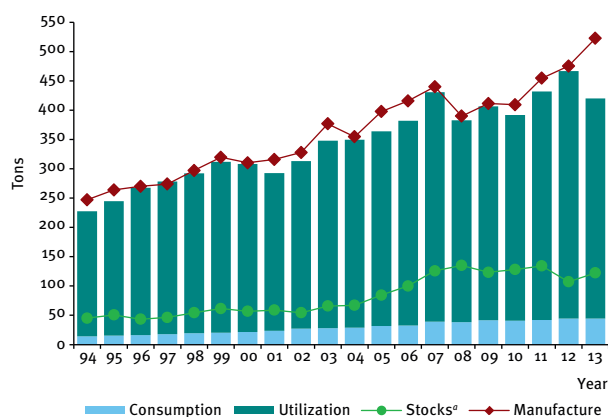
55. At the end of 2013, global stocks of opiate raw materials rich in morphine were sufficient to cover global demand for 14 months. Global stocks of opiate raw materials rich in thebaine were sufficient to cover global demand for 12 months. In 2014, the global production of opiate raw materials rich in morphine was greater than the utilization of those materials. The global supply (stocks and production) of opiate raw materials rich in morphine was fully sufficient to cover global demand.

56. Figure 1 presents data on the manufacture, stocks, consumption and utilization³³ of morphine during the period 1994-2013. Global manufacture of morphine doubled during that 20-year period, increasing from about 247.1 tons in 1994 to 522.6 tons in 2013, which was a further increase from the 475.3 tons recorded in 2012. Around 70 per cent of the morphine manufactured globally is converted into other narcotic drugs or into substances not covered by the 1961 Convention. The rest is used directly for medical purposes.

³²*Report of the International Narcotics Control Board for 2014* (E/INCB/2014/1), para. 90.

³³ "Consumption" indicates the quantity of the drug to be consumed directly for domestic medical and scientific purposes, while "utilization" refers to quantity of the drug to be utilized for the manufacture of other drugs, preparations included in Schedule III of the 1961 Convention or substances not covered by the 1961 Convention.

Figure 1. Morphine: global manufacture, stocks, consumption and utilization, 1994-2013

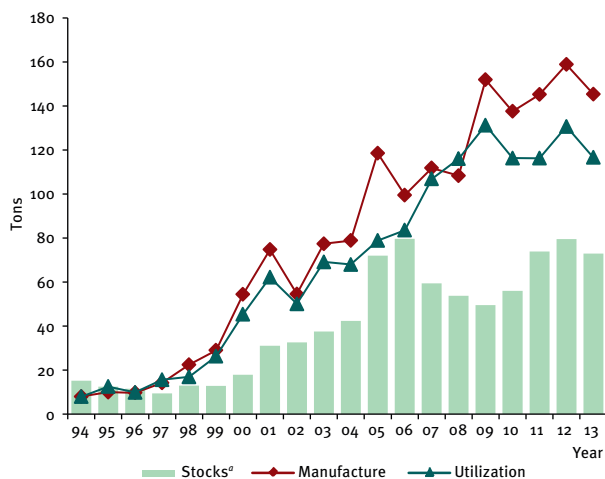


Source: International Narcotics Control Board.

^a Stocks as at 31 December of each year.

57. Until the 1990s, thebaine, the other main alkaloid obtained from opium poppy, was manufactured mainly from opium; since 1999, it has been obtained primarily from poppy straw. Thebaine may also be obtained through the conversion of oripavine or from semi-synthetic opioids, such as hydrocodone. Thebaine itself is not used therapeutically, but it is an important starting material for the manufacture of a number of opioids, mainly codeine, dihydrocodeine, etorphine, hydrocodone, oxycodone and oxymorphone (all of which are controlled under the 1961 Convention) and buprenorphine (which is controlled under the 1971 Convention). Global manufacture of thebaine has increased sharply since the late 1990s, as a consequence of the growing demand for oxycodone and other drugs and substances that may be derived from it (see figure 2).

Figure 2. Thebaine: global manufacture, utilization and stocks, 1994-2013



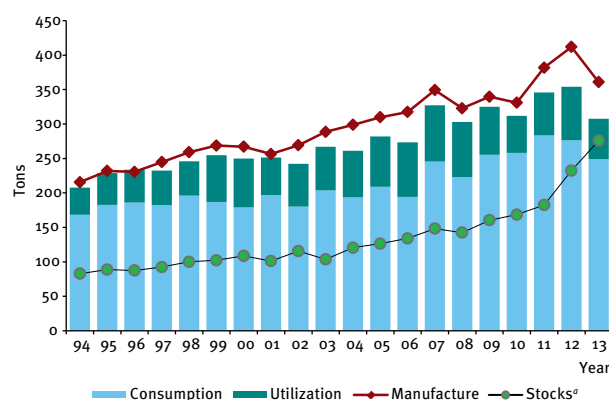
Source: International Narcotics Control Board.

^a Stocks as at 31 December of each year.

58. The information available to the Board indicates that global production of opiate raw materials rich in thebaine exceeded global demand in 2014. Total stocks of opiate raw materials rich in thebaine were sufficient to cover global demand for about one year. The plans of producing countries indicate that global production of opiate raw materials rich in thebaine will be slightly less than global demand in 2015. Total stocks of opiate raw materials rich in thebaine are therefore expected to decrease. The global supply (stocks and production) of opiate raw materials rich in thebaine will continue to be sufficient to fully cover global demand.

59. Codeine is a natural alkaloid of the opium poppy plant, but most of the codeine currently being manufactured is obtained from morphine through a semi-synthetic process. There has been an increase in the cultivation of the opium poppy variety that is rich in codeine and in the manufacture of concentrate of poppy straw rich in codeine, which is used for the extraction of codeine. Global utilization of concentrate of poppy straw rich in codeine amounted to 24.6 tons in 2013, which is a fraction of the amount of morphine used. Codeine is used mainly for the manufacture of preparations in Schedule III of the 1961 Convention, while a smaller quantity is used for the manufacture of other narcotic drugs, such as dihydrocodeine and hydrocodone. The trends relating to global manufacture, consumption, utilization and stocks of codeine during the period 1994-2013 are shown in figure 3.

Figure 3. Codeine: global manufacture, stocks, consumption and utilization, 1994-2013



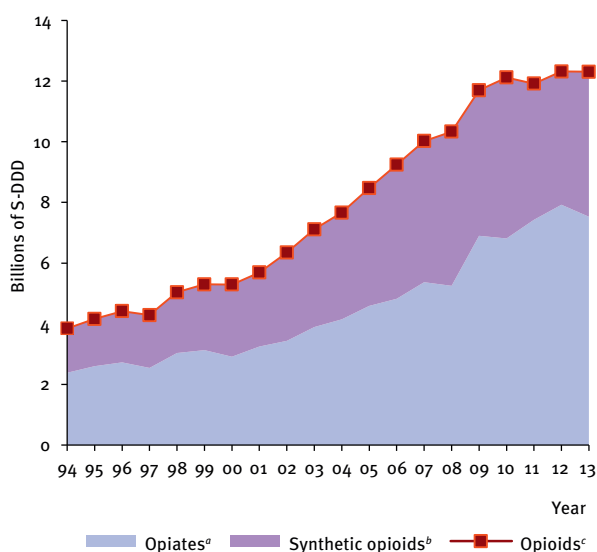
Source: International Narcotics Control Board.

^a Stocks as at 31 December of each year.

60. Global demand for opiate raw materials rich in morphine and rich in thebaine is expected to rise in the future. It is anticipated that global demand for opiates

and opiate raw materials will also continue to rise. Figure 4 presents the global level of consumption of opiates and synthetic opioids, including buprenorphine and pentazocine, which are opioids controlled under the 1971 Convention, during the 20-year period from 1994 to 2013. To allow the aggregation of consumption data for substances having different potencies, the levels of consumption are expressed in billions of S-DDD.

Figure 4. Global consumption of opioids, 1994-2013



Source: International Narcotics Control Board.

^aIncluding buprenorphine, an opiate controlled under the 1971 Convention.

^bIncluding pentazocine, a synthetic opioid controlled under the 1971 Convention.

^cIncluding opiates and synthetic opioids.

61. Over the past 20 years, global consumption of opioids has more than tripled. The consumption of opiates as a percentage of total consumption of opioids fluctuated between 62 per cent in 1994 and 52 per cent in 2006, rising again to 61 per cent in 2013. As a result, the share of synthetic opioids, which are used for the same indications as opiates, increased from 38 per cent in 1994 to 48 per cent in 2008, but declined to 39 per cent in 2013. Between 2010 and 2013, the ratio of consumption of opiates to synthetic opioids stabilized at about 60 per cent for opiates and 40 per cent for synthetic opioids. Throughout the period, the supply of opiate raw materials from which opiates were obtained was sufficient to cover increasing demand. It is expected that the demand for opiates will increase again in the future, while their share of the total

consumption of opioids may decline, owing to expected growth in the consumption of synthetic opioids.

62. Overall, the available data indicate that the amount of opiate raw materials available for the manufacture of narcotic drugs for pain relief is more than sufficient to satisfy the current level of demand as estimated by Governments. In addition, both production and stocks continue to increase.

B. Availability of opioid analgesics

63. Opioid analgesics are essential medicines for palliation therapy.³⁴ They are prescribed mainly in relation to cancer, but palliation therapy is also needed for other health situations that require the management of pain (such as surgery and childbirth) and for chronic conditions such as cardiovascular diseases, chronic respiratory diseases, HIV/AIDS and diabetes.

64. Each year, around 5.5 million terminal cancer patients, 1 million end-stage HIV/AIDS patients and 800,000 patients with lethal injuries caused by accidents or violence, in addition to patients with chronic illnesses, patients recovering from surgery, women in labour and paediatric patients, are subjected to untreated or under-treated moderate to severe pain. All in all, WHO estimates that annually tens of millions of people are suffering without adequate treatment.³⁵

65. It is estimated that, out of the 20 million people in need of palliative care at the end of their lives, about 80 per cent live in low- or middle-income countries.³⁶ According to the Worldwide Palliative Care Alliance, every year at least 100 million people worldwide would benefit from palliative care; however, fewer than 8 per cent of people in need of palliative care have access to it. According to the Harvard Global Equity Initiative-Lancet Commission on Global Access to Pain Control and Palliative Care, “the absence of palliative care also undermines efforts to improve human well-being, and

³⁴World Health Organization, Model List of Essential Medicines, 19th list (April 2015, amended June 2015). Available from www.who.int/medicines/publications/essentialmedicines.

³⁵World Health Organization, *Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines* (Geneva, 2011).

³⁶Report by the secretariat of the World Health Organization on the strengthening of palliative care as a component of integrated treatment throughout the life course.

impoverishes a host of interventions intended to reduce human suffering and strengthen health systems”.³⁷

66. In many countries, especially in less developed regions, the possibility of preventing, treating and curing cancer early is severely limited by a number of factors, including a lack of early detection and prevention policies, and the limits of the health system. In many situations, palliation may be the only option available for handling an increasing number of cases.

67. Other internationally controlled drugs, such as methadone and buprenorphine (an opioid analgesic which is controlled under the 1971 Convention and whose use in substitution therapy continues to increase), can be used in the management of pain but are mostly used in the treatment of drug dependence. However, their use is also limited in some countries despite a considerable prevalence of heroin abuse.

68. In spite of the common prevalence of the above-mentioned conditions in all regions, pain relief drugs are not available in sufficient quantities, are difficult to obtain because of unduly restrictive procedures, and are not prescribed, owing to a lack of training and capacity of health professionals or because of fear of addiction, which discourages health professionals from prescribing such medications.

69. Consequently, severe pain is often left untreated, although medical professionals have the capacity to relieve most such pain. Untreated pain diminishes the quality of life of patients, their families, their friends and their communities, and may lead to wider losses for society.³⁸

³⁷F. Knaul and others, “Closing the divide: the Harvard Global Equity Initiative-Lancet Commission on Global Access to Pain Control and Palliative Care”, *The Lancet* (8 March 2015).

³⁸N.I. Cherny and others, “The Global Opioid Policy Initiative (GOPI) project to evaluate the availability and accessibility of opioids for the management of cancer pain in Africa, Asia, Latin America and the Caribbean, and the Middle East: introduction and methodology”, *Annals of Oncology*, Vol. 24, Suppl. No. 11 (2013), pp. xi7-xi13.

1. Global patterns of consumption of opioid analgesics

(a) Inadequate access

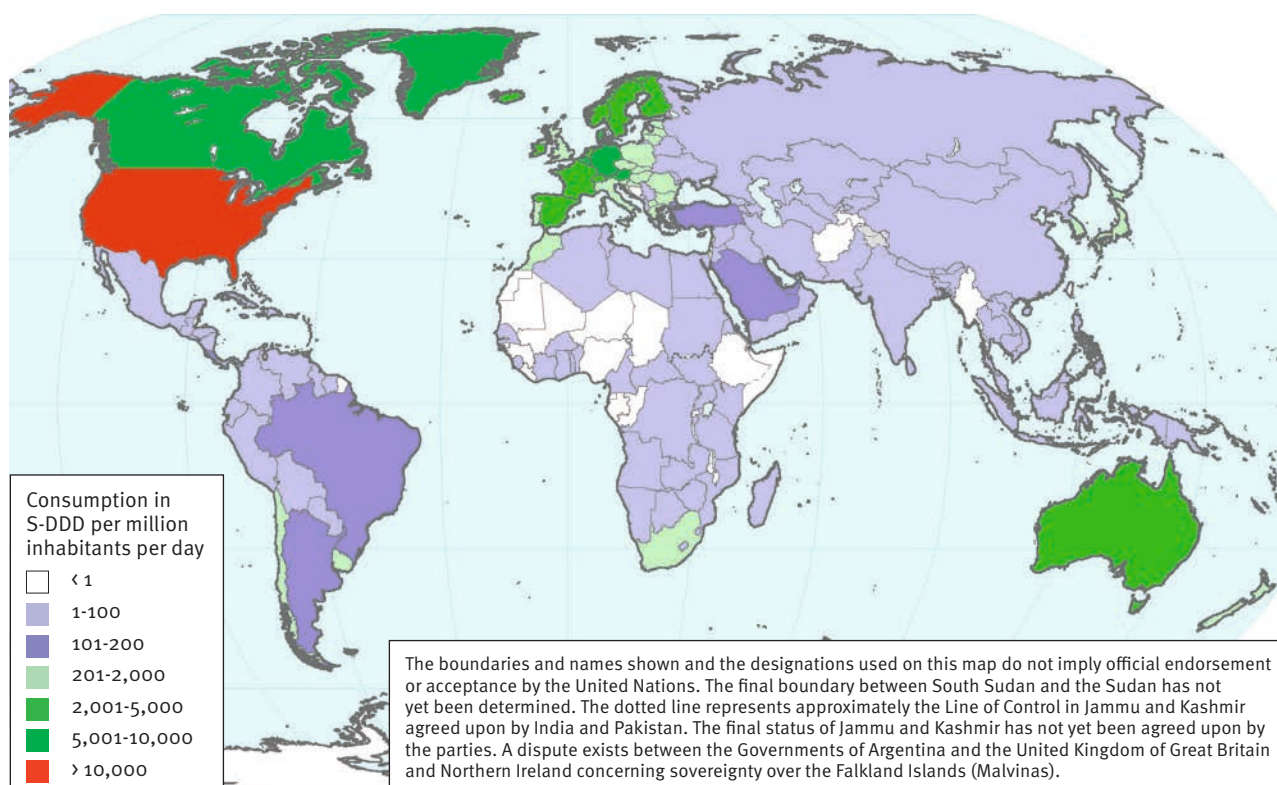
70. The data available to INCB indicate an increase in the level of reported consumption in S-DDD in the 2011-2013 period in comparison with the 2001-2003 period (see maps 1 and 2). In particular, there was visible progress with regard to availability in Latin America and in the Middle East. In Latin America, consumption of opioid analgesics could possibly be even higher than reported because methadone (which is not included in the global S-DDD calculation because of its prevalent use in opiate substitution treatment) is more frequently used for pain relief in this region than in other regions. Very little is used for drug dependence treatment, since the prevalence of heroin abuse is relatively low and therefore opiate substitution treatment services are not common.

71. There have been some small improvements in the Russian Federation and in some countries in Central Asia. However, the situation remains problematic in most of Africa and parts of Asia.

72. The United States, Canada, Australia and some countries in Western Europe have increased their levels of consumption to above 10,000 S-DDD per million inhabitants per day. In some of these countries, there has been a considerable increase in prescription drug abuse, which Governments have taken action to reduce without limiting access for people in need of pain relief medicines.

73. Overall, there has been encouraging progress towards ensuring availability and increasing access to opioid analgesics, but that goal is still a distant one for a considerable number of countries.

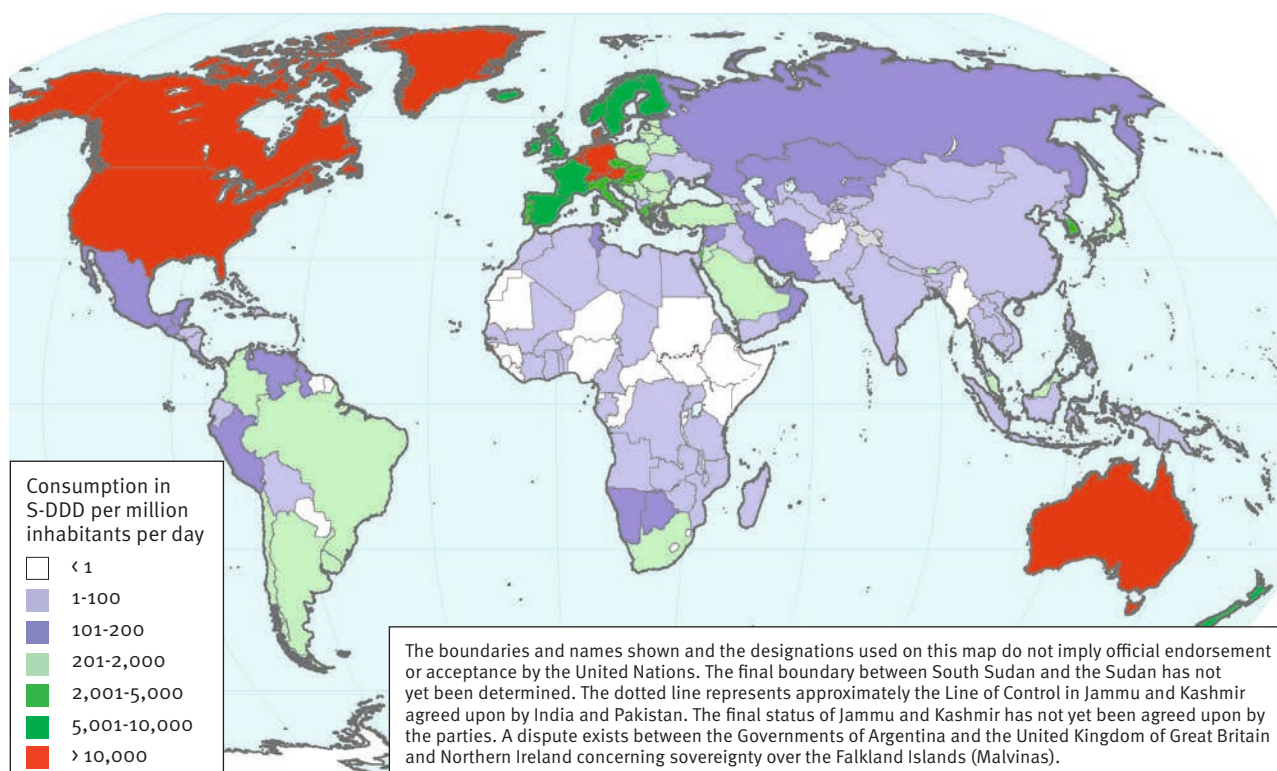
Map 1. Availability of opioids for pain management (2001-2003 average)



Source: International Narcotics Control Board.

Note: Opioids defined as codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine.

Map 2. Availability of opioids for pain management (2011-2013 average)



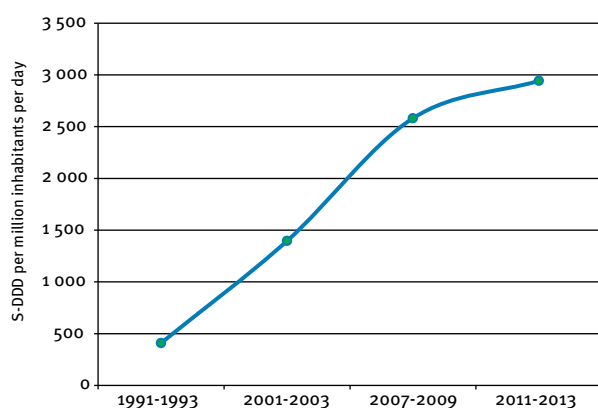
Source: International Narcotics Control Board.

Note: Opioids defined as codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine.

(b) Evolution of the consumption of opioid analgesics over time

74. In the past two decades, global consumption of opioid analgesics expressed in S-DDD has increased considerably. The long-term trend shows an overall increase of 618 per cent between the 1991-1993 period and the 2011-2013 period (see figure 5). That trend was especially pronounced during the initial years: between 1991-1993 and 2001-2003, there was an increase of 240 per cent, compared with an increase of 84 per cent between 2001-2003 and 2007-2009. The growth rate declined further to 14 per cent during the period between 2007-2009 and 2011-2013. The increase in consumption is mainly the result of an increase in the consumption of fentanyl and, to a limited extent, the consumption of morphine. Global consumption of codeine and pethidine for the treatment of pain has decreased.

Figure 5. Global trend in the consumption of opioid analgesics, 1991-1993, 2001-2003, 2007-2009 and 2011-2013 averages



Source: International Narcotics Control Board.

75. The growth in consumption of opioid analgesics observed since 1991 has been uneven among regions. It has been driven mainly by North America, but also by Europe and Oceania, the three major consumer regions (see figures 6-17).

76. In Asia, the situation is mixed. Here, most countries saw an increase in their consumption during the past decade, although with varying trends at the subregional level. A moderate increase was observed in East, South-East and West Asia, while there was a decrease in South Asia, which continued to have the lowest level of consumption in the world. This decrease is probably attributable to a considerable decrease to the consumption of opioid analgesics in India as a consequence of legislative restrictions that had been introduced in the past. Those restrictions have recently been lifted, but it will take some time before the gap in consumption is closed.

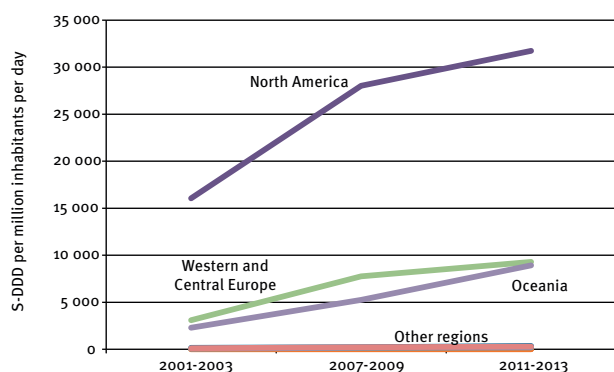
77. In Africa, the situation is problematic and consumption continues to be very low despite progress in a few countries. Patterns of consumption fluctuated considerably both in countries with higher levels of consumption and in countries with lower levels of consumption. This is probably due to a lack of capacity of competent national authorities to estimate correctly their national needs.

78. In Central America and the Caribbean, the overall trend shows increased consumption, but there were considerable variations among countries. Consumption in Central American and Caribbean countries was still below an adequate level. In South America, most countries had increased their consumption in 2011-2013, even though some of them had experienced drops in consumption in earlier periods. The data for these two subregions, but particularly for South America, have some limitations because, while methadone is used in some of the countries of the region as a pain relief medication and not in substitution treatment—heroin abuse in the region is not common—it is excluded from the S-DDD calculation at the global level.

79. In Europe, the overall trend showed an increase, with some stabilization for some countries.

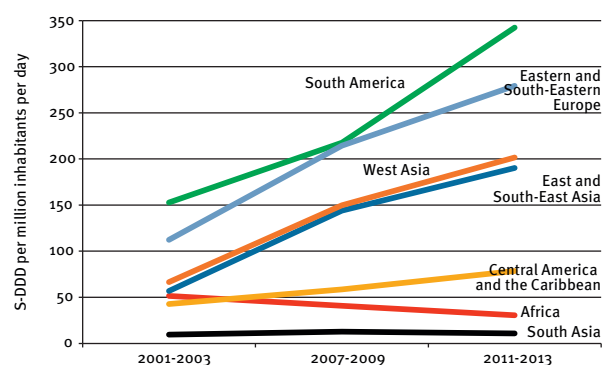
80. In Australia and New Zealand, consumption increased, which influenced the trend for the whole region.

Figure 6. Trends in consumption, by region, 2001-2013



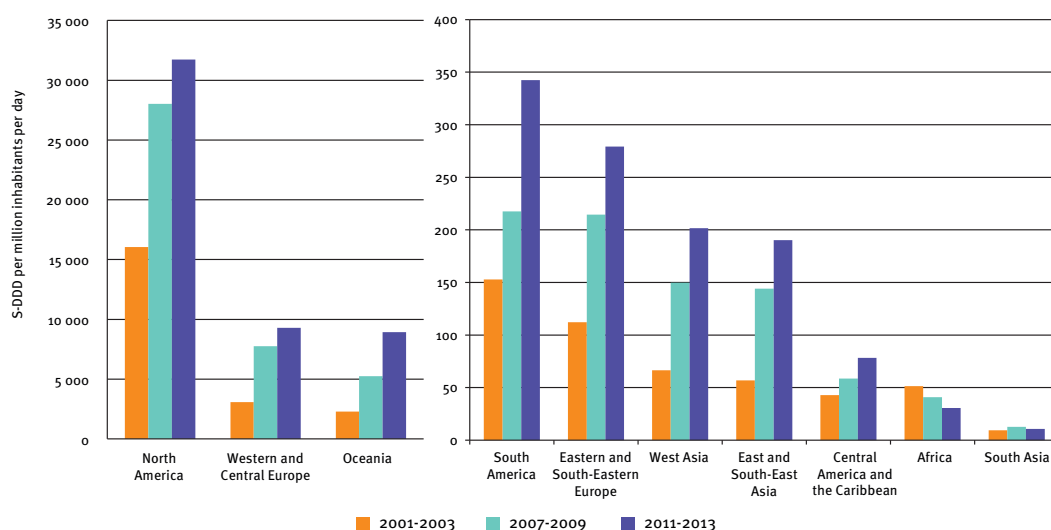
Source: International Narcotics Control Board.

Figure 7. Trends in consumption for selected subregions, 2001-2013



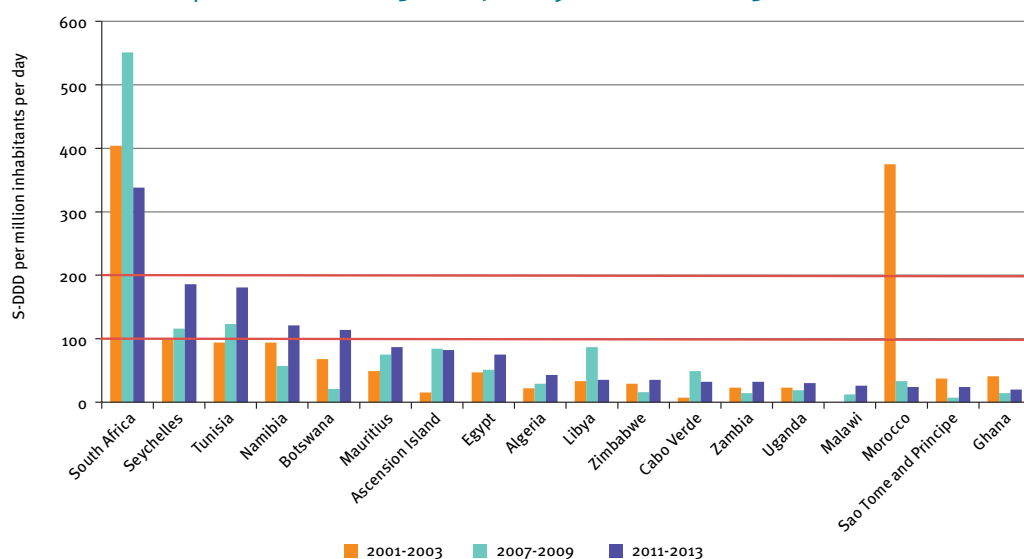
Source: International Narcotics Control Board.

Figure 8. Average consumption of opioid analgesics, all regions, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

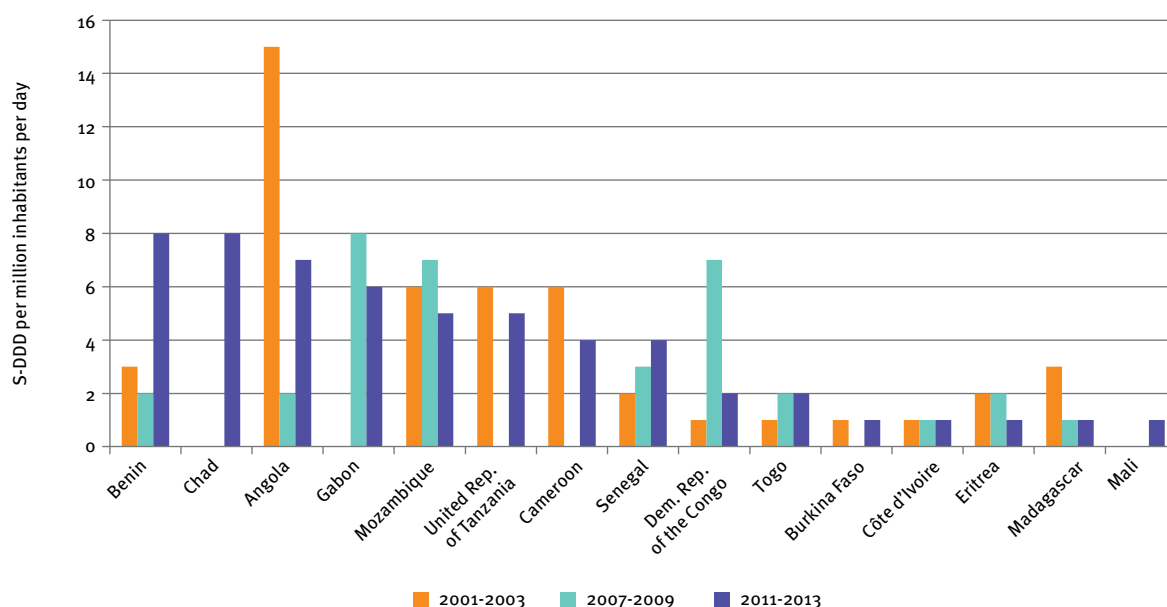
Figure 9. Average consumption of opioid analgesics in African countries and territories with higher levels of consumption, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

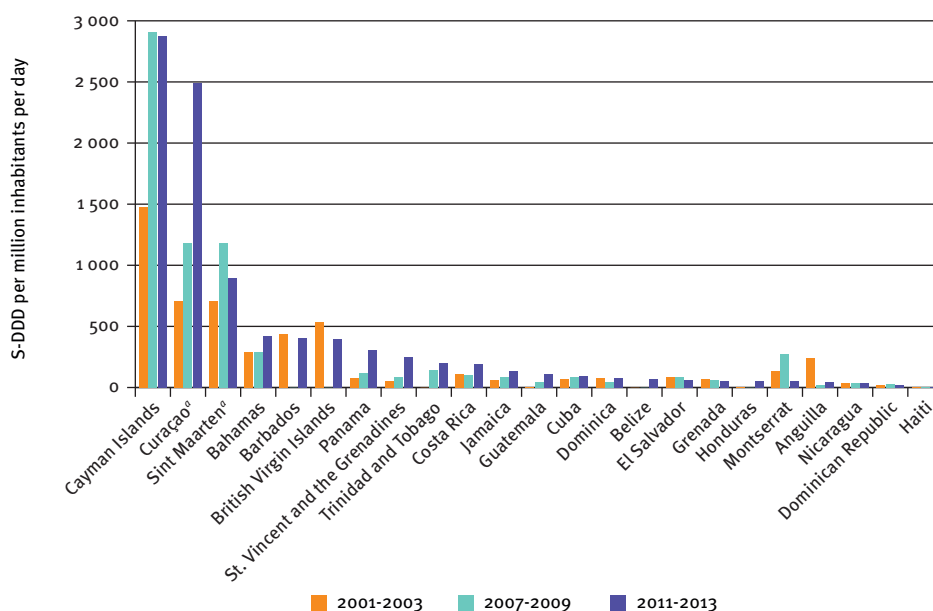
Note: Red lines: levels less than 200 S-DDD are considered inadequate; levels less than 100 S-DDD are considered very inadequate. For further information on inadequate and very inadequate levels of consumption as identified by the Board, see paragraph 46, above.

Figure 10. Average consumption of opioid analgesics in African countries with lower levels of consumption, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

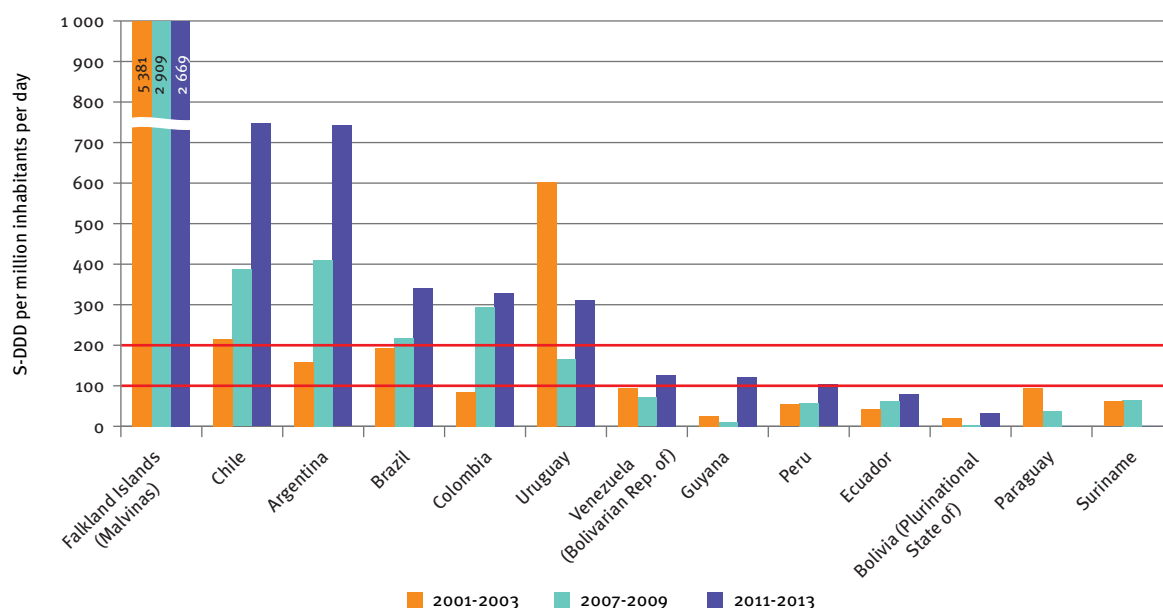
Figure 11. Average consumption of opioid analgesics in Central America and the Caribbean, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

^a The Netherlands Antilles was dissolved on 10 October 2010, resulting in two new constituent entities, Curaçao and Sint Maarten.

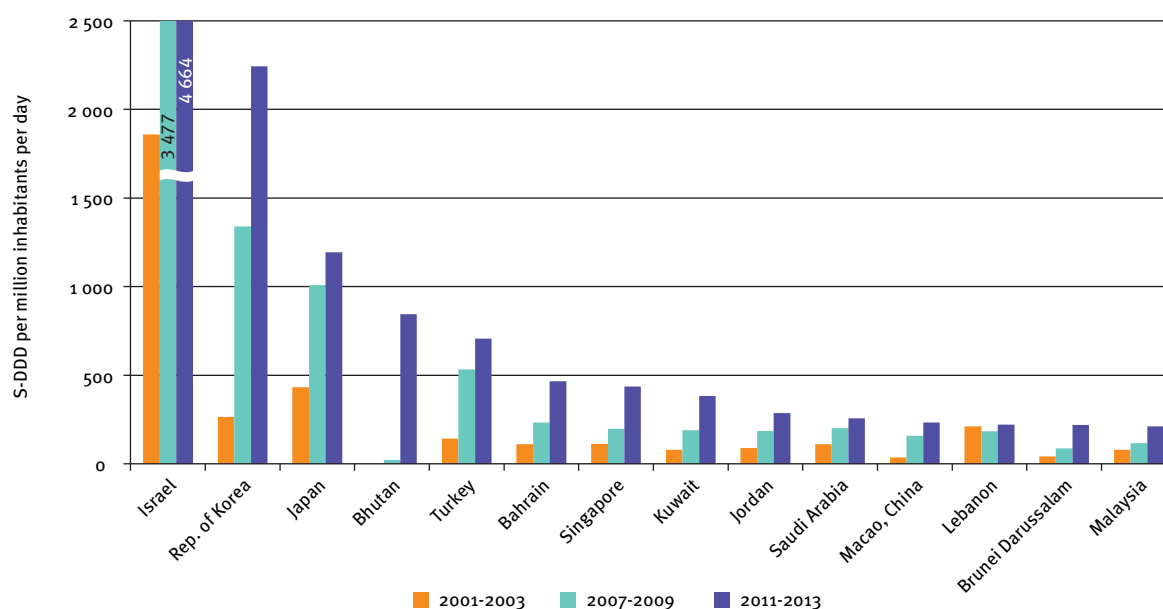
Figure 12. Average consumption of opioid analgesics in South America, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

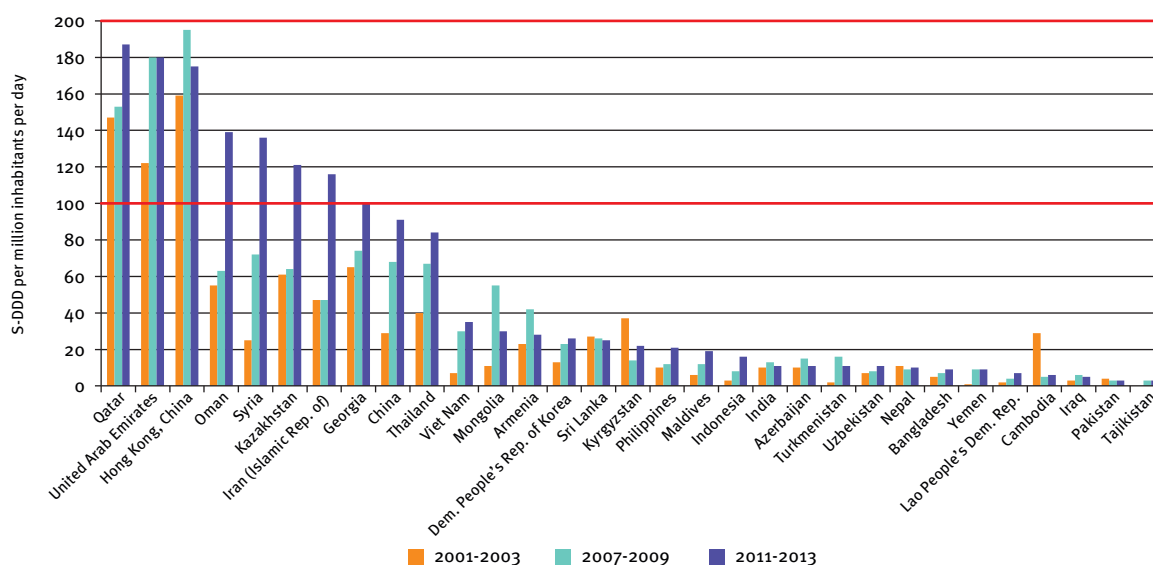
Note: Red lines: levels less than 200 S-DDD are considered inadequate; levels less than 100 S-DDD are considered very inadequate. For further information on inadequate and very inadequate levels of consumption as identified by the Board, see paragraph 46, above.

Figure 13. Average consumption of opioid analgesics in Asian countries and territories with higher levels of consumption, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

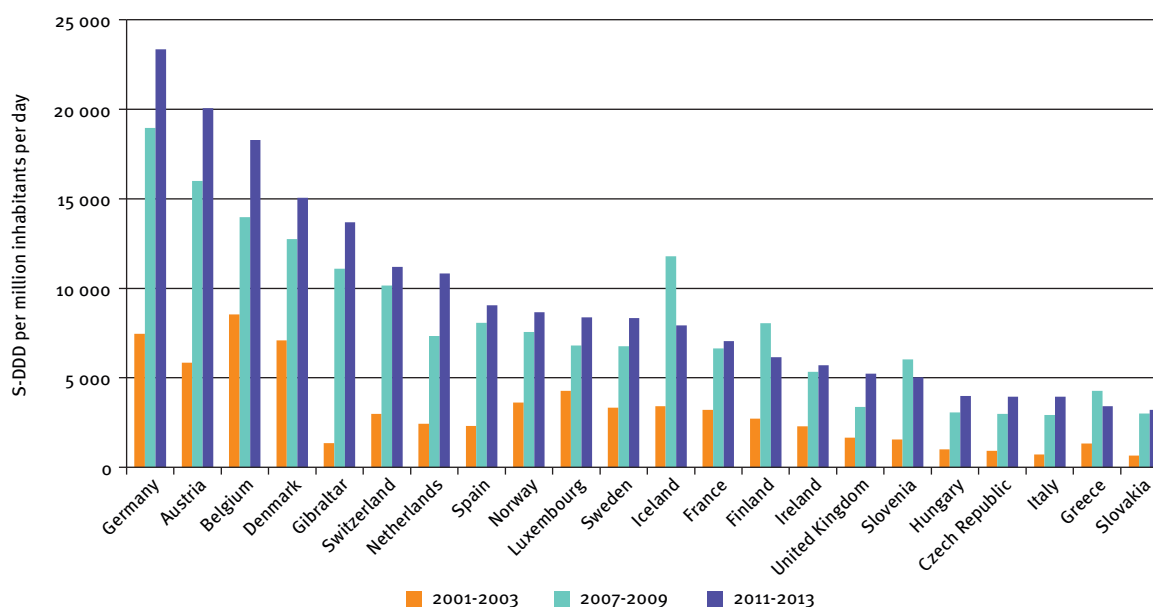
Figure 14. Average consumption of opioid analgesics in Asian countries and territories with lower levels of consumption, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

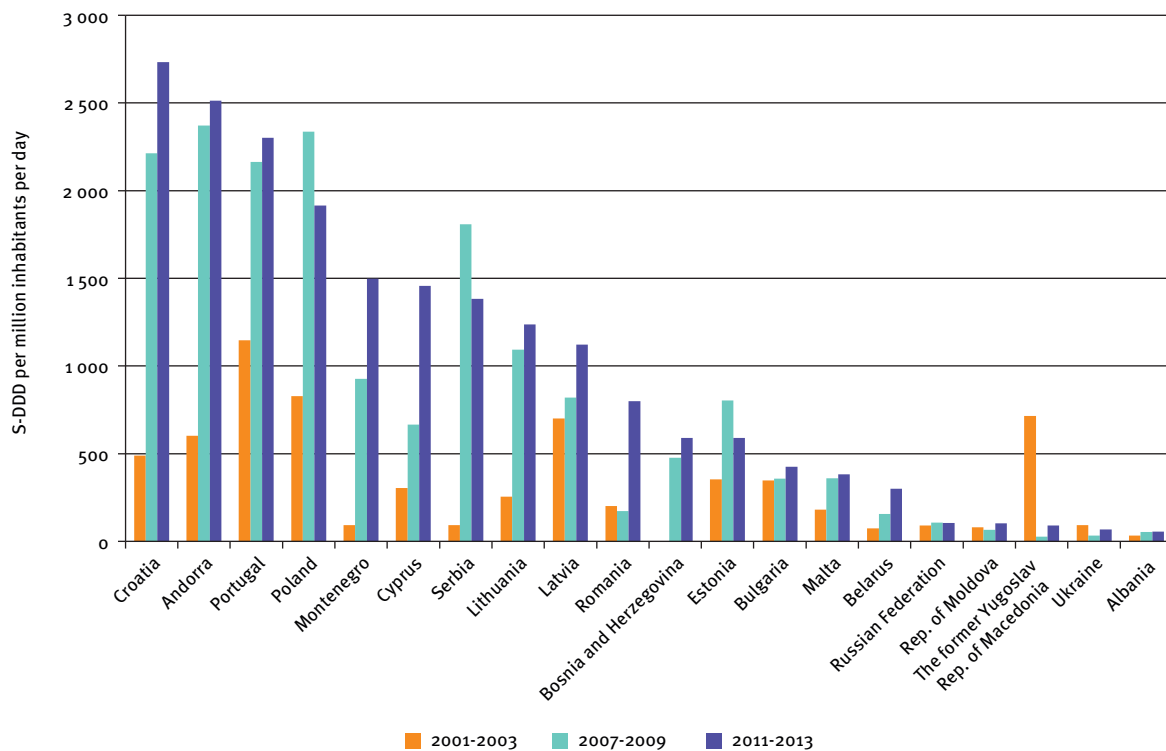
Note: Red lines: levels less than 200 S-DDD are considered inadequate; levels less than 100 S-DDD are considered very inadequate. For further information on inadequate and very inadequate levels of consumption as identified by the Board, see paragraph 46, above.

Figure 15. Average consumption of opioid analgesics in European countries and territories with higher levels of consumption, 2001-2003, 2007-2009 and 2011-2013



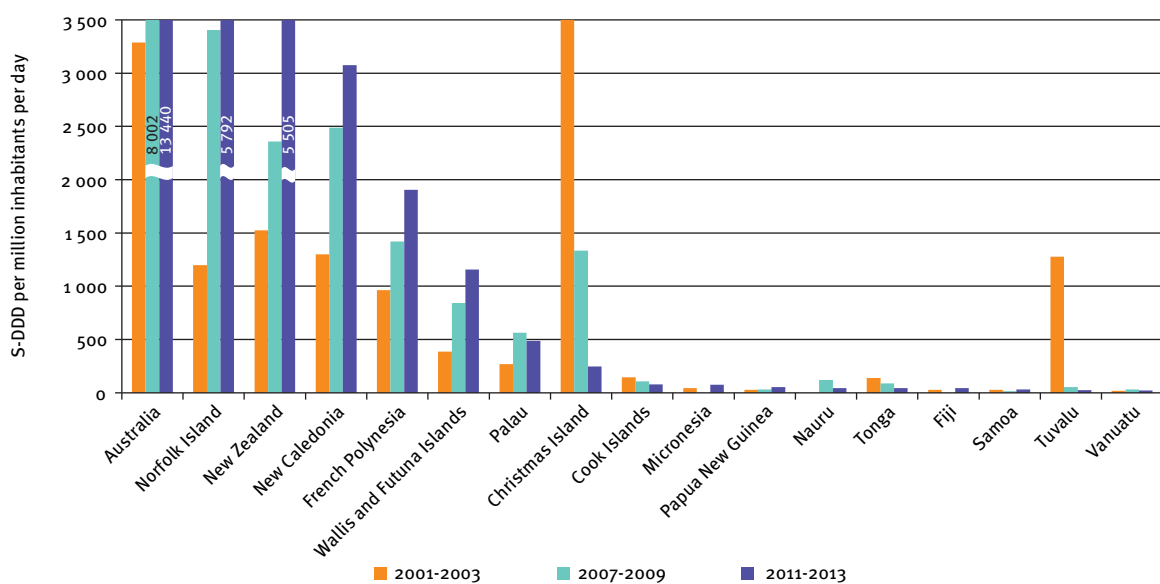
Source: International Narcotics Control Board.

Figure 16. Average consumption of opioid analgesics in European countries with lower levels of consumption, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

Figure 17. Average consumption of opioid analgesics in Oceania, 2001-2003, 2007-2009 and 2011-2013



Source: International Narcotics Control Board.

(c) Overconsumption and prescription drug abuse

81. While inadequate access to opioid analgesics in some regions is a matter of concern, it is important to also consider that in regions with high levels of consumption there are growing public health concerns regarding the abuse of prescription drugs, which in some countries has outpaced the abuse of illegal drugs.

82. Many factors are contributing to this development, but the main ones are the widespread availability of prescription drugs and the erroneous perception that they are less susceptible to abuse than illicit drugs. The non-prescription use of prescription drugs for self-medication has further exacerbated the problem.

83. A comparative analysis by UNODC³⁹ of the consumption of opioid analgesics and the prevalence of their

³⁹World Drug Report 2014, United Nations publication, Sales No. E.14.XI.7.

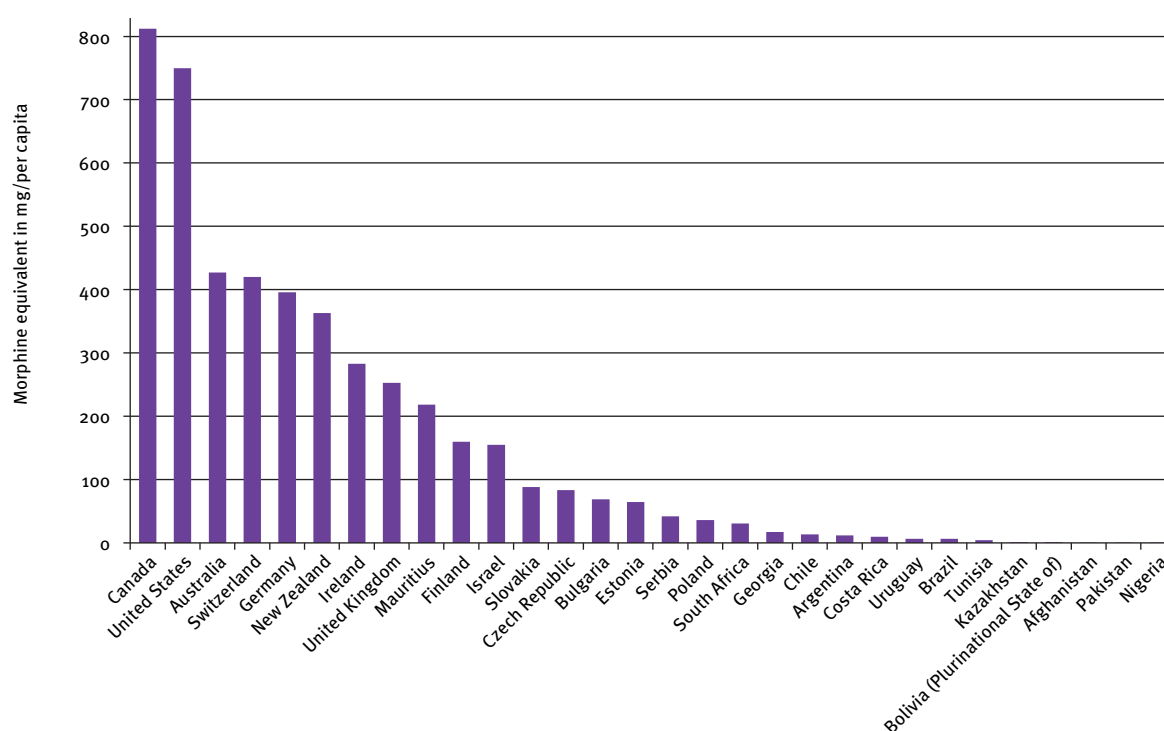
misuse shows a high prevalence of misuse of opioids in some countries. This is reported by high-income countries⁴⁰ such as Australia, Canada and the United States and by lower-middle-income countries such as Nigeria and Pakistan, which have the lowest per capita consumption of opioids for medical purposes (see figures 18-19).⁴¹ According to UNODC, that suggests that the misuse of prescription opioids does not necessarily follow from making opioids accessible or available for medical purposes.⁴²

⁴⁰Based on the World Bank classification of income levels and development.

⁴¹The annual prevalence of misuse of prescription opioids is as follows: Australia, 3.1 per cent; Canada, 1 per cent; Nigeria, 3.6 per cent; Pakistan, 1.5 per cent; and United States, 5.2 per cent.

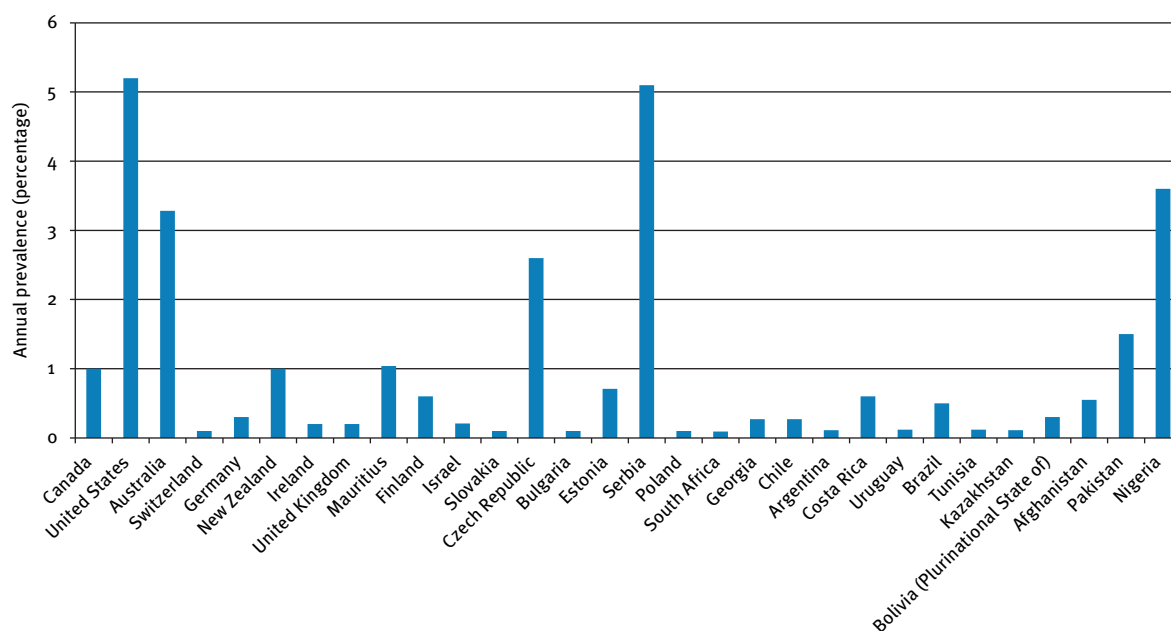
⁴²World Drug Report 2014.

Figure 18. Per capita consumption of opioid analgesics, 2011



Source: UNODC.

Figure 19. Prevalence of misuse of prescription opioids in the general population, 2013 or latest available data



Source: UNODC.

84. To address this problem, countries need to develop a comprehensive strategy aimed at tackling the root causes of the excessive supply of prescription drugs, including overprescribing by medical professionals, “doctor shopping” and inadequate controls on the issuing and filling of prescriptions. In addition, public health officials identified the presence in households of prescription drugs that are no longer needed or used for medical purposes as one of the main sources of prescription drugs diverted from licit channels for abuse. Surveys of the prevalence of abuse undertaken in several countries have revealed that a significant percentage of individuals abusing prescription drugs for the first time had obtained the drug from a friend or family member who had acquired them legally.

85. Among the measures increasingly being used to address this problem are mechanisms to ensure the safe return and disposal of medications possessing psychoactive properties, particularly those containing narcotic drugs or psychotropic substances, including through prescription drug take-back days. The setting up of such initiatives in many jurisdictions has yielded significant results at a relatively low cost.

86. The importance of these measures has been recognized by the international community, including by the

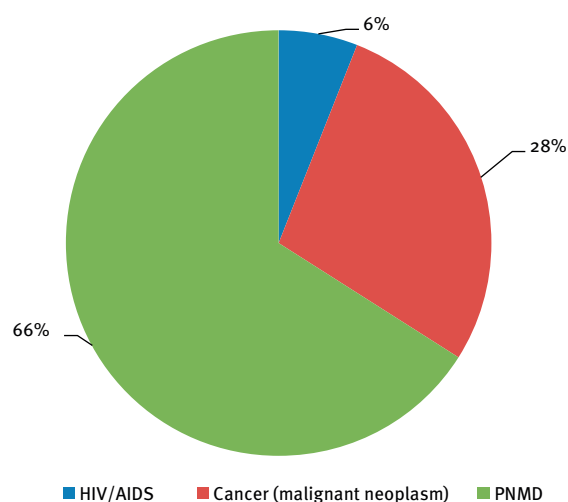
Commission on Narcotic Drugs. Accordingly, in March 2013 the Commission adopted resolution 56/8, on promoting initiatives for the safe, secure and appropriate return for disposal of prescription drugs, in particular those containing narcotic drugs and psychotropic substances under international control.

87. In that resolution, the Commission encouraged States to consider the adoption of a variety of courses of action to address prescription drug abuse, in cooperation with various stakeholders such as public health officials, pharmacists, pharmaceutical manufacturers and distributors, physicians, consumer protection associations and law enforcement agencies, in order to promote greater awareness of the risks associated with the non-medical use of prescription drugs, in particular those containing narcotic drugs or psychotropic substances.

(d) Consumption of opioid analgesics and the need for palliative care

88. The patterns of consumption of opioid analgesics expressed in S-DDD or in milligrams per capita tell only part of the story. In order to ascertain if the level of consumption is appropriate, it is important to measure it in relation to the prevalence of health conditions requiring

Figure 20. Deaths from diseases requiring palliative care at the end of life, by type of disease, 2011



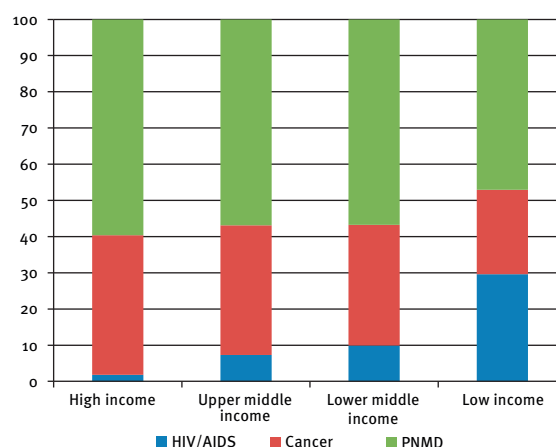
Source: World Health Organization and Worldwide Palliative Care Alliance, *Global Atlas of Palliative Care at the End of Life* (Worldwide Palliative Care Alliance, 2014).

palliative care, which include not only cancer but also other conditions. Also, while consumption of opioid analgesics is concentrated in a few countries, the prevalence of conditions requiring their use is much more widespread.

89. Information from the *Global Atlas of Palliative Care at the End of Life*,⁴³ prepared by WHO and the Worldwide Palliative Care Alliance, indicates that cancer is responsible for 28 per cent of adult deaths requiring palliative care. The majority (66 per cent) of deaths requiring such care are related to progressive non-malignant diseases (PNMD).⁴⁴ The remaining 6 per cent are due to AIDS (see figure 20).

90. In all but low-income countries, the share of adults in need of palliative care for cancer remains more or less constant at around 33-38 per cent; that share drops to around 23 per cent in low-income countries (see figure 21). Progressive non-malignant diseases continue to comprise the majority of cases in all regions. The need for AIDS palliative care comprises one third of palliative

Figure 21. Distribution of adults in need of palliative care at the end of life by income group and disease category, 2011



Source: World Health Organization and Worldwide Palliative Care Alliance, *Global Atlas of Palliative Care at the End of Life* (Worldwide Palliative Care Alliance, 2014).

care cases in low-income countries, but remains below 10 per cent in countries with higher income levels.

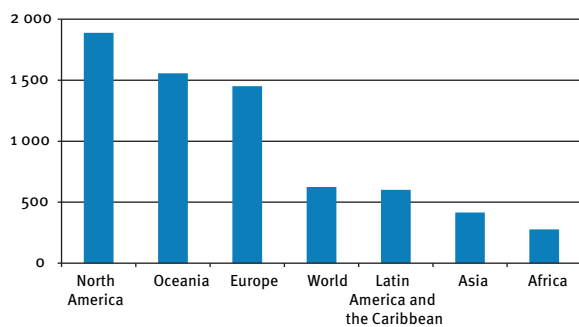
91. The latest data available from the International Agency for Research on Cancer, the specialized cancer research agency of WHO, show that the global burden of cancer has risen to 14.1 million new cases and 8.2 million cancer deaths in 2012, compared with 12.7 million new cases and 7.6 million deaths in 2008. Prevalence estimates for 2012 show that there were 32.6 million people alive and over the age of 15 years who had been diagnosed with cancer in the previous five years (see figure 22). According to projections based on estimates presented by the GLOBOCAN project for 2012, a substantial increase in new cancer cases to 19.3 million per year by 2025 is expected, owing to the expected increase and ageing of the global population.

92. More than half of all cancer cases (56.8 per cent) and cancer deaths (64.9 per cent) in 2012 occurred in less developed regions of the world. Those proportions will increase further by 2025. Cancer is often presented as a disease of wealthy or developed populations. In reality, over 70 per cent of cancer deaths occur in low- and middle-income countries. Without sustained action, the incidence of cancer is projected to increase further in low- and middle-income countries by 2030. Cancer is present throughout the world, but countries that lack the health infrastructure to cope with the increasing number of people suffering from the disease are particularly affected.

⁴³World Health Organization and Worldwide Palliative Care Alliance, *Global Atlas of Palliative Care at the End of Life* (Worldwide Palliative Care Alliance, 2014).

⁴⁴Progressive non-malignant diseases among adults are considered to be Alzheimer's disease and other dementias, cardiovascular diseases (excluding sudden deaths), chronic obstructive pulmonary diseases, cirrhosis of the liver, *Diabetes mellitus*, multiple sclerosis, kidney diseases, Parkinson's disease, rheumatoid arthritis and tuberculosis (multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis only).

Figure 22. Prevalence of cancer diagnoses within the previous five years, per 100,000 population, 2012



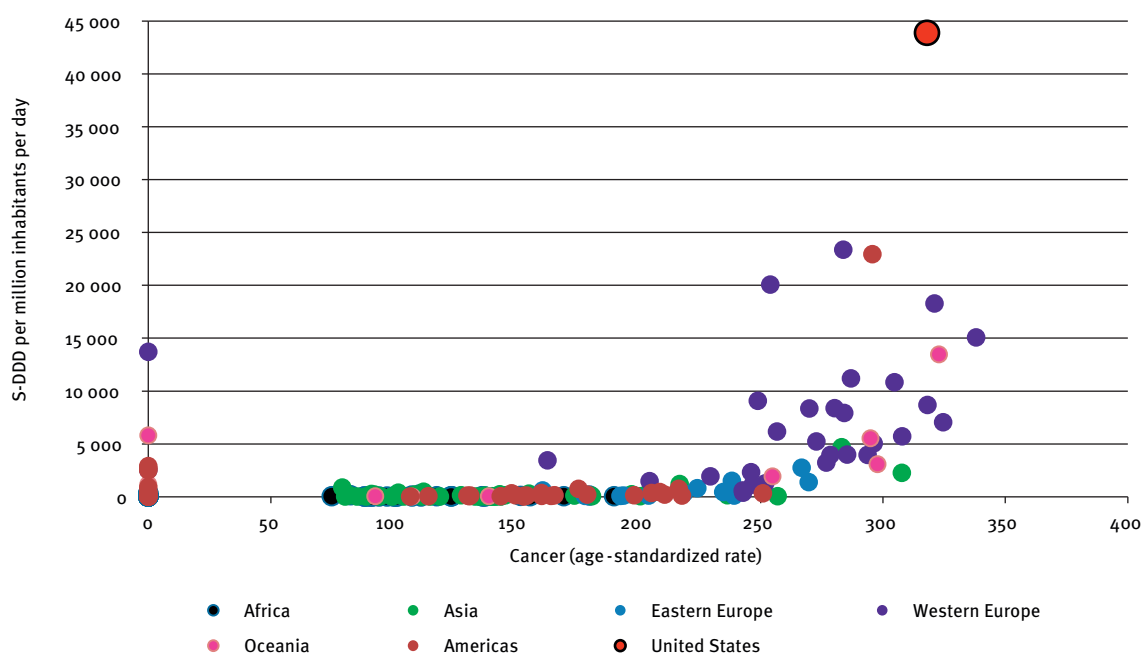
Source: GLOBOCAN database.

93. In low- and middle-income countries, where there is limited capacity with regard to prevention and early detection of cancer, the disease is mostly discovered when it is at an advanced stage. By then, there are not many treatment options and palliation is required. Opioid analgesics for cancer treatment are therefore indispensable in these countries.

94. Plotting the level of consumption of opioid analgesics against the cancer age-standardized rate⁴⁵ confirms the global imbalance in the consumption of such substances, with the United States, Canada, Australia, New Zealand and Western and Central European countries registering high levels of consumption, with a corresponding high cancer age-standardized rate. A global comparison is difficult owing to the fact that most countries are clustered together in the lower levels as a result of the high level of consumption in a few countries (see figure 23). If the patterns in each region are examined in detail, it is possible to gain a better idea of the global variations.

⁴⁵GLOBOCAN presents cancer data in an age-standardized rate, which is a summary measure of the rate that a population would have if it had a standard age structure. Standardization is necessary when comparing several populations that differ with respect to age because age has a powerful influence on the risk of cancer. The age-standardized rate is a weighted mean of the age-specific rates; the weights are taken from the population distribution of the standard population. The most frequently used standard population is the World Standard Population. The calculated incidence or mortality rate is then called age-standardized incidence or mortality rate (world), and is expressed per 100,000 people. The age-standardized rate is calculated using 10 age groups (0-14, 15-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74 and 75+). The result may be slightly different from that computed using the same data categorized using the traditional five-year age bands.

Figure 23. Relationship between cancer incidence, 2012, and consumption of narcotic drugs, 2011-2013



95. In the North America region, there is a considerable gap between Mexico on the one hand, and the United States and Canada on the other hand (see figure 24).

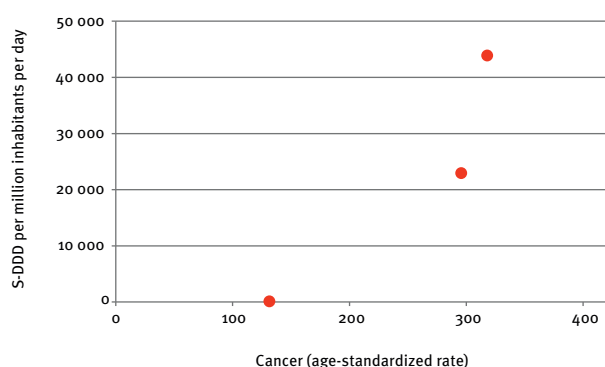
96. In Central and South America and the Caribbean, the distribution of the countries seems to indicate that South American countries have increased their consumption of opioid analgesics and that this is the result of an increasing rate of cancer (see figure 25). In Central America and the Caribbean, there are countries with relatively higher rates of cancer, but their consumption of narcotic drugs for palliative care is below the adequate level.

97. In Africa, there seems to be a concentration of countries with a cancer age-standardized rate of 100, with

a number of countries exceeding it while the consumption of opioid analgesics remains well below the level of 200 S-DDD per million inhabitants per day (see figure 26).

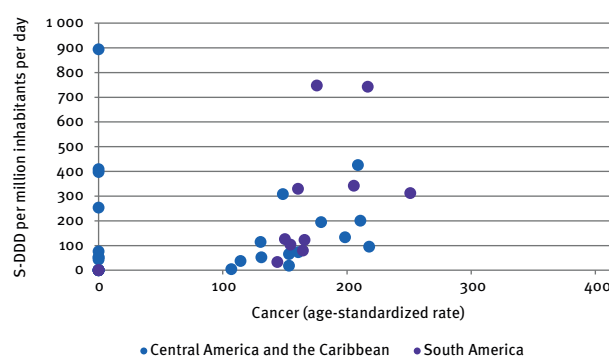
98. In Asia, the level of consumption in S-DDD per million inhabitants per day is higher, but this corresponds to higher cancer rates. In Western Europe, consumption is high and seems to match the level of cancer prevalence. In Eastern and South-Eastern Europe, cancer rates are similar to Western Europe but the level of consumption of pain relief drugs is considerably lower. Australia and New Zealand have very high levels of consumption, while other, smaller countries in Oceania have much lower levels (see figures 27-30).

Figure 24. Relationship between the cancer age-standardized rate, 2012, and consumption of narcotic drugs, 2011-2013, North America



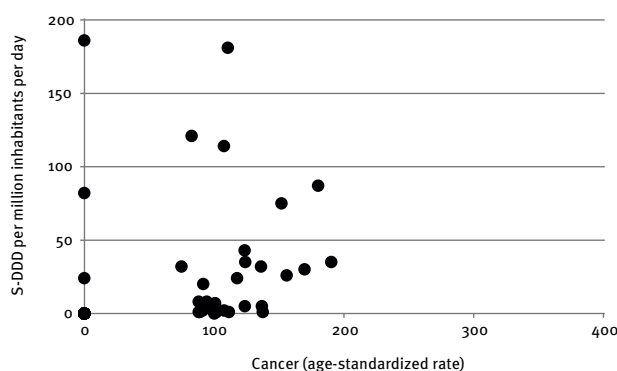
Source: GLOBOCAN database and International Narcotics Control Board.

Figure 25. Relationship between the cancer age-standardized rate, 2012, and consumption of narcotic drugs, 2011-2013, Central and South America and the Caribbean



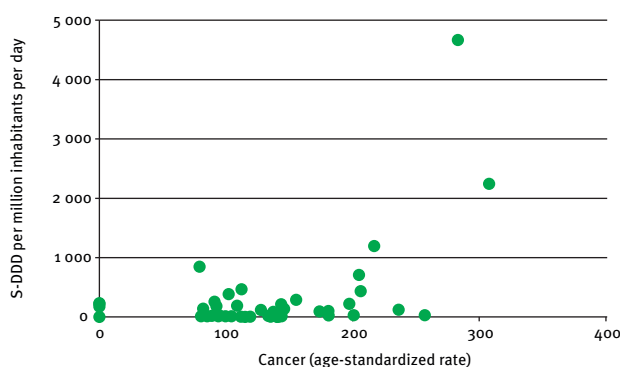
Source: GLOBOCAN database and International Narcotics Control Board.

Figure 26. Relationship between cancer incidence, 2012, and consumption of narcotic drugs, 2011-2013, Africa



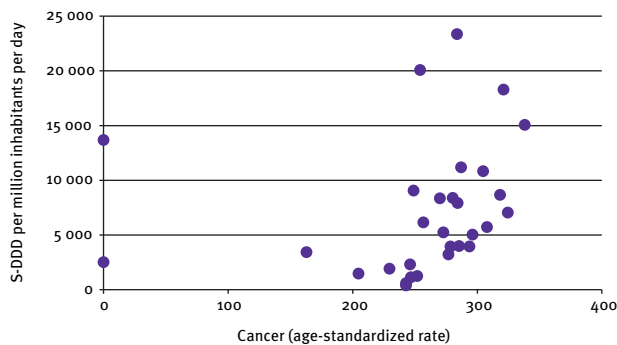
Source: GLOBOCAN database and International Narcotics Control Board.

Figure 27. Relationship between cancer incidence, 2012, and consumption of narcotic drugs, 2011-2013, Asia



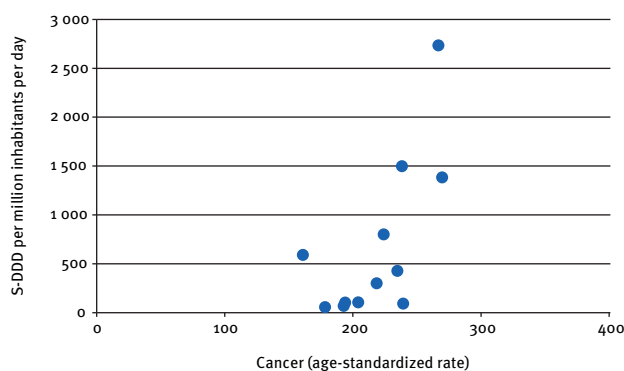
Source: GLOBOCAN database and International Narcotics Control Board.

Figure 28. Relationship between cancer incidence, 2012, and consumption of narcotic drugs, 2011-2013, Western Europe



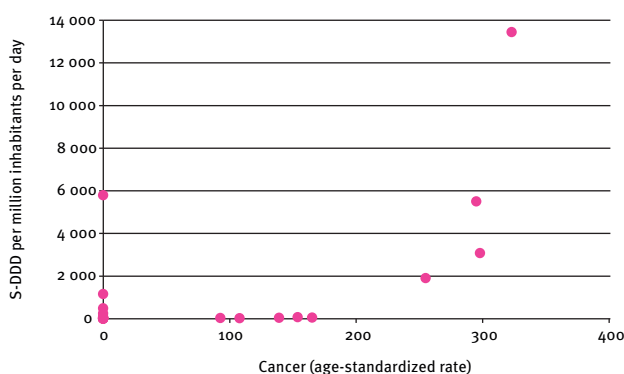
Source: GLOBOCAN database and International Narcotics Control Board.

Figure 29. Relationship between cancer incidence, 2012, and consumption of narcotic drugs, 2011-2013, Eastern and South-Eastern Europe



Source: GLOBOCAN database and International Narcotics Control Board.

Figure 30. Relationship between cancer incidence, 2012, and consumption of narcotic drugs, 2011-2013, Oceania



Source: GLOBOCAN database and International Narcotics Control Board.

99. Palliative care is also required for AIDS. A comparison among the various WHO regions in the *Global Atlas of Palliative Care at the End of Life* shows that the percentage of adults in need of palliative care in relation to AIDS is larger in low-income countries, particularly in Africa, than in countries in other income groups. Expanded access to antiretroviral therapy and a declining incidence of HIV infection have led to a steep fall globally in the number of adults and children dying from HIV-related causes. The drop in HIV-related mortality is especially evident in the regions with the greatest burden of HIV infection, including the African region, which was home to about three in four people who died from HIV-related causes in 2013. However, HIV and AIDS prevalence remains high in low-income countries, and the availability of antiretroviral therapy is still limited, despite efforts made in that regard by UNAIDS and the broader international community. The inadequate availability of opioid analgesics to manage AIDS-related pain is a major problem for an even larger percentage of the population in low-income countries.

100. When comparing the estimated number of AIDS deaths in 2013⁴⁶ with the level of consumption of opioid analgesics, expressed in S-DDD per million inhabitants per day, the countries with highest number of deaths and lowest levels of consumption were in sub-Saharan Africa and Asia (see table 1). Nigeria, with an estimated 210,000 AIDS deaths in 2013, reported no consumption of opioid analgesics to INCB. India had an estimated 130,000 AIDS deaths and just 11 S-DDD per million inhabitants per day. Mozambique, with only 5 S-DDD per million inhabitants per day, had an estimated number of deaths in 2013 of 82,000. The United Republic of Tanzania had the same level of S-DDD and 78,000 estimated deaths. Zimbabwe had 64,000 estimated deaths and only 35 S-DDD. Uganda had only 30 S-DDD and 63,000 estimated AIDS-related deaths. South Africa had 338 S-DDD, but the estimated number of AIDS-related deaths was 200,000.

⁴⁶World Health Organization, Global Health Observatory.

Table 1. Estimated number of AIDS deaths, 2013, compared with the level of consumption of opioid analgesics, 2011-2013

Country	Estimated AIDS deaths in 2013	S-DDD per million inhabitants per day, 2011-2013
Nigeria	210 000	0
South Africa	200 000	338
India	130 000	11
Mozambique	82 000	5
United Republic of Tanzania	78 000	5
Zimbabwe	64 000	35
Uganda	63 000	30
Kenya	58 000	0
Malawi	48 000	26
Ethiopia	45 000	0
Cameroon	44 000	4
Democratic Republic of the Congo	30 000	2
Indonesia	29 000	16
Côte d'Ivoire	28 000	1
Zambia	27 000	32

Source: International Narcotics Control Board and WHO Global Health Observatory.

101. Even though the table above confirms that AIDS is a major health condition requiring palliation, the diseases classified as progressive non-malignant diseases are the major reasons for the demand for palliative care in all regions. However, reliable prevalence rates for these diseases are not available at the global level, making it impossible to compare them with levels of consumption of opioid analgesics.

(e) Consumption of opioid analgesics and the level of development of palliative care

102. An important aspect of the availability of opioid analgesics is the capacity of health systems to prescribe

and dispense such substances through appropriate palliative care services. In the *Global Atlas of Palliative Care at the End of Life*, WHO and the Worldwide Palliative Care Alliance classified countries in relation to the development of the level of palliative care services in six categories:

- Level 1: no known activity
- Level 2: capacity-building activity
- Level 3a: isolated provision
- Level 3b: generalized provision
- Level 4a: preliminary health system integration
- Level 4b: advanced health system integration

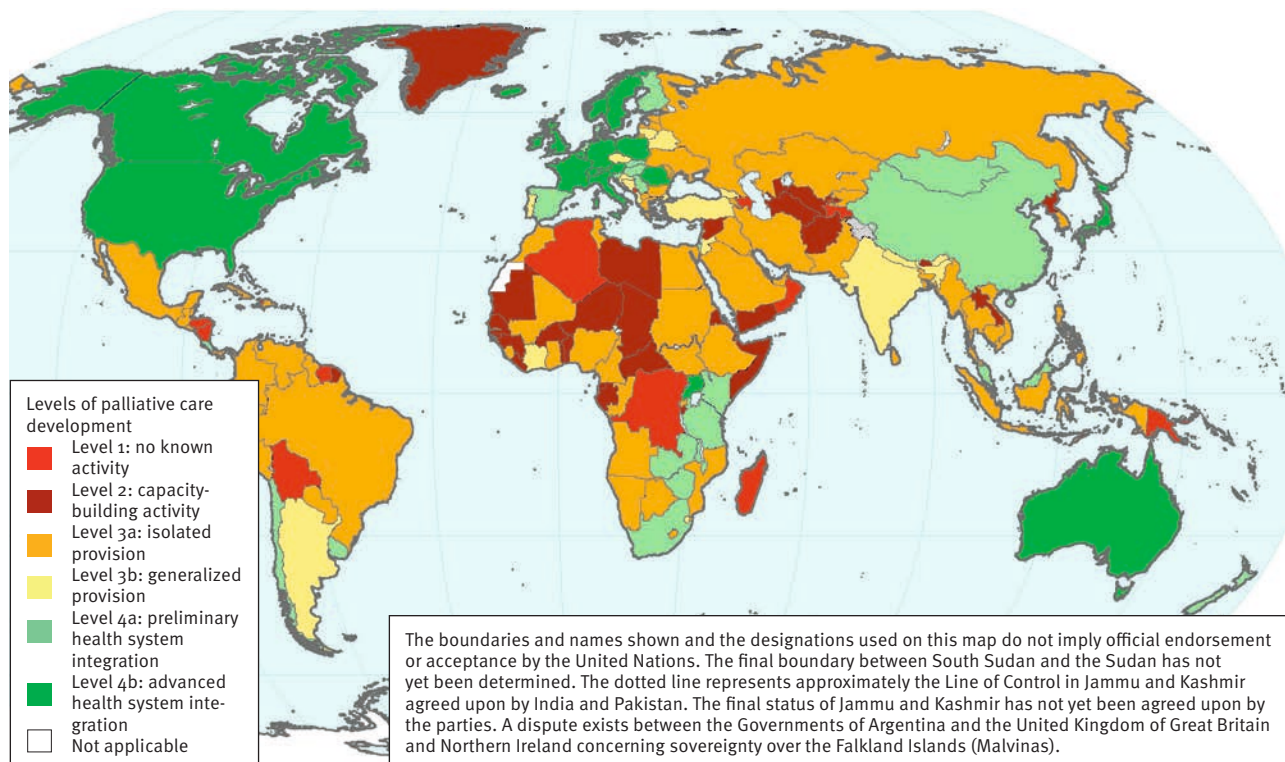
103. By looking at the map illustrating the different levels of palliative care services (see map 3) and comparing it with the map illustrating the levels of consumption of opioid analgesics expressed in S-DDD (see map 4), it is possible to see that, even though there is generally a positive direct correlation between high levels of consumption and high levels of development of palliative care services, there are some inconsistencies.

104. In East and Southern Africa, for example, there are a number of countries at level 4a (Kenya, Malawi, South Africa, United Republic of Tanzania, Zambia and Zimbabwe) or level 4b (Uganda), but in all of these countries (except South Africa) the reported consumption of opioid analgesics is fairly low.

105. In South America (with the exception of Chile and Uruguay, which are considered to be at level 4a, and Argentina, which is rated as level 3b), most countries are rated at level 3a (Brazil, Colombia, Ecuador, Guyana, Paraguay and Peru) or level 2 (Bolivia (Plurinational State of) and Suriname). Nevertheless, levels of consumption are relatively high in the region. The apparent inconsistency with the level of palliative care services may be an indication that consumption is high but concentrated in limited or privileged areas.

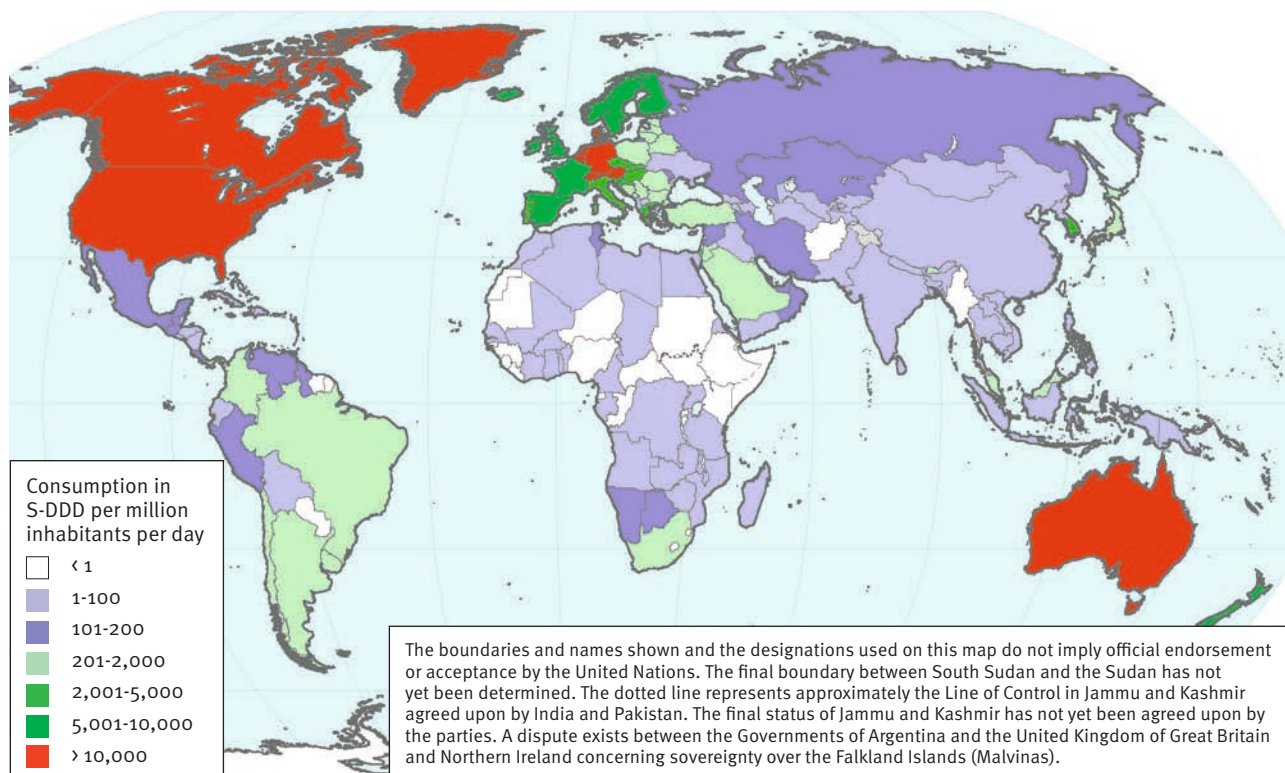
106. The development of palliative care services is important to ensure that, when opioid analgesics are made available, they can actually be efficiently and rationally prescribed.

Map 3. Global levels of palliative care, 2014



Source: World Health Organization and Worldwide Palliative Care Alliance, *Global Atlas of Palliative Care at the End of Life* (Worldwide Palliative Care Alliance, 2014).

Map 4. Consumption of opioids for pain management, 2011-2013



Source: International Narcotics Control Board.

Note: Opioids defined as codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine.

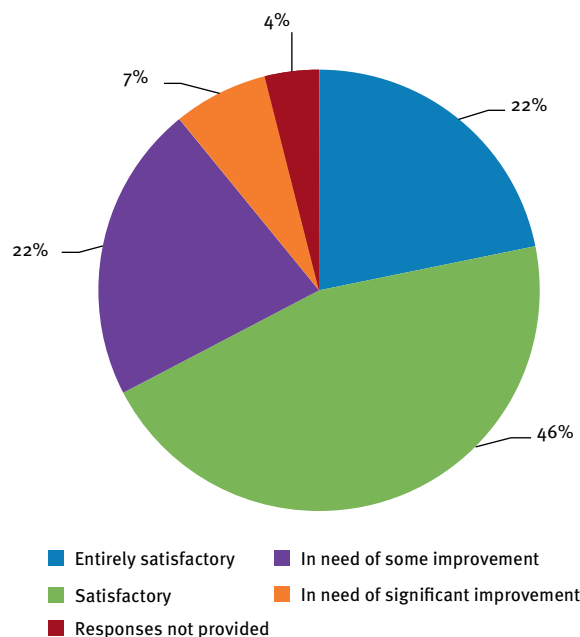
C. Impediments to the availability of narcotic drugs

107. In 2014, INCB carried out a survey asking countries to provide information on policies and practices at the national level to implement the provisions of the 1961 Convention to ensure the availability of narcotic drugs for medical and scientific purposes. The Board received responses from 107 countries. The following paragraphs are an analysis of those responses, with a particular focus on the impediments to availability identified by the competent national authorities.⁴⁷

108. An analysis of the responses indicates that in recent years Member States have taken action to improve availability. This is likely to have contributed to the increase in the consumption of opioid analgesics, as expressed in S-DDD per million inhabitants per day, reported earlier. The answers to the survey show that a large number of countries that are paying attention to the issue of availability and have taken action to overcome legislative, administrative and other impediments have increased access to narcotic drugs for medical purposes and improved the quality of life of people in need of palliative care.

109. This conclusion emerges from an analysis of the consumption patterns examined in previous chapters, but it also derives from self-evaluations by countries of their performance in relation to the availability of narcotic drugs. As shown in figure 31, two thirds of countries consider their situation satisfactory or entirely satisfactory (46 and 22 per cent, respectively), while others indicated the need for some (22 per cent) or significant improvement (7 per cent). Obviously, these self-evaluations need to be checked against the real situation, but they provide an insight into how countries perceive their own performance and therefore whether they are considering taking action or not.

Figure 31. Availability of narcotic drugs, as evaluated by countries themselves, 2014

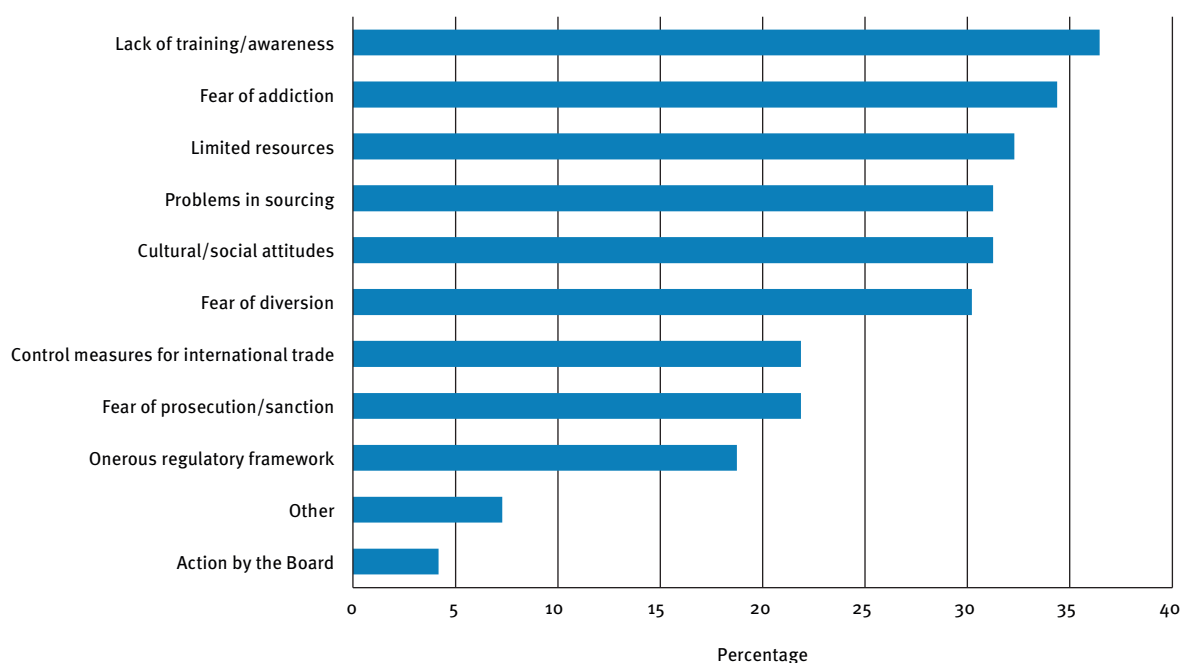


Source: International Narcotics Control Board survey 2014.

110. Member States have reported to the Board on the main factors that unduly limit the availability of narcotic drugs needed for medical or scientific purposes (see figure 32). Out of 96 valid responses to this specific question, 36 per cent of countries indicated as a major impediment a lack of training or awareness among members of the medical profession regarding the use of narcotic drugs. This was followed by fear of addiction (34 per cent) and limited financial resources (32 per cent).

⁴⁷Results shown in the figures are based on replies submitted by Member States to the INCB questionnaire on availability. The number of responses taken into consideration for the calculation of percentages relates to the total number of valid responses for each of the questions, and therefore varies. The sum of all percentages may not amount to 100 in some figures, as countries are given the option of marking one or more options in multiple-choice questions.

Figure 32. Impediments to availability of narcotic drugs



Source: International Narcotics Control Board survey 2014.

111. The Board also reviewed the impediments identified by researchers and civil society organizations involved in health and palliative care. Sometimes the impediments and their prioritization identified by these stakeholders did not match those identified by the competent national authorities. Civil society and academia often consider onerous regulations, strict trade control measures and problems in sourcing as being among the causes of limited access to pain relief medications. Countries responding to the questionnaire, however, highlighted lack of training/awareness and fear of addiction as the main problems.

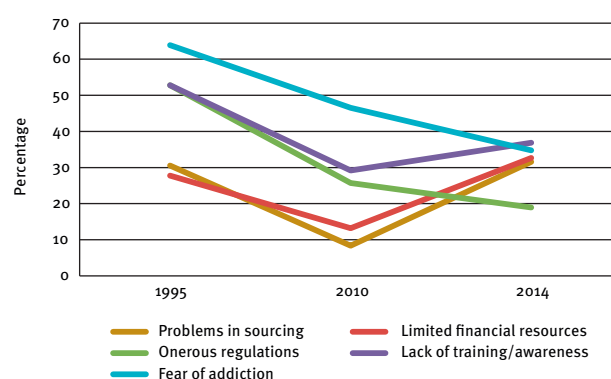
112. For some of these factors, it is possible to make a comparison with information from the surveys carried out by the Board in 1995 and 2010. Fear of addiction, for example, was identified as an impediment by 64 per cent of countries in 1995, but only by 47 per cent in 2010; in the most recent survey, it declined even further, to 34 per cent. Similarly, the mention of onerous regulations and legislative restrictions decreased considerably, as shown in figure 33.

113. The mention of lack of training/awareness among medical professionals as an impediment declined between 1995 and 2010, but it has since increased. It was the most mentioned impediment in the 2014 survey, indicated by 36 per cent of countries. Problems in sourcing or insufficient supply followed a similar trajectory. From

31 per cent in 1995, they dropped to 8 per cent in 2010, and bounced back to 31 per cent in 2014.

114. Similar fluctuations can be seen in responses citing the cost of medicines or lack of financial resources: from 28 per cent in 1995 to 32 per cent in 2014, with a drop to 13 per cent in 2010.

Figure 33. Impediments to availability, 1995-2014



Source: International Narcotics Control Board surveys 1995, 2010 and 2014.

115. The paragraphs below provide an analysis of responses by countries to the 2014 survey. The identified impediments are discussed in descending order by number of mentions.

1. Lack of training or awareness among health professionals

116. Lack of training and awareness among health professionals was the most often mentioned impediment in the responses received from Member States. Several studies and analyses of the problem confirm this. In several countries, health professionals may not have sufficient professional knowledge about pain and pain management. There may be excessive concerns about the side effects of opioids and the possibility that patients may become dependent. Doctors may lack confidence in the patient's report of pain, or assign low priority to pain management. A possible reason for this situation may be the limited attention devoted to palliative care in the curricula of medical schools. In other cases, doctors may be reluctant to prescribe opioid analgesics because they do not trust the ability of the patients and their families to safely manage them.

117. Because of insufficient education and training on palliative care treatment, doctors sometimes underestimate the degree of relief that can be attained with proper treatment, and the extent to which pain is undermedicated. Physicians may also underestimate the need to use potent opioids, such as morphine, for severe pain, and instead prescribe less effective drugs. Also, some physicians may not be able to establish, or may not be used to establishing, an interpersonal relationship that would help to identify the adequate pharmacological therapy and allow for personalized prescriptions that take the patient's needs and current health status into account.

118. In addition, nurses in some countries may not be adequately trained to manage pain and support patients, and may have misconceptions and prejudices about opioid medications similar to those held by doctors, as described above. In some cases, nurses may administer lower dosages than required or none at all, or they may try to convince the patient to wait and endure the situation without adequate pain medication.

119. In the 2014 survey, 70 countries reported having an educational curriculum for medical practitioners that included content on the rational prescription and use of narcotic drugs. Of those, 73 per cent (51 countries) had registered an increased per capita consumption between the 2007-2009 and the 2011-2013 periods.

120. Out of 61 countries that reported implementing awareness-raising measures to foster a deeper understanding of responsible prescribing practices for narcotic drugs among health professionals, 45 countries (74 per cent) had observed an increase in S-DDD per million

inhabitants per day. Such measures have included workshops, seminars, special training and supervision, and distribution of informative materials, as well as working groups with pharmacists, representatives of the pharmaceutical industry and medical associations.

2. Fear of addiction

121. Thirty-three countries (34 per cent) reported fear of addiction as an impediment to availability, the second most mentioned impediment in the 2014 survey. Out of those countries, 18 (55 per cent) remained below the minimum levels of consumption.

122. According to Human Rights Watch, the reluctance among health professionals to prescribe opioid analgesics may be related more to the fear of causing addiction or respiratory distress in patients than the fear of prosecution or sanction.⁴⁸ This emerges also from the 2014 survey, in which fear of addiction was identified as an impediment by 33 countries and fear of prosecution or sanction by 21 per cent.

123. It seems that fear of addiction is related to lack of awareness and training, as well as cultural attitudes. Both patients and medical professionals may be reluctant to prescribe and use narcotic drugs due to lack of knowledge about their properties and safe ways to prescribe them, as well as prejudices against the use of such substances.

3. Limited financial resources

124. Thirty-one countries (32 per cent) identified financial issues as an impediment to the availability of narcotic drugs. Lack of resources can be particularly prohibitive when narcotic drug prices are high. While some formulations, such as oral morphine, can be produced quite cheaply, prices of narcotic drugs may be driven up by government regulation, licensing and taxation, as well as poor distribution systems (e.g. ones that require expensive and lengthy travel to collect medicines), among other things.⁴⁹ For example, the Latin-American Association of Palliative Care reported that, in one country in Central America, the price of a one-month treatment with injectable morphine was more than double the national minimum monthly wage. In this context, availability is dependent on the ability of patients to afford narcotic drugs that are prescribed. Therefore, it is important to consider whether patients are

⁴⁸Human Rights Watch, *Global State of Pain Treatment: Access to Palliative Care as a Human Right* (2011), chap. II.

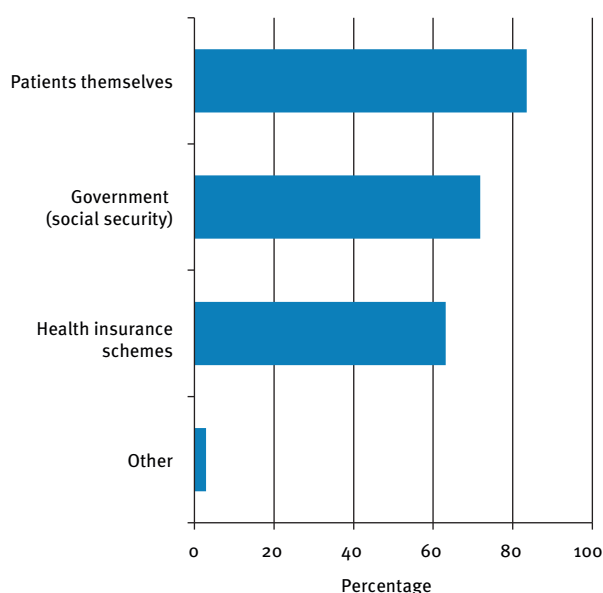
⁴⁹Ibid.

expected to cover all or most costs for such drugs, or if there is financial support through social security or national health insurance schemes. In the responses to the question on who pays for narcotic drugs prescribed (see figure 34), patients were mentioned the most (83 per cent), followed by the government (72 per cent) and health insurance schemes (63 per cent).

125. A cross-sectional study carried out in 2014 suggests that, particularly in countries with limited resources for subsidy and reimbursement schemes for opioid analgesics, the additional costs arising from regulatory requirements might thus be transferred directly onto patients. The study also found that the price of oral solid immediate-release morphine was 5.8 times higher in lower-middle-income countries than in high-income countries. This difference in dispensing prices may be related to the artificial lowering of the price of other more expensive formulations (fentanyl) owing to heavy subsidies, which in turn creates a condition of economic disadvantage for oral solid immediate-release morphine.⁵⁰

126. Thus, impediments to the affordability of narcotic drugs can derive from lack of resources, high prices created by restrictive national regulations and international trade control measures, and non-supportive policies, including lack of public health reimbursement schemes.

Figure 34. Who bears the cost of prescribed narcotic drugs, 2014



Source: International Narcotics Control Board survey 2014.

⁵⁰Liliana De Lima and others, "Cross-sectional pilot study to monitor the availability, dispensed prices, and affordability of opioids around the globe", *Journal of Pain and Symptom Management*, vol. 48, No. 4 (October 2014).

4. Problems in sourcing from industry or imports

127. Many responses indicated problems in sourcing. Some formulations of narcotic drugs, such as oral morphine, may not be available in sufficient quantities, as manufacturers and importers/exporters, especially in the case of smaller populations and/or low market demand, may prefer to produce and trade only more expensive formulations. Marketing of such formulations, coupled with the subsidies granted for specific products (for example, fentanyl), may explain why an analysis of consumption data shows a much steeper increase in the consumption of fentanyl than of morphine.

128. In several countries, local pharmaceutical companies lack interest in manufacturing oral morphine, in part because the prescribing of opioids by physicians is too limited and the demand from hospitals insufficient to justify production. In some developing countries, morphine is only available through import from international pharmaceutical companies, with prices that are unaffordable both for the government and the population. Finally, some local pharmaceutical companies are not interested in producing opioid medications because of security costs and legal risks associated with this kind of product.

129. In addition to the lack of local production, another obstacle to the availability of narcotic drugs is the difficulty in sourcing through imports. Several countries indicated that there were shortages of medications as a result of delays in the supply chain due to lengthy and burdensome regulatory requirements (e.g. import/export licensing). The supply of narcotic drugs has also been found to be restricted by inadequate national estimates, time-consuming reporting requirements and difficulties in the management of narcotic drugs.

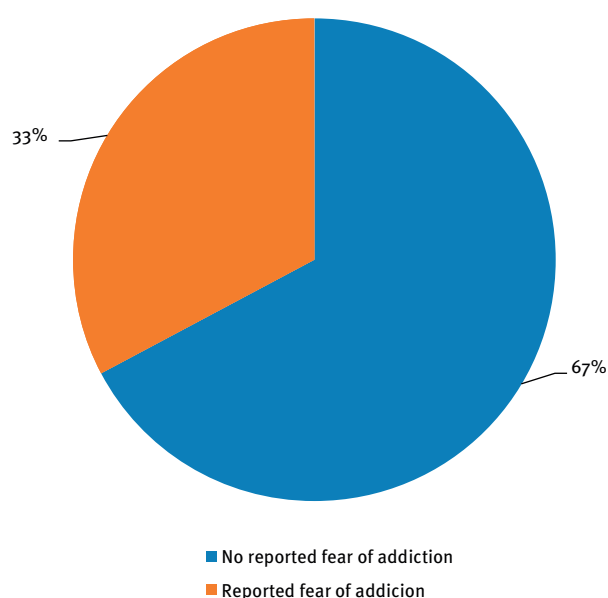
5. Cultural and social attitudes towards the treatment of pain

130. Impediments related to attitudes and knowledge, identified by 31 per cent of countries, included the beliefs of doctors, patients and their families, as well as policy-makers. Patients may sometimes be the ones to refuse pain relief due to their reluctance to report pain or to accept the idea of taking opioids. Some patients and/or their family members may be concerned about the side effects of opioids and try to reduce the dosages. They may also worry about the stigma associated with the use of opiates or pain medication. Some patients may avoid taking opioids owing to their sedative effects, because they want to remain conscious, especially patients in the

terminal stages of a disease who may be afraid to lose the bond with their families.

131. Out of 61 countries that had implemented awareness-raising measures among health professionals, a large proportion (67 per cent) did not report fear of addiction as an impediment to availability (see figure 35). This may indicate that investing in fostering a deeper understanding of responsible prescribing practices for narcotic drugs among health professionals can contribute to overcoming the impediments created by the fear of addiction and other misconceptions regarding opioid analgesics and the management of pain.

Figure 35. Reports of fear of addiction among countries and territories that have implemented awareness-raising measures, 2014



Source: International Narcotics Control Board survey 2014.

6. Fear of diversion into illicit channels

132. Out of 96 responding countries, 29 (30 per cent) reported fear of diversion as an impediment to availability. Out of these, 20 countries (69 per cent) had levels of consumption below 200 S-DDD per million inhabitants per day, a level that is not considered to be adequate by the Board.

133. Reported fear of diversion can result from the experiences of countries with the emergence of unregulated parallel markets for narcotic drugs. Among the countries that reported fear of diversion as an impediment, 41 per cent also reported experiencing problems

with parallel markets. One country mentioned that limited availability had been the result of stricter regulatory measures enacted in response to the use of the Internet to purchase and sell opioid analgesics without prescription.

7. Fear of prosecution or sanction

134. Out of 99 responding countries, 81 (82 per cent) reported the existence of penalties for inadequate record-keeping. Reported penalties ranged from monetary fines, to licence revocation, to prison sentences. Reports by the Access to Opioid Medication in Europe project⁵¹ and Human Rights Watch⁵² suggest that fear of sanction may arise in the context of unclear, often stigmatizing legislation, lack of legal knowledge among health professionals and harsh penalties, including penalties for unintentional violations. In the survey, out of 21 countries reporting fear of prosecution/sanction as an impediment, almost all indicated the existence of penalties, and three quarters of them showed inadequate S-DDD levels, i.e. below 200 per million inhabitants per day.

8. International trade control measures

135. Policies, rules and regulations to control the production, import and export of controlled substances have been established and are monitored at the international level by INCB. For some countries, the effort to estimate the amount of controlled medication needed may be beyond their capacities and existing resources, and therefore technical and logistical support may be required.

136. Countries have reported difficulties with the issuance of import/export permits, along with other international drug control measures that require lengthy procedures and thus may lead to delays and shortages.

9. Onerous regulations

137. Out of 53 countries that reported having taken legislative or regulatory action in the previous 10 years to

⁵¹ Access to Opioid Medication in Europe, *Final Report and Recommendations to the Ministries of Health*, Lukas Radbruch and others, eds. (Bonn, Germany, Pallia Med Verlag, November 2014).

⁵² *Global State of Pain Treatment*, chap. II.

increase the availability of narcotic drugs for medical purposes, 37 countries (70 per cent) had observed an increase in S-DDD rates since the 2007-2009 period. Among such legislative or regulatory actions, countries reported the following: facilitating the prescription and dispensing of narcotic drugs, which could include the elimination of obligatory prescription pads for doctors and the extension of prescription periods; allowing nurses and midwives to prescribe and administer narcotic drugs; facilitating accessibility of treatment for patients; simplifying record-keeping; and issuing informative leaflets on uses, side effects, warnings and precautions concerning narcotic medicines.

138. At the national level, some countries, out of fear of diversion and risk of addiction, have developed regulatory systems that go beyond the requirements provided in the drug control treaties, with unnecessary impediments that do not take into full account the WHO and INCB recommendations.

139. Regulations that restrict opioid prescription mechanisms include the following: requiring special patient permits; limiting the authority of physicians to prescribe opioids, even for cancer patients with strong pain; imposing dose limits that restrict the ability to adjust the dose to individual patient needs; imposing severe limits on the duration of prescriptions; restricting the dispensing of opioids, making it harder for patients to access such medication; increasing bureaucratic burdens through the use of complex or poorly accessible prescription forms or complex reporting requirements; and introducing disproportionate legal sanctions that result in the intimidation of health-care providers and pharmacists.

140. In some countries, regulations prevent doctors from prescribing appropriate substances and sufficient dosages, so that patients have to visit their physicians very frequently, for example, because they are not allowed to get a prescription for morphine for more than 7 or 10 days. Of the countries responding, only 21 per cent stated that they allowed refills under certain circumstances without requiring a new prescription.

141. Particularly in low-income countries, the ability to prescribe morphine and other potent opioids is limited to a small number of physicians, who are required to undergo a special registration procedure. In some cases, not even specialists in diseases requiring palliative care have independent prescribing authority.

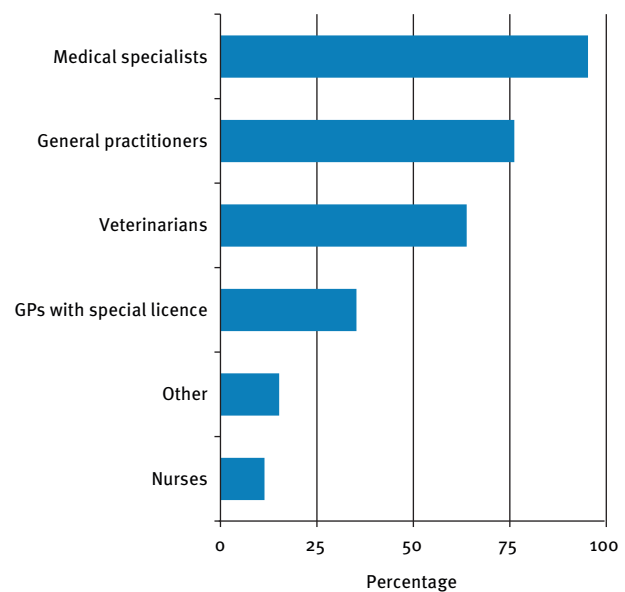
142. Another example of a regulatory impediment is the special triplicate forms doctors have to fill out, which can be difficult to obtain and for which in many cases

doctors have to pay. According to WHO, special multiple-copy prescription requirements typically “reduce prescribing of covered drugs by 50 per cent or more”.⁵³

143. Of 102 responding countries, 75 per cent legally required prescribers to keep records of narcotic drug prescriptions. This may discourage the stocking of opioid analgesics owing to costs and time-consuming procedures, and possibly fear of prosecution and sanctions. It is certainly possible to find a way to ensure that records are kept while preventing this basic requirement from becoming too onerous for those who are doing the prescribing.

144. As illustrated in figure 36, nurses are seldom allowed to prescribe narcotic drugs. This may also be an impediment to availability, especially in countries facing challenges in their health-care systems and infrastructure.

Figure 36. Prescribers of narcotic drugs, 2014



Source: International Narcotics Control Board survey 2014.

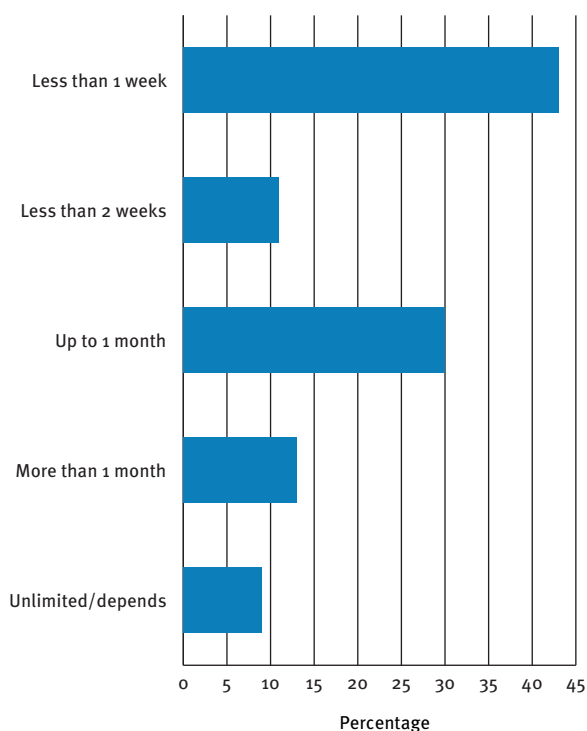
145. Some countries that have been able to considerably increase their levels of consumption in S-DDD per million inhabitants per day during the past two decades have reported that midwives are also allowed to prescribe narcotic drugs. The issue of pain during labour is mostly overlooked in the discussion, despite its ubiquity, which calls for measures to ensure its adequate management, including the use of narcotic drugs.

⁵³World Health Organization, *Cancer Pain Relief, With a Guide to Opioid Availability*, second edition (1996), part 2.

146. There was a wide range of prescription validities among countries (see figure 37). Forty-three per cent of countries reported that prescriptions were valid for up to seven days. The second most often reported validity (30 per cent of countries) was between two weeks and a month.

147. Centralized systems can furthermore limit adequate distribution, because opioids are often only available in major cities and are not delivered to rural areas. Sometimes, doctors have to travel to major cities to get medications and even prescription forms; patients may have to do the same. In some countries, it can take more than a month for an opioid medication to be delivered from urban centres to provincial and rural areas.

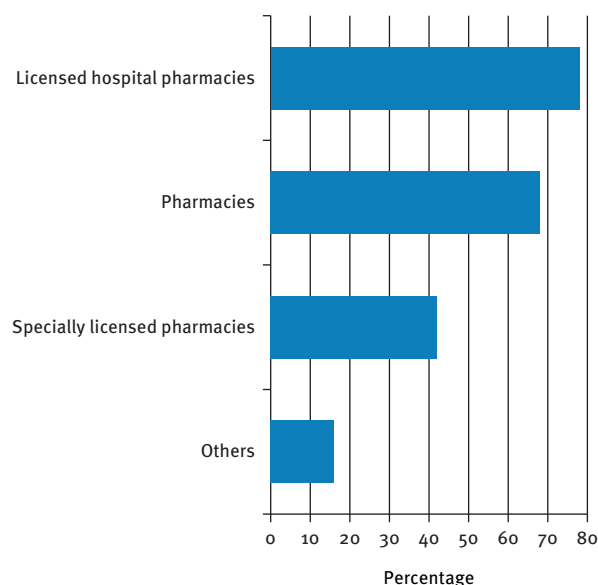
Figure 37. Maximum validity period of prescriptions that contain narcotic drugs, 2014



Source: International Narcotics Control Board survey 2014.

148. Member States reported that narcotics were dispensed mostly in licensed hospital pharmacies (75 per cent). Slightly more than half of responding countries (54 per cent) reported that narcotics could be dispensed in regular pharmacies (see figure 38).

Figure 38. Facilities where prescriptions for narcotic drugs can be dispensed, 2014



Source: International Narcotics Control Board survey 2014.

149. Restrictions on the number of pharmacies that are allowed to dispense controlled substances may also reduce availability. The administrative burden for pharmacies is an additional factor. In some countries, pharmacists must collect a standard set of information: patient name, address and date of birth; drug dispensed, as well as the date, quantity and dosage, the number of days' supply and the number of refills; and the patient's health-care provider. Pharmacies are also required to keep such information in a central database for several years. This necessitates the use of human resources, time and access to specific technology for monitoring and data collection. The existence of a legal requirement for dispensing agents to keep records was reported by 101 (98 per cent) of 103 responding countries.

150. In many countries, only one institution, or else a few pharmacies, are allowed to stock opioid medication. To do so, they have to seek permission from drug regulatory authorities through a lengthy process. Even in acute-care hospitals, morphine may not be included in the drug list for emergencies. In addition, some pharmacies located in unsafe areas are afraid to sell opioids because of the risk of being robbed.

10. Other impediments

151. Other impediments identified by a smaller number of countries (seven) point to insufficient supply due to a lack of certain opioid formulations, an unexpected increase in demand for a specific drug, or business

decisions by industry and importers of narcotic drugs. Also mentioned were a lack of awareness on the part of patients, inadequate estimates and reporting, and the existence of illegal markets.

11. Action by the Board

152. In the survey, countries could also indicate that actions taken by the Board had been an impediment. Only four countries did so.

153. In addition, countries were asked to suggest measures the Board could take to improve the availability of narcotic drugs for medical and scientific purposes. Most countries mentioned the provision of training and information to authorities and stakeholders on several issues: benefits, rational prescription and use of narcotic drugs; management, distribution and control of narcotic drugs; estimates and assessments; and awareness-raising programmes to address fears relating to prescribing or dispensing narcotics.

154. Other countries pointed to the need to facilitate the procurement of narcotic drugs through quick and flexible approval of estimates and supplementary estimates by the Board, as well as the introduction of online software for import and export licensing. In addition, INCB was requested to play a more active role by urging manufacturers to deliver the necessary medications on time, asking Governments to provide the necessary human and financial resources, and facilitating the availability of limited quantities for the purpose of test and reference standards. A few countries mentioned the need for more research on availability, the development of recommendations to increase access and the establishment of a laboratory for quality control of narcotic drugs.

155. Among responding countries, there was a high level of awareness of the procedures for submitting estimates and supplementary estimates (97 per cent), as well as knowledge of INCB training materials (82 per cent) and joint INCB/WHO guidelines (87 per cent) on the preparation of estimates.

Chapter III.

Psychotropic substances

156. There are currently 125 psychotropic substances⁵⁴ 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 substances⁵⁵ currently under international control are included in the latest WHO Model List of Essential Medicines.⁵⁶ 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

⁵⁴Nine 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.

⁵⁵Buprenorphine, diazepam, lorazepam, midazolam and phenobarbital.

⁵⁶World Health Organization, Model List of Essential Medicines, 19th list (April 2015, amended June 2015). Available from 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.

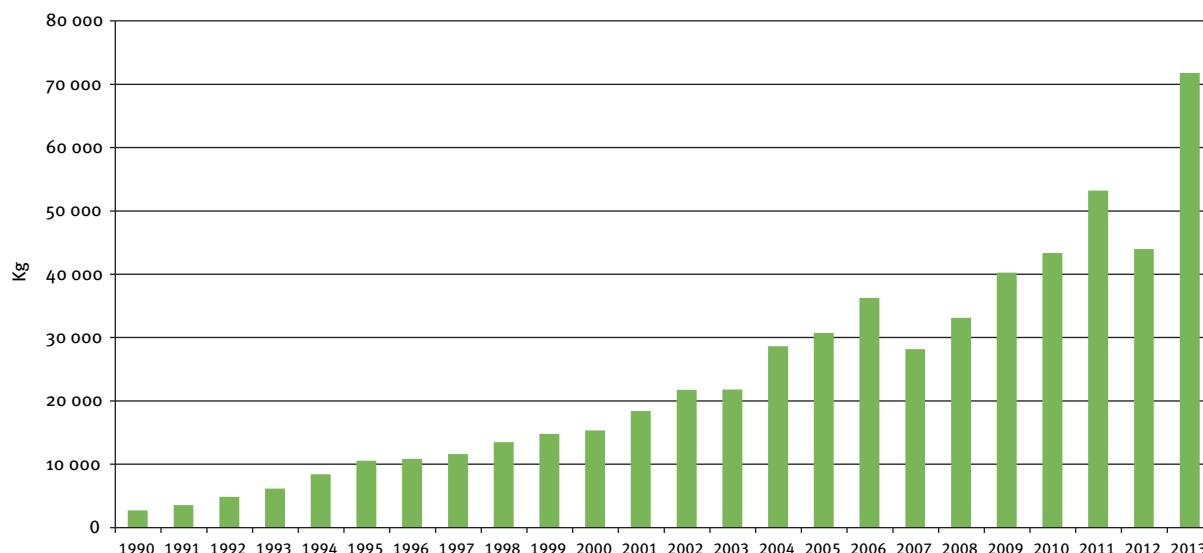
169. Amphetamines and methylphenidate are the only stimulants in Schedule II that are manufactured and traded in large quantities. In particular, they are manufactured in very large quantities in the United States and a few European countries. These substances are mostly used for the treatment of attention-deficit 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 countries⁵⁷ 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.

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).

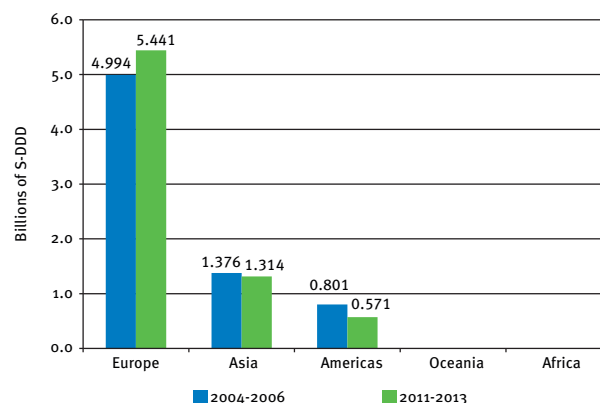
3. Supply of benzodiazepines

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

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

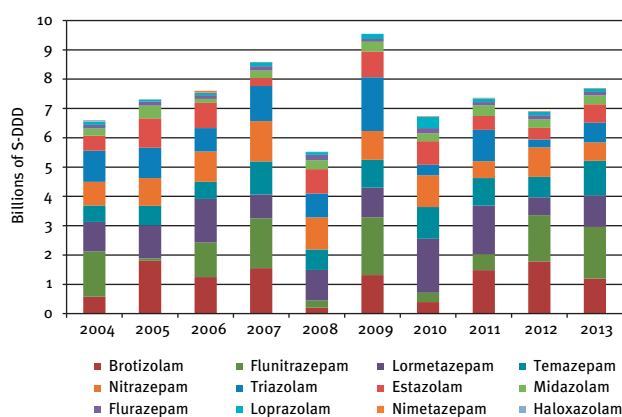


Source: International Narcotics Control Board.

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

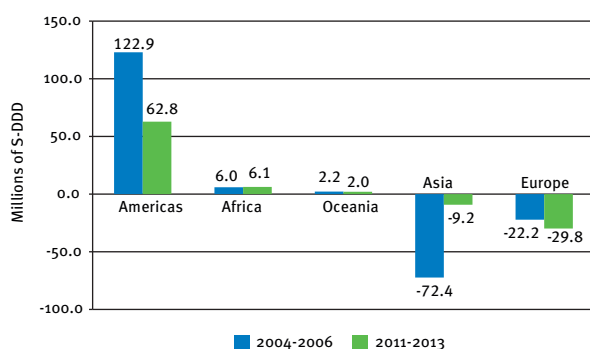
175. In the past 10 years, global reported manufacture of benzodiazepine-type sedative-hypnotics fluctuated around an annual average of 7.4 billion S-DDD (see figure 41). Out of the 12 substances in this group (brotizolam, estazolam, flunitrazepam, flurazepam, haloxazolam, loprazolam, lormetazepam, midazolam, nimetazepam, 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



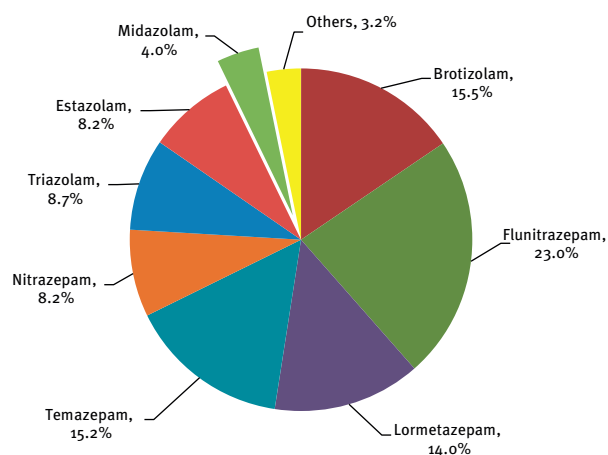
Source: International Narcotics Control Board.

(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.

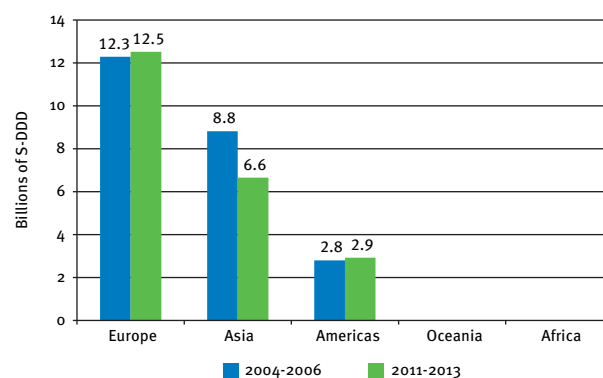
177. In the past 10 years, global reported manufacture of benzodiazepine-type anxiolytics fluctuated between 18.3 and 29.9 billion S-DDD, around an annual average of 22 billion (see figure 45). Twenty-two benzodiazepines

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.

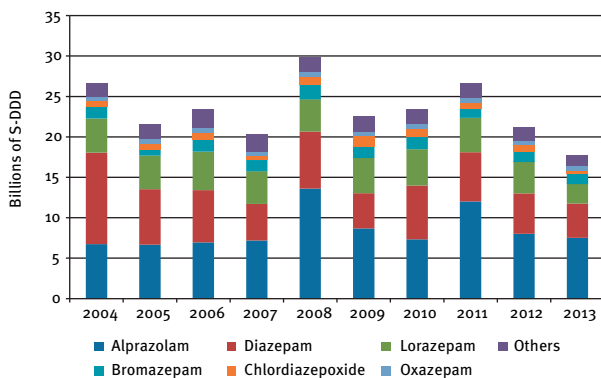
are generally classified as anxiolytics; two of them, diazepam and lorazepam, are included in the WHO Model List of Essential Medicines. During the 2004-2013 period, diazepam and lorazepam accounted for 26 and 18 per cent, respectively, of global supply of this group of substances. The shares of total 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

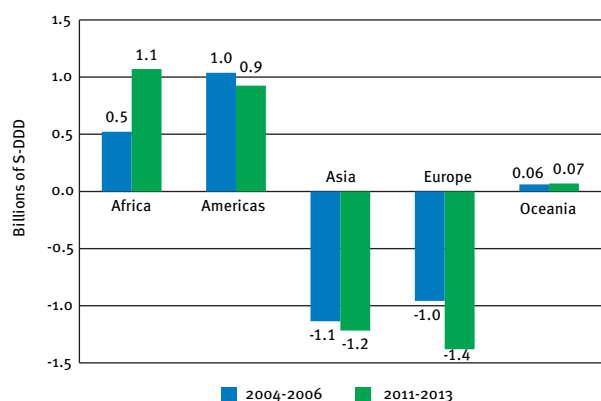
178. There have been divergent patterns in the manufacture and trade of barbiturate-type anti-epileptics (phenobarbital and methylphenobarbital) and benzodiazepine-type anti-epileptics (clonazepam) included in Schedule IV during the past 10 years. Phenobarbital is included in the WHO Model List of Essential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

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



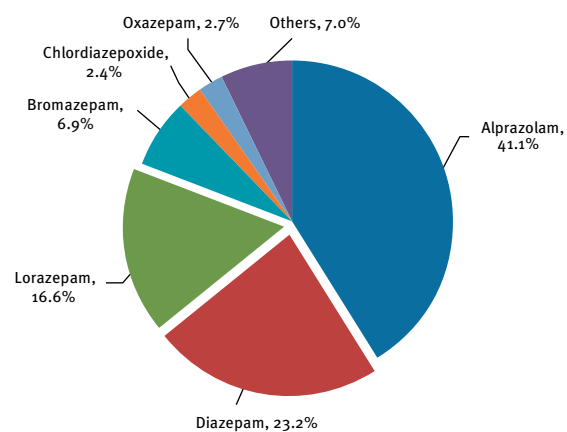
Source: International Narcotics Control Board.

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



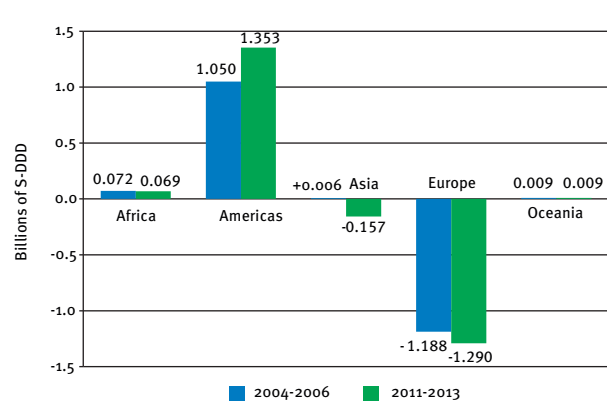
Source: International Narcotics Control Board.

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



Source: International Narcotics Control Board.

Figure 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.

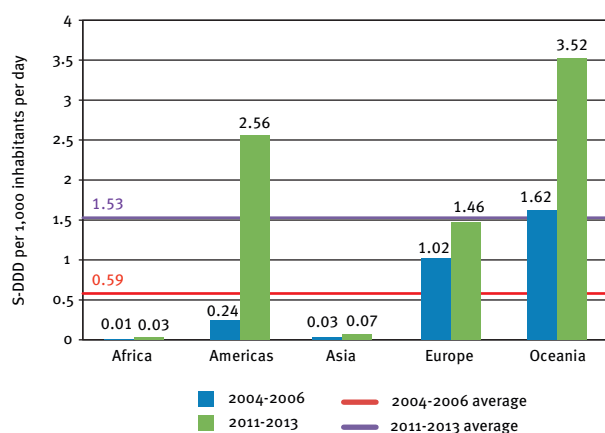
183. The degree of availability of psychotropic substances is approximated in the present report by using measures of calculated consumption of individual substances and groups of substances. The 1971 Convention does not foresee reporting on consumption of psychotropic substances to the Board. Therefore, 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.

Figure 49. Average consumption of opioid analgesics, by region, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

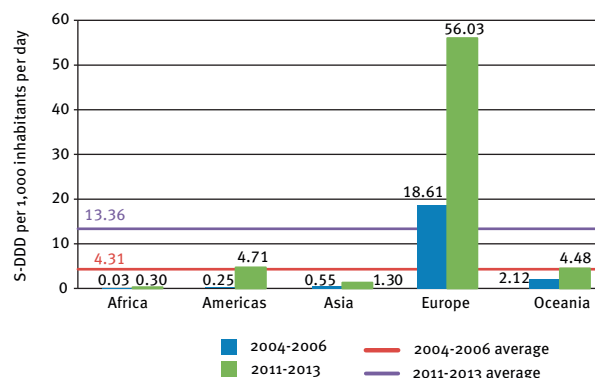
1. Availability of opioids controlled under the 1971 Convention

187. The number of countries and territories using one or more of the analgesics controlled under the 1971 Convention (buprenorphine, lefetamine⁵⁸ and pentazocine) has remained stable at about 100 since 2004. In contrast, the volume of consumption of these opioids increased in all regions of the world between 2004 and 2013 (see figure 49). During the 2004-2006 period, levels of consumption were highest in Europe and Oceania (the high levels of consumption in Oceania are the result of manufacture and calculated consumption in Australia). While consumption continued to increase markedly in Europe by the 2011-2013 period, it increased more than tenfold in the Americas, and almost sixfold in Africa, albeit from a low level.

188. The national per capita level of consumption of opioids controlled under the 1971 Convention during the 2004-2006 and 2011-2013 periods are shown in maps 5 and 6. As can be seen, the majority of countries and territories continue to have a level of consumption below 0.1 S-DDD per 1,000 inhabitants per day. However, there has been a marked increase in the highest level of consumption, of over 1 S-DDD per 1,000 inhabitants per day, in the past 10 years. While during the 2004-2006 period, only four countries had a per capita level of consumption greater than 1 S-DDD per 1,000 inhabitants per day, in the 2011-2013 period 16 countries had attained that level.

⁵⁸Lefetamine has not been manufactured and consumed since the 1990s (see para. 167).

Figure 50. Average consumption of buprenorphine, by region, 2004-2006 and 2011-2013



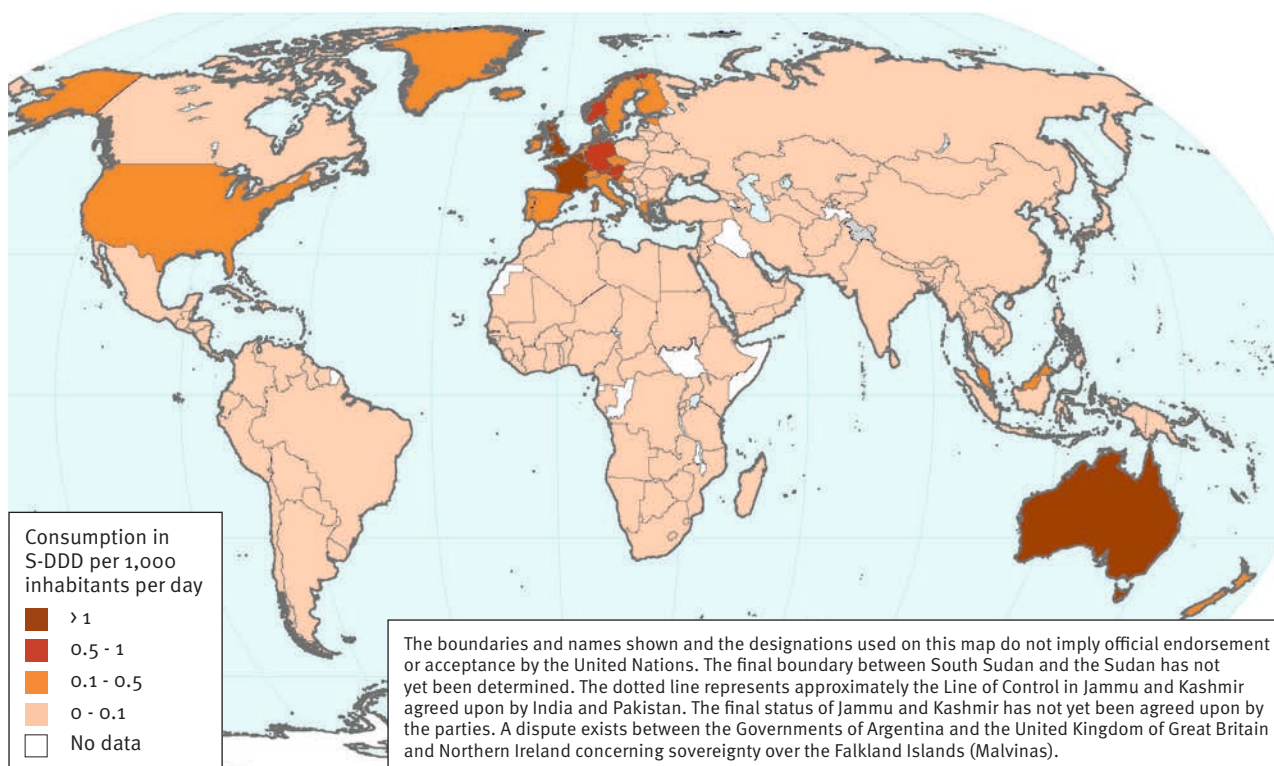
Source: International Narcotics Control Board.

189. The consumption of buprenorphine, which is listed in the Model List of Essential Medicines of WHO (complementary list), accounted on average for 97 per cent of global consumption of opioid analgesics controlled under the 1971 Convention during the 2009-2013 period. Consumption of pentazocine, which has properties and uses similar to those of morphine, accounted for the remainder.

190. Global calculated consumption of buprenorphine has steadily increased since 2000, from less than 1 ton (100 million S-DDD) to a new record of almost 10 tons (1.2 billion S-DDD) in 2013. During the 1990s, buprenorphine was used by no more than 20 countries worldwide, whereas in the 2011-2013 period, buprenorphine was used in about 90 countries and territories, in every region, or about 40 per cent of all countries and territories. That increase in the consumption of buprenorphine is mainly due to its increasing use in higher-dosage forms for the treatment of pain, and for detoxification and substitution treatment for opioid dependence. The countries with the highest levels of consumption for buprenorphine in the period 2011-2013 were Iceland, Belgium, Switzerland, the United Kingdom and the United States, in descending order (see figure 50 and maps 7 and 8).

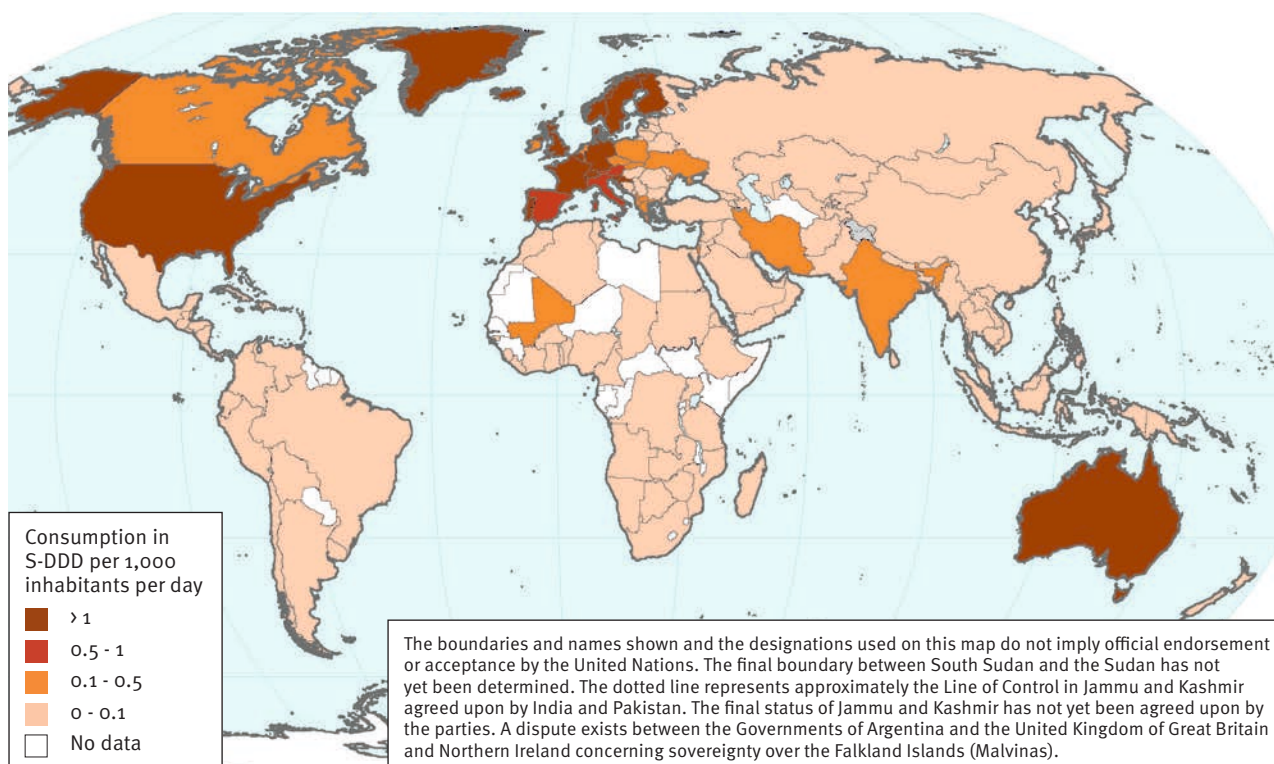
191. Global consumption of pentazocine has averaged about 5 tons per year during the past decade. The substance is used in approximately 50 countries. Its use, in contrast to that of buprenorphine, is not spreading to other countries. The same 50 countries have been using pentazocine since 2004, with India, Nigeria, Pakistan and the United States accounting for 87 per cent of the global total in the period 2011-2013.

Map 5. Average national consumption of opioid analgesics, 2004-2006



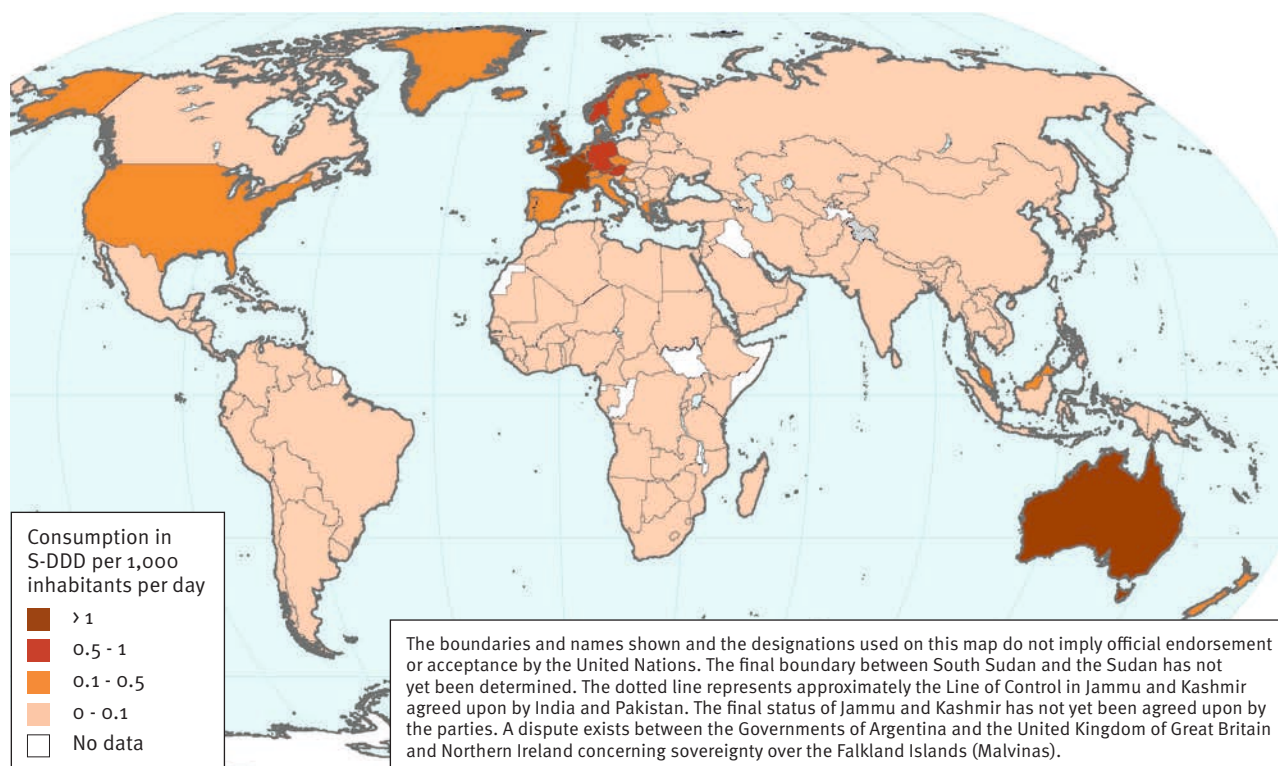
Source: International Narcotics Control Board.

Map 6. Average national consumption of opioid analgesics, 2011-2013



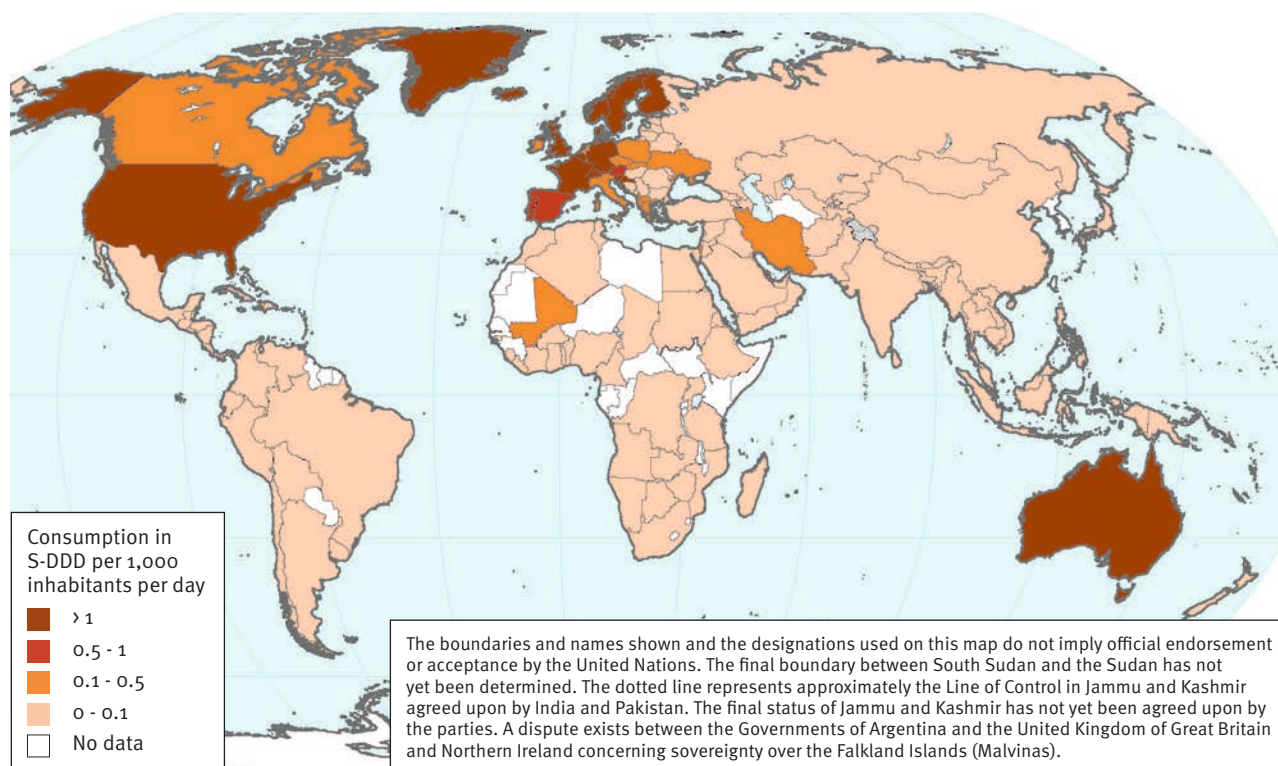
Source: International Narcotics Control Board.

Map 7. Average national consumption of buprenorphine, 2004-2006



Source: International Narcotics Control Board.

Map 8. Average national consumption of buprenorphine, 2011-2013



Source: International Narcotics Control Board.

2. Availability of central nervous system stimulants

192. As mentioned in paragraph 168 above, none of the central nervous system stimulants controlled under the 1971 Convention 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.

193. Since the early 1990s, the highest per capita calculated consumption of amphetamines has traditionally been in the Americas. The United States remains the major consumer of these substances, mainly for the treatment of ADHD and narcolepsy. These high levels of consumption have increased steadily, and were seven times higher in the late 2000s than in the 1990s.

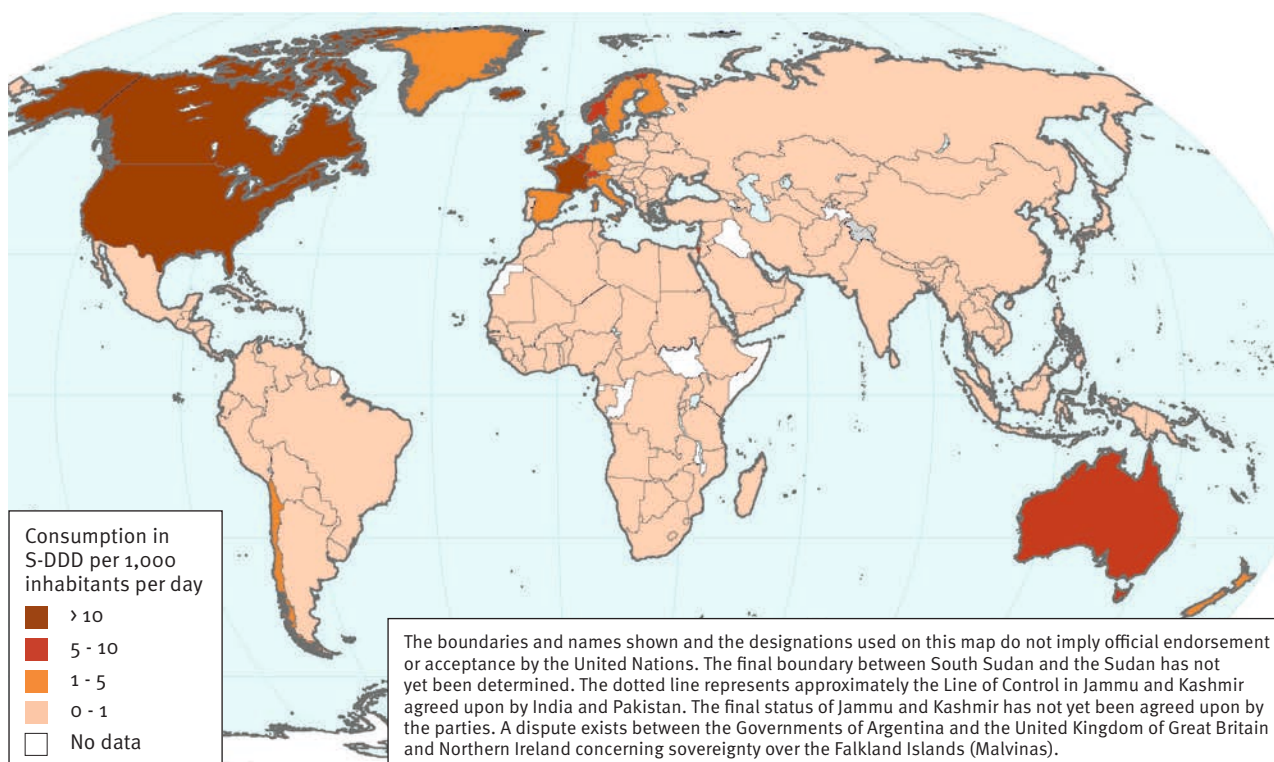
194. Use of this group of substances was extremely rare in Asia⁵⁹ and nearly non-existent in Africa. Consumption

rates increased in Oceania, from an average of 0.03 S-DDD per 1,000 inhabitants per day during the 1988-1990 period to 1.31 S-DDD in the 2011-2013 period, mainly due to steadily rising use of dexamfetamine in Australia.

195. In Europe, levels of consumption have been very irregular. Main consuming countries during the past decade included Germany, Hungary and Switzerland. Hungary was a significant consumer of these substances until 2002, when the level of consumption fell drastically.

196. Countries that were the main users of stimulants listed in Schedule II during the 2004-2006 period continued to have the highest levels of consumption during the 2011-2013 period. A marked increase was observed for some countries (mainly in Europe and the Americas), while the vast majority of countries and territories continued to have a level of consumption below 1 S-DDD per 1,000 inhabitants per day (see maps 9 and 10).

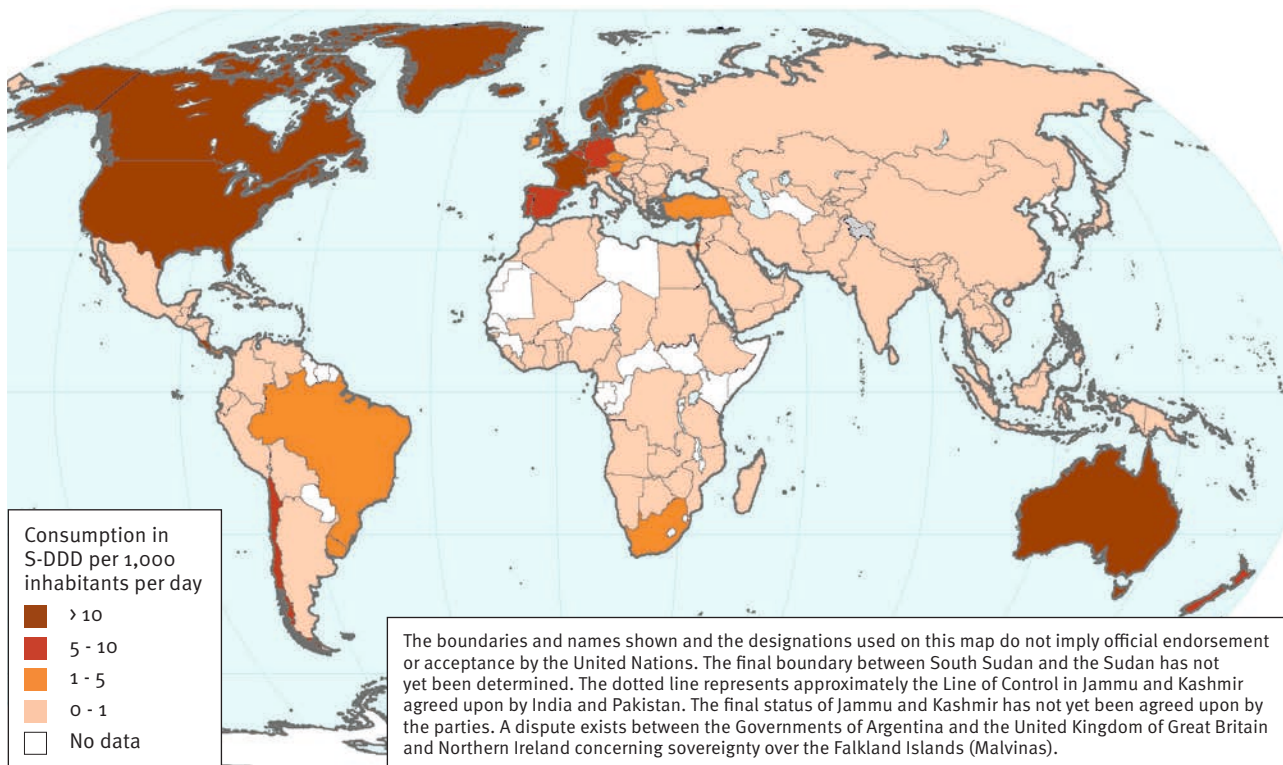
Map 9. Average national consumption of stimulants in Schedule II, 2004-2006



Source: International Narcotics Control Board.

⁵⁹Japan is the only country in the Asia-Pacific region that has had a noticeable rate of use of the substance.

Map 10. Average national consumption of stimulants in Schedule II, 2011-2013

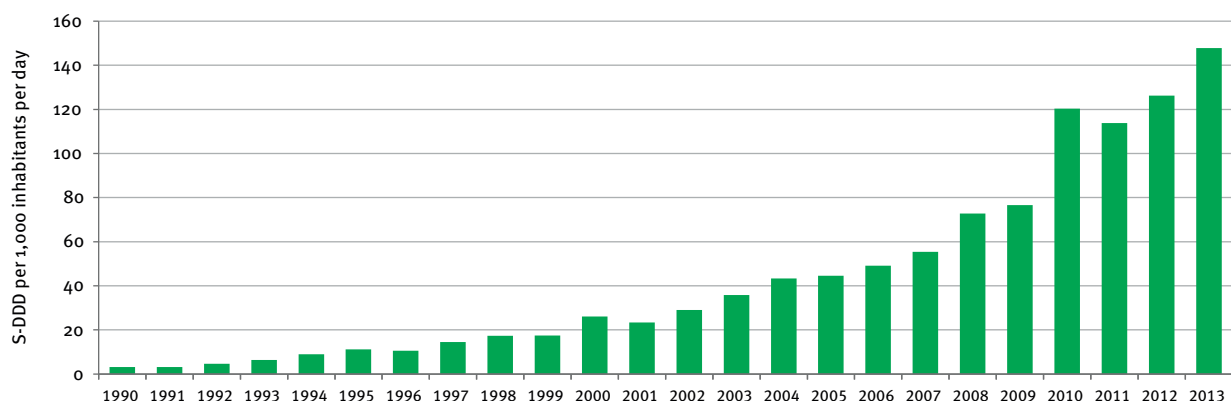


Source: International Narcotics Control Board.

197. Methylphenidate is used for the treatment of various mental and behavioural disorders, in particular of ADHD (primarily in children) and narcolepsy, a sleeping disorder. Use of methylphenidate started to increase noticeably at the beginning of the 1990s (see figure 51). In 1994, for example, global use amounted to more than

five times the level of consumption of the early 1980s. This development was mainly due to increasing consumption in the United States, although increasing levels of consumption were also observed in several other countries and parts of the world.

Figure 51. Global consumption of methylphenidate per 1,000 inhabitants per day, 1990-2013



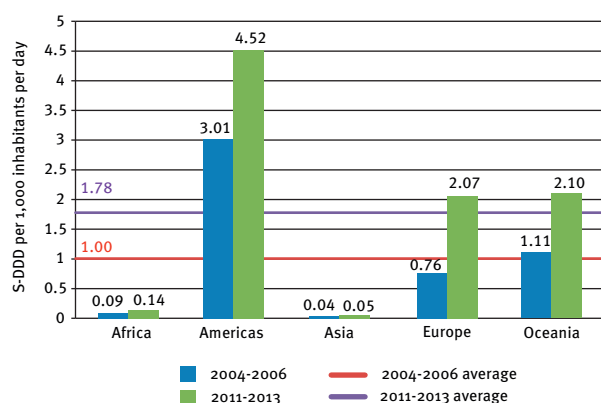
Source: International Narcotics Control Board.

198. While the United States continues to account for more than 80 per cent of the calculated global consumption of methylphenidate, the use of that substance for the treatment of ADHD has also sharply risen in many other countries, in particular those in Oceania and Europe (see figure 52). The prescription levels in most of those

countries are still low compared with those in the United States, however. Growth of global consumption of methylphenidate has continued unabated. In 2013, a new record of 2.4 billion S-DDD was attained, with fewer than 20 countries accounting for almost 85 per cent of the total. The countries reporting a significant increase in the

consumption of methylphenidate included Iceland, which has had the highest per capita consumption of the substance in the world for the past several years, as well as Australia, Canada, Germany, Israel, Norway, Spain, Sweden and the United Kingdom. At the same time, the Board is also concerned about the underprescription, and resulting low use, of methylphenidate in other countries.

Figure 52. Consumption of methylphenidate, all regions, 2004-2006 and 2011-2013

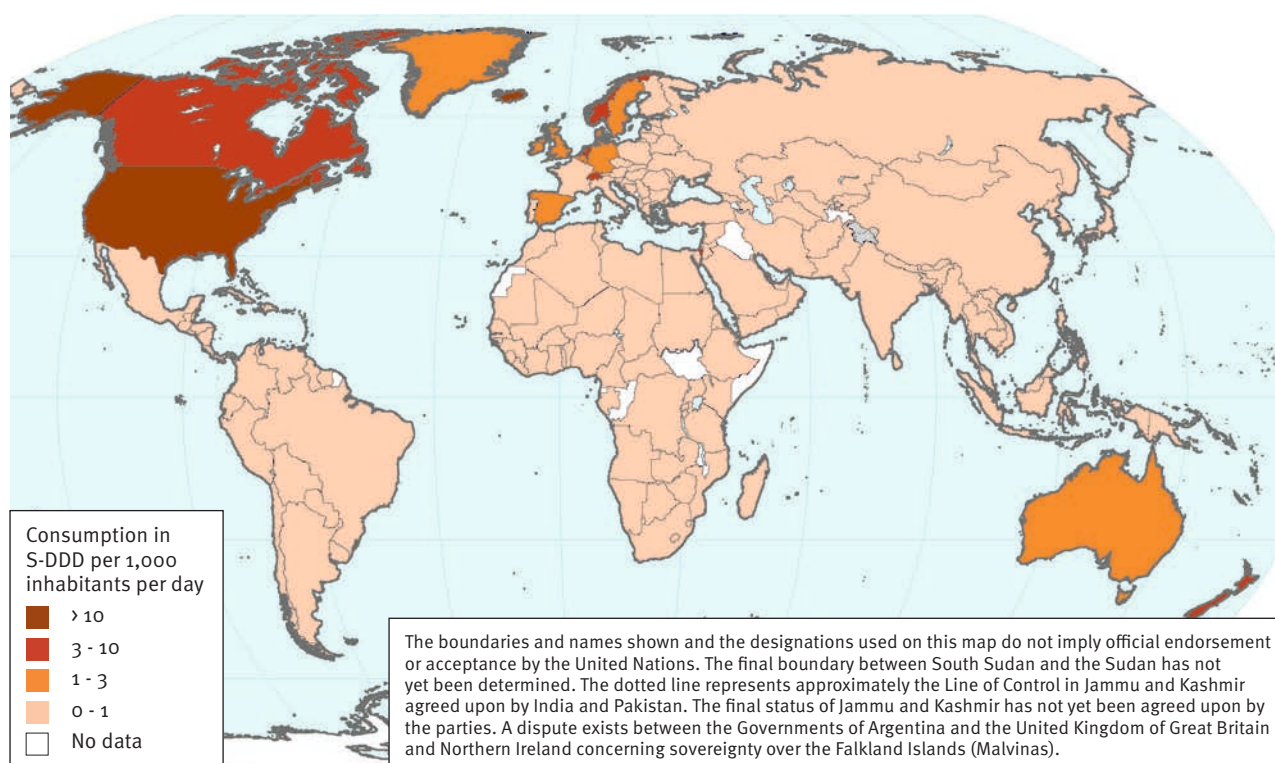


Source: International Narcotics Control Board.

199. National per capita levels of consumption for methylphenidate during the 2004-2006 and 2011-2013 periods, approximated by measures of average annual calculated consumption (in S-DDD per 1,000 inhabitants per day), are shown in maps 11 and 12. As can be seen, the majority of countries and territories continued to have a level of consumption below 1 S-DDD per 1,000 inhabitants per day, while a handful of countries remained the main users of the substance, with a marked increase noted in some countries in the Americas, Europe and Oceania in the 2011-2013 period. While during the 2004-2006 period only five countries had a per capita consumption greater than 5 S-DDD per 1,000 inhabitants per day, by the 2011-2013 period 17 countries had reached that high consumption threshold, including nine countries where consumption was greater than 10 S-DDD per 1,000 inhabitants per day.

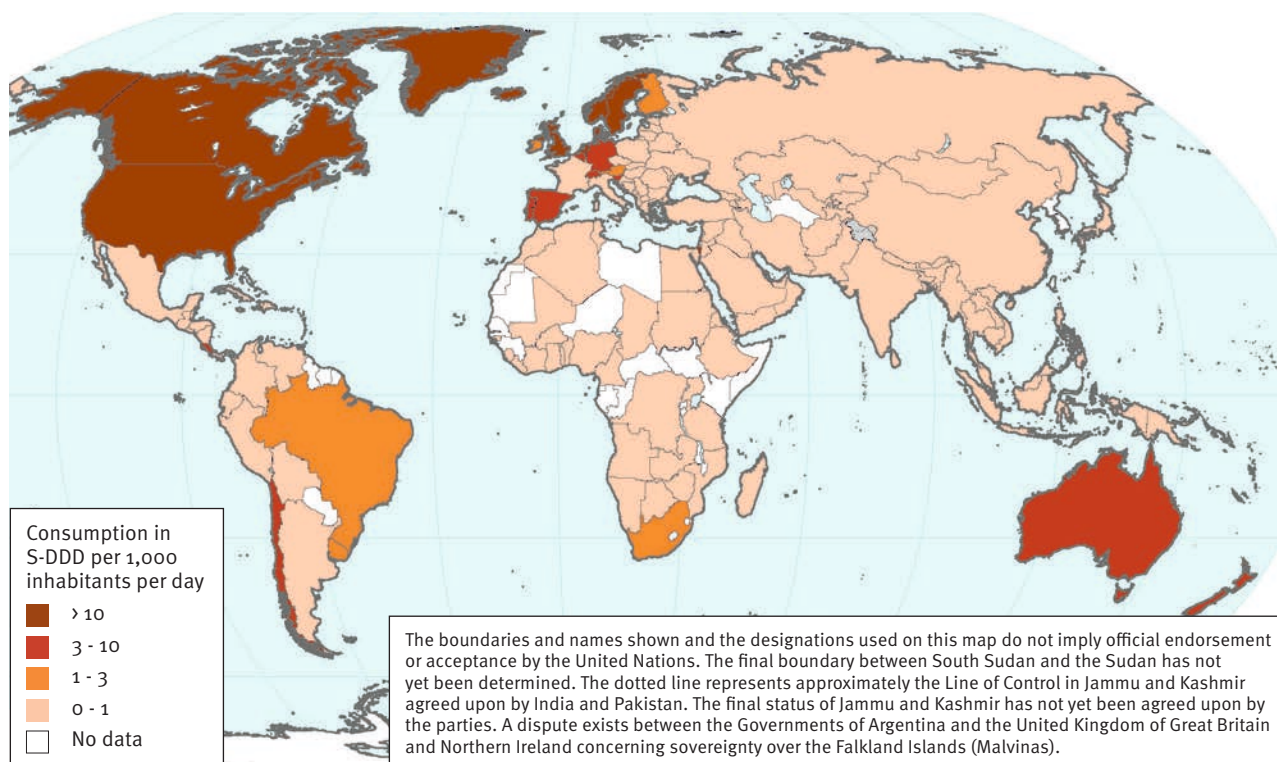
200. The Board has regularly voiced its concern about the possible overdiagnosis of ADHD and the overprescribing of methylphenidate. In 2009, the Board also advised against promotional campaigns for the substance, including advertisements directed at potential consumers. More recently, in its annual report for 2014, the Board considered the use of methylphenidate as a special topic.

Map 11. Average national consumption of methylphenidate, 2004-2006



Source: International Narcotics Control Board.

Map 12. Average national consumption of methylphenidate, 2011-2013



Source: International Narcotics Control Board.

201. Stimulants included in Schedule IV of the 1971 Convention are used as anorectics and, to a lesser extent, for the treatment of ADHD. Their global use has increased steadily since the end of the 1980s. This increase was partly due to high consumption in some Latin American countries (Argentina, Brazil and Chile), in the United States and in some Asian countries and territories (Republic of Korea, Singapore and Hong Kong, China).

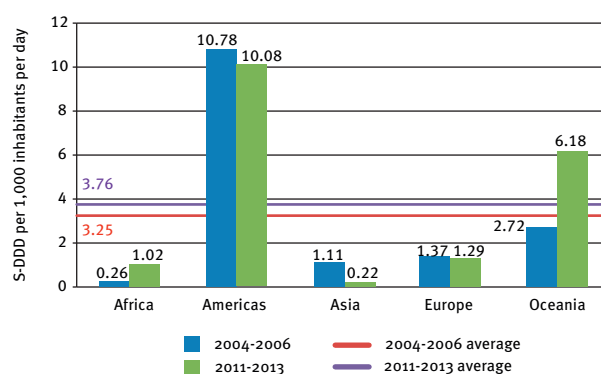
202. Since the early 1990s, the highest per capita consumption of stimulants in Schedule IV has always been in the Americas. The decline in the use of phentermine after a peak observed in 1996 in the United States and the adoption of measures against inappropriate use of certain stimulants in some countries of Latin America, such as Brazil, led to some decrease in consumption. However, the levels of consumption in that region remained high in comparison to other regions, except for some countries in Asia.

203. Among the stimulants included in Schedule IV of the 1971 Convention, phentermine has always been the substance comprising the main share of manufacture and consumption, fluctuating between one quarter and two thirds. In 2013, its share of global consumption reached nearly 86 per cent. Reports of misuse of anorectics have been received from several countries in all regions of the world. In recent years, there has been an observed increase in levels of consumption in Africa and Oceania, owing

to increased calculated consumption in South Africa and Australia (see figure 53).

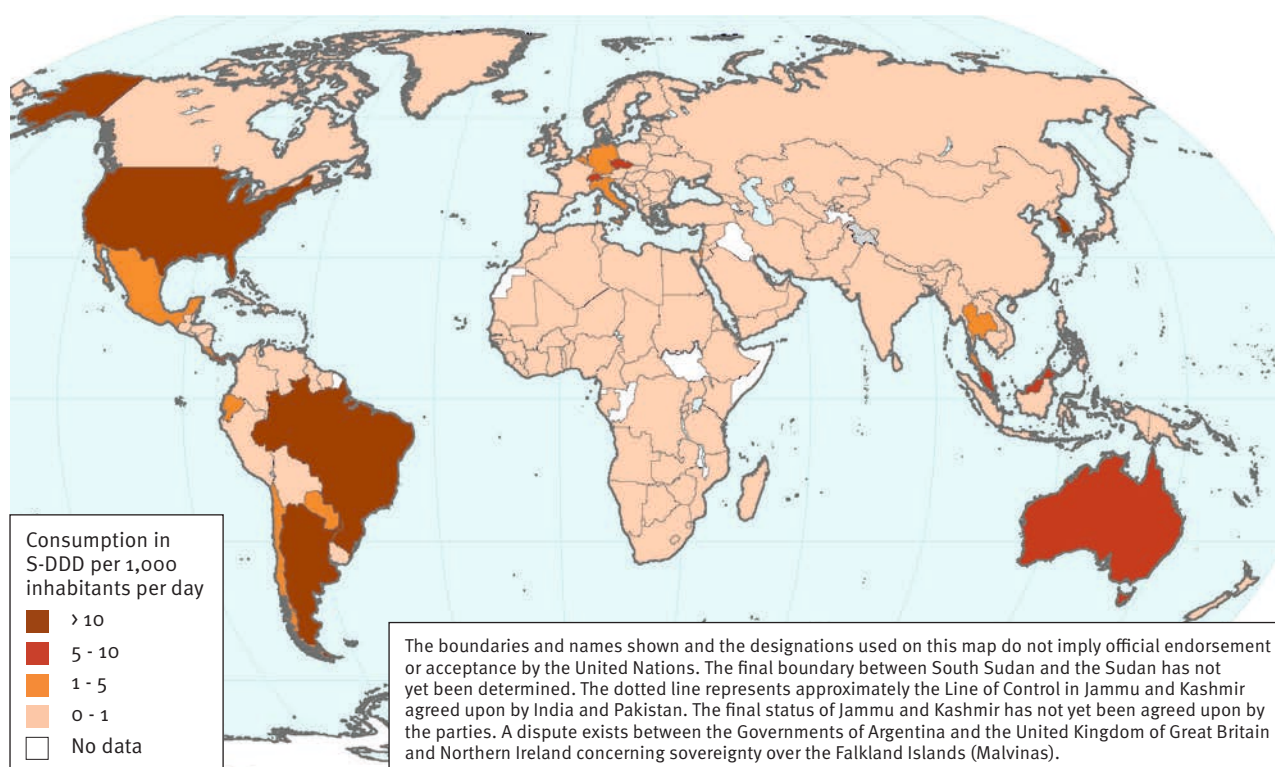
204. Severe restrictions on the use of anorectics and stricter policies regarding their medical use were introduced in a number of countries and were successful in curbing their inappropriate use, thus preventing irrational use and abuse. The changes in consumption of stimulants in Schedule IV by country, approximated by measures of average annual calculated consumption (in S-DDD per 1,000 inhabitants per day) between 2004-2006 and 2011-2013, are presented in maps 13 and 14.

Figure 53. Consumption of stimulants in Schedule IV, all regions, 2004-2006 and 2011-2013



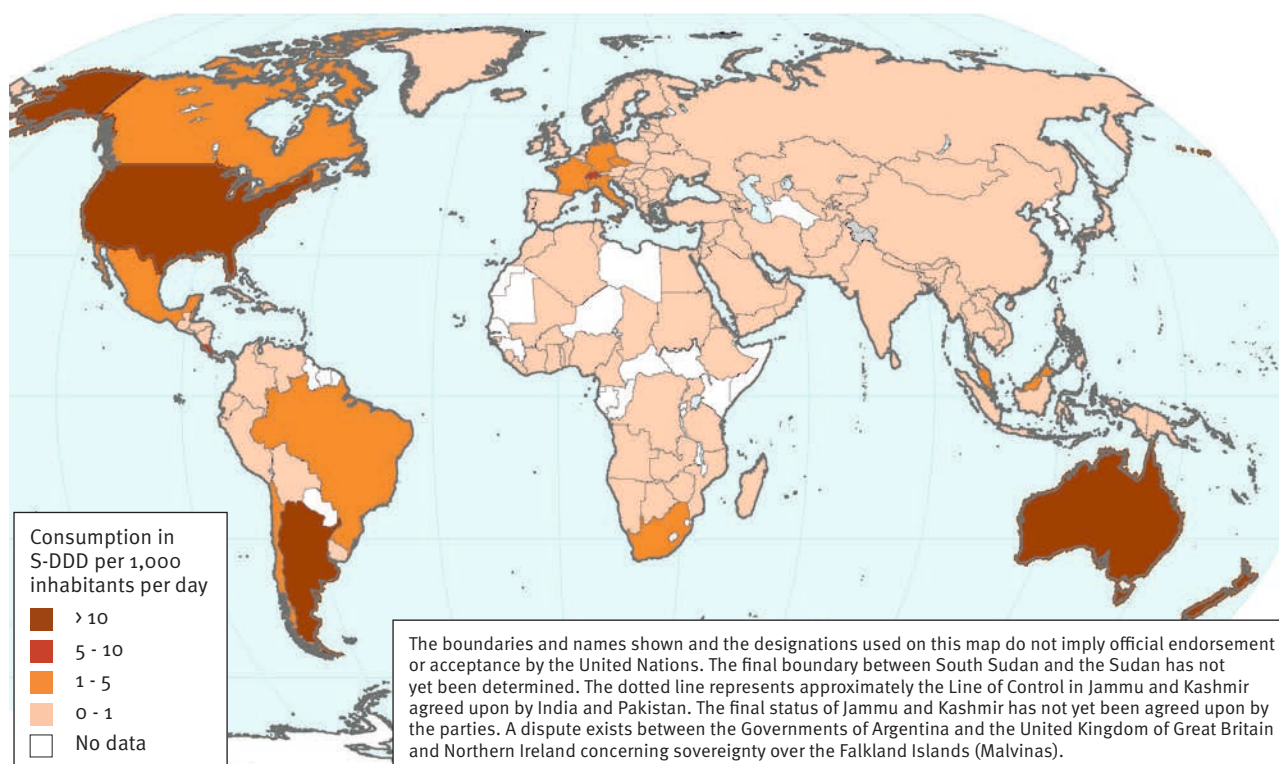
Source: International Narcotics Control Board.

Map 13. Average national consumption of stimulants in Schedule IV, 2004-2006



Source: International Narcotics Control Board.

Map 14. Average national consumption of stimulants in Schedule IV, 2011-2013



Source: International Narcotics Control Board.

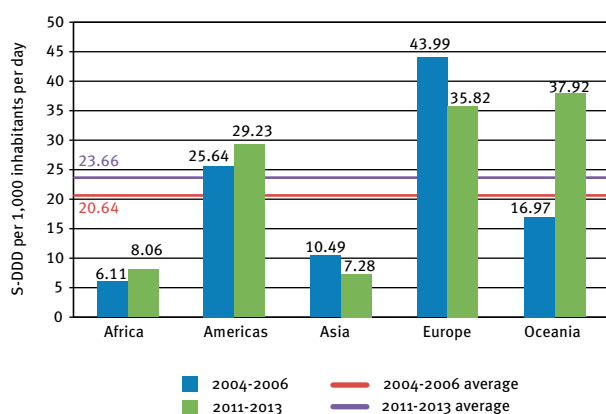
3. Availability of benzodiazepines

205. For the two groups of benzodiazepines, anxiolytics and sedative-hypnotics, the global calculated rate of average annual consumption showed distinct patterns during the 2004-2013 period. While the average annual rate of per capita consumption of benzodiazepine-type anxiolytics showed an upward trend, the global average annual calculated consumption rate of benzodiazepine-type sedative-hypnotics decreased. During that period, practically all countries and territories that reported to INCB manufactured or traded in benzodiazepines, and the reported statistics enabled the Board to calculate consumption rates for over 190 countries and territories. In 2013, alprazolam and diazepam remained the most used substances among anxiolytics (9.2 and 4.4 billion S-DDD, respectively), whereas lormetazepam and brotizolam were the most used sedative-hypnotics (1.4 and 1.3 billion S-DDD, respectively).

(a) Benzodiazepine-type anxiolytics

206. Globally, the average annual rate of per capita consumption of benzodiazepine-type anxiolytics increased somewhat during the 2004-2013 period, from 20.6 to 23.7 S-DDD per 1,000 inhabitants per day. As can be seen in figure 54, in the beginning of the period the rate of average annual consumption for this group of substances was highest in European countries and the Americas, reflecting the fact that benzodiazepines tend to be prescribed frequently for the large cohort of elderly people in those regions. Towards the end of that decade, the highest increases in the rate of average annual consumption were observed in Oceania (123 per cent) and Africa (32 per cent). The consumption rates in Africa and Asia remained below the global average.

Figure 54. Average annual consumption of benzodiazepine-type anxiolytics, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

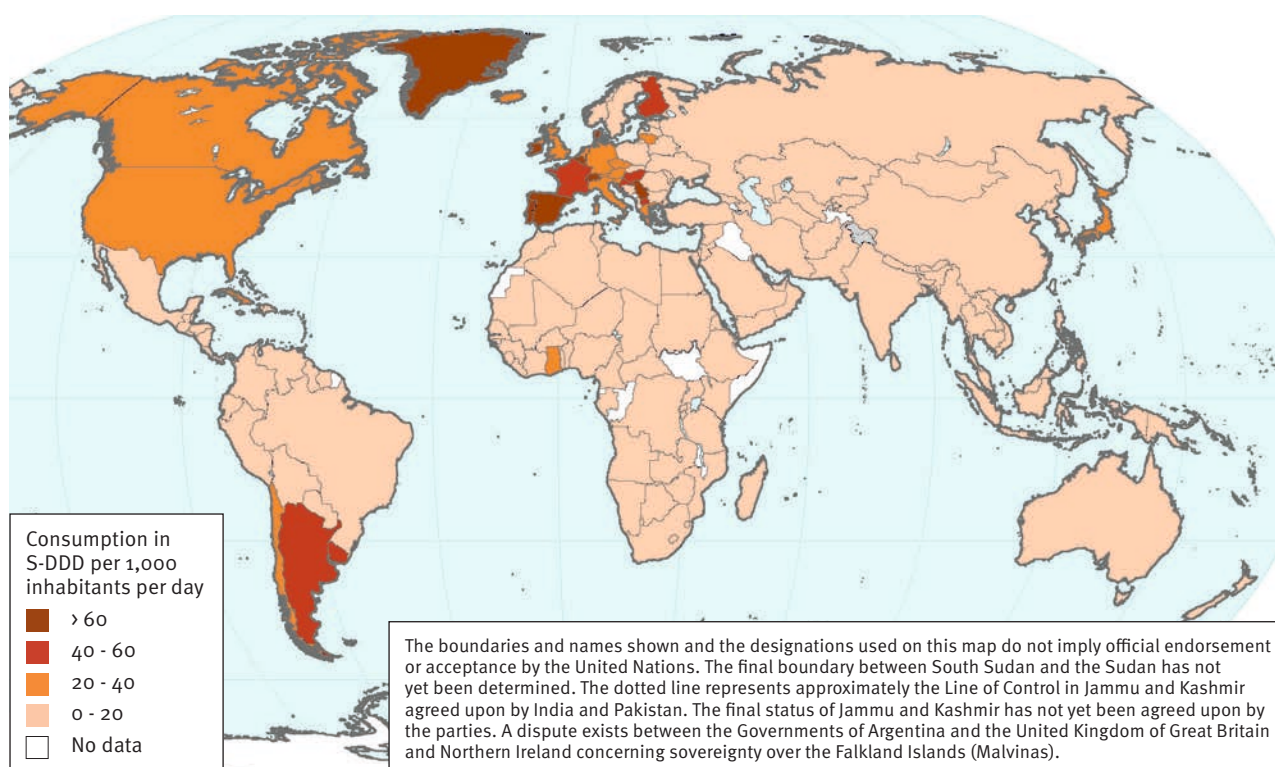
207. During the past decade, the average annual level of consumption in Europe decreased from 43.99 to 35.82 S-DDD per 1,000 inhabitants per day, although an increase in consumption was observed in 23 out of 41 countries in this region that submitted data, in particular in Finland, where there was a 517 per cent increase. The largest decrease in consumption was recorded for Denmark (84 per cent, from 77 to 13 S-DDD per 1,000 inhabitants per day) and Switzerland (73 per cent, from 266 to 72 S-DDD per 1,000 inhabitants per day). During 2011-2013, calculated consumption rates exceeded the regional average in 15 countries; in six countries, the levels were above the global average of 23.7 S-DDD per 1,000 inhabitants per day. The European countries with average levels of consumption below the global average were Iceland, the Czech Republic, the Netherlands, Latvia, Norway, Estonia, Germany, Sweden, Denmark, Poland, Albania, Greece, Romania, the United Kingdom, Bulgaria, the Republic of Moldova, the Russian Federation, Belarus, Ukraine and Cyprus, in descending order.

208. Consumption of this group of anxiolytics averaged 29.2 S-DDD per 1,000 inhabitants per day in the Americas during the 2011-2013 period. Only four countries had rates of consumption that were higher than the regional average: Uruguay (67.9 S-DDD), Argentina (60.1 S-DDD), Canada (55.8 S-DDD) and the United States (42.2 S-DDD). Furthermore, in the Americas significant disparities in levels of consumption of anxiolytics were observed among subregions, with North America having the highest per capita consumption rate during the 2011-2013 period, followed by South America and Central America and the Caribbean (see maps 15 and 16).

209. The regional average in Oceania (37.9 S-DDD per 1,000 inhabitants per day), although much higher than the global average (23.7 S-DDD per 1,000 inhabitants per day), was driven mainly by Australia, which was the only country in the region to have calculated consumption above the global average during 2011-2013. The rates of consumption showed an increase in all countries of the region, except for New Zealand, which saw a decrease of 8 per cent, from 5.1 to 4.6 S-DDD per 1,000 inhabitants per day.

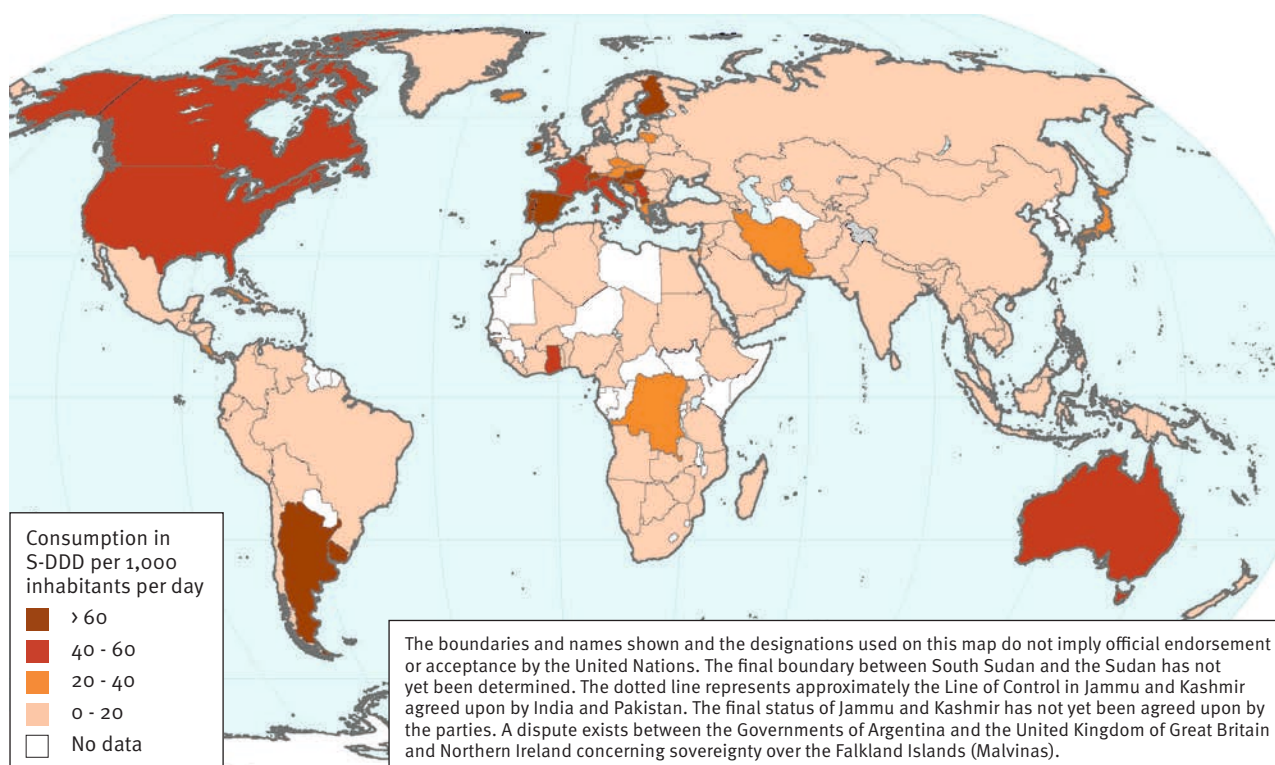
210. In Asia, all but 1 of the 48 countries that submitted data had rates of consumption below the global average. Israel (27.9 S-DDD per 1,000 inhabitants per day), Iran (Islamic Republic of) (22.3 S-DDD), Japan (21.1 S-DDD) and an additional three countries (Jordan, Lebanon and Thailand) had calculated rates of consumption above the regional average of 7.3 S-DDD per 1,000 inhabitants per day during the 2011-2013 period.

Map 15. Average national consumption of benzodiazepine anxiolytics, 2004-2006



Source: International Narcotics Control Board.

Map 16. Average national consumption of benzodiazepine anxiolytics, 2011-2013



Source: International Narcotics Control Board.

211. In Africa, the average annual rate of consumption of benzodiazepine-type anxiolytics increased from 6.1 S-DDD to 8.6 S-DDD per 1,000 inhabitants per day between the 2004-2006 and the 2011-2013 periods. The average calculated consumption rate increased in 19 African countries or territories, most notably in Saint Helena (by a factor of nearly seven, from 1.3 to 9 S-DDD per 1,000 inhabitants per day), and Namibia and the Democratic Republic of the Congo (both by a factor of more than 4.5, from 4.9 to 22.5 S-DDD). Ghana remained the country with the highest consumption rate in the region (and seventeenth highest in the world), with an increase of 146 per cent between the 2004-2006 and 2011-2013 periods, from 21.3 to 52.3 S-DDD. Next came the Democratic Republic of the Congo, with 22.5 S-DDD per 1,000 inhabitants per day, which remained slightly below the global average of 23.7 S-DDD. At the same time, there were more than 16 countries that consumed less than 1 S-DDD per 1,000 inhabitants per day during 2011-2013, and more than 10 countries recorded a decrease in the rate of consumption. The biggest decrease in the average annual rate of calculated consumption was recorded for Cabo Verde (from 6.5 to 0.7 S-DDD), Sierra Leone (from 0.6 to 0.1 S-DDD), Eritrea (from 0.1 to 0.02 S-DDD), the United Republic of Tanzania (from 2 to 0.7 S-DDD) and Botswana (from 1.4 to 0.7 S-DDD).

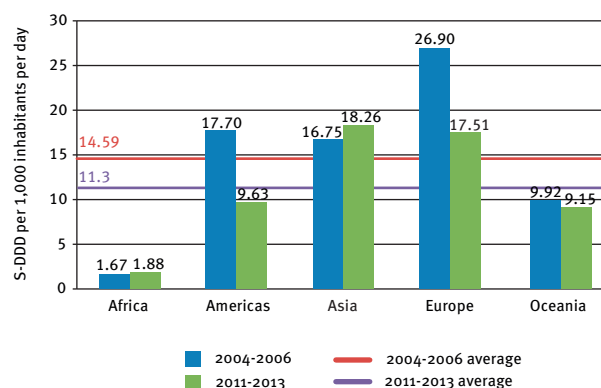
(b) Benzodiazepine-type sedative-hypnotics

212. The global average annual calculated consumption rate of benzodiazepine-type sedative-hypnotics, when measured in S-DDD per 1,000 inhabitants per day, decreased by more than 22 per cent between the 2004-2006 and 2011-2013 periods, from 14.6 S-DDD to 11.3 S-DDD per 1,000 inhabitants per day. Consumption was consistently highest in Europe, while decreases were observed in the Americas, Europe and Oceania, and increases in Africa and Asia (see figure 55).

213. In Europe, the average annual rate of calculated consumption decreased by 35 per cent between the 2004-2006 and 2011-2013 periods, from 26.9 S-DDD to 17.5 S-DDD per 1,000 inhabitants per day. A decrease in consumption rates was observed in 29 countries in this region, including Cyprus (from 20.5 S-DDD per 1,000 inhabitants per day to almost zero), the Republic of Moldova (from 0.15 to 0.003 S-DDD), the United Kingdom (from 47.3 to 4 S-DDD) and Switzerland (from 42.6 to 11.4 S-DDD), reflecting a possible change in the types of benzodiazepine that were prescribed in medical practice. An increase was observed in 12 countries, most notably in Andorra (365 per cent), Croatia (300 per cent)

and Slovakia (244 per cent). During the 2011-2013 period, five countries had rates of average annual consumption above the regional average of 17.5 S-DDD per 1,000 inhabitants per day and an additional six countries had rates of consumption above the global average of 11.3 S-DDD.

Figure 55. Average annual consumption of benzodiazepine-type sedative-hypnotics, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

214. The average annual consumption rate of benzodiazepine-type sedative-hypnotics in Oceania, also decreased between the 2004-2006 and 2011-2013 periods, from 9.9 S-DDD to 9.1 S-DDD per 1,000 inhabitants per day. Although their consumption rates decreased by 20 and 22 per cent, respectively, Australia and New Zealand remained the two countries in the region with the highest average calculated consumption rates. Micronesia (Federated States of), New Caledonia and Wallis and Futuna Islands showed increases in average annual consumption rates, albeit from low levels. Except for Australia, New Zealand, New Caledonia and French Polynesia, the rest of the countries and territories of this region had rates of average annual consumption for this group of substances below 0.1 S-DDD per 1,000 inhabitants per day.

215. In the Americas, the average annual rate of calculated consumption decreased by 45 per cent between the 2004-2006 period and the 2011-2013 period, from 17.7 S-DDD to 9.8 S-DDD per 1,000 inhabitants per day. However, there was a great disparity between subregions. As consumption rates increased in countries of North America and Central America and the Caribbean, they decreased in South America. Only three countries in the Americas had consumption rates above the regional average of 9.8 S-DDD per 1,000 inhabitants per day: Cuba (30.1 S-DDD), Uruguay (23.3 S-DDD) and Canada (14.6 S-DDD). The consumption rates of 33 countries and territories were below the global average, including

24 countries with rates below 1 S-DDD and 11 countries with rates below 0.1 S-DDD per 1,000 inhabitants per day.

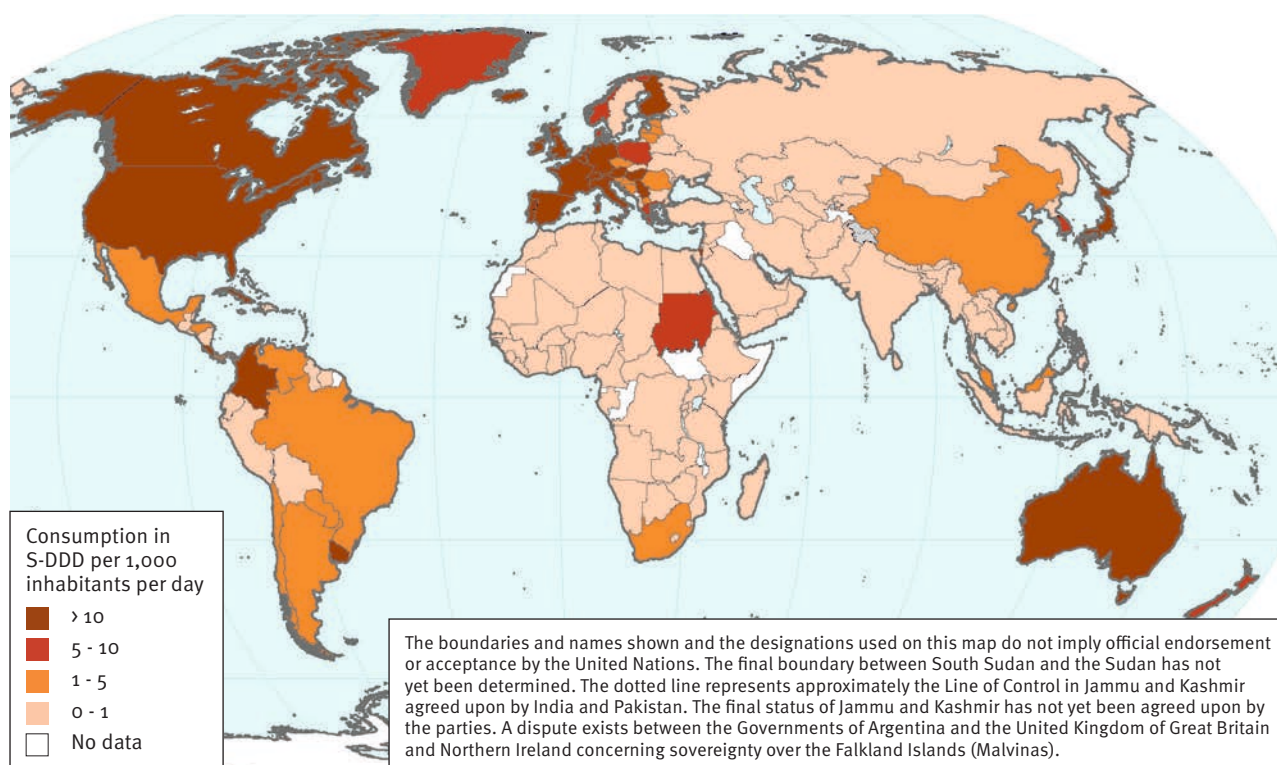
216. In Asia, the rate of consumption of benzodiazepine-type sedative-hypnotics increased, from an average annual rate of 16.8 S-DDD per 1,000 inhabitants per day during the 2004-2006 period to 18.3 S-DDD per 1,000 inhabitants per day during the 2011-2013 period. During the latter period, Japan (54.2 S-DDD), Israel (9.5 S-DDD), Macao, China (2.6 S-DDD), Hong Kong, China (1.3 S-DDD) and Bangladesh (1.2 S-DDD) were the only countries or territories with average annual rates of calculated consumption above 1 S-DDD per 1,000 inhabitants per day. The high rates in Japan and Israel have traditionally been attributed to their large cohorts of elderly people. During the 2011-2013 period, 37 countries in Asia had average annual consumption rates of

benzodiazepine-type sedative-hypnotics below 1 S-DDD per 1,000 inhabitants per day, including 22 countries with rates of consumption below 0.1 S-DDD.

217. In Africa, during the 2011-2013 period, only South Africa (2 S-DDD) had an average rate of annual calculated consumption above the regional average of 1.9 S-DDD per 1,000 inhabitants per day. That country was followed by Nigeria (1.1 S-DDD) and Namibia (0.6 S-DDD). Twenty-one countries had rates of consumption below 0.1 S-DDD, including 14 countries with rates below 0.01 S-DDD.

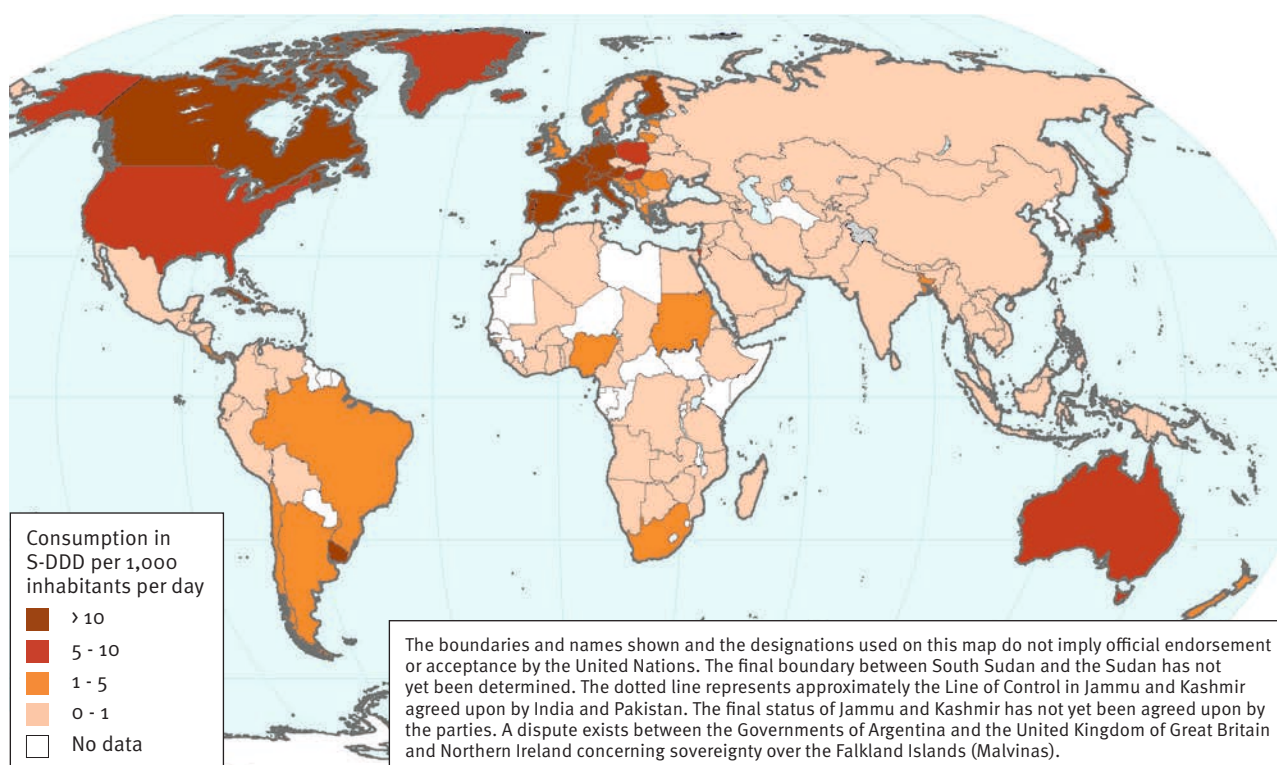
218. The changes in consumption of benzodiazepine-type sedative-hypnotics by country, approximated by measures of average annual calculated consumption (in S-DDD per 1,000 inhabitants per day) between 2004-2006 and 2011-2013 are presented in maps 17 and 18.

Map 17. Average national consumption of benzodiazepine sedative-hypnotics, 2004-2006



Source: International Narcotics Control Board.

Map 18. Average national consumption of benzodiazepine sedative-hypnotics, 2011-2013



Source: International Narcotics Control Board.

(c) Essential medicines containing benzodiazepines

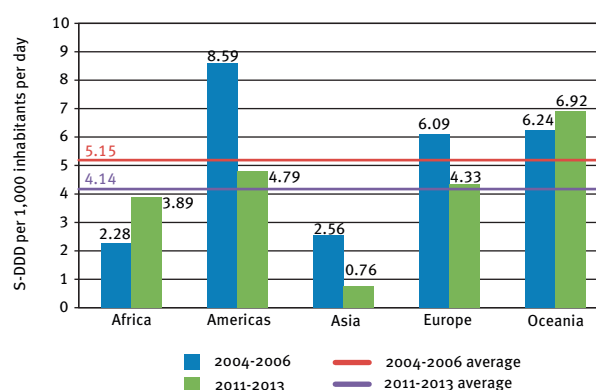
219. Three benzodiazepine substances are included in the WHO Model List of Essential Medicines: diazepam and lorazepam (anxiolytics) and midazolam (sedative-hypnotic).

Diazepam

220. The global average annual consumption rate of diazepam decreased by 20 per cent between the 2004-2006 and 2011-2013 periods, from 5.2 S-DDD to 4.1 S-DDD per 1,000 inhabitants per day (see figure 56). The biggest decreases in average consumption were observed in Asia (70 per cent) and the Americas (44 per cent). By contrast, Africa and Oceania were the regions where the average annual consumption rate increased (by 70 per cent and 11 per cent, respectively). Significant increases in Africa were mainly the result of increases in the calculated consumption for the Democratic Republic of the Congo and Ghana. Globally, during 2011-2013, out of 164 countries on record, the consumption rates of 37 countries were above the global average, with Ghana

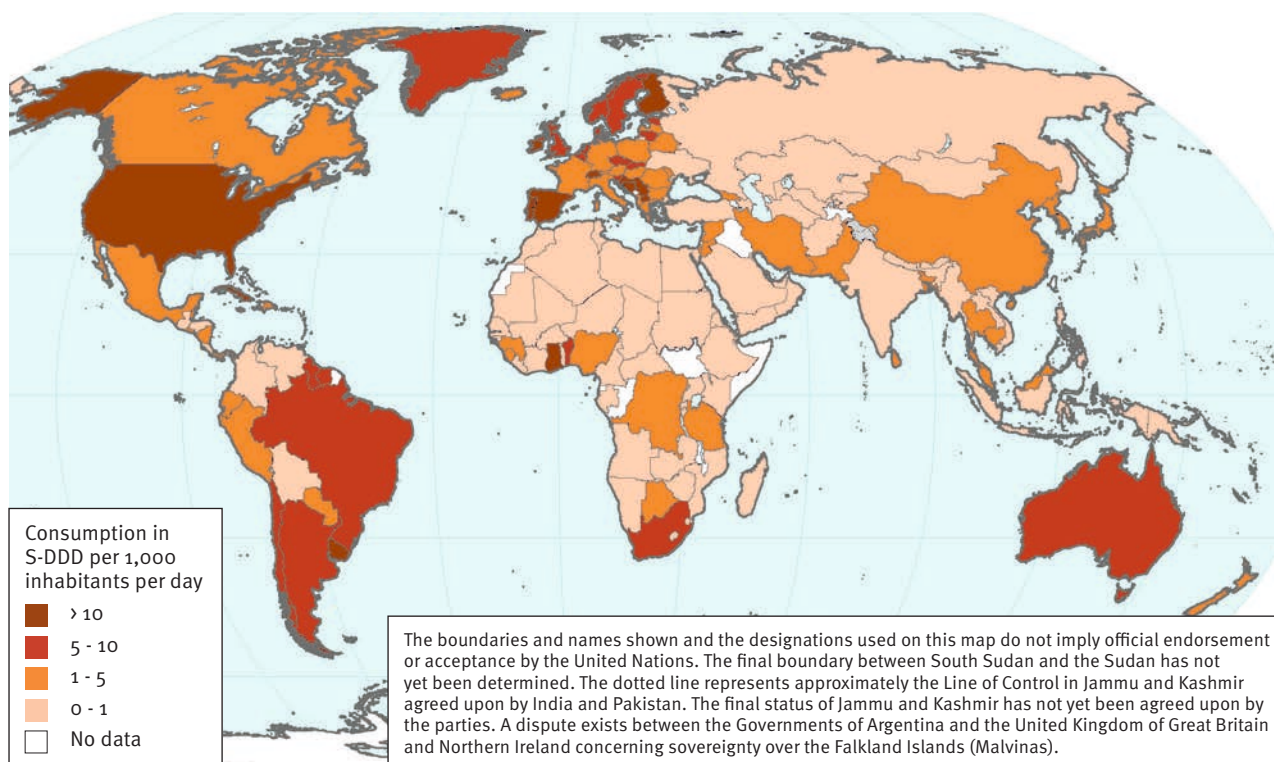
(50.5 S-DDD), the former Yugoslav Republic of Macedonia (26.1 S-DDD) and Croatia (25.9 S-DDD) having the highest rates. At the bottom end, about 90 countries had consumption rates below 1 S-DDD per 1,000 inhabitants per day, with 22 countries consuming at a rate below 0.1 S-DDD (see maps 19 and 20).

Figure 56. Average annual consumption of diazepam, 2004-2006 and 2011-2013



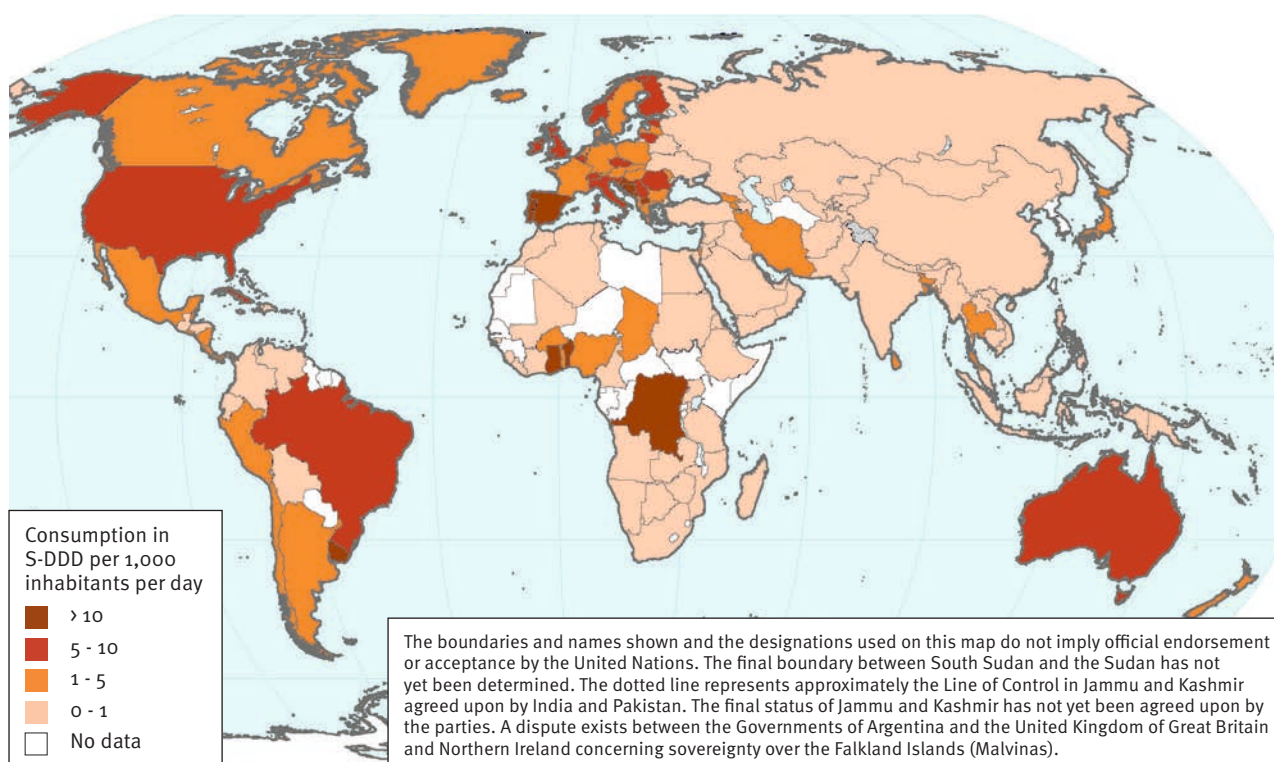
Source: International Narcotics Control Board.

Map 19. Average national consumption of diazepam, 2004-2006



Source: International Narcotics Control Board.

Map 20. Average national consumption of diazepam, 2011-2013



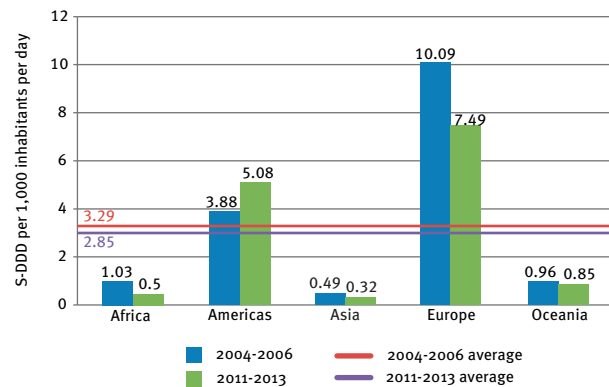
Source: International Narcotics Control Board.

Lorazepam

221. As presented in figure 57, the global average annual consumption rate of lorazepam also decreased between 2004-2006 and 2011-2013, from 3.3 S-DDD to 2.8 S-DDD per 1,000 inhabitants per day. However, this relatively small (13.4 per cent) decrease was the result of significant volatility in different regions. During that period, average annual consumption rates increased in the Americas by 31 per cent while decreasing in all other regions, with the highest declines observed in Africa (51.4 per cent), Asia (34.5 per cent), and Europe (25.8 per cent). Out of 134 countries that submitted statistics during the 2011-2013 period, 31 countries had average annual calculated consumption rates above the global average. The highest rates were observed in Europe, led by Ireland (85.9 S-DDD), Portugal (27.7 S-DDD) and Spain (27.2 S-DDD). Eighty-three countries had average annual consumption rates below 1 S-DDD per 1,000 inhabitants per day, including 44 countries with rates below 0.1 S-DDD, most notably Bhutan, Chad and Papua

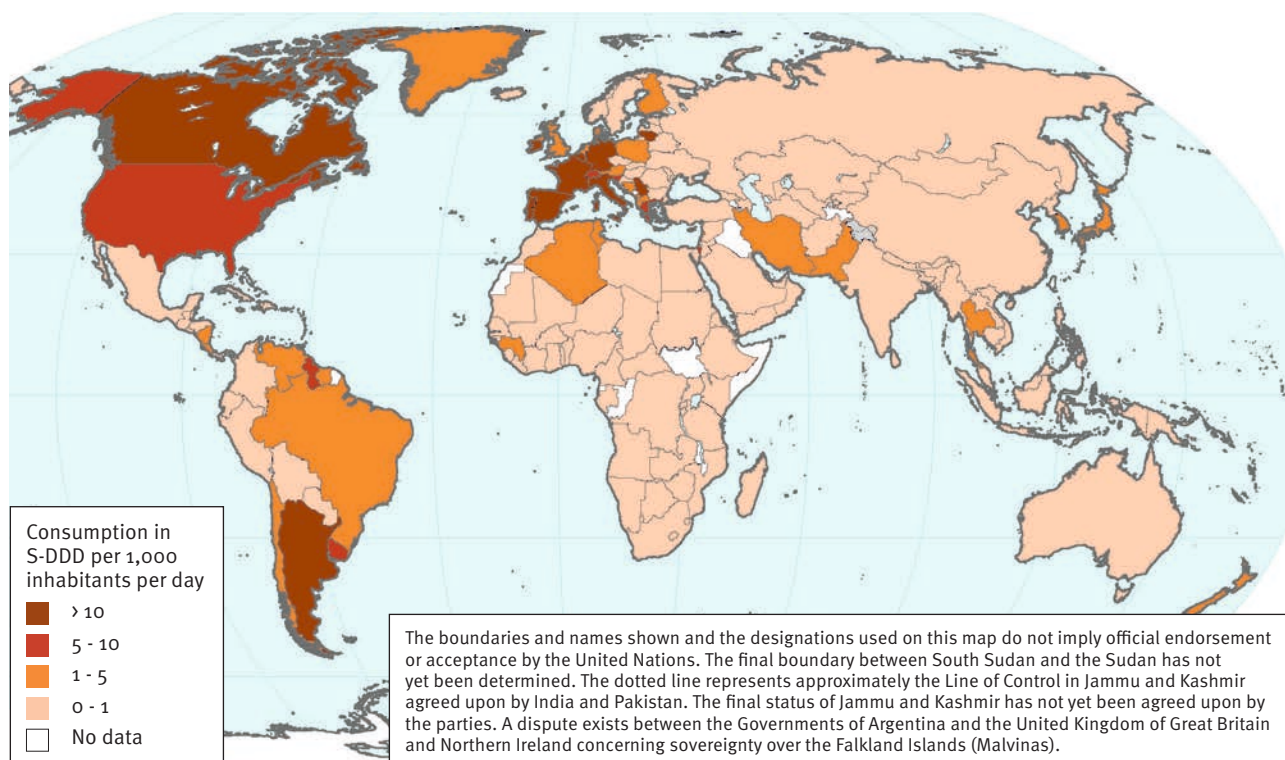
New Guinea, which had rates below 0.02 S-DDD. Changes in the consumption of lorazepam by country are presented in maps 21 and 22 below.

Figure 57. Average annual consumption of lorazepam, 2004-2006 and 2011-2013



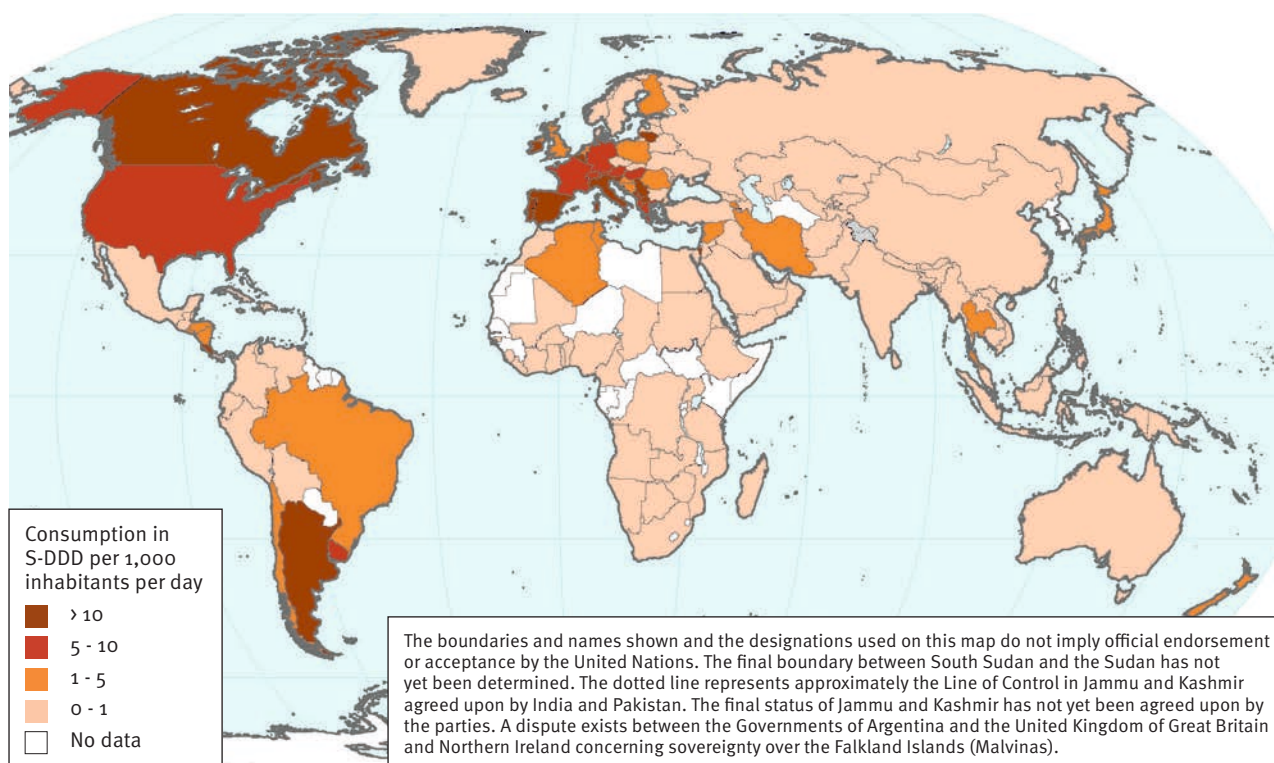
Source: International Narcotics Control Board.

Map 21. Average national consumption of lorazepam, 2004-2006



Source: International Narcotics Control Board.

Map 22. Average national consumption of lorazepam, 2011-2013



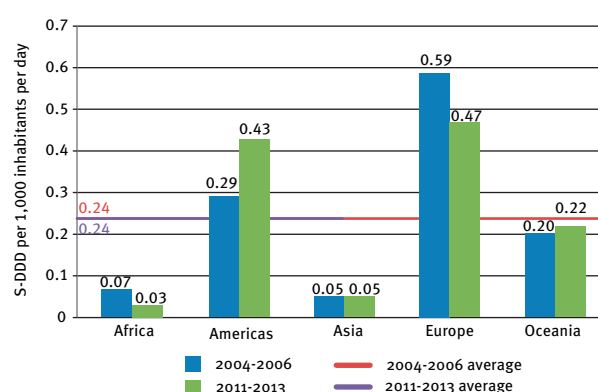
Source: International Narcotics Control Board.

Midazolam

222. The global average annual rate of calculated consumption of midazolam decreased by 0.4 per cent between the 2004-2006 period and the 2011-2013 period, from 0.238 S-DDD to 0.237 S-DDD per 1,000 inhabitants per day (see figure 58). Europe and the Americas have traditionally had the highest rates of consumption of midazolam. During the past decade, the most significant increases in average consumption rates were observed in the Americas (47.2 per cent). At the same time, consumption rates decreased in Africa (by 56 per cent), Europe (20 per cent) and Asia (10 per cent). During the 2011-2013 period, only eight countries and territories had average annual calculated consumption rates above 1 S-DDD per 1,000 inhabitants per day: Switzerland (5 S-DDD), Sint Maarten (2.7), Portugal (1.9), Curaçao (1.6), Uruguay (1.5), Hungary (1.4), Costa Rica (1.1) and the United Kingdom (1), while 37 countries and territories had consumption rates above the global average of 0.237 S-DDD. Among the countries and territories having consumption rates below the global average, 89 of them had rates below

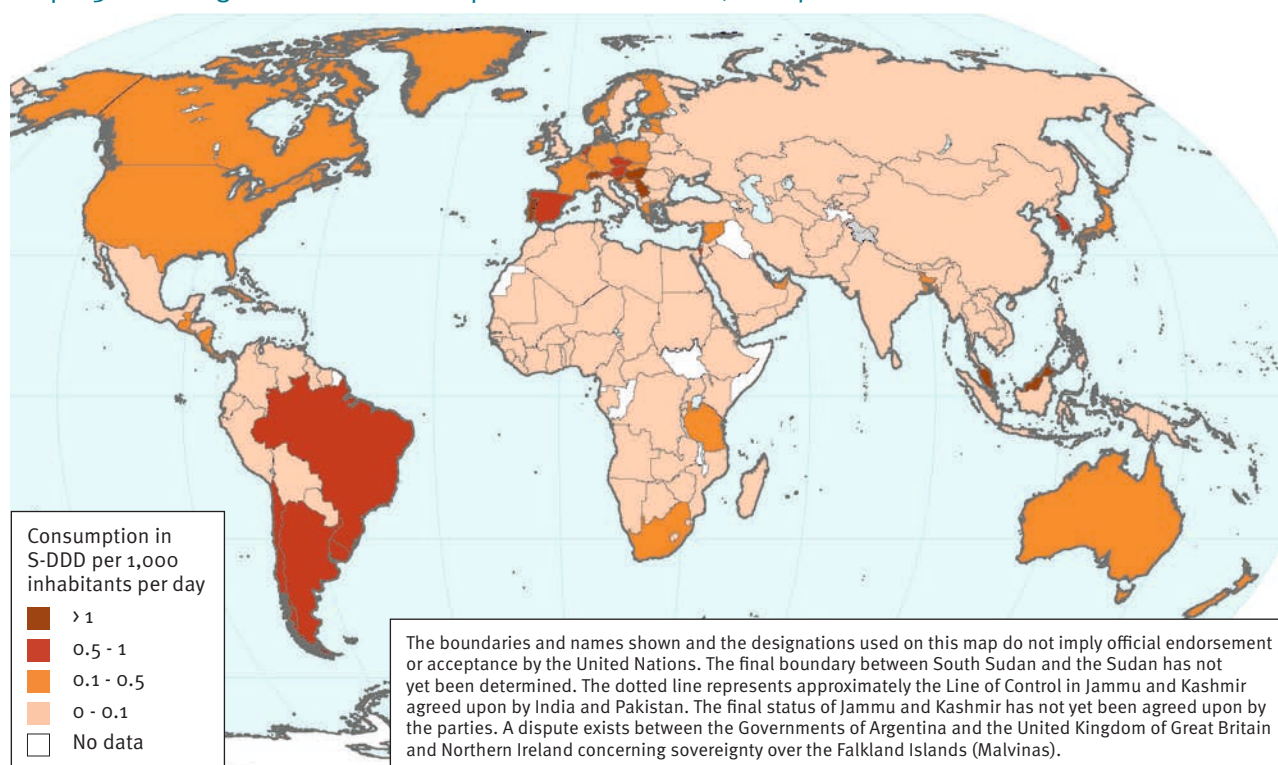
0.1 S-DDD, including 51 with rates below 0.01 S-DDD. The changes in consumption of midazolam by country between 2004-2006 and 2011-2013 are presented in maps 23 and 24.

Figure 58. Average annual consumption of midazolam, 2004-2006 and 2011-2013



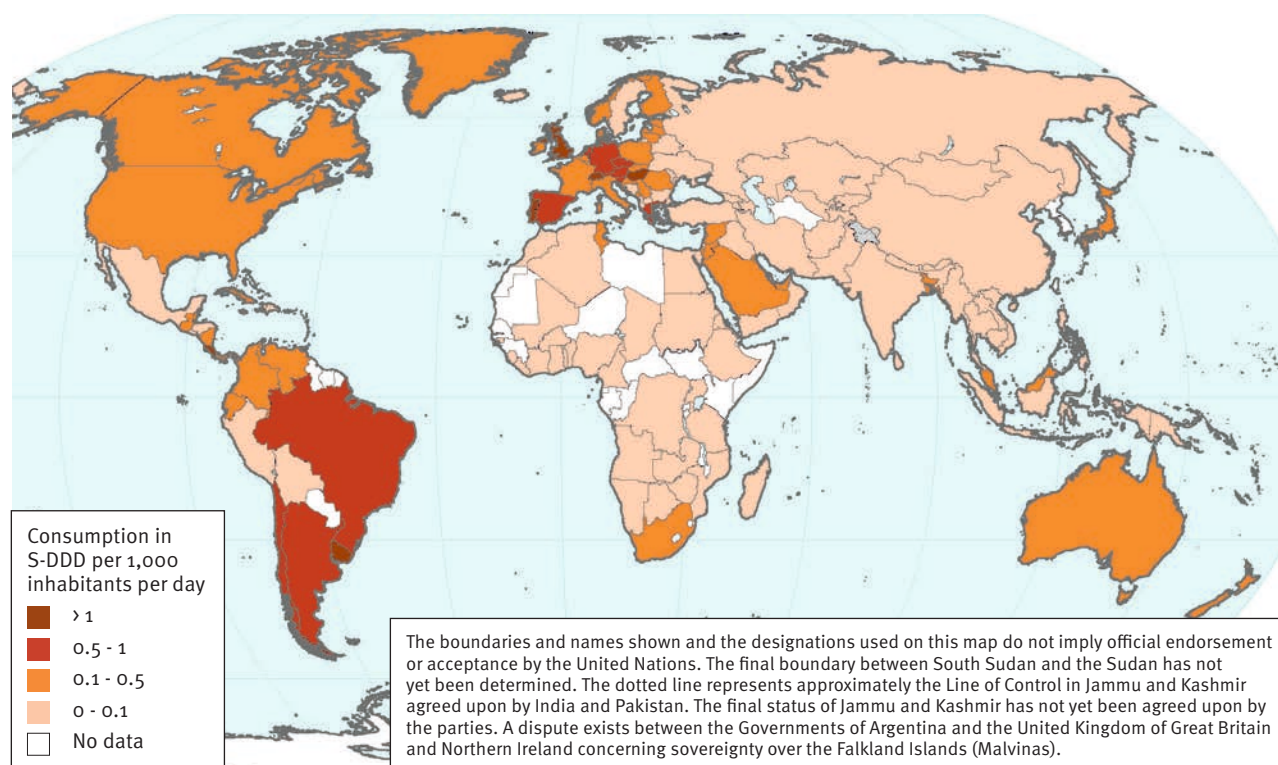
Source: International Narcotics Control Board.

Map 23. Average national consumption of midazolam, 2004-2006



Source: International Narcotics Control Board.

Map 24. Average national consumption of midazolam, 2011-2013



Source: International Narcotics Control Board.

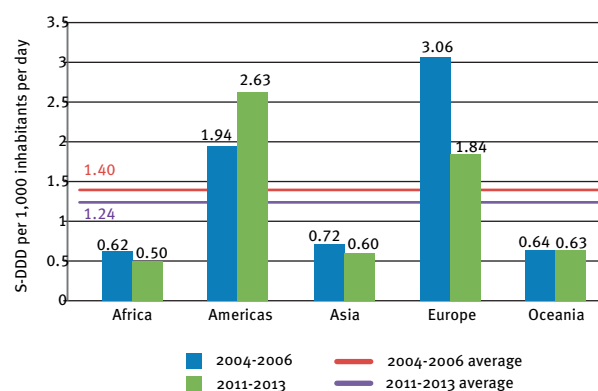
(d) Availability of anti-epileptics

223. Both barbiturate-type anti-epileptics (phenobarbital and methylphenobarbital) and benzodiazepine-type anti-epileptics (clonazepam) are included in Schedule IV of the 1971 Convention. In addition to being used for the treatment of epilepsy, these substances are also used to induce sleep. As one of the substances on the WHO Model List of Essential Medicines, phenobarbital accounted for almost all of global consumption of anti-epileptics during the 2004-2013 period.

224. During that time, the global consumption of anti-epileptics decreased in all regions except the Americas. In particular, the largest reductions were found in Europe (40 per cent), Africa (20 per cent) and Asia (16 per cent). At the same time, the rate of consumption of anti-epileptics in Oceania remained roughly the same, but that in the Americas has increased by 35 per cent (see

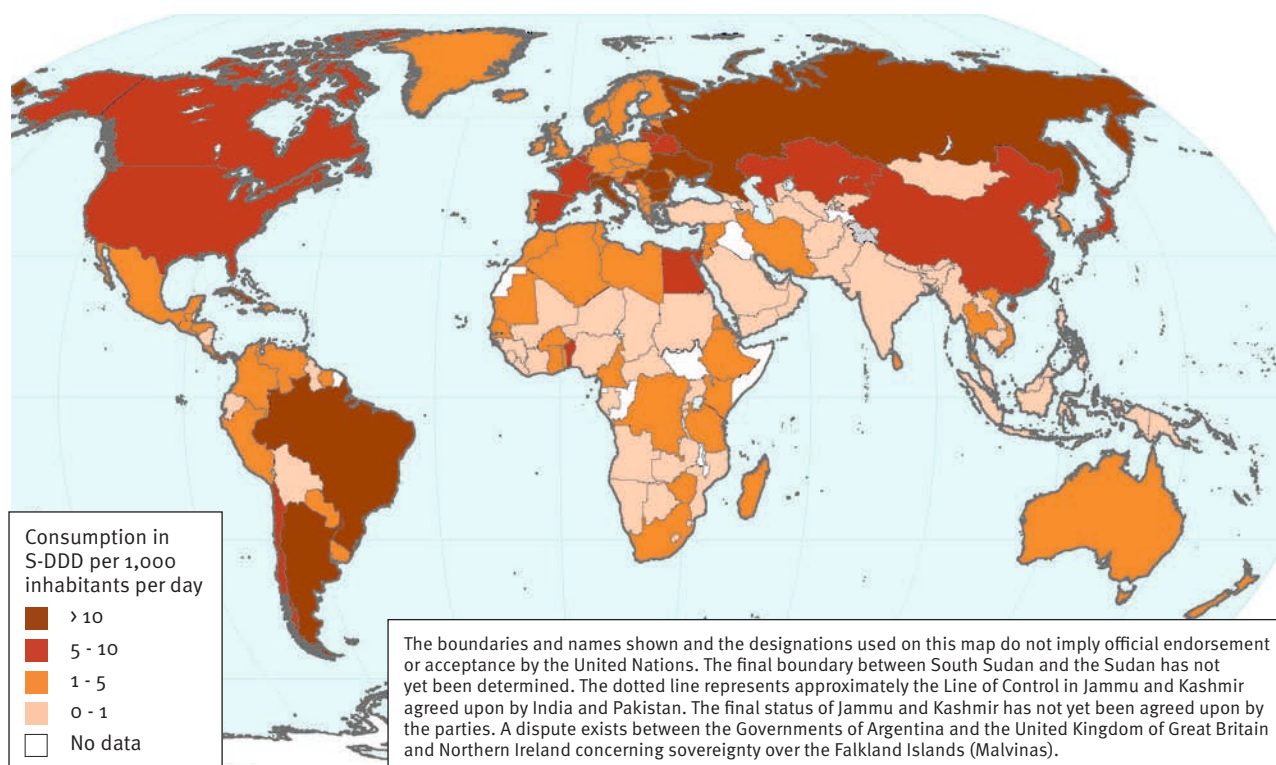
figure 59). The changes in consumption of anti-epileptics by country are presented in maps 25 and 26 below.

Figure 59. Consumption of anti-epileptics, all regions, 2004-2006 and 2011-2013



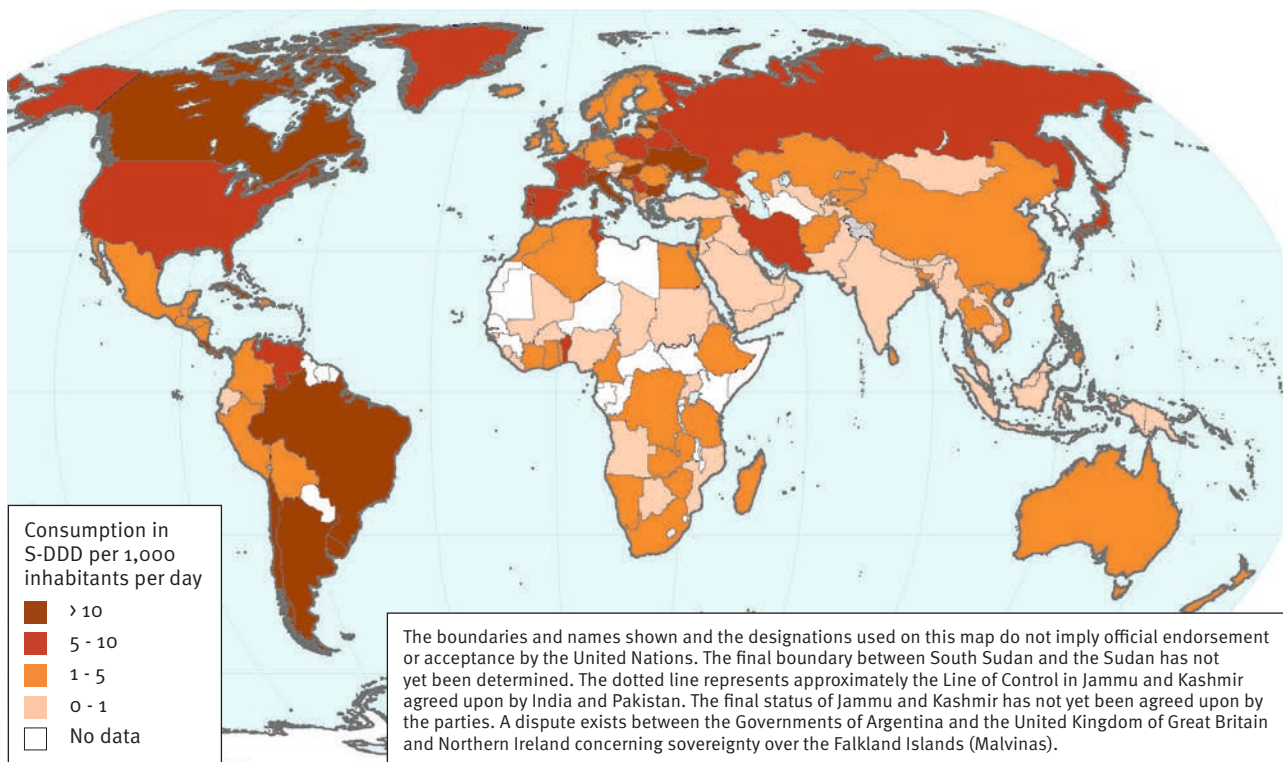
Source: International Narcotics Control Board.

Map 25. Average national consumption of anti-epileptics, 2004-2006



Source: International Narcotics Control Board.

Map 26. Average national consumption of anti-epileptics, 2011-2013

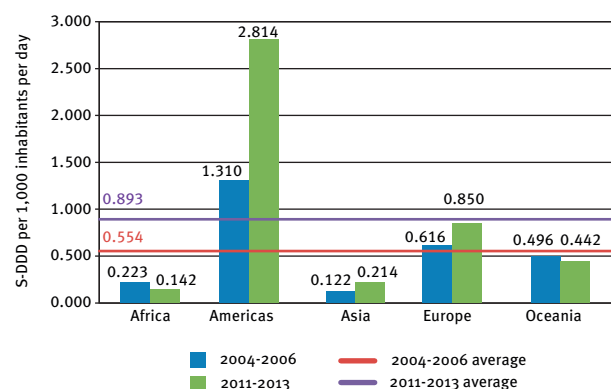


Source: International Narcotics Control Board.

(e) Benzodiazepine-type anti-epileptics (clonazepam)

225. The significant increases in consumption of anti-epileptics in the Americas were mainly driven by higher consumption of benzodiazepine-type anti-epileptics (clonazepam) in Brazil, Costa Rica, Nicaragua and Panama. Contrary to the overall trend in the consumption of anti-epileptics, consumption of benzodiazepine-type anti-epileptics (clonazepam) increased in most parts of the world during the 2004-2013 period (see figure 60). The rise was greatest in the Americas (115 per cent), Asia (75 per cent) and Europe (38 per cent). Meanwhile, the consumption of clonazepam in Africa and Oceania decreased moderately, by 36 per cent and 11 per cent, respectively. Regardless of the changes observed in different regions, the regional distribution of the consumption of clonazepam has stayed the same—with the highest levels of consumption found in the Americas, followed by Europe, Oceania, Asia and Africa.

Figure 60. Consumption of clonazepam, all regions, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

(f) Barbiturate-type anti-epileptics

226. Global consumption of barbiturate-type anti-epileptics (phenobarbital and methylphenobarbital) dropped

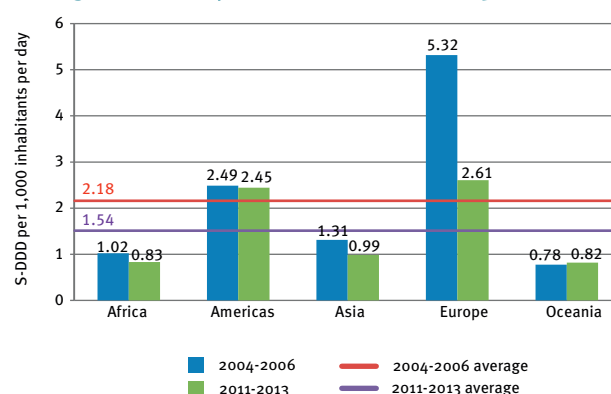
substantially during the 2004-2013 period. While the consumption of such substances fell by 95 per cent in Europe, it also declined in Asia and Africa, by 33 per cent and 20 per cent, respectively. The regional pattern of consumption of barbiturate-type anti-epileptics remained the same, with Europe and the Americas having the highest levels of consumption, followed by Asia, Africa and Oceania. As consumption of phenobarbital accounted for almost all of global consumption of barbiturate-type anti-epileptics, the consumption trend relating to this type of anti-epileptic has been very similar to that of phenobarbital.

Phenobarbital

227. Between 2004 and 2013, global consumption of phenobarbital, calculated in S-DDD per 1,000 inhabitants per day, declined by nearly 30 per cent,⁶⁰ with rather significant regional differences (see figure 61). While both Europe and the Americas had higher levels of consumption than the rest of the world, the consumption of phenobarbital in Europe fell by 51 per cent while that in the Americas only edged down by 2 per cent. Among all European countries, the largest reductions were in Lithuania, Hungary and Greece, in that order. Meanwhile, the consumption of phenobarbital in Asia and Africa also shrank, by 25 per cent

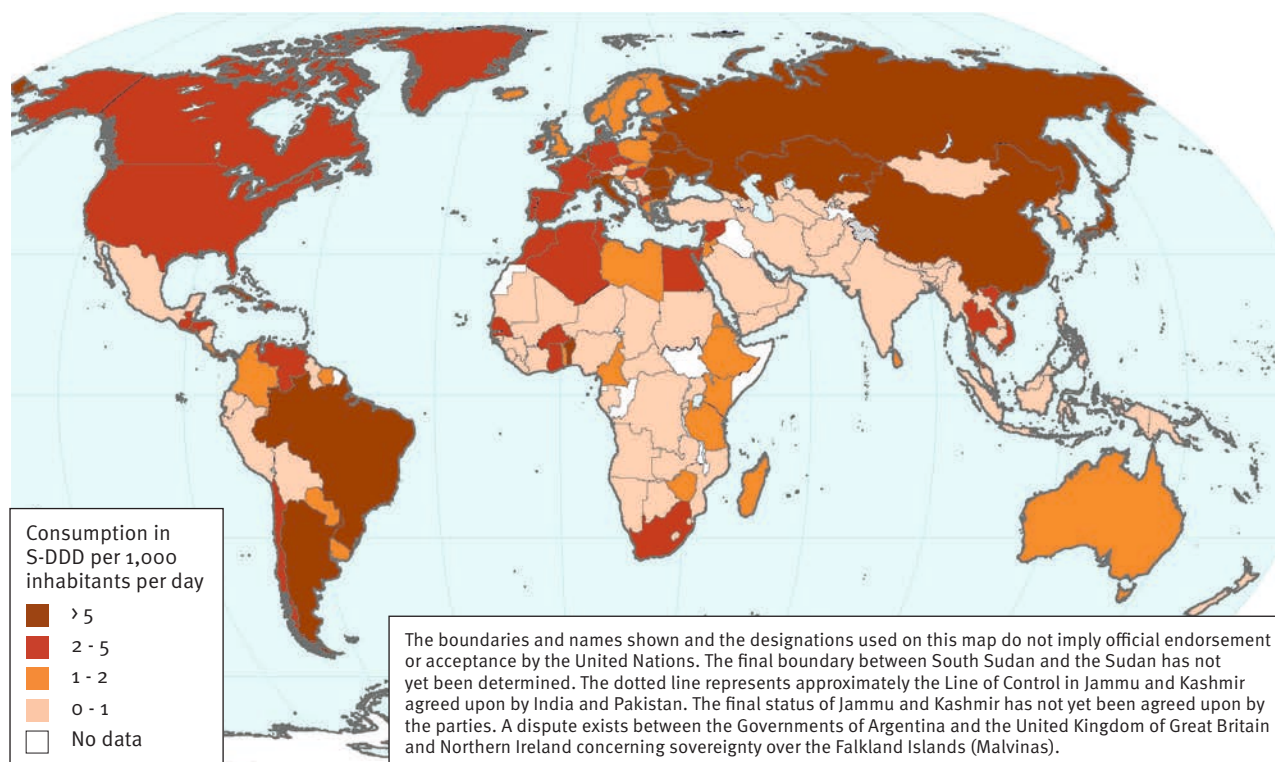
and 18 per cent respectively, while that in Oceania went up by 6 per cent. Despite these differences in trends, the regional distribution of the global consumption of phenobarbital remained the same throughout the 2004-2013 period, with Europe and the Americas being the two regions with the highest average levels of consumption, followed by Asia, Africa and Oceania. The changes in consumption of phenobarbital by country, approximated by measures of average annual calculated consumption (in S-DDD per 1,000 inhabitants per day) between 2004-2006 and 2011-2013, are presented in maps 27 and 28 below.

Figure 61. Consumption of phenobarbital, all regions, 2004-2006 and 2011-2013



Source: International Narcotics Control Board.

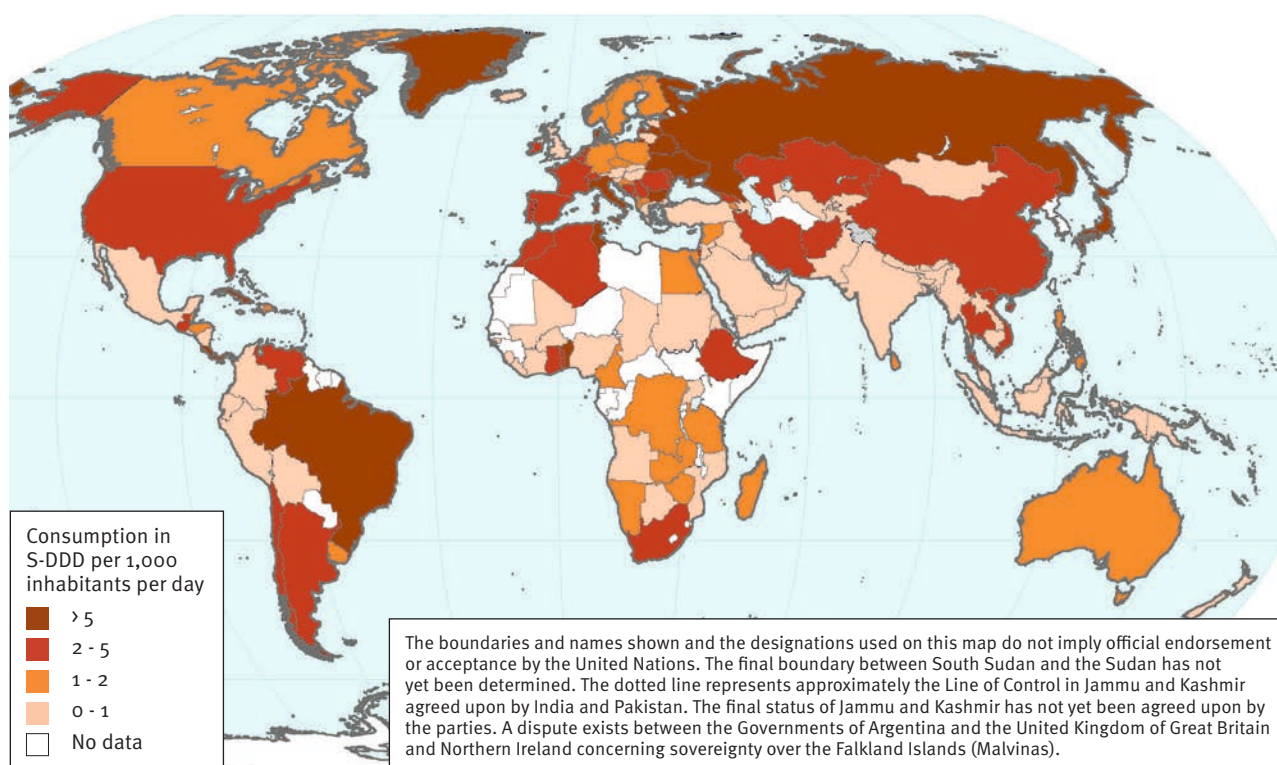
Map 27. Average national consumption of phenobarbital, 2004-2006



Source: International Narcotics Control Board.

⁶⁰The calculation is based on a comparison between the three-year averages of 2004-2006 and 2011-2013.

Map 28. Average national consumption of phenobarbital, 2011-2013



Source: International Narcotics Control Board.

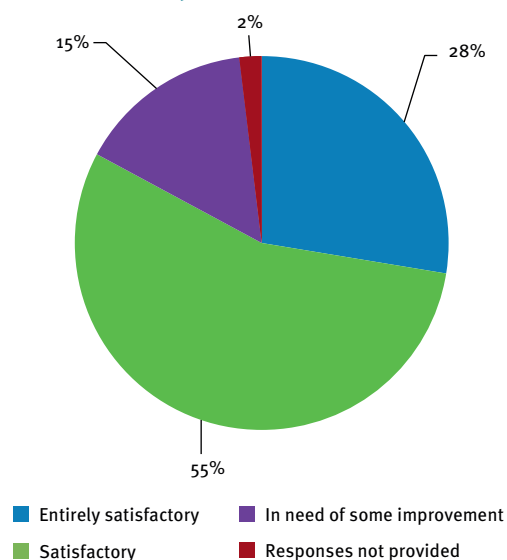
C. Impediments to the availability of psychotropic substances

228. The availability of psychotropic substances is influenced by various social and economic factors, including (a) the structure and capacity of health-care systems; (b) the degree of priority given by the authorities to the relief of pain and suffering; and (c) social attitudes towards health care and medical therapies, as well as related laws and regulations. In fact, the availability of controlled substances does not necessarily imply that they are accessible to all patients who need them. In reality, further criteria and conditions determine the accessibility of the drugs and have an impact on the relief of patients.

229. According to the second survey on the availability of controlled substances, carried out by the Board in 2014, to which 107 countries responded, the vast majority of Governments evaluated the situation in their countries as satisfactory. As shown in figure 62, more than three quarters of countries considered their situation to be satisfactory or entirely satisfactory (55 and 28 per cent, respectively), while others (15 per cent) indicated that the

availability of those substances in their countries was in need of some improvement. Nevertheless, the Board wishes to interpret this assessment with a certain amount of caution.

Figure 62. Availability of psychotropic substances, as evaluated by countries themselves, 2014



Source: International Narcotics Control Board survey 2014.

230. Furthermore, the availability of controlled substances in a country is not always a pertinent factor in determining the accessibility of such substances. Many aspects must be taken into account and addressed in order to achieve a fair and balanced distribution across the entire geographical area of a country and among its entire population.

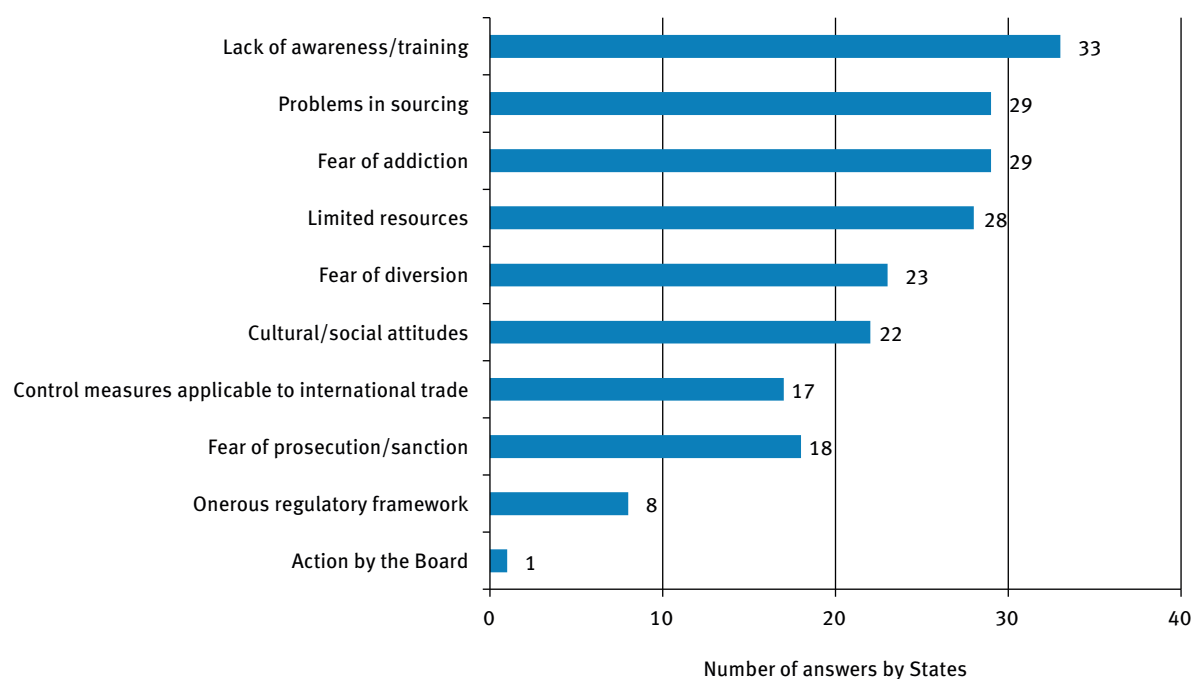
231. The extent of medical use of drugs depends on many factors. For instance, prescribers will select treatments according to their established therapeutic effectiveness, their availability and, importantly, the stability of their supply, which would entail a good awareness and knowledge of the market situation. The availability and accessibility of psychotropic substances have a direct impact on the level of consumption of such substances, but they do not automatically imply the existence of such a level of consumption, given that prescribers may select different protocols of treatment that will result in the prescription of other substances (for example, non-controlled or cheaper substances). In such cases, access by patients to treatment is ensured, but it does not involve

controlled substances and may result in the artificially low availability of such substances.

232. As figure 63 shows, the Board's 2014 survey on the availability of controlled substances revealed the major impediments to the availability of such substances under international control as perceived by Governments.

233. With the exception of the fear of diversion, which was cited more frequently in relation to narcotic drugs than psychotropic substances, the main impediment to the availability of psychotropic substances, as was the case with regard to narcotic drugs, was inappropriate knowledge and lack of awareness among health-care professionals regarding rational use of those substances. Moreover, the survey also showed that the impediment least frequently cited by responding countries was action by the Board, with regard to the availability of both narcotic drugs and psychotropic substances. This is a positive and encouraging finding that shows that the Board is not perceived as a contributor to unduly limited availability of controlled substances, but rather the opposite.

Figure 63. Impediments to the availability of psychotropic substances, 2014



Source: International Narcotics Control Board survey 2014.

234. The environment surrounding a patient may hinder access to treatment, for example, if the necessary health structures (hospitals, clinics or pharmacies) are lacking in certain areas of a country or, as is unfortunately common in the rural communities of some developing countries, the closest health facilities are too

far to be reached. The capacity of health systems to reach patients affects the accessibility of controlled substances without influencing their availability (if sufficient stocks are available in distant regions). The emergence of parallel markets and counterfeit products, with the health hazard they represent, is the result when

proper and timely access to safe medicines is not possible.

235. In developing countries where the availability of medicines is determined by economic factors rather than by real medical needs, mental health care might not be given the priority it deserves. Furthermore, cultural attitudes vis-à-vis mental disorders and illnesses and the fear of addiction were also indicated as impediments to the consumption of psychotropic substances. A low level of prescription by health-care providers is a deterrent to their manufacture and/or import.

236. In some cases, misinformation and misconception concerning controlled substances, added to a fear of prosecution for storing these substances, often force distributors to refrain from holding large stocks.

237. The most often cited impediment was a lack of awareness among health-care professionals about the concept of rational use of psychotropic substances. Such an impediment may result from a lack of training and knowledge on the matter and will contribute greatly to low levels of prescription of these substances.

238. In several countries, a lack of knowledge among health-care professionals may result in non-justified concerns about the prescription, use and dependence potential of such substances. As is the case for narcotic drugs, insufficient attention to the rational prescription and use of psychotropic substances in the curricula of medical schools may also be a factor. Consequently, doctors may instead prescribe substances with which they are more familiar, in particular, substances that are not under international control.

239. According to the answers to the Board's survey, the curriculum for medical practitioners in 66 countries includes rational prescription and use of psychotropic substances. In addition, 58 countries reported implementing awareness-raising measures among health-care professionals regarding best prescription practices for psychotropic substances.

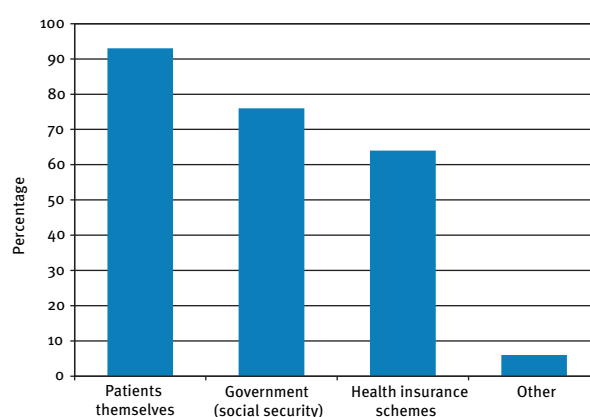
240. Furthermore, among responding countries, 39 per cent (29 countries) identified fear of addiction as an impediment to the availability of psychotropic substances, making it one of the most frequently mentioned impediments in the 2014 survey.

241. As was observed in the case of narcotic drugs, the fear of addiction to psychotropic substances seems to be related to a lack of awareness and training of health-care professionals, as well as cultural attitudes and misconceptions.

242. Clearly, one of the main impediments to access to a particular medical treatment is its cost; hence, such a treatment might be available but not accessible to those who need it most. Furthermore, access to medicines, provided that they are available, may depend on other factors, such as the health-care structure itself. Twenty-eight countries (37 per cent) identified financial aspects as a potential impediment to the availability of psychotropic substances. Indeed, limited available financial resources can have an impact on the choice of which medicines to purchase, and priority might be given to substances that are perceived as essential (such as antibiotics).

243. Furthermore, the availability of psychotropic substances is also dependent on their affordability for patients. In this context, the presence of social security or national health insurance schemes plays a crucial role. In the responses to the question about who pays for medical treatments containing psychotropic substances prescribed, patients were mentioned the most often (89 per cent), followed by the government (73 per cent) and health insurance schemes (62 per cent) (see figure 64).

Figure 64. Who bears the cost of prescribed psychotropic substances, 2014

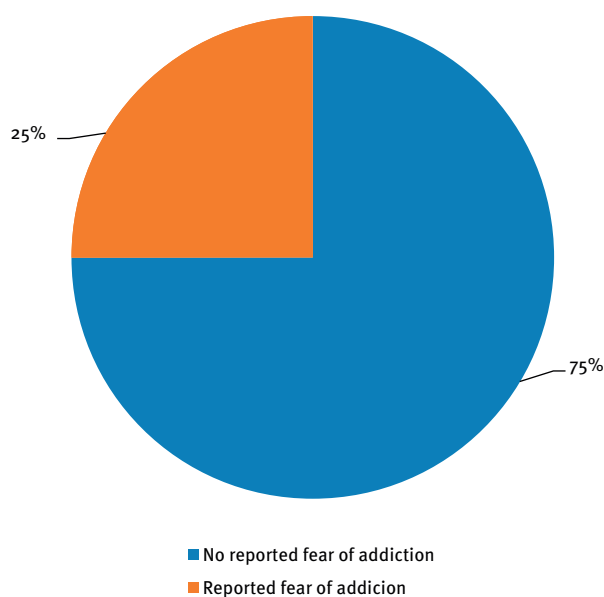


Source: International Narcotics Control Board survey 2014.

244. Cultural and social attitudes regarding the use of psychotropic substances were also recognized as playing a major role in contributing to restrictions on the use of such substances.

245. A better awareness of rational use and prescription of psychotropic substances among health-care professionals can greatly contribute to overcoming restrictions on use that result from fear of addiction. The Board survey shows that, out of 58 countries that had implemented awareness-raising measures among health-care

Figure 65. Reports of fear of addiction among countries that have implemented awareness-raising measures, 2014



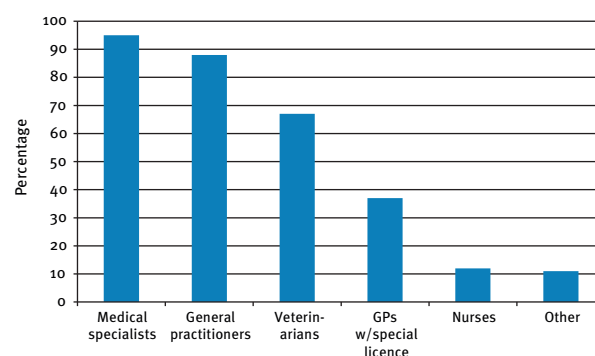
Source: International Narcotics Control Board survey 2014.

professionals, a large proportion (75 per cent) did not report the fear of addiction as an impediment to the availability of psychotropic substances (see figure 65).

246. Countries may refrain from the manufacture and/or import of controlled substances in order to avoid their diversion into illicit traffic and abuse networks. Out of 75 responding countries, 26 reported fear of diversion of psychotropic substances as an impediment to the availability of such substances. Furthermore, the emergence of unregulated and parallel markets for psychotropic substances can also greatly contribute to the fear of diversion. Patients may sometimes refuse a treatment that contains psychotropic substances, as they may be concerned about possible side effects and also worry about the stigma associated with the use of such substances.

247. Other major impediments perceived by responding countries included the burden imposed by some internal administrative frameworks for regulating the use of controlled substances and the various rules and regulations regarding international trade in those substances, as well as the fear of prosecution and/or sanction associated with dealing with controlled substances. These measures may concern international trade in psychotropic substances and domestic distribution networks (prescription and dispensing). The survey found that, out of 37 countries that reported having taken legislative or regulatory action in the previous 10 years to increase the availability of psychotropic substances for medical purposes,

Figure 66. Prescribers of psychotropic substances, 2014



Source: International Narcotics Control Board survey 2014.

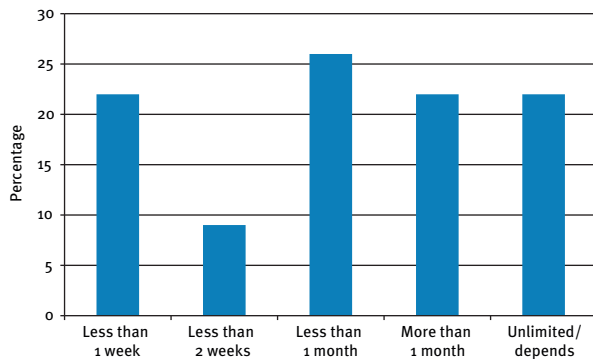
35 countries had observed an increase in consumption expressed in S-DDD since the 2007-2009 period. However, out of 83 responding countries, 75 reported the existence of penalties for inadequate record-keeping.

248. Of 102 responding countries, 66 per cent legally required prescribers to keep records of prescriptions for psychotropic substances. This may discourage the stocking of such substances, owing to costs and time-consuming procedures, and possibly because of fear of prosecution and sanctions.

249. As illustrated in figure 66, general practitioners and specialized doctors have a nearly identical degree of authority in terms of prescribing psychotropic substances. In a large proportion of responding countries, nurses were not allowed to prescribe psychotropic substances, which may be an impediment to availability, especially in rural areas with basic health-care systems and infrastructure.

250. Lower levels of access to psychotropic substances could also result from overly restrictive rules concerning distribution networks and dispensing protocols. The validity period of a medical prescription that contains psychotropic substances, as well as constraints on or inflexibility regarding a prescription's refill, could also play a role, especially since treatment that includes psychotropic substances can very often last for years. In this context, 26 per cent of countries reported prescriptions to be valid for one month or less. The second most

Figure 67. Maximum validity period of medical prescriptions that contain psychotropic substances, 2014



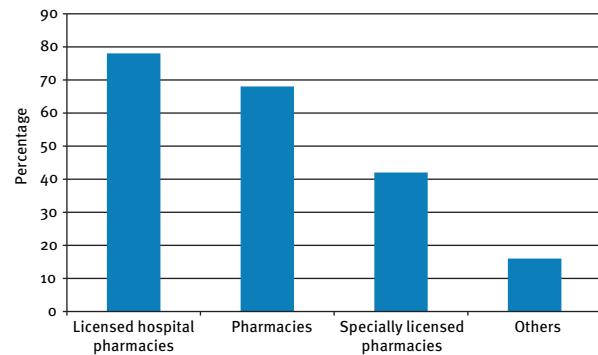
Source: International Narcotics Control Board survey 2014.

frequently reported validity period was up to one week (22 per cent) (see figure 67).

251. Member States reported that psychotropic substances were dispensed mostly in licensed hospital pharmacies or in regular pharmacies. Less than half of responding countries reported that psychotropic substances could be dispensed in specially licensed pharmacies (see figure 68).

252. Restrictions on the number of pharmacies that are allowed to dispense psychotropic substances, although not as stringent as those observed for the dispensing of narcotic drugs, may still reduce the availability of such drugs.

Figure 68. Facilities where prescriptions for psychotropic substances can be dispensed. 2014



Source: International Narcotics Control Board survey 2014.

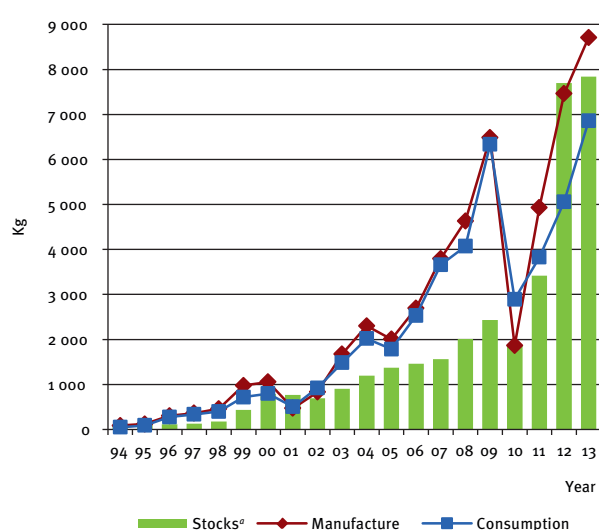
253. Finally, in only one country was action by the Board identified as an obstacle to the availability of psychotropic substances. While the large majority of countries are familiar with the procedures for establishing, submitting and modifying assessments of their medical requirements for psychotropic substances (98 per cent), and furthermore more than 80 per cent of responding countries were using the INCB training materials, as well as the joint INCB/WHO guidelines on the preparation of estimates, some responding authorities proposed actions that could be taken by the Board that could contribute to the improvement of the availability of psychotropic substances, including the training of and the provision of information to competent national authorities.

Chapter IV.

Availability of internationally controlled drugs for the treatment of opioid dependence

254. Methadone and buprenorphine are used in the management of pain, but they are also extensively used in the treatment of opioid dependence. In some countries, other controlled substances, such as opium, opium tincture, heroin and morphine, are used for the treatment of opioid dependence. The data reported by countries to INCB do not indicate the purpose of use, but estimates for methadone and buprenorphine are mainly submitted in relation to programmes for the treatment of opioid dependence.

Figure 69. Reported manufacture and stocks of buprenorphine, 1994-2013



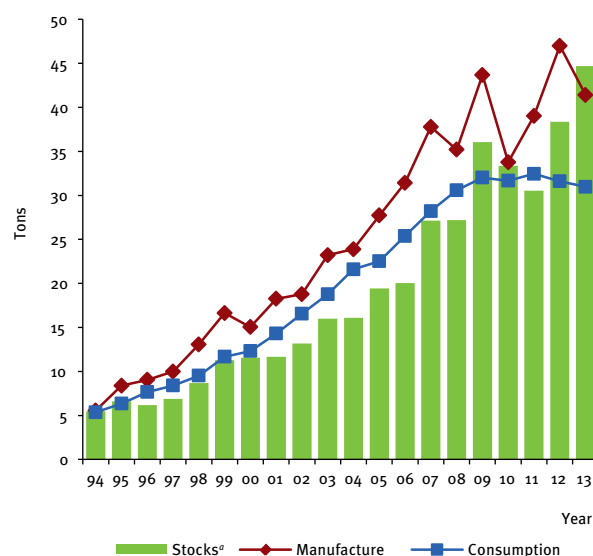
Source: International Narcotics Control Board.

Note: Approximate calculated global consumption, determined on the basis of statistical data submitted by Governments.

^aStocks as at 31 December of each year; data are provided on a voluntary basis and may therefore be incomplete.

255. An analysis of the trends related to the consumption, manufacture and stocks of both substances shows a steady increase over the past 20 years. The global manufacture of buprenorphine has increased steadily (with the exception of 2010, when there was a sharp decrease), reaching a peak of 8.7 tons in 2013. Similarly, the global manufacture of methadone also increased steadily during the same period, with some fluctuations, and decreased slightly in 2013 to 41.4 tons (5.5 tons less than in 2012) (see figures 69 and 70). As mentioned in relation to other opioid analgesics, it seems that there is no problem with the supply of these substances.

Figure 70. Global manufacture, consumption and stocks of methadone, 1994-2013



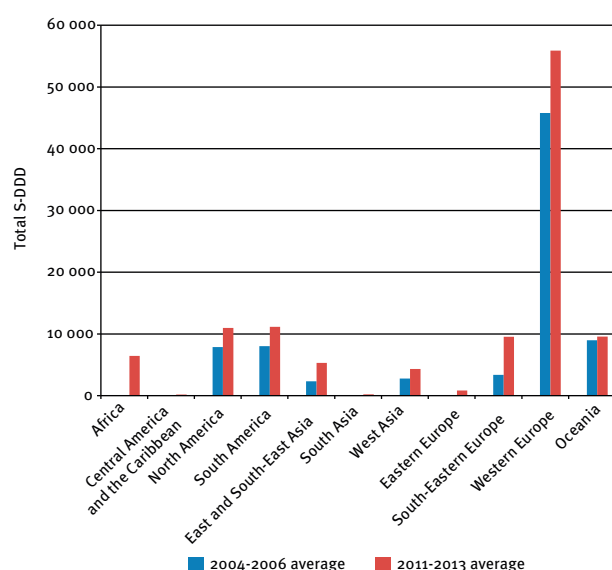
Source: International Narcotics Control Board.

^aStocks as at 31 December of each year.

256. However, there are large differences in the patterns of consumption at the global level, as shown in maps 29-33. In some cases, the different level of consumption (expressed in S-DDD, see figures 71 and 72) is related to the presence or absence of people who inject drugs. In other cases, despite the existence (more or less prevalent) of that phenomenon, it seems that the consumption of methadone and buprenorphine, and also the presence of opiate substitution treatment services, are limited or not

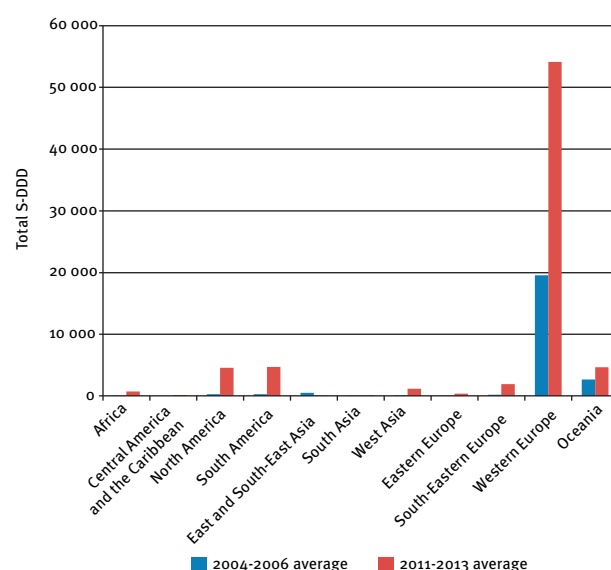
present. This is sometimes because of government policies that do not recognize the effectiveness of these kinds of services in the treatment of opioid dependence, political and cultural resistance, or simply inaction by the responsible authorities or incapacity to recognize the problem. In the survey carried out by the Board in 2014, 67 per cent of countries indicated that they were using narcotic drugs for the treatment of drug dependency with substitution therapy.

Figure 71. Variations in the consumption of methadone between 2004-2006 and 2011-2013



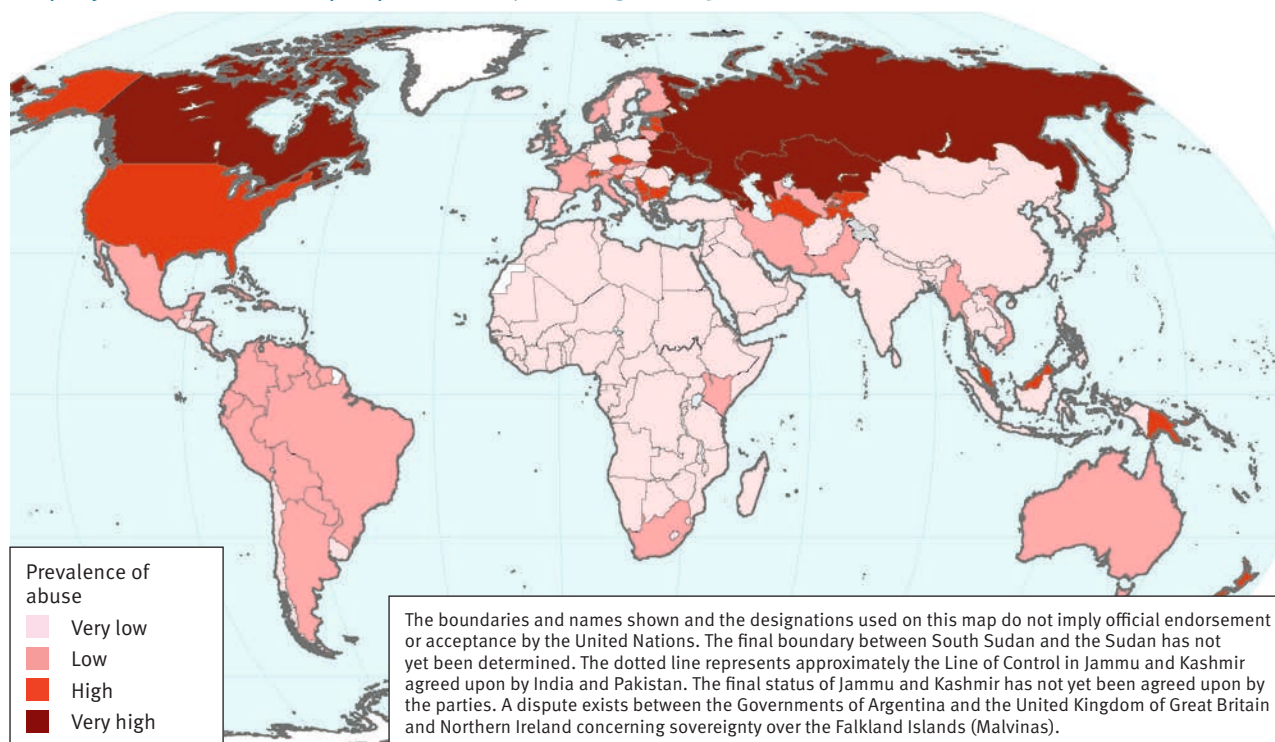
Source: International Narcotics Control Board.

Figure 72. Variations in the consumption of buprenorphine between 2004-2006 and 2011-2013



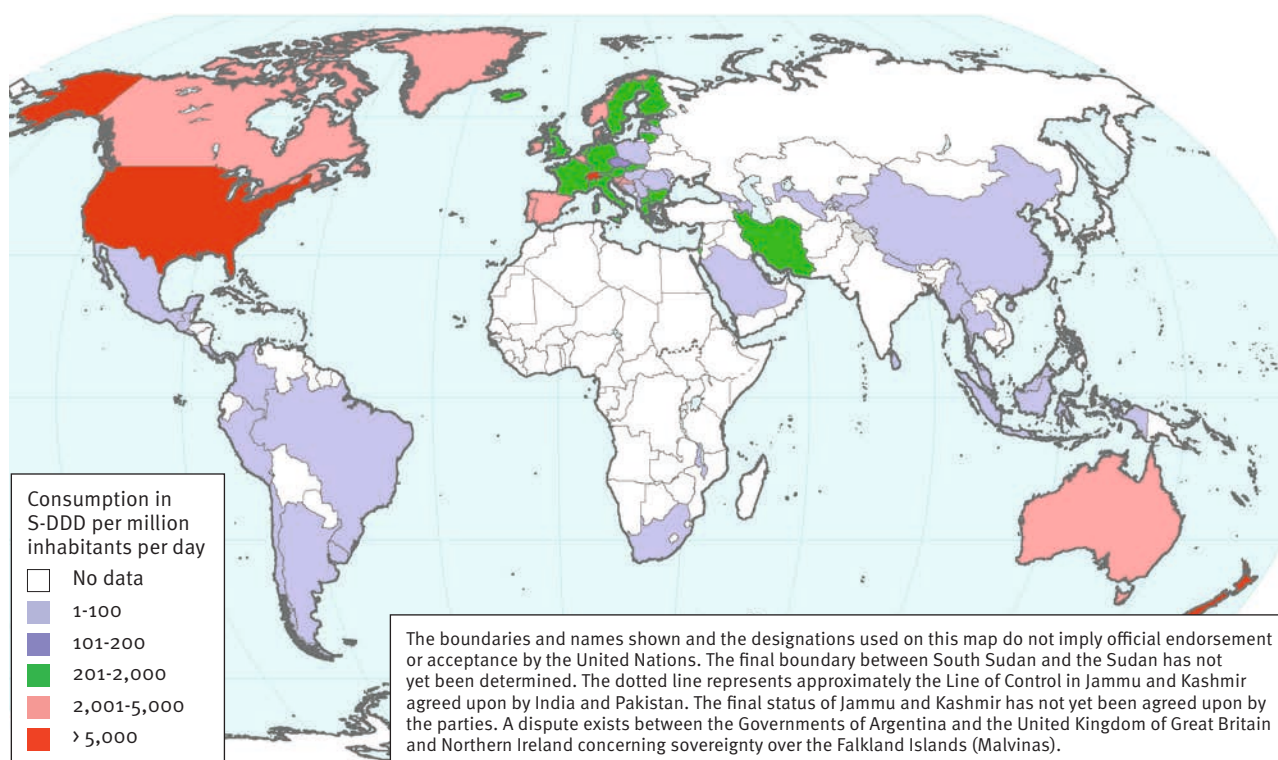
Source: International Narcotics Control Board.

Map 29. Prevalence of people who inject drugs, 2013



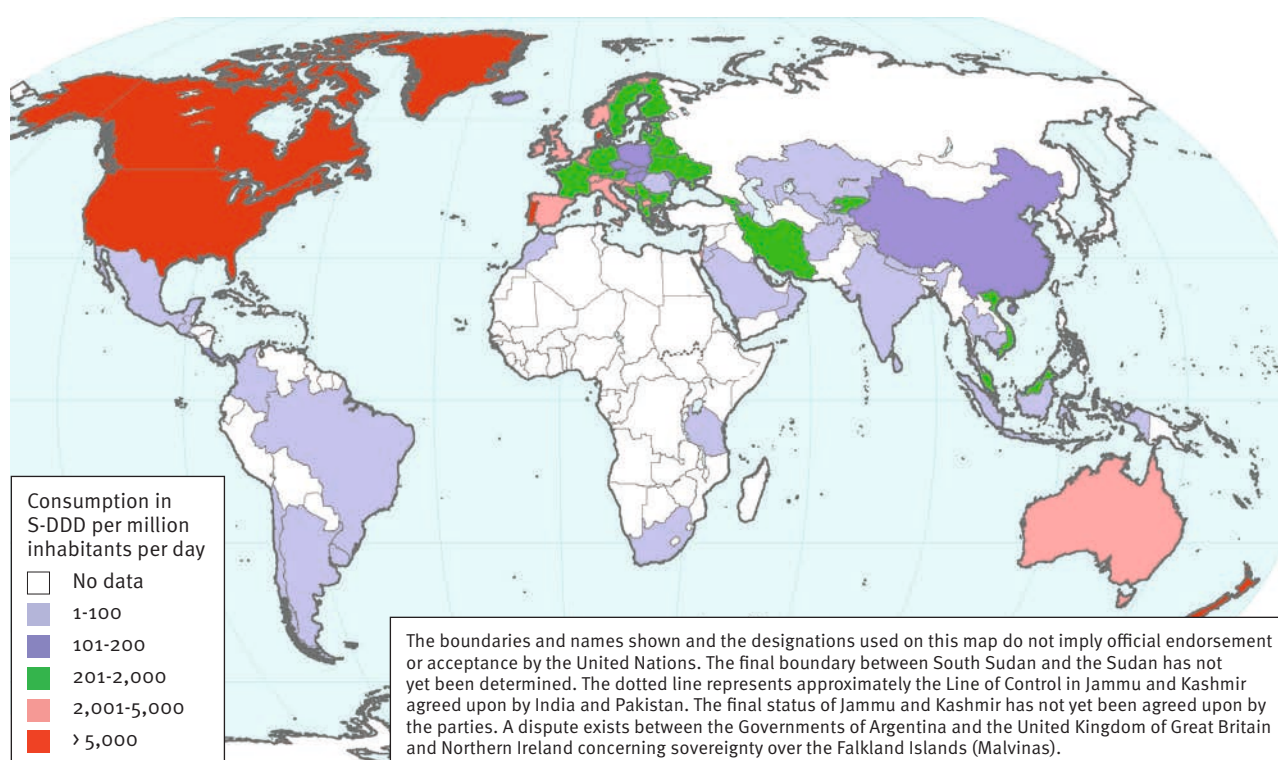
Source: UNODC.

Map 30. Consumption of methadone, 2004-2006



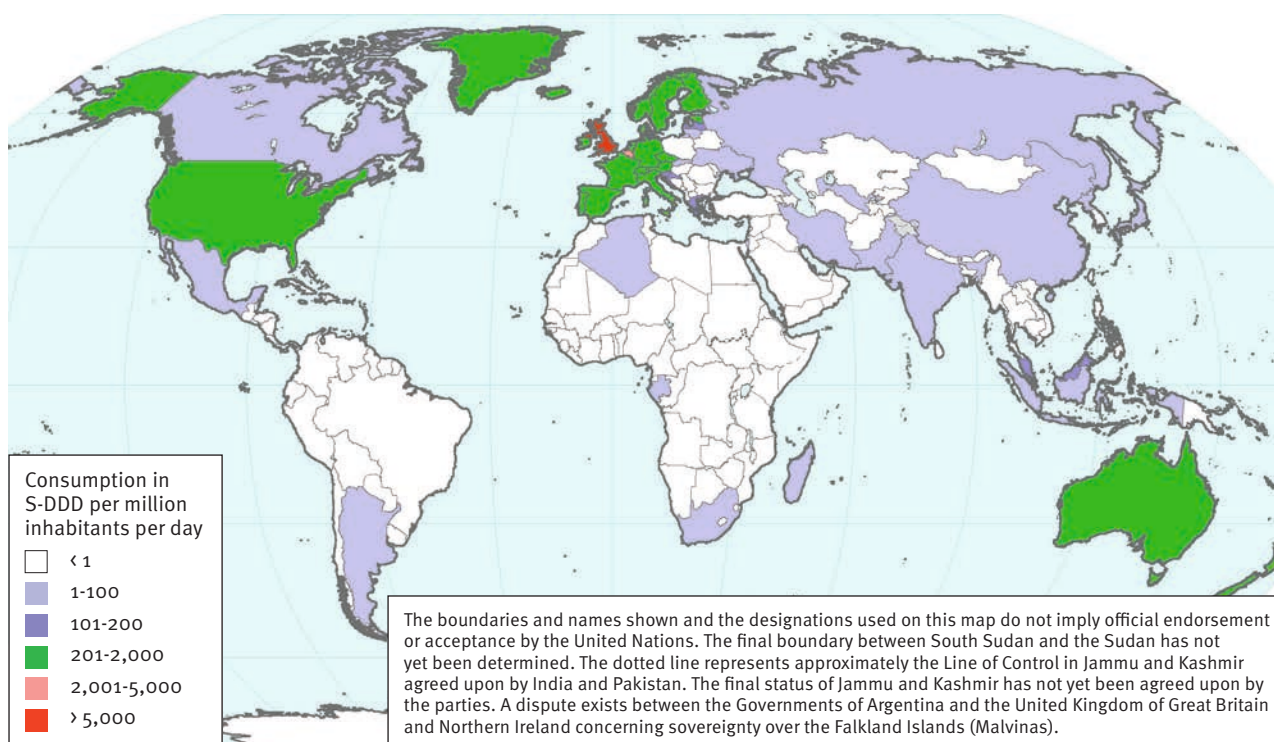
Source: International Narcotics Control Board.

Map 31. Consumption of methadone, 2011-2013



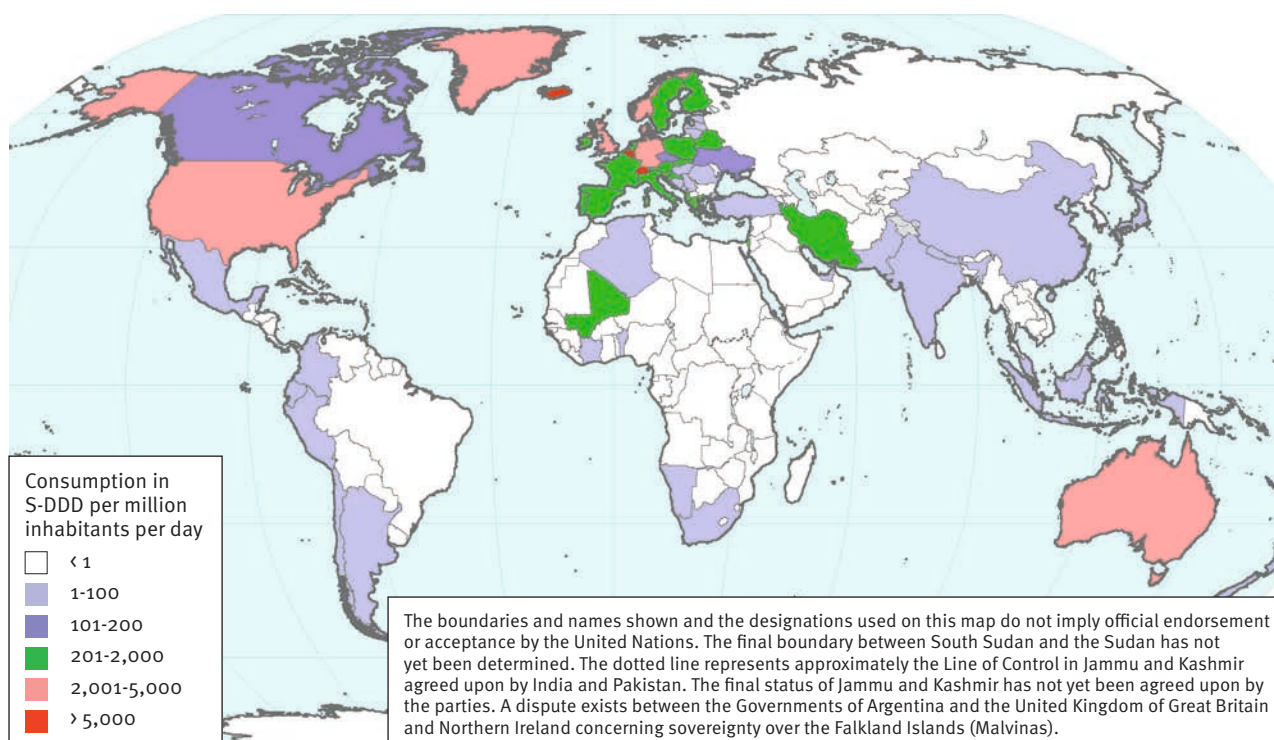
Source: International Narcotics Control Board.

Map 32. Consumption of buprenorphine, 2004-2006



Source: International Narcotics Control Board.

Map 33. Consumption of buprenorphine, 2011-2013



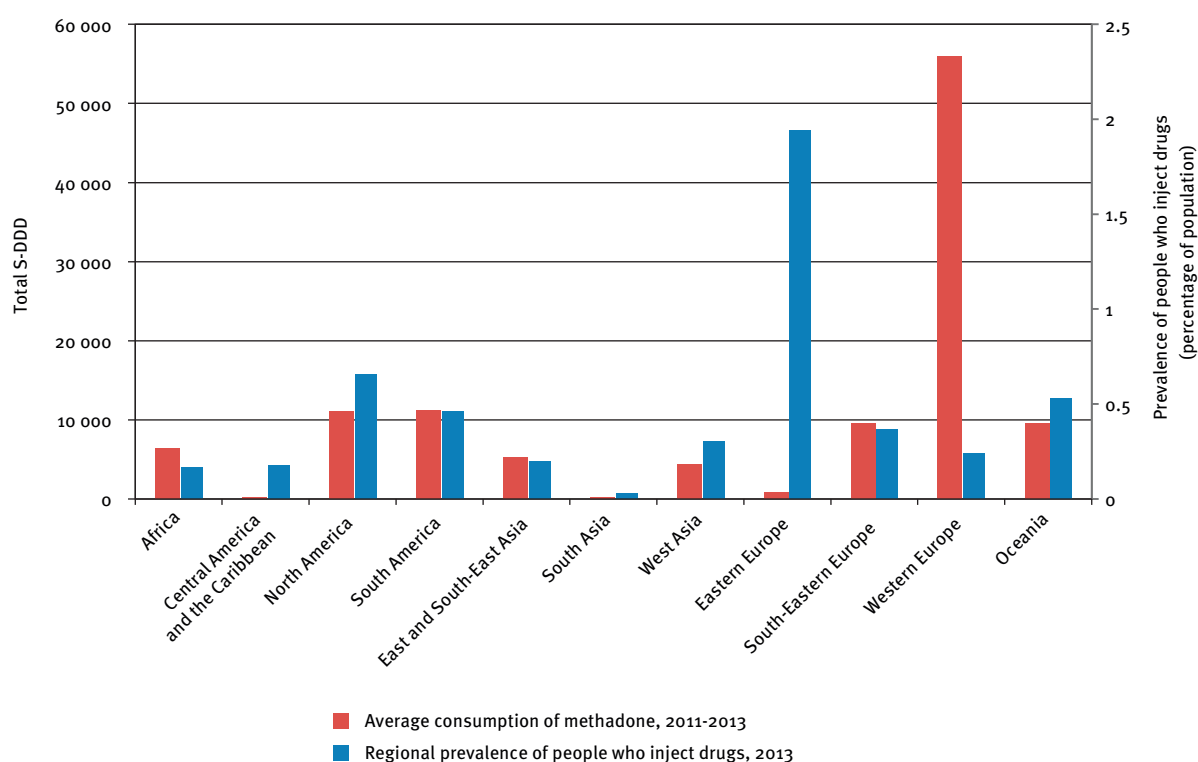
Source: International Narcotics Control Board.

257. For methadone, it is important to note the increase in consumption in Africa and South-Eastern Europe, which corresponds to the expansion of opioid substitution treatment services in some countries in those regions. For buprenorphine, there was a large increase in consumption in Western Europe. The increase in the consumption of buprenorphine registered in some regions may be the result of various factors: aggressive marketing by producing companies; easier accessibility due to the less strict control regime of the 1971 Convention compared with the 1961 Convention (under which methadone is controlled); and increasing use for pain relief. In Central and South America, methadone is used for pain management and not for opioid substitution

treatment, because the prevalence of people who inject drugs in the region is relatively low.

258. A comparison of the level of consumption of methadone and the prevalence of people who inject drugs in various regions indicates an imbalance in that regard in Eastern Europe (see figure 73). As mentioned above, the use of methadone is not recognized in some of the countries of that region. In Western Europe, there seems to be a very high level of methadone consumption despite a lower prevalence of people who inject drugs. This may be due to the fact that the opioid substitution treatment services provided in the region reach a large number of people who inject drugs.

Figure 73. Comparison between consumption of methadone, 2011-2013, and prevalence of people who inject drugs, 2013



Source: International Narcotics Control Board and UNODC.

Chapter V.

Ensuring the availability of internationally controlled drugs in emergency situations

259. Most narcotic drugs and a large number of psychotropic substances controlled under the international treaties are indispensable for medical practice. Simplified control measures are in place for the provision of internationally controlled medicines for emergency medical care. Emergencies are defined as follows:

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.⁶¹

260. 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 remove the need for import authorizations, provided that the import and delivery are 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.

261. Emergency situations arise following natural or man-made catastrophic events in which the need to provide treatment to the many victims leads to a

sudden need for and an acute shortage of medicines. Many of those needed medicines contain narcotic drugs, such as morphine, or 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.

262. In responding to humanitarian crises, the Board takes active steps to hasten the supply of controlled medicines by reminding all exporting countries that clear guidelines are in place for the international provision of controlled medicines for emergency medical care and that countries can apply those simplified control procedures to hasten the supply of urgently needed medicines. The Board also informs providers of humanitarian assistance about the simplified regulations.

263. Competent national authorities may allow the export of internationally controlled substances to affected countries even in the absence of import authorizations or estimated requirements. 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 that purpose.

264. 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.

⁶¹World Health Organization, Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care.

265. In addition, 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.

Chapter VI.

Conclusions and recommendations

266. Ensuring the availability of internationally controlled substances for medical and scientific purposes while preventing their illicit trafficking and abuse is the role of the control system as established by the international drug control conventions. An efficient and successful drug regulatory system that maintains this balance requires the involvement of the entire community, as well as the commitment of Governments.

267. The issue of ensuring the availability of narcotic drugs and psychotropic substances for medical purposes is a complex one. The previous chapters have discussed the unequal distribution of these drugs, as well as the barriers and impediments that cause this inequality. Apart from the data on consumption and prevalence of health conditions requiring palliative care, and the information presented by Member States, the Board has also reviewed information provided by international organizations (WHO, UNODC and UNAIDS), academia, research centres and civil society organizations. The analysis of this entire set of information suggests that there are some key areas that require action at the national and international levels.

A. Legislation and regulatory systems

268. The regulatory machinery that countries have established to implement the provisions of the international drug control conventions needs to be reviewed. Most studies and analyses indicate that some countries, when developing legislation and regulations, were concerned mostly with the need to avoid diversion and abuse rather than the need to ensure availability and make adequate provisions to that end. In fact, concerns about the risk of addiction

are still reported to be a major impediment by countries. However, in the three surveys carried out by the Board over the past 20 years, the percentage of countries indicating this as an impediment has dropped from over 70 per cent in 1995 to 34 per cent in 2014. This unbalanced or asymmetrical view of the conventions has, in a number of countries, generated regulatory systems that make it difficult or almost impossible for people in need to obtain opioid analgesics.

269. The Board has in the past expressed concerns in this regard and issued recommendations. It seems that some countries have taken action, but there are still countries that need to address this issue. The Board recommends that they take the following actions:

- Review national legislation and regulatory and administrative mechanisms, as well as procedures, including domestic distribution channels, with the aim of simplifying and streamlining those processes, and removing unduly restrictive regulations and impediments to ensure accessibility while maintaining adequate control systems.
- Allow a larger base of health-care professionals (including trained general practitioners, nurses and others, as appropriate) to prescribe opioids to increase availability, particularly in remote or rural areas.
- Take measures to prevent the emergence of unregulated markets and illicit or counterfeit manufacture of narcotic drugs and psychotropic substances.
- Ensure adequate prescription policies, including, where appropriate, by increasing the validity

period of prescriptions to enable patients to procure medications when they need them.

- Remove legal sanctions for unintentional mistakes in the handling of opioids.
- Improve inter-agency and interministerial cooperation and coordination at the national level, particularly between health and drug control agencies.
- Provide the medical and pharmaceutical community with updated information on all new legislative and administrative measures enacted in connection with controlled substances and on modalities of distribution and prescription of psychotropic substances to ensure and sustain the requisite availability that would satisfy requirements with regard to both quantity and quality.

B. Health system

270. The availability of pain relief drugs or psychotropic substances alone will not solve the problem of pain management or mental health treatment. There is broad consensus that it is important for countries to give appropriate attention to the improvement of the health system. To that end, the Board recommends that countries:

- Implement the recommendations contained in resolution WHA67.19, adopted by the sixty-seventh World Health Assembly on 24 May 2014, entitled “Strengthening of palliative care as a component of comprehensive care throughout the life course”.
- Develop an appropriate and well-resourced health infrastructure that not only ensures the availability of opioid analgesics but also provides for such availability in the context of the broader delivery of palliative care.
- Consider, where appropriate, the option of low-cost, home-based palliative care services.
- Improve the distribution of opioid analgesics and psychotropic substances to all areas of the country, including rural areas.

C. Affordability

271. Another important aspect of improving availability is ensuring that opioid analgesics are affordable. In this connection, the Board recommends that countries:

- Improve access to essential drugs in general and to opioid analgesics in particular.
- Ensure funding for the purchase of opioid analgesics.
- Develop and improve health insurance and reimbursement schemes that guarantee access to medications.

272. With respect to affordability, pharmaceutical companies have an important role to play. The Board will, as part of its ongoing efforts to improve the situation, commence consultations with pharmaceutical industry groups about the lack of controlled medications in many regions, involving relevant international organizations (e.g. WHO), and relevant international professional groups and interested Governments in these discussions, which will focus on the availability and accessibility in developing countries of affordable, effective monotherapies, such as morphine for pain, especially cancerous pain. The Board recommends that the pharmaceutical industry:

- Manufacture high-quality opioid preparations that are more affordable.
- Manufacture generic pharmaceutical preparations that are bioequivalent and cost effective.

D. Training of health-care professionals

273. Patients have the right to be treated and to receive medications that are rationally prescribed. Lack of training and lack of awareness among health-care providers concerning the rational use of narcotic drugs and psychotropic substances, and the resulting reduced levels of prescription, will limit the use of such substances. Furthermore, certain cultural attitudes towards the management of mental health disorders and palliation are acting as an impediment to the use of narcotic drugs and psychotropic substances. To this end, health-care professionals need to be properly educated and trained. It is recommended that countries:

- Include palliative care in the educational curricula of medical schools and in the mandatory training of all health professionals.
- Provide continued education, training and information on palliative care to health-care professionals, including on rational use and on the importance of reducing prescription drug abuse.

- Provide education and training to doctors and other health-care professionals on the rational use of psychoactive drugs, since this is of paramount importance for the prevention of the abuse of such drugs. Health actors must exercise vigilance to prevent possible misdiagnoses and inappropriate prescribing.
- Ensure that psychotropic substances are prescribed in conformity with sound medical practice as set forth in the 1971 Convention (art. 9, para. 2), promote the rational use of such substances and take the necessary measures to limit their use to actual medical needs.

E. Education and awareness-raising

274. Opioid analgesics and palliative care in general are also limited in some countries by social and cultural norms. In some societies and cultures, there is resistance to dealing with things related to the end of life or associated with the fear of addiction. Also, the use of psychotropic substances faces considerable resistance because of the stigma associated with the mental health conditions that may require their use. The Board recognizes that it is necessary for Governments in cooperation with civil society to:

- Develop and implement educational programmes for the general public and the pharmaceutical community involving competent national authorities, interest groups (e.g. professional and consumer interest groups) and the media.
- Organize workshops to disseminate information on palliative care to overcome cultural resistance to it.
- Ask educational institutions to include education on palliative care in their curricula.
- Engage civil society organizations representing patients, families and other relevant groups to advocate for palliative care and for the acceptability of the medical use of opioid analgesics.
- Educate the public to reduce stigma and unreasonable fear of addiction.
- Reduce excessive marketing by industry and improve consumer awareness.
- Promote ethical attitudes among medical doctors and pharmaceutical companies, together

with appropriate information for the general public and continued education and training of health-care professionals to encourage a better-justified and more rational use of psychotropic substances.

- Support campaigns and efforts to prevent the non-medical consumption of psychotropic substances, and encourage the active participation of the medical and pharmaceutical community in all measures related to the rational use of controlled medicines.

F. Estimates, assessments and reporting

275. One of the problems that the Board has noted over the past several years is that some countries are not able to properly estimate their needs for opioid analgesics and to monitor the consumption of those substances. Furthermore, many countries still find it difficult to identify with precision their requirements for psychotropic substances. Consequently, they are unable to establish and provide the Board with adequate assessments for their legitimate use. In addition, in its resolution 53/4 and 54/6, the Commission on Narcotic Drugs encouraged Governments to provide the Board with data on the consumption of psychotropic substances, in the same manner as for narcotic drugs. Finally, the punctuality of the submission of reports and their comprehensiveness and reliability are important aspects of each Government's cooperation with INCB. The Board recommends that countries:

- Improve their method of assessing their needs by making use of the *Guide on Estimating Requirements for Substances under International Control* developed in 2012 by INCB and WHO for use by competent national authorities.
- Submit appropriate and realistic estimates that take into consideration possible variations in demand.
- Establish proper and feasible monitoring mechanisms at the national level and make use of improved technical systems such as the electronic International Import and Export Authorization System (I2ES) for narcotic drugs and psychotropic substances, which was developed by INCB in close cooperation with UNODC.

- Establish a procedure and develop mechanisms that will allow their competent national authorities to more accurately assess the actual requirements for psychotropic substances and submit such data to the Board.
- Develop adequate systems that will enable the collection of reliable data that would be essential in enabling the Board to better analyse trends in the consumption of psychotropic substances and, ultimately, to promote their adequate availability for medical and scientific purposes while preventing their diversion and abuse.

G. Benchmarks for consumption of substances under international control

276. The results of the analysis of the data on availability and consumption reported to INCB, and the answers to the questionnaire on availability provided by Governments demonstrate the complexity of this analysis. In particular, the levels of consumption of psychotropic substances calculated by the Board on the basis of statistics on manufacture and trade provided to the Board by Governments cannot reflect with precision the levels of consumption of these substances.

277. Furthermore, in the absence of thresholds for per capita consumption in S-DDD, the Board is not in a position to evaluate and assess levels of consumption of psychotropic substances, and therefore cannot estimate whether in some countries or regions the level of

consumption of such substances is adequate, too high or too low. The Board recommends that WHO work with INCB to:

- Establish benchmarks for the consumption of psychotropic substances.

This would greatly support the work of INCB and of the national Governments, as standards would serve as indicators when assessing the availability for legitimate medical and scientific purposes of psychotropic substances. This can be achieved only by using reliable morbidity data, and prevalence rates that include geographical distribution and the medical practice with regard to specific psychotropic substances for a related medical condition.

H. International community

278. Some Governments are not in a position to implement the above recommendations on their own. They need advice, training and resources to address the limitations of their systems. For this reason, the international community has a role to play. The Board believes that the international community should:

- Improve cooperation among Governments, international organizations (INCB, WHO, UNODC, UNAIDS and UNDP, among others), the donor community and civil society organizations to ensure the sharing of expertise and the coordinated delivery of resources and technical support to countries in need of assistance.

Annex.

Questionnaire sent in 2014 to competent national authorities of Member States on the availability of internationally controlled substances for medical and scientific purposes

Questionnaire for National Competent Authorities on the availability of Internationally Controlled Substances for medical and scientific purposes

Part 1 of 2 — Narcotic drugs

Please return this questionnaire by 31 October 2014 to:

INCB Secretariat
Vienna International Centre
P.O. Box 500
1400 Vienna
Austria

Fax: (+43-1) 26060-5867
Tel.: (+43-1) 26060-4933
E-mail: secretariat@incb.org

Please state the name of the submitting authority:

Country:

Authority:

Contact person:

Tel.: Fax: E-mail:

Please provide the names of authorities and contact persons who might be able to provide additional information if required:

Authority/ies:

Contact person/s:

Tel.: Fax: E-mail:

Instructions for filling out this questionnaire.

This questionnaire consists of two parts:

Part 1 relates to the availability of narcotic drugs subject to international control under the 1961 Single Convention on Narcotic Drugs

Part 2 relates to the availability of psychotropic substances subject to international control under the 1971 Convention on Psychotropic Substances

According to the national regulatory framework in place in each State, these substances may be dealt with by the same competent authority or be controlled by two distinct institutional actors. In both cases, each part should be duly filled out by the appropriate stakeholder, and the consolidated questionnaire, containing both parts, should be returned to the INCB secretariat using the contact details provided on the cover page by the deadline indicated.

For the purpose of expediency, electronic submission of the completed questionnaire is encouraged.

Part 1. Narcotic drugs

A. Availability of narcotic drugs

1. How would you qualify the situation in your country with respect to the availability of opioid analgesics for medical and scientific purposes?
 - ☐ Entirely satisfactory
 - ☐ Satisfactory
 - ☐ In need of some improvement
 - ☐ In need of significant improvement

2. What factors are taken into account by your national competent authority in the quantification of your country's consumption needs for narcotic drugs? (Please select one or more answers as appropriate.)
 - ☐ Consumption patterns in previous year(s)
 - ☐ Existence of specialized treatment services (e.g. oncology, palliative care, opioid substitution or therapy)
 - ☐ Information of planned manufacture submitted by industry
 - ☐ Epidemiological data, including prevalence rates for common illnesses
 - ☐ Other (please specify):

3. Please describe the methodology employed by your national competent authorities in establishing consumption estimates for medical and scientific use of narcotic drugs:

4. Are you aware of the procedure to submit supplementary estimates for narcotic drugs to INCB to meet greater than expected need or due to unforeseen circumstances (e.g. natural disasters, epidemics)?
 - ☐ Yes
 - ☐ No

5. Are you aware of the INCB training materials published by the Board in order to assist States in preparing their estimates of narcotic drug requirements for submission to the Board, which are available from: http://www.incb.org/documents/Narcotic-Drugs/Training-Materials/English/NAR_2_English_2005.pdf?

☐ Yes

☐ No

6. Are you aware of the joint WHO/INCB *Guide on Estimating Requirements for Substances under International Control*, available from: http://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf?

☐ Yes

☐ No

B. Appropriate use of narcotic drugs

7. Is the use of narcotic drugs in your country restricted to specific medical conditions, including treatment for palliative care?

☐ Yes

☐ No

If you answered “Yes”, please provide details as to the types of conditions for which the use of narcotic drugs is allowed:

8. Does your country use narcotic drugs for the treatment of drug dependency (e.g. substitution therapy)?

☐ Yes

☐ No

If you answered “Yes”, please provide details:

C. Regulatory framework governing prescriptions for narcotic drugs

9. According to your national legislative and regulatory framework, which of the following professional categories is permitted to prescribe narcotic drugs for medical treatment?

- ☐ General practitioners
- ☐ General practitioners licensed to issue prescriptions for narcotic drugs
- ☐ Medical specialists (e.g. psychiatrists, oncologists, surgeons, dentists)
- ☐ Nurses (including nurse practitioners)
- ☐ Veterinarians
- ☐ Others (please specify):

10. Is a second opinion a requirement prior to the issuance of a prescription for narcotic drugs?

- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

11. How long is a prescription for narcotic drugs valid for from the date of issuance?

Is the issuance of prescriptions for narcotic drugs subject to any particular legal/regulatory formalities compared to other prescription medications (e.g. requirements for additional authorizations, shorter validity period of prescription)?

- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

12. Can a single prescription for narcotic drugs cover the entire duration of the treatment, or is it limited to a shorter period?

☐ Yes

☐ No

If you answered “No”, please provide details:

13. Are there any circumstances that exist where a prescription for narcotic drugs may be deemed refillable?^a

☐ Yes

☐ No

If you answered “Yes”, please provide details:

D. Regulatory framework governing the dispensing of narcotic drugs

14. Are narcotic drugs dispensed in:

☐ Licensed hospital pharmacies

☐ Specially licensed pharmacies

☐ Pharmacies

☐ Others (please specify):

^aPlease note that the term “refillable” is defined as not requiring subsequent doctor’s approval.

E. Record-keeping and prescription drug monitoring

15. Are prescribers legally required to keep records of prescriptions issued for narcotic drugs?

☐ Yes

☐ No

If you answered “Yes”, please provide details, including the length of time for which records should be kept:

16. Are dispensing agents (see question 14) legally required to keep records of prescriptions issued for narcotic drugs?

☐ Yes

☐ No

If you answered “Yes”, please provide details including the length of time for which records should be kept:

17. Does the legislative/regulatory framework in place in your country provide for penalties for inadequate record-keeping?

☐ Yes

☐ No

If you answered “Yes”, please provide details:

F. Measures to promote adequate availability and rational use of narcotic drugs

18. Who pays for narcotic drugs prescribed?

- ☐ Government (social security)
- ☐ Patients themselves
- ☐ Health insurance schemes
- ☐ Others

19. Does the educational curriculum for medical practitioners in your country include any content with respect to the rational prescription and use of prescription narcotic drugs?

- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

20. Have any awareness-raising measures been implemented by the authorities of your country to foster a deeper understanding of responsible prescribing practices for narcotic drugs among health-care professionals?

- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

21. In the last 10 years, has your Government taken any legislative or regulatory action to increase the availability of narcotic drugs for medical purposes?

- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

G. Impediments to availability

22. In the context of your country, have any of the factors below had the effect of unduly limiting the availability of narcotic drugs needed for medical or scientific purposes (please select all applicable factors)?

- ☐ Limited financial resources
- ☐ Problems in sourcing from industry/imports
- ☐ Fear of diversion into illicit channels
- ☐ Fear of criminal prosecution/sanction
- ☐ Lack of awareness/training among members of the medical profession regarding the rational use of narcotic drugs
- ☐ Onerous regulatory framework for the prescription of narcotic drugs for medical use
- ☐ Fear of addiction
- ☐ Cultural attitudes towards the treatment of pain
- ☐ Control measures applicable to international trade, such as requirements for import or export authorizations
- ☐ Action by the Board
- ☐ Other(s):

Please elaborate as applicable:

23. What do you consider to be the most significant obstacle to the availability of narcotic drugs in your country to meet medical and scientific needs?

24. Are any particular measures in place in your country to facilitate the availability of narcotic drugs for medical purposes in rural or remote regions of your country?

- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

25. Are there any additional measures that could be taken by INCB to contribute to greater availability of narcotic drugs for medical and scientific purposes in your country?

H. Overprescription of narcotic drugs

26. Has your country experienced the following with respect to narcotic drugs:

- ☐ Overprescription
- ☐ “Doctor shopping”^b
- ☐ Self-medication
- ☐ Parallel unregulated markets
- ☐ Counterfeiting of prescription narcotic drugs

Please provide details, as applicable:

Additional information (as required):

^b“Doctor shopping” or “double doctoring” refers to the practice of a patient requesting care from multiple physicians, often simultaneously, without making efforts to coordinate care or informing the physicians of the multiple caregivers.

Questionnaire for National Competent Authorities on the availability of Internationally Controlled Substances for medical and scientific purposes

Part 2 of 2 — Psychotropic substances

Please return this questionnaire by 31 October 2014 to:

INCB Secretariat
Vienna International Centre
P.O. Box 500
1400 Vienna
Austria

Fax: (+43-1) 26060-5867
Tel.: (+43-1) 26060-4933
E-mail: secretariat@incb.org

Please state the name of the submitting authority:

Country:

Authority:

Contact person:

Tel.: Fax: E-mail:

Please provide the names of authorities and contact persons who might be able to provide additional information if required:

Authority/ies:

Contact person/s:

Tel.: Fax: E-mail:

Instructions for filling out this questionnaire.

This questionnaire consists of two parts:

Part 1 relates to the availability of narcotic drugs subject to international control under the 1961 Single Convention on Narcotic Drugs

Part 2 relates to the availability of psychotropic substances subject to international control under the 1971 Convention on Psychotropic Substances

According to the national regulatory framework in place in each State, these substances may be dealt with by the same competent authority or be controlled by two distinct institutional actors. In both cases, each part should be duly filled out by the appropriate stakeholder, and the consolidated questionnaire, containing both parts, should be returned to the INCB Secretariat using the contact details provided on the cover page by the deadline indicated.

For the purpose of expediency, electronic submission of the completed questionnaire is encouraged.

Part 2. Psychotropic substances

A. Availability of psychotropic substances

27. How would you qualify the situation in your country with respect to the availability of psychotropic substances for medical and scientific purposes?
- ☐ Entirely satisfactory
 - ☐ Satisfactory
 - ☐ In need of some improvement
 - ☐ In need of significant improvement
28. What factors are taken into account by your national competent authority in the quantification of your country's consumption needs for psychotropic substances? (Please select one or more answers as appropriate.)
- ☐ Consumption patterns in previous year(s)
 - ☐ Existence of specialized treatment services (e.g. specialized mental health services, palliative care, opioid substitution therapy)
 - ☐ Information on planned manufacture submitted by industry
 - ☐ Epidemiological data including prevalence rates for mental health conditions
 - ☐ Other (please specify):
29. Please describe the methodology employed by your national authorities in establishing annual assessments of requirements for psychotropic substances.
30. Are you aware of the procedure to submit supplementary assessments for psychotropic substances to INCB to meet greater than expected need or due to unforeseen circumstances (e.g. natural disasters, armed conflicts)?
- ☐ Yes
 - ☐ No

31. Are you aware of the INCB training materials published by the Board in order to assist States in preparing their assessments of psychotropic substances requirements for submission to the Board, which are available from: <http://www.incb.org/documents/Psychotropics/training-materials/training-material-eng-2013-86360.pdf>?
- ☐ Yes
- ☐ No
32. Are you aware of the joint WHO/INCB publication *Guide on Estimating Requirements for Substances under International Control*, available from: http://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf?
- ☐ Yes
- ☐ No

B. Appropriate use of psychotropic substances

33. Is the use of psychotropic substances in your country restricted to specific mental health disorders, including ADHD, insomnia, anxiety, palliative care?
- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

34. Does your country use psychotropic substances for the treatment of drug dependency (e.g. substitution therapy)?
- ☐ Yes
- ☐ No

If you answered "Yes", please provide details:

C. Regulatory framework governing prescriptions for psychotropic substances

35. According to your national legislative and regulatory framework, which of the following professional categories is permitted to prescribe psychotropic substances for medical treatment?

- ☐ General practitioners
- ☐ General practitioners licensed to issue prescriptions for psychotropic substances
- ☐ Medical specialists (e.g. psychiatrists, oncologists, surgeons, dentists)
- ☐ Nurses (including nurse practitioners)
- ☐ Veterinarians
- ☐ Others (please specify):

36. Is a second opinion a requirement prior to the issuance of a prescription for psychotropic substances?

- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

37. How long is a prescription for psychotropic substances valid for from the date of issuance?

Is the issuance of prescriptions for psychotropic substances subject to any particular legal/regulatory formalities compared to other prescription medications (e.g. requirements for additional authorizations, shorter validity period of prescription)?

- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

38. Can a single prescription for psychotropic substances cover the entire duration of the treatment, or is it limited to a shorter period?

☐ Yes

☐ No

If you answered “No”, please provide details:

39. Are there any circumstances that exist where a prescription for psychotropic substances may be deemed refillable?^c

☐ Yes

☐ No

If you answered “Yes”, please provide details:

D. Regulatory framework governing the dispensing of psychotropic substances

40. Are psychotropic substances dispensed in:

☐ Licensed hospital pharmacies

☐ Specially licensed pharmacies

☐ Pharmacies

☐ Other (please specify):

^cPlease note that the term “refillable” is defined as not requiring subsequent doctor’s approval.

E. Record-keeping and prescription drug monitoring

41. Are prescribers legally required to keep records of prescriptions issued for psychotropic substances?

☐ Yes

☐ No

If you answered “Yes”, please provide details, including the length of time for which records should be kept:

42. Are dispensing agents (see question 40) legally required to keep records of prescriptions issued for psychotropic substances?

☐ Yes

☐ No

If you answered “Yes”, please provide details, including the length of time for which records should be kept:

43. Does the legislative/regulatory framework in place in your country provide for penalties for inadequate record-keeping?

☐ Yes

☐ No

If you answered “Yes”, please provide details:

F. Measures to promote adequate availability and rational use of psychotropic substances

44. Who pays for psychotropic substances prescribed?

- ☐ Government (social security)
- ☐ Patients themselves
- ☐ Health insurance schemes
- ☐ Others

45. Does the educational curriculum for medical practitioners in your country include any content with respect to the rational prescription and use of psychotropic substances?

- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

46. Have any awareness-raising measures been implemented by the authorities of your country to foster a deeper understanding of responsible prescribing practices for psychotropic substances among health-care professionals?

- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

47. In the last 10 years, has your Government taken any legislative or regulatory action to increase the availability of psychotropic substances for medical purposes?

- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

G. Impediments to availability

48. In the context of your country, have any of the factors below had the effect of unduly limiting the availability of psychotropic substances needed for medical or scientific purposes? (Please select all applicable factors.)

- ☐ Limited financial resources
- ☐ Problems in sourcing from industry/imports
- ☐ Fear of diversion into illicit channels
- ☐ Fear of criminal prosecution/sanction
- ☐ Lack of awareness/training regarding the rational use of psychotropic substances among members of the medical profession
- ☐ Onerous regulatory framework for the prescription of psychotropic substances for medical use
- ☐ Fear of addiction
- ☐ Cultural attitudes towards the treatment of mental health disorders
- ☐ Control measures applicable to international trade such as requirements for import or export authorizations
- ☐ Action by the Board
- ☐ Other(s):

Please elaborate as applicable:

49. What do you consider to be the most significant obstacle to the availability of psychotropic substances in your country to meet medical and scientific needs?

50. Are any particular measures in place in your country to facilitate the availability of psychotropic substances for medical purposes in rural or remote regions of your country?

- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

51. Are there any additional measures that could be taken by INCB to contribute to greater availability of psychotropic substances for medical and scientific purposes in your country?

G. Overprescription of psychotropic substances

52. Has your country experienced the following with respect to psychotropic substances:

- ☐ Overprescription
- ☐ “Doctor shopping”^d
- ☐ Self-medication
- ☐ Parallel unregulated markets
- ☐ Counterfeiting of prescription drugs containing psychotropic substances

Please provide details, as applicable:

53. Does your country permit the advertising of psychotropic substances to the general public?

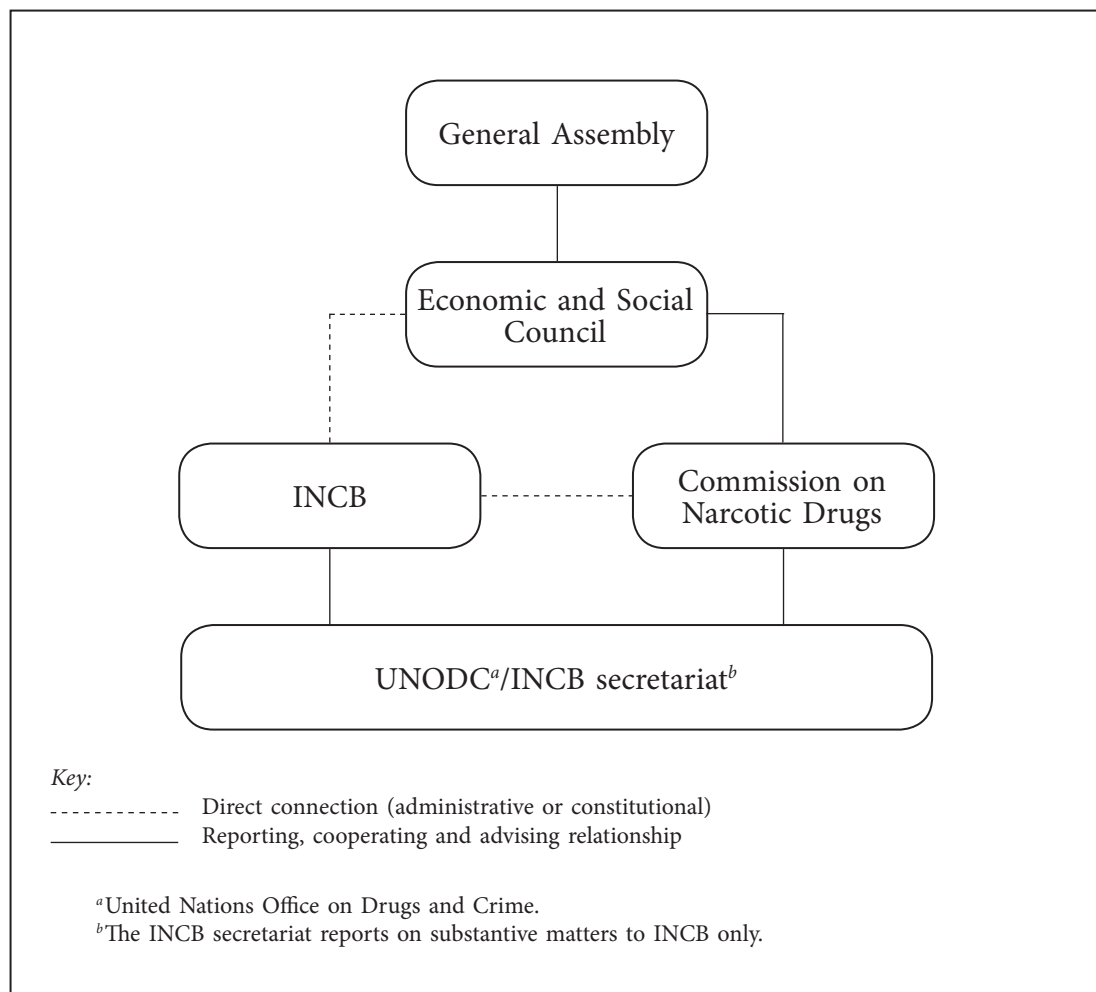
- ☐ Yes
- ☐ No

If you answered “Yes”, please provide details:

Additional information (as required)

^d “Doctor shopping”, or “double doctoring”, refers to the practice of a patient requesting care from multiple physicians, often simultaneously, without making efforts to coordinate care or informing the physicians of the multiple caregivers.

United Nations system and drug control organs and their secretariat





INTERNATIONAL NARCOTICS CONTROL BOARD

The International Narcotics Control Board (INCB) is the independent monitoring body for the implementation of United Nations international drug control conventions. It was established in 1968 in accordance with the Single Convention on Narcotic Drugs, 1961. It had predecessors under the former drug control treaties as far back as the time of the League of Nations.

Based on its activities, INCB publishes an annual report that is submitted to the United Nations Economic and Social Council through the Commission on Narcotic Drugs. The report provides a comprehensive survey of the drug control situation in various parts of the world. As an impartial body, INCB tries to identify and predict dangerous trends and suggests necessary measures to be taken.

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