INTERNATIONAL NARCOTICS CONTROL BOARD

Progress in ensuring adequate access to internationally controlled substances for medical and scientific purposes

UNITED NATIONS

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Progress in ensuring adequate access to internationally controlled substances for medical and scientific purposes (E/INCB/2018/1/Supp.1)

Narcotic Drugs: Estimated World Requirements for 2019—Statistics for 2017 (E/INCB/2018/2)

Psychotropic Substances: Statistics for 2017—Assessments of Annual Medical and Scientific Requirements for Substances in Schedules II, III and IV of the Convention on Psychotropic Substances of 1971 (E/INCB/2018/3)

Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances: Report of the International Narcotics Control Board for 2018 on the Implementation of Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (E/INCB/2018/4)

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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UNITED NATIONS
Vienna, 2019

E/INCB/2018/Supp. 1

UNITED NATIONS PUBLICATION
Sales No. E.19.XI.4
ISBN: 978-92-1-148310-9
eISBN: 978-92-1-047696-6

Publishing production: English, Publishing and Library Section, United Nations Office at Vienna.

Preface

The drafters of the Single Convention on Narcotic Drugs of 1961[1] made it clear in the preamble that the main concern of the parties was the health and welfare of humankind. Together with that fundamental assertion was the recognition of the medical use of narcotic drugs and of their indispensable role in the relief of pain, for which countries needed to ensure their availability and make adequate provision. Those principles were reaffirmed in the Convention on Psychotropic Substances of 1971,[2] in which it was added that it is necessary to restrict the use of psychotropic substances to legitimate purposes and that the availability of such substances for medical and scientific purposes should not be unduly restricted.

Almost 60 years later, the 1961 Convention has been ratified by 187 countries and the 1971 Convention has been ratified by 184 countries. However, the goal of ensuring the availability of and access to narcotic drugs and psychotropic substances for medical and scientific purposes is still far from being universally met. People are still suffering; such people range from those who have to undergo surgery without anaesthesia to those without access to the medication they need and those who are dying in unnecessary pain. The imbalance in the availability of and access to opioid analgesics is particularly troublesome: the Board wishes to raise the alarm and a call to action, as data show that many of the conditions requiring pain management, including cancer, are prevalent, and that their prevalence is increasing in low- and middle-income countries,[3] while the medicines and knowledge to alleviate the situation exist and are affordable.

Pain relief and pain management are needed for the treatment of many health conditions. In several regions of the world, pain relief drugs are not commonly prescribed. Internationally controlled substances such as methadone and buprenorphine can also be used in the management of drug dependence; notwithstanding their proven effectiveness in this field, their use is limited in some countries, including where there are significant prevalence levels of opioid dependence.

While the lack of access to opioid analgesics has been the focus of much attention, the data related to the availability of and access to psychotropic substances also show considerable disparities among countries and regions of the world. In addition to the inadequate availability of and poor access to necessary medical treatments in some regions, recent studies on the use of benzodiazepines in some countries also point to an oversupply of such substances relative to medical needs, contributing to heightened risks of diversion and giving rise to significant challenges to their control.

The importance of making internationally controlled substances available and accessible for medical and scientific purposes was most recently reaffirmed in the outcome document of the special session of the General Assembly on the world drug problem held in 2016.[4] This reaffirmation amplified the calls for action contained in the 2009 Political Declaration and Plan of Action on International Cooperation Towards an Integrated and Balanced Strategy to Counter the World Drug Problem[5] 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.[6]

Ensuring the availability and accessibility of controlled substances was also called for by the Commission on Narcotic Drugs and the Economic Social Council in a number of their resolutions. In 2010 and 2011, the Commission on Narcotic Drugs adopted resolutions 53/4 and 54/6 with a view to promoting the adequate availability of internationally controlled substances for medical and scientific purposes while preventing their diversion and abuse.

The International Narcotics Control Board (INCB), in accordance with its mandate, has continuously called the attention of Governments to the need to ensure the adequate availability of and access

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[1] United Nations, *Treaty Series*, vol. 520, No. 7515.

[2] Ibid., vol. 1019, No. 14956.

[3] International Agency for Research on Cancer, "Latest world cancer statistics", 12 December 2013.

[4] General Assembly resolution S-30/1, annex.

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

[6] See *Official Records of the Economic and Social Council, 2014, Supplement No. 8* (E/2014/28), chap. I, sect. C.

to internationally controlled substances for medical purposes, while at the same time preventing diversion and abuse. In 2016, INCB published a supplement to its annual report for 2015 entitled *Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes—Indispensable, Adequately Available and Not Unduly Restricted*.[7]

Based on the analysis and recommendations presented by INCB in the above-mentioned supplement, the international community recognized the seriousness of the situation and, at the special session of the General Assembly on the world drug problem held in 2016, Member States adopted the outcome document entitled "Our joint commitment to effectively addressing and countering the world drug problem". It contains, for the first time in a document on the world drug problem, a whole section about access to internationally controlled substances for medical and scientific purposes, with specific operational recommendations.

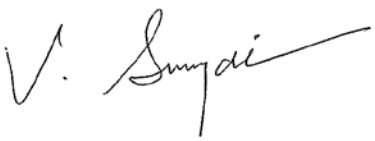
Ensuring the adequate availability of and access to internationally controlled substances for medical and scientific purposes while preventing their abuse, diversion and trafficking are functions of the international drug control system as established by the international drug control conventions. The recommendations contained in the outcome document of the 2016 special session of the General Assembly and in the supplement to the INCB annual report for 2015 are to be translated into action at the national and international levels.

To assist Governments in doing so, INCB decided to review the implementation of the recommendations on the availability of and access to controlled substances contained in the outcome document and the supplement to the INCB annual report for 2015. To this end, INCB invited Member States to inform it about the action that they had taken. Responses were received from 130 States (representing 78 per cent of the world population) and analysed for the present report. At the invitation of INCB, contributions from some 30 civil society organizations were received and were considered in the preparation of the report.

The recommendations contained in the outcome document and the supplement to the INCB annual report for 2015 are also in support of the Sustainable Development Goals. Among them, Goal 3 (Ensure healthy lives and promote well-being for all at all ages) includes target 3.8, which calls for achieving universal health coverage, including access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines for all. INCB stresses that not all people who are in need of treatment requiring the use of narcotic drugs and psychotropic substances, in particular in low- and middle-income countries, are receiving the treatment or medicines that can help alleviate their health conditions.

INCB calls upon Governments, international and regional organizations as well as civil society to work towards achieving Sustainable Development Goal 3 and its target 3.8 by redoubling efforts to ensure the adequate availability of, access to and rational use of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes.

INCB offers Member States this review of progress in the implementation of the recommendations related to availability of and access to internationally controlled drugs for medical and scientific purposes. This review is intended to assist Governments in developing and implementing further measures to ensure the achievement of one of the fundamental goals of the international drug control conventions: the safe use and rational delivery of the best affordable medicines to those patients who need them, while preventing their diversion, misuse and abuse.



Viroj Sumyai
President
International Narcotics Control Board

[7] E/INCB/2015/Supp.1.

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Acknowledgements

Many individuals contributed to the preparation of the report. The International Narcotics Control Board extends its appreciation to all those who provided inputs, suggestions, ideas, information and data.

The Board would like to acknowledge the contribution of the following:

Stefano Berterame, Beate Hammond, Juliana Erthal, Kebebush Welkema, Simona Schreier, Nabil Katkhouda, Johny Thomas, Janna Shrestha and Mina Balooch of the Narcotics Control and Estimates Section of the INCB secretariat, and Debora Ferreira Rodrigues, intern in the Section.

Hanifa Rebbani, Ha Fung Cilla Ng, Tatiana Jehl, Martin Dessart and Lilian Sandouk of the Psychotropics Control Section of the INCB secretariat, and Kamal Samra, intern in the Section.

Competent national authorities from 130 countries responded to the questionnaire and provided information essential to the preparation of the present report.

Thirty civil society organizations contributed by responding to a questionnaire sent to them through the Vienna NGO Committee on Drugs.

The United Nations Office on Drugs and Crime and the World Health Organization provided comments and inputs during the preparation of the report.

Contents

Executive summary

The recommendations on the availability of internationally controlled drugs for medical and scientific purposes formulated by the International Narcotics Control Board (INCB) in the supplement to its annual report for 2015[1] and those contained in the outcome document of the special session of the General Assembly on the world drug problem held in 2016[2] concern the main issues that require action by Governments, international organizations and civil society organizations. Following up on the progress made in the implementation of those recommendations, in 2018, INCB sent a questionnaire to competent national authorities and also sought the opinion of civil society organizations.

The responses from Member States indicate that the impediments to the availability of controlled substances for medical and scientific purposes arising from cultural issues and biases are progressively diminishing; impediments such as a lack of training or awareness, problems in sourcing and limited financial resources are increasingly reported. Civil society organizations considered restrictive legislation to be a major impediment to the availability of controlled substances for medical and scientific purposes.

Recent data on the availability for consumption of opioid analgesics show that, despite global increases, global disparity and imbalance remain evident. North America is the region with the highest level of availability for consumption, with 27,557 S-DDD on average in the period 2014–2016, followed by Western and Central Europe, with 10,382 S-DDD on average in the same period. In all other regions, levels of availability for consumption are considerably lower. An increase in the use of expensive synthetic opioids, mostly in high-income countries, has not been matched by an increase in the use of affordable morphine. Most (88 per cent) morphine available is not utilized for palliative care, but is used instead for the manufacturing of other controlled substances, especially codeine. That makes it difficult for countries with fewer resources to procure any of the limited amount of morphine available for palliative care.

The availability for consumption of some essential psychotropic substances (diazepam, midazolam, lorazepam and phenobarbital) has declined or has remained stable in the majority of countries for which data on the consumption of psychotropic substances was provided to INCB, despite an increasing number of people living with anxiety disorders and epilepsy. There is also a significant global disparity in the availability for consumption of those substances, with higher availability for consumption being reported in high-income countries, despite the fact that most of the people suffering from epilepsy live in low- and middle-income countries. Based on the consumption data submitted by 70 countries and territories in 2016, close to 90 per cent of the four above-mentioned essential psychotropic substances were consumed in high- and upper-middle-income countries. However, only 19 low- and lower-middle-income countries submitted such data, and their overall consumption accounted for only 10 per cent of the total.

About 40 per cent of the responding authorities reported some changes in legislation and regulatory systems, but the categories of health-care professionals able to prescribe opioid analgesics have not expanded, with trained nurses being allowed to prescribe opioid analgesics in only 2 per cent of the countries for which responses were provided. This affects low-income countries in particular, where the number of doctors allowed to prescribe is limited. Legal sanctions for unintentional mistakes made while handling opioid analgesics still exist in 26 per cent of the countries for which responses were provided. In terms of prescription policies, prescriptions remain valid for one month or more in a large proportion of the countries. Just over half of the responding authorities reported the introduction of new palliative care policies and even more were considering the introduction of low-cost palliative care services. Lack of resources was a problem reported by 23 per cent of the authorities.

Regarding the training of health-care professionals, 62 per cent of the responding authorities reported that palliative care was part of the curricula of medical schools and that education programmes, training and information on palliative care, including on rational use of narcotic drugs and the importance of reducing prescription drug abuse, were provided to health-care professionals. Similarly, specific campaigns and awareness-raising programmes to overcome the cultural resistance and stigma associated with the consumption of opioid analgesics or psychotropic substances had been implemented in most countries.

[1] E/INCB/2015/Supp.1.

[2] General Assembly resolution S-30/1, annex.

Although the available data show that the levels of opioid analgesics available for consumption reported by competent national authorities are well below what would be necessary for the palliative care needs of their population, many authorities believe their estimates of requirements to be appropriate and realistic and reported having regular contact with pharmaceutical companies or other stakeholders to that effect. Electronic tools for processing import and export authorizations have been established in only 46 countries. The analysis of the data and of the responses shows promising developments in some areas, but there are still important issues that require more action, not only by Member States but also by the international community, to achieve the goal of ensuring adequate access to internationally controlled substances for medical and scientific purposes.

Background

It is a standard practice of INCB to follow up periodically with countries on the implementation of specific recommendations that it has made; it also monitors the implementation of the general recommendations that it makes in its reports. Early in 2018, the Board sent questionnaires to competent national authorities asking for information on the implementation of the recommendations made in the supplement to its annual report for 2015 and on the implementation of the recommendations contained in the outcome document of the special session of the General Assembly on the world drug problem held in 2016, some of which were based on those contained in the supplement to the INCB report. In total, competent national authorities from 130 countries (representing 78 per cent of the world population) responded, providing important information that is discussed in the present report.

This report also contains an update on the availability of internationally controlled substances, with a focus on opioid analgesics and the psychotropic substances contained in the World Health Organization (WHO) *Model List of Essential Medicines*[3] (diazepam, lorazepam, midazolam and phenobarbital).

Every year, INCB receives information on the amounts of narcotic drugs that competent national authorities estimate are required for consumption and report as consumed or, more precisely, the amount distributed by wholesalers that is available for consumption. INCB evaluates those data in terms of defined daily doses for statistical purposes (S-DDD). S-DDD are used by INCB as a technical unit of measurement for the purpose of statistical analysis and are not a recommended prescription dose. The availability levels of narcotic drugs, excluding those listed in Schedule III of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol,[4] expressed in S-DDD, are calculated by dividing annual availability by 365 days; the result obtained is divided by the population, in millions, of the country or territory during the year in question, and then by the defined daily dose. In the analysis of the availability of opioid analgesics by S-DDD, INCB includes codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine. Methadone and buprenorphine are not included because of the impossibility of distinguishing, on the basis of the information provided to the Board, their use for pain relief from their use for the treatment of drug dependence.

The Convention on Psychotropic Substances of 1971[5] does not foresee the reporting on consumption of psychotropic substances to the Board; therefore, the submission of data on the consumption of psychotropic substances is not mandatory under that Convention. In March 2011, the Commission on Narcotic Drugs adopted resolution 54/6, in which it encouraged Member States to report to INCB data on the consumption of psychotropic substances for medical and scientific purposes.

The analysis of the availability of psychotropic substances contained in the present report is based on the data provided by the Governments since the Commission adopted resolution 54/6. The availability levels of psychotropic substances expressed in S-DDD are calculated using the following formula: annual availability for reported consumption divided by 365 days; the result obtained is then divided by the population of the country, in thousands, during the year in question, and then by the defined daily dose.

[3] 20th ed. (Geneva, 2017).

[4] United Nations, *Treaty Series*, vol. 976, No. 14152.

[5] Ibid., vol. 1019, No. 14956.

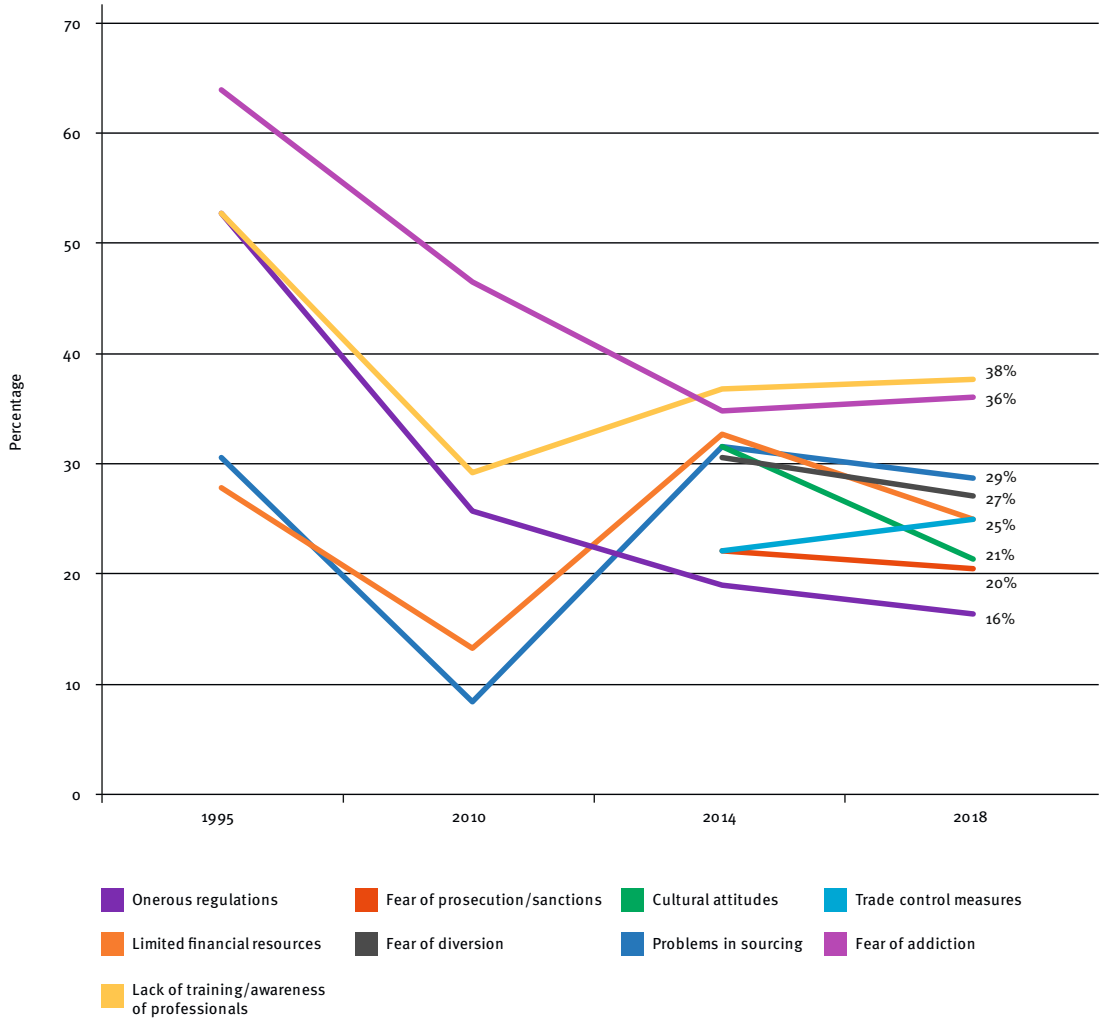
I. Factors limiting the availability of narcotic drugs and psychotropic substances

1. Over the years, INCB has reviewed and reported on the impediments to the availability of controlled substances. The questionnaire sent to competent national authorities in 2018 contained a general question, also used in previous surveys, about the factors unduly limiting the availability of controlled substances for scientific and medical purposes. Comparing the responses provided in 1995, 2010, 2014 and 2018, it is possible to observe a decrease in the number of times that onerous regulations are mentioned as impediments to availability. The number of times that fear of addiction was mentioned increased slightly between 2014 and 2018 after a sharp decline between 1994 and 2014. Lack of training and awareness of health professionals was the factor most often mentioned as an impediment in both 2014 and 2018, followed by fear of addiction. The number of times that the issue of limited financial resources was mentioned declined in 2018, after increasing between 2010 and 2014 (see figure I).

2. Although questions relating to fear of diversion or prosecution, trade control measures and cultural attitudes have only been included in the questionnaire since 2014, it is possible to see that the fear of diversion of controlled substances has decreased, together with the fear of prosecution or sanctions. The role of cultural attitudes in limiting availability decreased noticeably between 2014 and 2018, while trade control measures were reported to be more of an issue in 2018 than they were in 2014 (see also figure I).

3. The review of the impediments as reported by competent national authorities constitutes an important element for identifying problems related to the limited availability of opioid analgesics and psychotropic substances and for developing policies and programmes that can effectively address the problem. It is encouraging that the number of times that some of the impediments that are not necessarily based on scientific evidence but are more related to cultural issues and bias are mentioned is progressively diminishing. The factors reported more often as obstacles are concrete and practical issues.

Figure I. Impediments to availability mentioned by competent national authorities (1995, 2010, 2014 and 2018)



Note: The above figure has been developed to illustrate general trends. Data from questionnaires from different years are not directly comparable owing to variations in the number of countries that replied to the questionnaires and in which countries replied.

II. Narcotic drugs

4. Since the publication of the supplement to its annual report for 2015, the data on access to and availability of opioid analgesics for consumption have not changed noticeably. While the focus of the present report is on the progress that has been made in relation to the recommendations made in the supplement to the 2015 report and in the outcome document of the special session of the General Assembly on the world drug problem held in 2016, the report highlights some issues related to narcotic drugs that are important to consider when reviewing what action has been taken or still needs to be taken at the national and global levels.

5. In relation to narcotic drugs, specifically opioid analgesics, recent data and analysis highlight the following issues:

(a) Despite a global increase in the availability of opioid analgesics, disparity and imbalance in access to them remain evident;

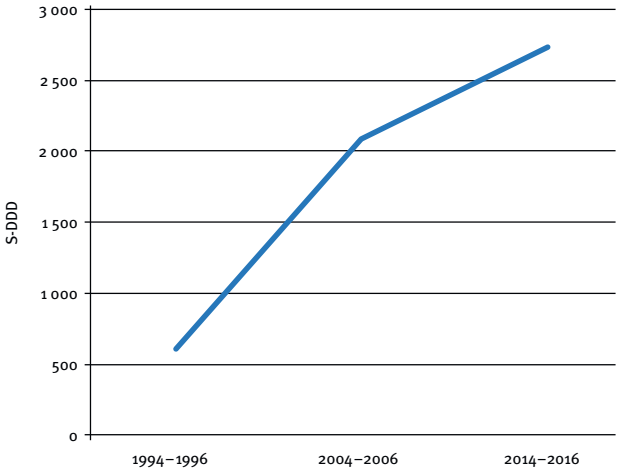
(b) The increase in the use of expensive synthetic opioids (which is connected to overconsumption and overdose crisis in some countries) has not been matched by an increase in the use of affordable morphine;

(c) Most of the morphine available is not utilized by pharmaceutical companies to prepare morphine preparations for palliative care; this reduces the overall amount that could be available for palliative care, which has a negative effect on the capacity of health services to treat pain, in particular in low- and middle-income countries[6] that cannot afford synthetic opioids.

Unbalanced increase in availability for consumption

6. The data on the global availability of opioid analgesics show a steep increase from an average of 602 S-DDD in the period 1994–1996 to an average of 2,735 S-DDD in the period 2014–2016 (figure II). However, the distribution of the availability for consumption provides a different perspective and shows that the increase in availability for consumption is concentrated in high-income countries. Over the years there has been some progress. Map 1 illustrates the changes in the patterns of availability for consumption of opioid analgesics since 1994. Availability of opioid analgesics for consumption increased in high-income countries, reaching a relatively high level per capita in some of them. However, despite some small improvements, availability for consumption has decreased and remains very inadequate in most countries in Africa and is inadequate in most countries in Asia, Central and South America, the Caribbean and Eastern Europe.

Figure II. Global availability of opioid analgesics for consumption, defined daily doses for statistical purposes per million inhabitants per day (1994–1996, 2004–2006 and 2014–2016)

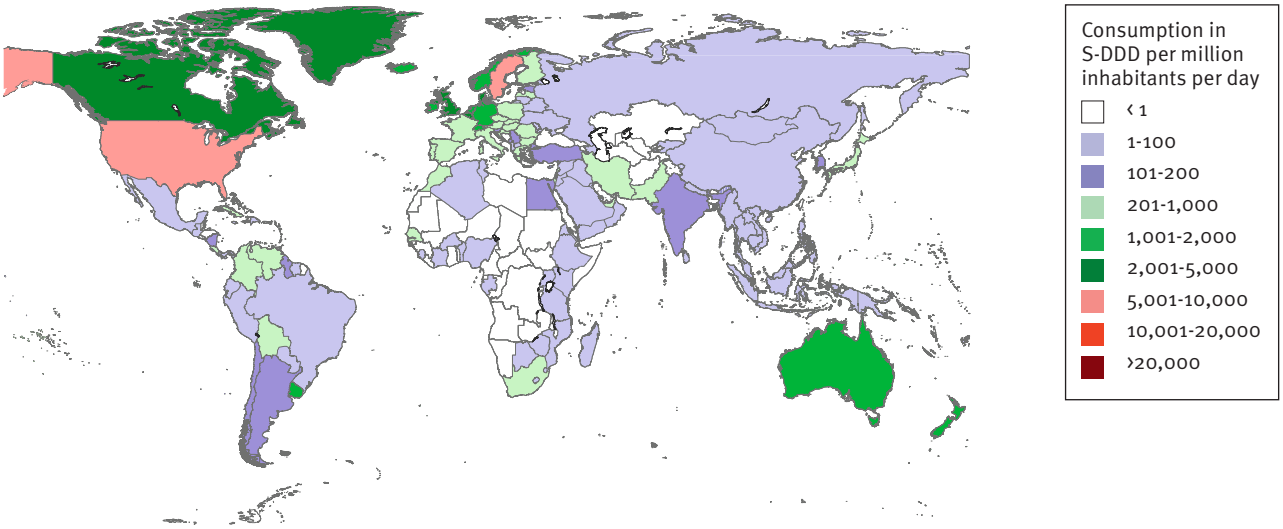


Note: S-DDD per million inhabitants per day, by total world population.

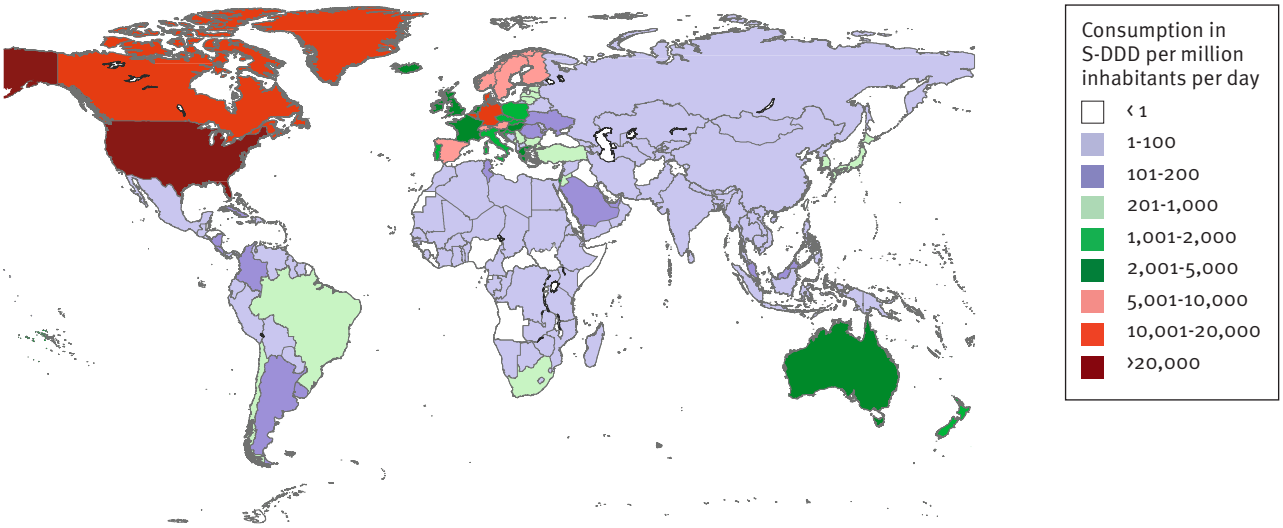
[6]The classification of countries on the basis of income used throughout the present publication is from the World Bank (see World Bank, "World Bank Country and Lending Groups", 1 August 2018).

Map 1. Availability of opioids for consumption for pain management (1994–1996, 2004–2006, 2014–2016 averages)

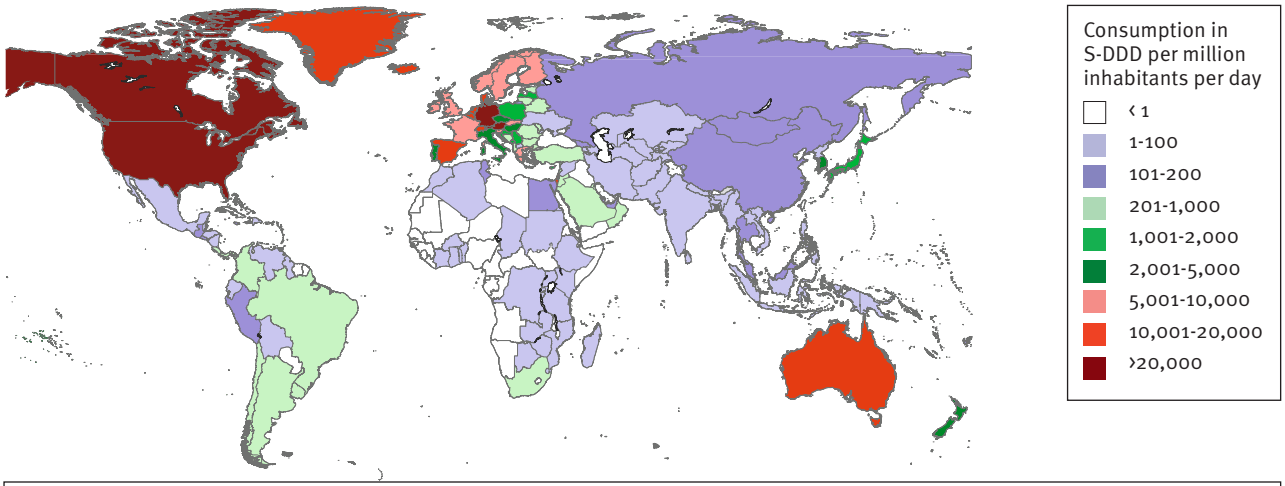
Availability of opioids for pain management, 1994–1996



Availability of opioids for pain management, 2004–2006



Availability of opioids for pain management, 2014–2016



The boundaries and names shown and the designations used on these maps do not imply official endorsement or acceptance by the United Nations. The final boundary between the Sudan and South Sudan has not yet been determined. The dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the parties. A dispute exists between the Governments of Argentina and the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas).

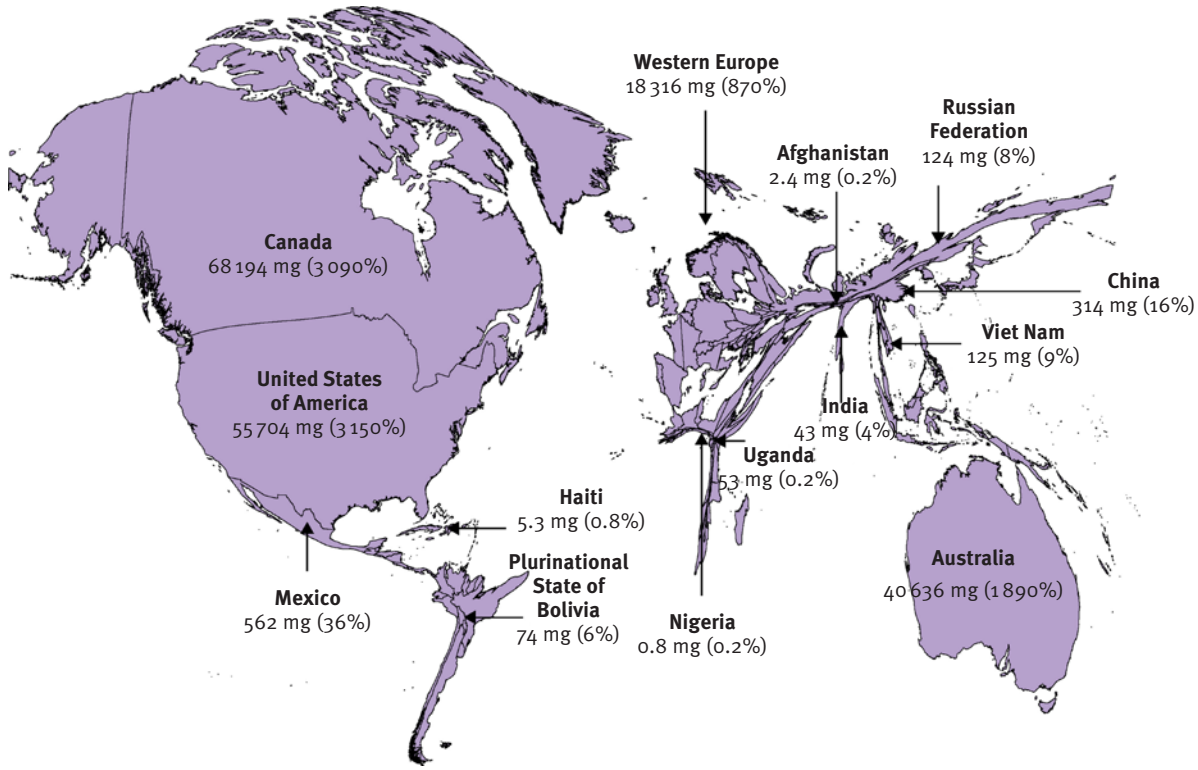
7. The reality of the global divide in access to opioid analgesics is shown in map 2 below, in which the data on the availability of opioid analgesics for consumption as reported by competent national authorities to INCB are measured against the estimated amount needed for the health conditions most associated with serious health-related suffering (an indicator developed by the Lancet Commission on Palliative Care and Pain Relief on the basis of existing health data and statistics).[7]

8. Map 2 illustrates the imbalance in the availability of opioid analgesics for consumption through the expansion or reduction in the size of each country. An excess in availability for consumption exists in the countries whose size is expanded (for example Australia, Canada and the United States of America) and the extremely low level of the need for opioid analgesics being met in areas of Africa, Asia, Central and South America, the Caribbean and Eastern Europe is shown by the shrunken size of those regions.

9. The table overleaf contains the data relating to that imbalance. In the period 2010–2013, high-income countries had available for consumption a total of 287.7 tons in distributed opioid morphine equivalent against a calculated need of 86.4 tons, an excess of 233 per cent. Low-income countries with a projected need of 37.2 tons and only 0.1 ton of distributed opioid morphine equivalent had a deficit of 99.7 per cent. Upper-middle income countries and low-middle income countries had deficits of 96.7 and 99.3 per cent, respectively.

[7] Felicia Marie Knaul and others. "Alleviating the access abyss in palliative care and pain relief: an imperative of universal health coverage—the Lancet Commission report", *The Lancet*, vol. 391, No. 10128 (April 2018).

Map 2. Availability of opioid analgesics against need for pain treatment



Source: Felicia Marie Knaul and others. "Alleviating the access abyss in palliative care and pain relief: an imperative of universal health coverage — the Lancet Commission report", *The Lancet*, vol. 391, No. 10128 (April 2018).

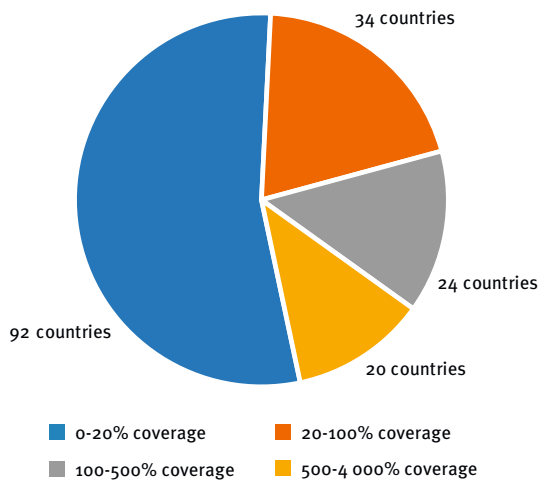
Note: Distributed opioid morphine equivalent (morphine in mg/patient in need of palliative care, average 2010–2013), and estimated percentage of need that is met for the health conditions most associated with serious health-related suffering.

Morphine-equivalent unmet and total need for palliative care due to health conditions most associated with serious health-related suffering and projected unmet and total need using the Western European benchmark, by country income group and distributed opioid morphine equivalent reported by the International Narcotics Control Board for the period 2010–2013 (tons)

	Unmet need arising from conditions most associated with serious health-related suffering	*Total need arising from conditions most associated with serious health-related suffering*	*Projected unmet need*	*Projected total need*	*Distributed opioid morphine equivalent*
High-income countries	0.4	22.7	64.0	86.4	287.7
Upper-middle-income countries	25.1	34.7	281.2	290.8	9.6
Lower-middle-income countries	18.7	19.8	165.7	166.8	1.1
Low-income countries	4.3	4.4	37.1	37.2	0.1
Total	48.5	81.6	548.0	581.2	298.5

Source: Felicia Marie Knaul and others. "Alleviating the access abyss in palliative care and pain relief: an imperative of universal health coverage — the Lancet Commission report", *The Lancet*, vol. 391, No. 10128 (April 2018).

Figure III. Percentage of pain treatment needs met by opioid analgesics available for consumption (2010–2013)

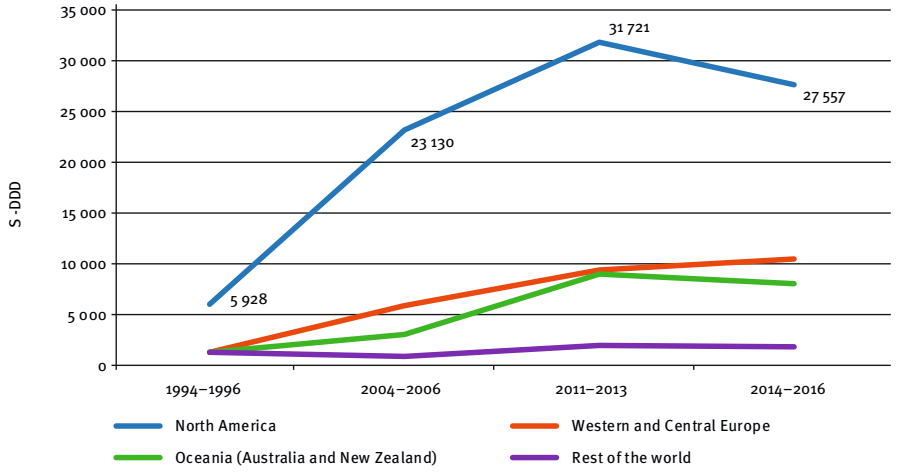


Source: Felicia Marie Knaul and others. "Alleviating the access abyss in palliative care and pain relief: an imperative of universal health coverage—the Lancet Commission report", *The Lancet*, vol. 391, No. 10128 (April 2018).

10. Of the 170 countries for which data were available, the Lancet Commission on Palliative Care and Pain Relief identified that 54 per cent (92 countries) had available for consumption 20 per cent or less of the amount of controlled substances needed for the treatment of pain, as calculated with the serious health-related suffering indicator (see figure III). Of those, 75 had available for consumption less than 10 per cent of the amount required. The vast majority of those are classified as low or lower-middle income but some are classified as upper-middle income. Just 20 countries had enough opioid analgesics available for consumption to cover their pain treatment needs many times over (between 500 and 4,000 per cent). Among those, eight countries (Austria, Australia, Belgium, Canada, Denmark, Germany, Switzerland and the United States) had opioid analgesics available for consumption sufficient to cover more than 1,000 per cent of their needs; Canada and the United States had above 3,000 per cent.

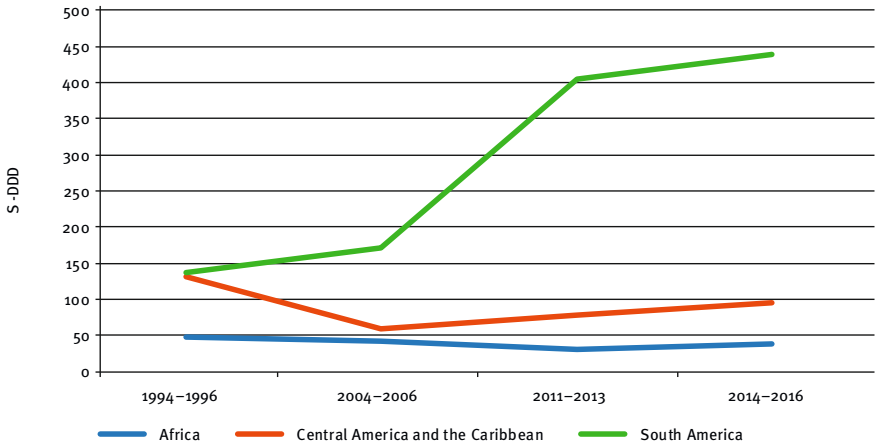
11. A regional analysis of the data covering the periods 1994–1996 and 2014–2016 confirms the disparity in the availability of opioid analgesics for consumption, with slightly differing trends in each region (see figure IV). North America is the region with the highest level of availability for consumption, with 27,557 S-DDD in the period 2014–2016, despite a decline from the peak of 31,721 S-DDD in the period 2011–2013. Western and Central Europe is the region with the second-highest levels of availability, with a stable trend of increase to 10,382 S-DDD in the period 2014–2016. Similarly to the trend observed in the countries in North America, Australia and New Zealand also saw a decrease in the average S-DDD, from 8,927 in the period 2011–2013 to 7,943 in the period 2014–2016. In other regions, levels of availability for consumption are considerably lower. Figures V to VII illustrate those trends in detail.

Figure IV. Trends in availability of opioid analgesics for consumption, by region, 1994–2016



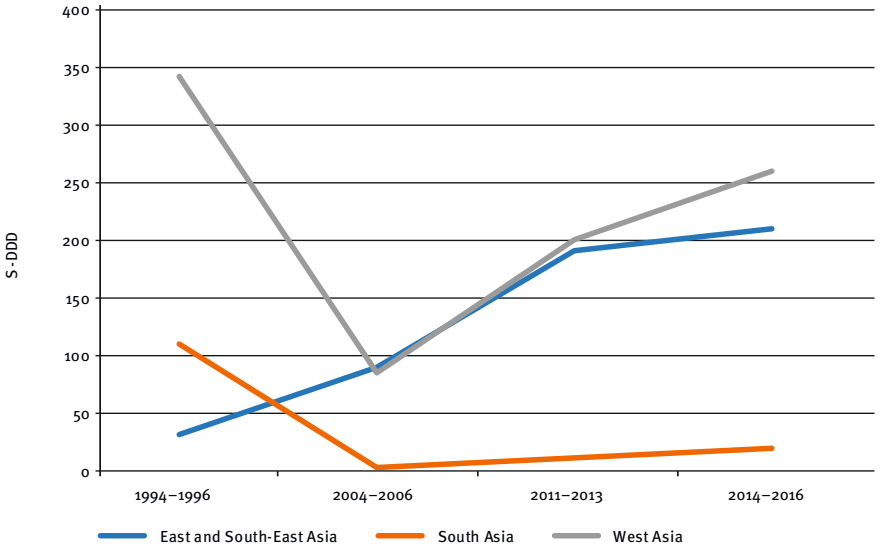
Note: S-DDD per million inhabitants per day, by total regional population.

Figure V. Trends in availability of opioid analgesics for consumption, selected subregions, 1994–2016



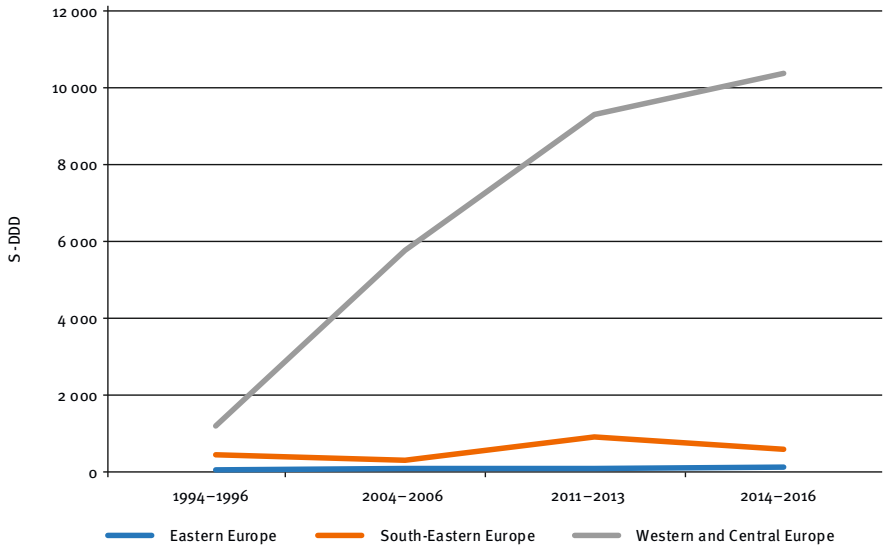
Note: S-DDD per million inhabitants per day, by total regional population.

Figure VI. Trends in availability of opioid analgesics for consumption, Asia, 1994–2016



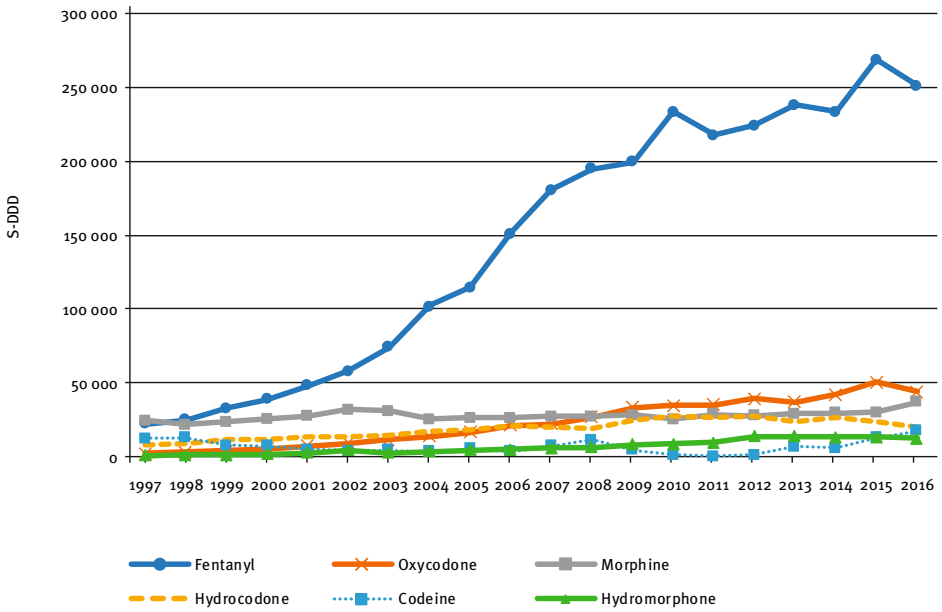
Note: S-DDD per million inhabitants per day, by total regional population.

Figure VII. Trends in availability of opioid analgesics for consumption, Europe, 1994–2016



Note: S-DDD per million inhabitants per day, by total regional population.

Figure VIII. Availability of fentanyl, oxycodone, morphine, hydrocodone, codeine and hydromorphone, for consumption, defined daily doses for statistical purposes, 1997–2016

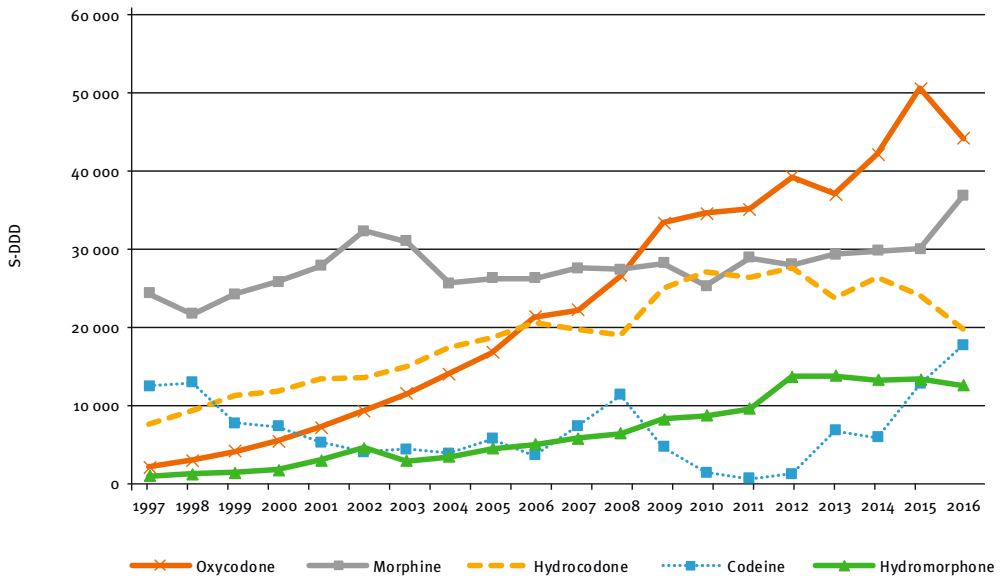


Note: S-DDD per million inhabitants per day, by total world population.

Increase in availability of synthetic opioids and stable trend in the availability of morphine

12. A comparison of trends in the availability for consumption of the main opioid analgesics (codeine, fentanyl, hydrocodone, hydromorphone, morphine and oxycodone), expressed in S-DDDs (see figures VIII and IX), shows that there has been a marked increase in the availability of fentanyl since 1997. Although the availability of fentanyl has been concentrated in high-income countries, in recent years there have been significant increases in availability in various countries in the Middle East, South-East Asia and Central and South America. While the availability of fentanyl has been increasing, together with that of oxycodone, albeit at a lower level, the availability of morphine, the most affordable opioid available, has remained stable. This is a matter of concern because the increased availability of morphine could significantly reduce the gap between the need for pain treatment and the limited access to opioid analgesics in low- and middle-income countries.

Figure IX. Availability of oxycodone, morphine, hydrocodone, codeine and hydromorphone for consumption, defined daily doses for statistical purposes, 1997–2016



Note: S-DDD per million inhabitants per day, by total world population.

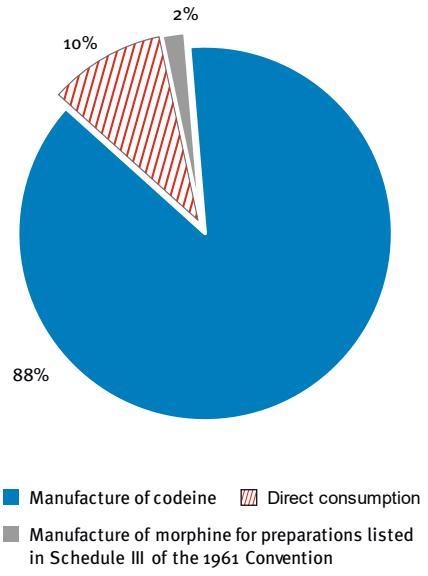
Limited use of morphine for palliative care

13. Over the years, INCB has monitored the supply of and demand for opiate raw materials and opioid analgesics in terms of the utilization of opiate raw materials (as reflected in the demand by manufacturers) and in terms of the global availability of all opiates for consumption. According to the data reported to INCB, overall supply is more than sufficient to cover the licit needs expressed by competent national authorities. However, the imbalance shown in maps 1 and 2 and in the table above indicates that many authorities are not estimating their needs accurately.

14. In the 20-year period 1997–2016, the manufacture of morphine increased considerably: from 273.9 tons in 1997, it stabilized at about 450 tons between 2011 and 2014, before decreasing to 419.2 tons in 2015 and remaining at roughly the same level (422.1 tons) in 2016. Since 2000, of the total amount of morphine utilized globally, on average only 10 per cent was reported to have been used for palliative care. A smaller amount (2 per cent, on average) was used to manufacture preparations containing morphine listed in Schedule III of the 1961 Convention. The majority (88 per cent, on average) was converted into codeine or into substances not covered by the 1961 Convention. Most of the codeine manufactured (89 per cent) was used to manufacture cough medication (figure X).

15. In 2016, of the limited amount (10 per cent) of morphine used directly for pain management, a small percentage (14 per cent) was available in countries constituting

Figure X. Utilization of morphine, 2000–2016



80 per cent of the world population. The remaining 86 per cent of available morphine, excluding preparations included in Schedule III of the 1961 Convention, was concentrated in a small number of countries located mainly in Europe and North America. Although the 14 per cent available for consumption in countries constituting 80 per cent of the world population represents an improvement over the level in 2014 (9.5 per cent), the disparity in availability for consumption of an affordable

opioid analgesic such as morphine continues to be a matter of concern. Although most countries had morphine available for consumption in 2016, many people still had limited access to it and a number of competent national authorities reported difficulties in procuring it.

16. The limited use of morphine and the difficulties in procuring it for pain relief are also related to the marketing of more expensive synthetic opioids that are used for the same indications as opiates. Since 1997, the overall availability of opioid analgesics for consumption has more than tripled. The share of availability of opiates in the total availability for consumption of opioid analgesics fluctuated between 59 per cent in 1997 and 51 per cent in 2008; it reached a peak of 68 per cent in 2014 but decreased to 61 per cent in 2016. The share of synthetic opioids increased from 32 per cent in 2014 to 39 per cent in 2016.

III. Psychotropic substances

17. In the preamble to the 1971 Convention, it was recognized that the use of psychotropic substances for medical and scientific purposes was indispensable and that their availability for such purposes should not be unduly restricted. This remains the overarching principle of that Convention.

18. Conducting a comprehensive assessment of the availability of psychotropic substances depends on the availability of adequate, reliable and accurate consumption data. Unlike for narcotic drugs, submission of data on the consumption of psychotropic substances is not mandatory under the 1971 Convention. However, in its resolution 54/6, the Commission on Narcotic Drugs encouraged Member States to report data on the consumption of psychotropic substances for medical and scientific purposes[8] to INCB on a voluntary basis.

19. Considerable improvement in the voluntary submission of data on the consumption of psychotropic substances has been observed since the adoption of Commission on Narcotic Drugs resolution 54/6, rendering it feasible for INCB to undertake the first analysis of the availability of internationally controlled psychotropic substances using reported consumption data as the basis. The amount of data submitted on the consumption of psychotropic substances, however, varies significantly across the regions of the world.

20. Psychotropic substances are essential for the treatment and management of a wide range of medical conditions, in particular mental and neurological health conditions, and the induction of anaesthesia in pre-operative procedures. Prescribing practices vary greatly and substances are used differently in different countries for the treatment of similar conditions, making the establishment of treatment protocols and the standardization of treatment measures highly complex.

21. Despite the important role that internationally controlled psychotropic substances play in the medical environment, assessing their global, regional and national availability remains a challenge as neither comprehensive data at the national level nor well-established ways of assessing the appropriate level of use of psychotropic substances to meet demand exist.

22. In the light of the above complexity, the scope of analysis for the present report is limited to four controlled substances listed in the 20th edition of the WHO *Model List of Essential Medicines*: diazepam, lorazepam, midazolam and phenobarbital.

23. First adopted in 1977, the concept of essential medicines was updated in 2012 and refers to those medicines that satisfy the priority health-care needs of the population. According to WHO, essential medicines are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.[9]

24. Comprising a core and a complementary list,[10] the *Model List of Essential Medicines* is updated every two years and categorizes essential medicines for priority conditions. Depending on the particular use of the essential medicines, some of them may be listed under more than one category. Among the four aforementioned substances, diazepam and

[8] For each psychotropic substance listed in Schedules I, II, III and IV of the 1971 Convention, the reporting authority should indicate (in grams or kilograms, as applicable) the quantity consumed during the year in question, i.e., supplied to any person or enterprise for retail distribution, medical use or scientific research.

[9] WHO, "The selection of essential medicines", WHO Policy Perspectives on Medicines, No. 4 (Geneva, June 2002).

[10] The core model list is defined as a list of minimum medicines needed for a basic health-care system. The complementary list contains essential medicines for the treatment of priority diseases for which specialized diagnostic or monitoring facilities and/or specialist training are needed.

midazolam are listed under three categories,[11] and lorazepam and phenobarbital are listed under one.[12] Focusing on the priority conditions, diazepam is used to treat anxiety disorders and all four substances (diazepam, lorazepam, midazolam and phenobarbital) are used to treat epilepsy.

25. In order to provide an approximate indication of some of the demand for diazepam,[13] lorazepam, midazolam and phenobarbital, the main global trends in the prevalence of anxiety disorders and epilepsy were first examined in 2006 and 2016. Examinations of the trends and patterns in the consumption of diazepam, lorazepam, midazolam and phenobarbital[14] were undertaken in both 2012 and 2016.

26. The analysis presented below points to three main findings since the publication of the supplement to the annual report of INCB for 2015:

(a) Despite an increasing number of people living with anxiety disorders and epilepsy around the globe, in the majority of countries for which data on the consumption of psychotropic substances were provided to INCB, the availability of some essential psychotropic substances for consumption in the treatment of those conditions has declined since 2012;

(b) While 80 per cent of people with epilepsy live in low- and middle-income countries, their level of consumption of some related psychotropic substances remains largely unknown. The limited data submitted to INCB, however, suggest that consumption of psychotropic substances is concentrated in high-income countries;

(c) The difference between the countries for which the highest and the lowest consumption rates were reported widened between 2012 and 2016, confirming the growing global consumption gap.

Global burden of disease and mental health disorders

27. While the global burden of disease caused by some non-communicable diseases (for instance, cancer, diabetes, and cardiovascular and lung diseases) is relatively well known, an increasing health burden caused by people with mental and neurological disorders (for example depression, anxiety disorders, bipolar disorder, schizophrenia and dementia) is also affecting many countries, at all stages of development. WHO estimates that non-communicable diseases kill 15 million people aged between 30 and 70 each year, causing 70 per cent of deaths worldwide. Over 300 million people suffer from depression and about 50 million live with dementia.[15] WHO data also suggest that non-communicable diseases account for about 20 per cent of all years lived with disability; mental and neurological disorders such as major depression and anxiety disorders are among the leading causes of years lived with disability. Worse still, mental and neurological disorders can lead to or be a consequence of non-communicable diseases and frequently occur in the same person, thereby aggregating the risk of suicide for people living with those conditions.

Anxiety disorders

28. Slightly more than 270 million people were estimated to be living with anxiety disorders in 2016, making it the ninth leading cause of global years lived with disability. Compared with 2006, both the total number of people living with anxiety disorders and the years lived with disability caused by anxiety disorders increased in 2016. Years lived with disability caused by anxiety disorders seem to be evenly distributed across economies with varying levels of income: in 2016, anxiety disorders were one of the leading 10 causes of years lived with disability in many countries, from low- to high-income countries. The burden of anxiety disorders falls disproportionally on females: anxiety was one of the main conditions contributing to higher years lived with disability rates in women in 2016.[16] According to WHO, women have a higher prevalence of anxiety disorder than men across all regions of the world. In particular, 7.7 per cent of the female population in the Americas were estimated to suffer from anxiety disorders in 2015, compared with 3.6 per cent of men in the same region.[17]

[11] Diazepam is listed under medicines for anxiety disorders, medicines for other common symptoms in palliative care, and anticonvulsants/antiepileptics. Midazolam is listed under pre-operative medication and sedation for short-term procedures, medicines for other common symptoms in palliative care, and anticonvulsants/antiepileptics.

[12] Both lorazepam and phenobarbital are listed as anticonvulsants/antiepileptics.

[13] As diazepam can also be used for the treatment of other conditions such as phobia, agitation, aggression and psychosis, in addition to anxiety disorders, the prevalence trend of anxiety disorders can only be indicative of part of the demand for the substance. A similar rationale also applies to lorazepam, midazolam and phenobarbital.

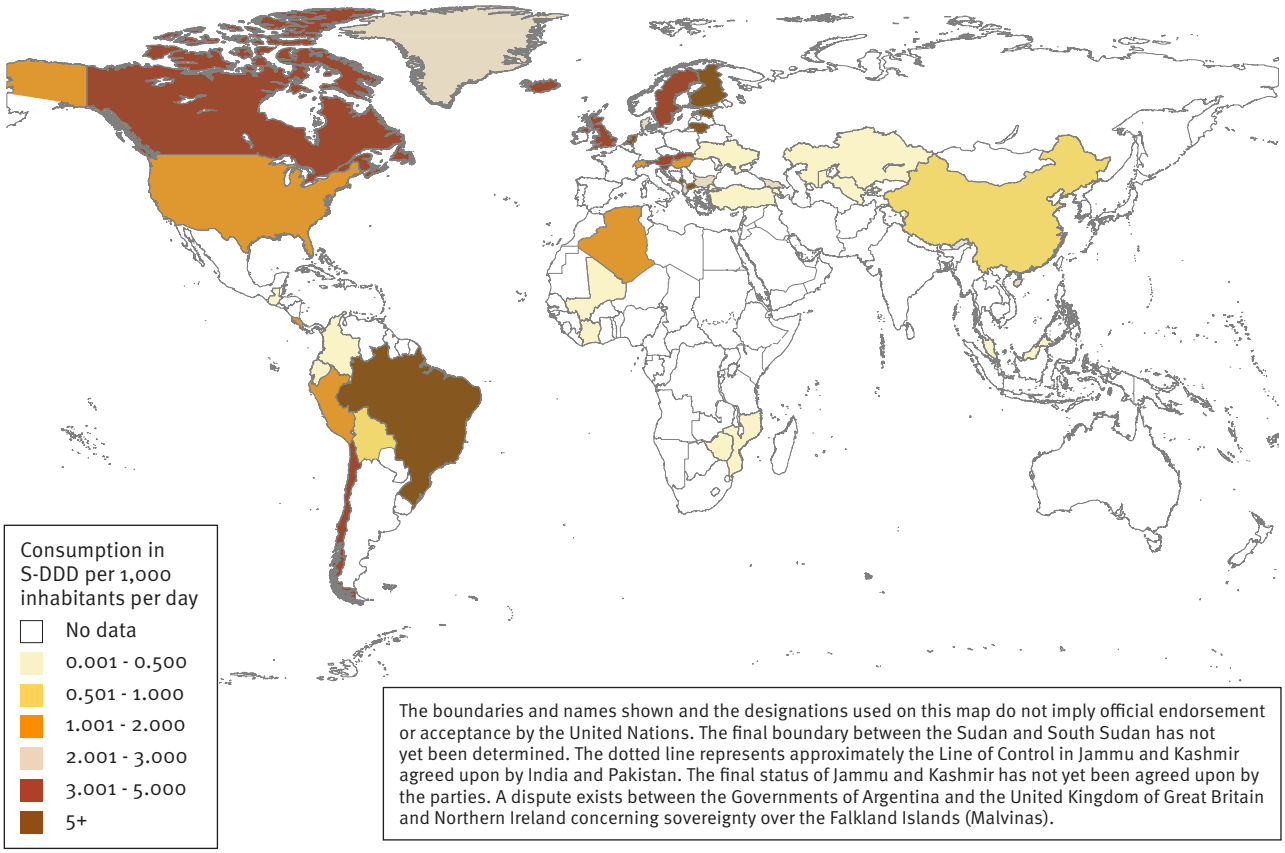
[14] Diazepam, lorazepam, midazolam and phenobarbital are hereinafter referred to as essential antiepileptics under international control.

[15] WHO, "Synergies for beating NCDs and promoting mental health and well-being" (20 March 2018).

[16] "Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016", *The Lancet*, vol. 390, No. 10110 (2017), p. 1211.

[17] WHO, "Depression and other common mental disorders: global health estimates" (Geneva, 2017).

Map 3. Average national consumption of diazepam, 2012



The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations. The final boundary between the Sudan and South Sudan has not yet been determined. The dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the parties. A dispute exists between the Governments of Argentina and the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas).

29. Given the increase in the prevalence of anxiety disorders and their associated health burden, an increasing demand for treatment and medication to treat anxiety disorders in countries with economies at all stages of development would be expected between 2006 and 2016, with bigger demand for those countries having a higher number of women.

Diazepam: reported consumption

30. In 2012, one year following the adoption of Commission on Narcotic Drugs resolution 54/6, competent national authorities of 48 countries reported data on the consumption of diazepam (see map 3). In comparison, competent national authorities from a total of 71 countries and territories reported data on the consumption of diazepam in 2016, an increase of 48 per cent over five years. Most of the data on the consumption of diazepam came from North America and Europe.

31. In 2012, 10 countries in Europe,[18] Brazil and Chile had the highest rate of consumption of diazepam (out of the 48 countries worldwide for which data were reported), with above 3 S-DDD per 1,000 inhabitants per day.[19] Consumption of between 1 and 3 S-DDD per 1,000 inhabitants per day was reported for parts of North America, South America and Europe,[20] along with Algeria, China, Costa Rica and Georgia. Competent national authorities that submitted data on national consumption in 2012 of below 1 S-DDD per 1,000 inhabitants per day were mostly from countries in West Asia and Africa.[21]

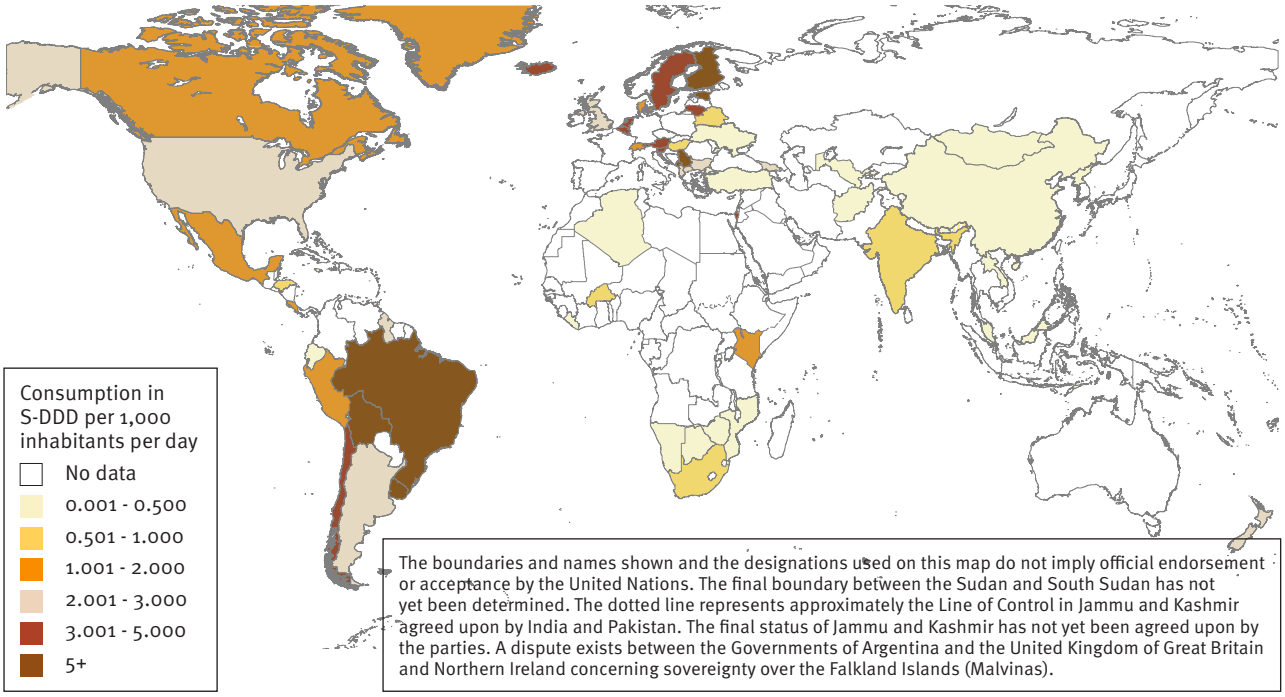
[18] Austria, Estonia, Finland, Iceland, Lithuania, Montenegro, Netherlands, Slovakia, Slovenia and United Kingdom.

[19] While competent national authorities submit their annual consumption data of psychotropic substances to INCB in kilograms, the consumption rates of different psychotropic substances are expressed in S-DDD per 1,000 inhabitants per day throughout the present report. Specifically, the consumption rate is calculated using the following formula: annual availability for reported consumption divided by 365 days; the result obtained is then divided by the population of the country, in thousands, during the year in question, and then by the defined daily dose (this is 10 mg for diazepam). The term S-DDD is used by INCB as a technical unit of measurement for the purpose of statistical analysis and is not a recommended prescription dose.

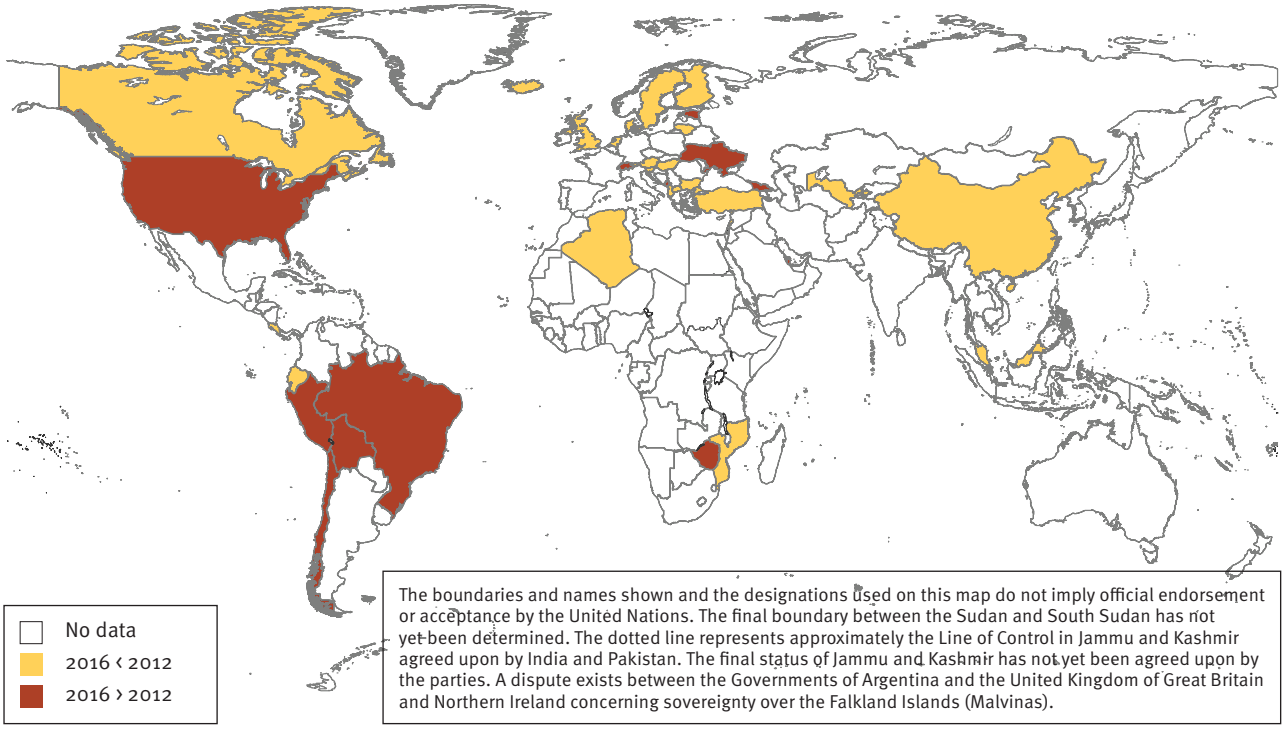
[20] Albania, Bulgaria, Denmark, Hungary, Luxembourg and Switzerland.

[21] Assuming that anxiety disorders are treated only by diazepam, a consumption rate of 10 S-DDD per 1,000 inhabitants per day for diazepam suggests that, on average, 1 per cent of the population receives treatment for anxiety disorders daily.

Map 4. Average national consumption of diazepam, 2016



Map 5. Changes in average national consumption of diazepam, 2012 and 2016



32. In 2016, the majority of the countries where the highest rate of consumption of diazepam was reported were again in Europe (Estonia, Finland, Lithuania, Montenegro and Serbia), together with Bolivia (Plurinational State of), Brazil, Chile, Israel and Uruguay, all of which had a consumption rate higher than 4 S-DDD per 1,000 inhabitants per day (see map 4). The competent national authorities of about 10 other countries in Europe, along with Argentina, Georgia, Guyana, New Zealand and the United States, reported consumption ranging between 2 and 4 S-DDD per 1,000 inhabitants per day. The consumption of diazepam in 2016 for the majority of countries in Africa and Asia that reported data was below 0.5 S-DDD per 1,000 inhabitants per day.

33. Among all the 40 countries and territories for which consumption data were submitted for both 2012 and 2016, 25 had a lower rate of consumption of diazepam in 2016 (see map 5).

34. While Global Burden of Disease data[22] seem to suggest an increasing global demand for treatment and medication for people living with anxiety disorders between 2006 and 2016, the majority of countries for which data on the consumption of diazepam were submitted to INCB had a decline in their consumption level over the period 2012–2016. Such declines were more commonly found in those countries with a consumption rate of less than 1 S-DDD per 1,000 inhabitants per day.

35. The global trend depicted in map 5 should be interpreted with great care and a number of caveats need to be mentioned. Firstly, while the submission of data on the consumption of psychotropic substances has improved considerably over the past five years, the amount of data submitted remained very low overall, thereby rendering a comprehensive assessment of the global situation impossible. Secondly, as the term S-DDD assumes a certain average maintenance dose per day for a drug used for its main indication and in adult patients, the actual prescription dose might be different from that of the assumed average maintenance dose, depending on the condition of the patient (age, health condition, severity of the condition, etc.). Thirdly, as anxiety disorders can also be effectively treated with psychological interventions and/or with substances other than diazepam, including substances not under international control, a decrease in the consumption of diazepam over the past few years does not necessarily point to a lack of treatment and/or medication for people living with anxiety disorders. Lastly, an increase in the consumption rate of diazepam does not necessarily suggest that no shortage of the required treatment and medication exists, as people living with anxiety disorders might not have been given a proper diagnosis for their condition.

36. Bearing in mind the above caveats, map 5 illustrates considerable disparities in the consumption of diazepam across the globe between 2012 and 2016, given the significant differences between the highest and the lowest rate of consumption. In particular, the difference between the countries with the highest and the lowest consumption rate of diazepam widened, from 10.781 S-DDD per 1,000 inhabitants per day in 2012 to 15.992 per 1,000 inhabitants per day in 2016, suggesting a growing consumption gap of diazepam among countries for which data was provided to INCB.

Epilepsy

37. As defined by WHO, epilepsy is a chronic disorder of the brain that can affect people of all ages. According to the latest WHO estimates, about 50 million people worldwide currently live with epilepsy, making it one of the most common neurological diseases globally.[23] At a given point in time, between 4 and 10 per 1,000 people of the general population are estimated to have active epilepsy, and epilepsy was ranked 26 in the leading causes of years lived with disability in 2016.[24]

38. The need for antiepileptics is much higher in low- and middle-income countries, given that 80 per cent of people with epilepsy live in low- and middle-income countries.[25] For instance, epilepsy was one of the 10 leading causes of years lived with disability in Sao Tome and Principe and Senegal[26] in 2016.

Reported consumption of essential antiepileptics under international control

39. In 2012, the competent national authorities of nearly 50 countries and territories submitted data on the consumption of at least one of the four essential antiepileptics under international control to INCB. In comparison, the authorities of a total of 74 countries and territories did so in 2016, with most data being submitted from countries in North America and Europe.

40. In 2012, Brazil, Canada and seven countries in Europe[27] had a consumption rate of above 10 S-DDD per 1,000 inhabitants per day for the essential antiepileptics under international control, the highest among all countries for which data were reported. Competent national authorities of about 15 countries and territories reported a rate of consumption ranging from 5 to 10 S-DDD per 1,000 inhabitants per day, the majority of which were in the Americas and Europe; those with a rate of consumption of diazepam of below 1 S-DDD per 1,000 inhabitants per day were mostly in Africa (see map 6).

[22] Global Burden of Disease is research first commissioned by the World Bank in 1990 and subsequently institutionalized at WHO. Findings in the present section are mostly extracted from "Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016".

[23] WHO, "Epilepsy", 8 February 2018.

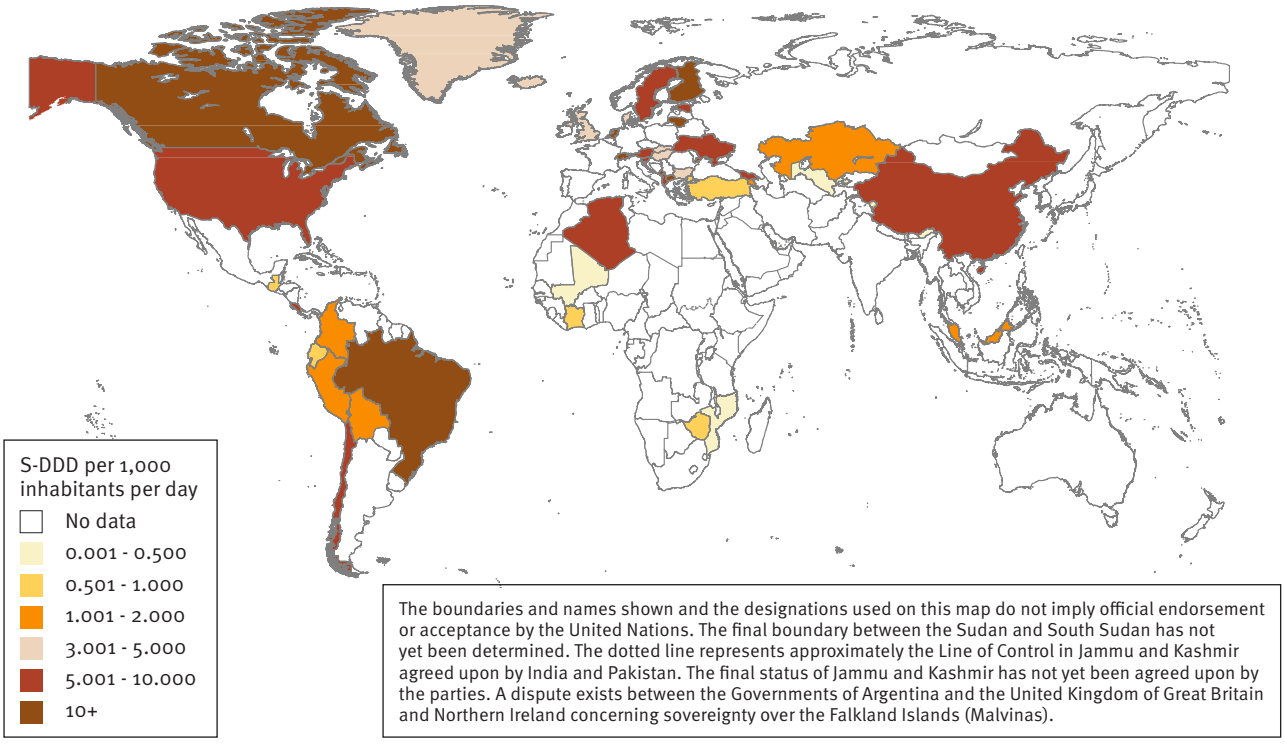
[24] "Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries, 1990–2016", figure 1.

[25] "Epilepsy".

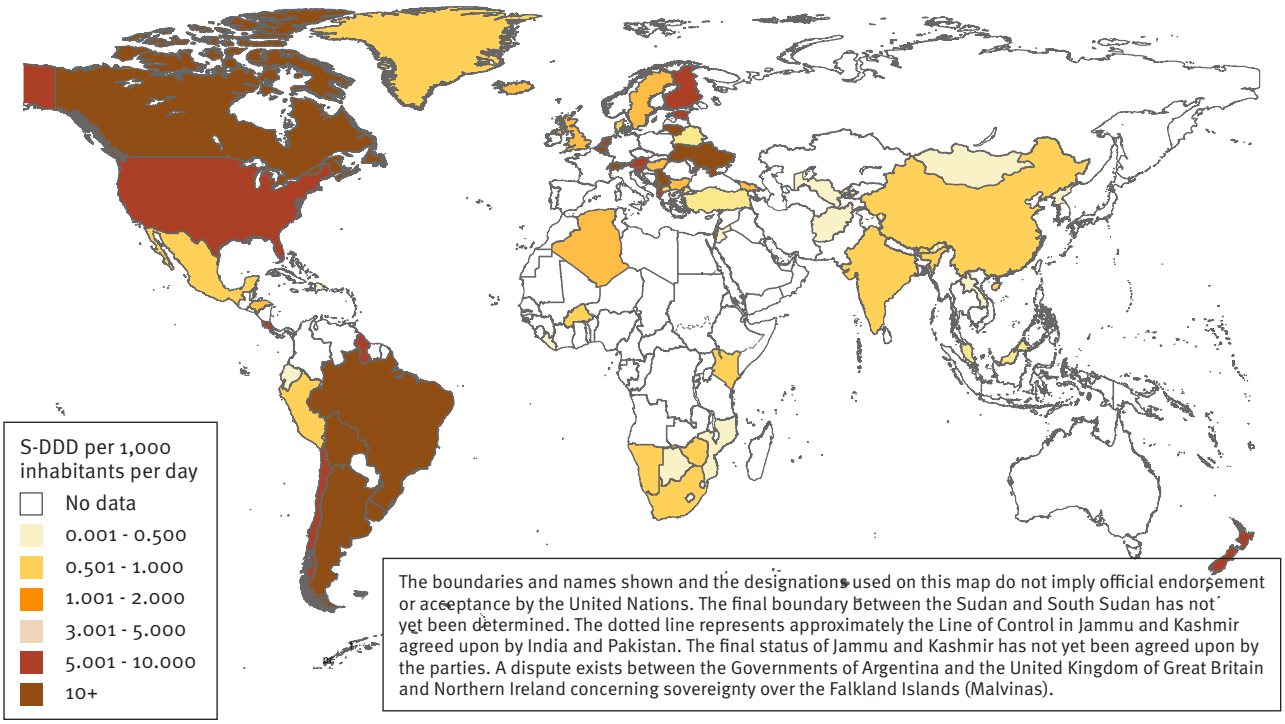
[26] "Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016", figure 7.

[27] Finland, Lithuania, Luxembourg, Montenegro, Netherlands, Switzerland and the former Yugoslav Republic of Macedonia.

Map 6. Average national consumption of essential antiepileptics under international control, 2012

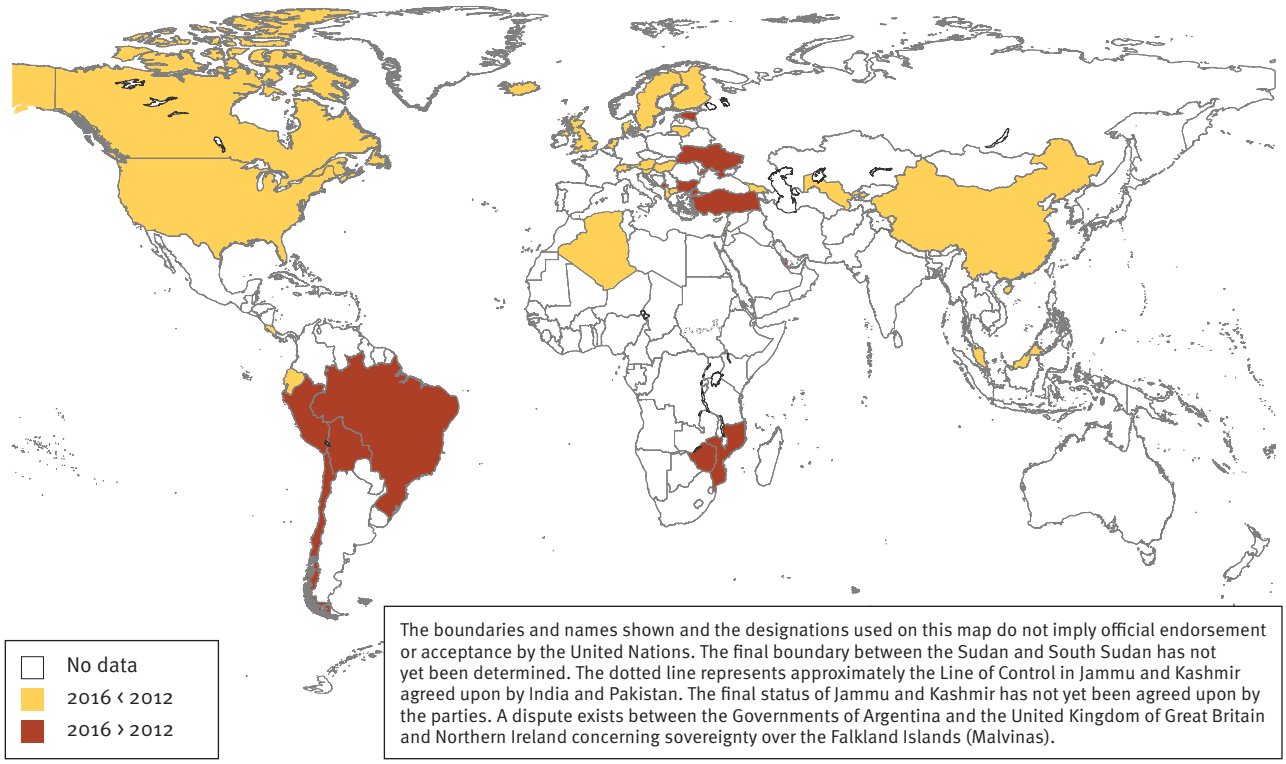


Map 7. Average national consumption of essential antiepileptics under international control, 2016



41. In comparison, in 2016, the countries with the highest consumption rates, of more than 10 S-DDD per 1,000 inhabitants per day, were Canada and countries in Europe and South America (see map 7). A rate of consumption of between 5 and 10 S-DDD per 1,000 inhabitants per day was reported by the competent national authorities of New Zealand and some countries in the Americas and Europe. The majority of countries in Africa and Asia for which data were submitted on consumption of essential antiepileptics under international control in 2016 had a consumption rate of below 0.5 S-DDD per 1,000 inhabitants per day.

Map 8. Changes in average national consumption of essential antiepileptics under international control, 2012 and 2016

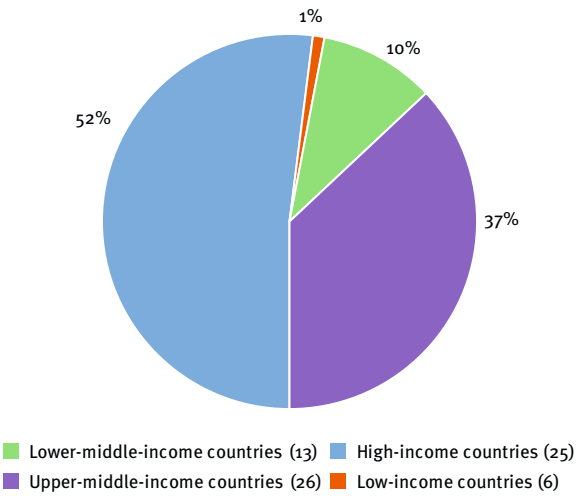


42. Of the 41 countries for which consumption data were submitted for both 2012 and 2016, 28 had a lower average rate of consumption of essential antiepileptics under international control in 2016 compared with 2012. The 13 countries with a higher rate of consumption of essential antiepileptics under international control in 2016 as compared with 2012 were in Africa, Europe and South America (see map 8).

43. Despite the fact that 80 per cent of people with epilepsy live in low- and middle-income countries, very little is known about the rate of consumption of essential antiepileptics under international control in those countries: data on consumption of those substances was provided from only 6 low-income countries (out of a total of 31) and 39 middle-income countries (out of a total of 109) in 2016 (see figure XI). By way of comparison, information was provided from 25 high-income countries (out of a total of 78) regarding the availability of those substances for consumption.

44. Keeping in mind the above-mentioned limitations, data provided to INCB revealed that, in 2016, over half (52 per cent) of some essential antiepileptics under international control were consumed in high-income countries and only 1 per cent was consumed in low-income countries.

Figure XI. Distribution of average rate of consumption of essential antiepileptics under international control, by country income level, 2016



Note: The numbers in parentheses refer to the number of countries that submitted data on consumption of essential antiepileptics under international control to INCB in 2016.

45. As in the case of diazepam, the global trends shown in map 8 and figure XI should be interpreted with great care, and several caveats need to be mentioned. Firstly, the

amount of data on consumption of psychotropic substances remained rather low overall, and varied considerably among countries with different income levels during the designated period. In particular, the amount of data on the consumption of psychotropic substances submitted from countries in Africa and Asia is very low. Secondly, as the term S-DDD assumes a certain average maintenance dose per day for a drug used for its main indication in adults, the actual prescription dose might be different from that of the assumed average maintenance dose, depending on the condition of the patient (age, health condition, severity of the condition, etc.). Thirdly, as epilepsy can be treated with substances other than the four essential antiepileptics under international control, the decrease in the consumption rate shown in map 8 does not necessarily point to a lack of medication for people living with epilepsy. Lastly, a higher rate of consumption of the essential antiepileptics under international control does not necessarily suggest that there is no shortage of the required treatment and medication for epilepsy, as the four essential antiepileptic drugs are not solely used for the management of epilepsy. In particular, lorazepam and midazolam have much broader applications, and in some countries they are not considered as a first-line treatment for the management of epilepsy.

46. Bearing in mind the above, considerable disparities existed in the consumption of essential antiepileptics under international control across the globe between 2012 and 2016, given the significant differences between the highest and the lowest rate of consumption. In particular, the gap between the country with the highest and the lowest consumption rate of essential antiepileptics under international control widened, from 23.181 S-DDD per 1,000 inhabitants per day in 2012 to 33.961 per 1,000 inhabitants per day in 2016, suggesting a growing consumption gap of essential antiepileptics under international control.

Importance of quality data on the consumption of psychotropic substances

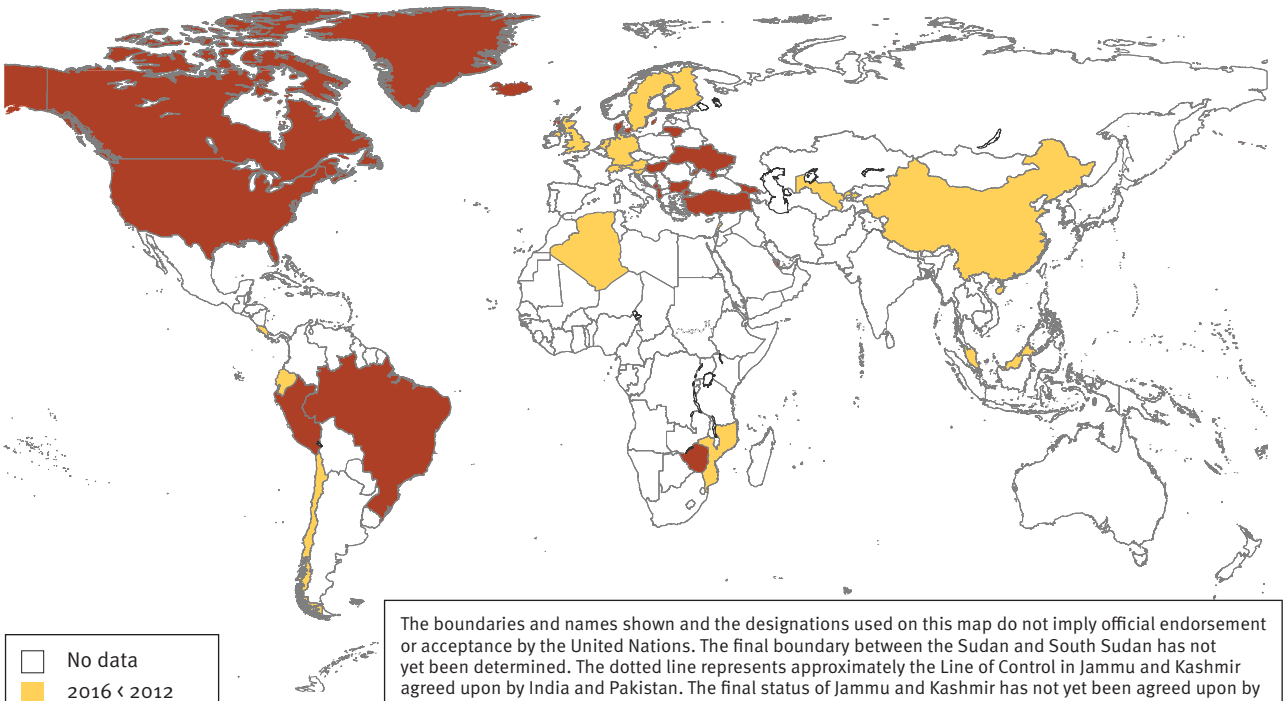
47. Given the multiple uses of psychotropic substances for a wide range of health conditions and the varying prescription practices in different countries, the analysis presented in the present section (based on the prevalence trends of two health conditions (anxiety disorders and epilepsy) and the consumption data reported to INCB since 2012) is, at best, a very preliminary assessment of the global availability of four essential psychotropic substances in a much-simplified context.

48. In fact, a comprehensive assessment of the availability of all psychotropic substances under international control, including those that are most commonly prescribed, is particularly challenging. For instance, changes in the consumption level of the four essential antiepileptics under international control (map 8) can be quite different from the changes in the consumption level of all benzodiazepines under international control (map 9) in some countries, suggesting that the assessment of the availability of these substances can be rather dependent on the scope of analysis.

49. Given such challenges, reliable data from competent national authorities are an essential starting point for the analysis of the availability of psychotropic substances. While data may be available in some countries with well-developed data-collection systems in place, other countries lack such systems. INCB stands ready to assist and guide Governments in improving their data-collection mechanisms, in particular with regard to data on the consumption of psychotropic substances. INCB encourages the competent national authorities of those countries that already have such data-collection systems in place to submit their data on the consumption of psychotropic substances in a regular, timely and consistent manner.

50. As stated above, there is currently no well-established way of assessing adequate levels of consumption of psychotropic substances under international control. However, assuming that the available data are sufficient and reliable, thresholds for high and low use of psychotropic substances could be considered. Such thresholds would present a new approach to measuring the availability of psychotropic substances for the treatment of mental health disorders and would provide a helpful guide for the analysis of adequate levels of consumption. Benchmarking the consumption of psychotropics would ultimately allow INCB and national Governments to monitor medical and scientific needs for psychotropic substances with a view to ensuring that needs for medical purposes are met. The Board therefore recommends that WHO and relevant international organizations work with INCB to those ends.

Map 9. Changes in average national consumption of all benzodiazepines, 2012 and 2016



The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations. The final boundary between the Sudan and South Sudan has not yet been determined. The dotted line represents approximately the Line of Control in Jammu and Kashmir agreed upon by India and Pakistan. The final status of Jammu and Kashmir has not yet been agreed upon by the parties. A dispute exists between the Governments of Argentina and the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas).

IV. Implementation of recommendations made by the Board and of the recommendations contained in the outcome document of the special session of the General Assembly on the world drug problem held in 2016

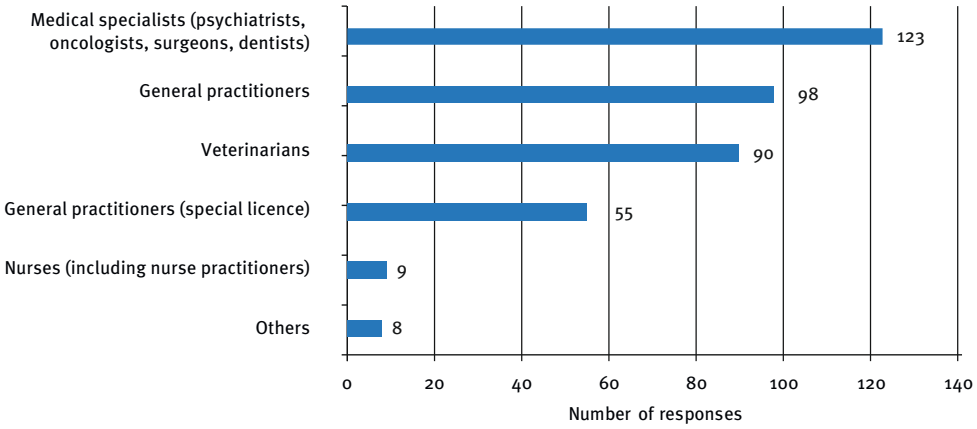
A. Member States

Legislation and regulatory systems

51. Both the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 contain recommendations related to legislation and regulatory systems. Some of the recommendations concern the need for Governments to review national legislation and regulatory and administrative mechanisms to simplify processes and remove unduly restrictive regulations. In the responses to the questionnaire by INCB in 2018, 40 per cent of the 130 competent national authorities that responded reported that, in the last five years, legislation and/or regulatory systems in their countries had been reviewed and/or changed. The same percentage reported that those reviews and/or changes had affected the availability of controlled drugs. The competent authorities of most of the countries where changes had been made to legislation and/or regulations referred to general changes, while some specified that changes had been made to the status of control of some substances or that electronic measures to facilitate prescription and procurement had been introduced.

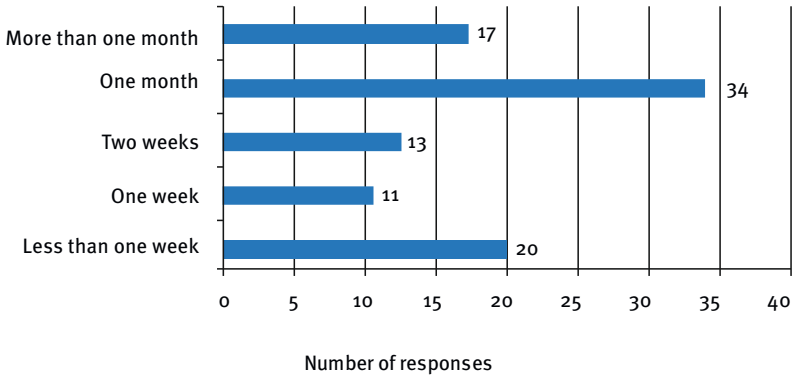
52. In a much smaller percentage of the countries for which responses were submitted (16 per cent), legislation and regulations had been modified in order to implement the recommendation to increase the base of health-care professionals able to prescribe controlled substances (opioid analgesics and psychotropic substances). Prescription of opioid analgesics and psychotropic substances were allowed by medical specialists in 123 countries and by general practitioners without a special licence in 98 countries. By contrast, nurses, including nurse practitioners, can prescribe controlled substances in only 9 countries (see figure XII). That

Figure XII. Who can prescribe opioid analgesics and psychotropics



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

Figure XIII. Prescription validity for opioid analgesics



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

limitation was reported as having a negative impact on access to services for people in need of palliative care and other treatment, in particular in low- and middle-income countries without decentralized health-care services and where the number of doctors is insufficient.

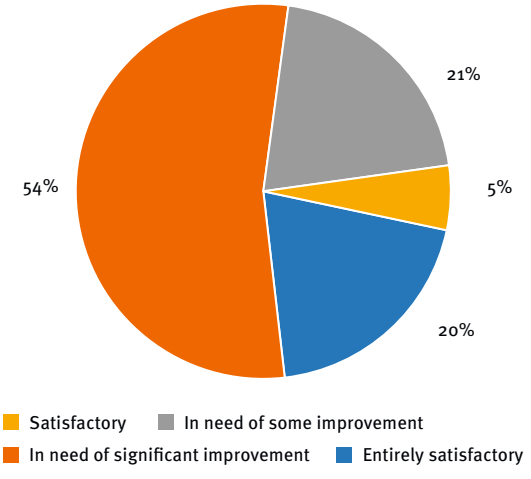
53. A second medical opinion for the prescription of opioid analgesics was required in 12 per cent of countries and in 9 per cent of countries for the prescription of psychotropic substances. In 22 per cent of countries, the prescription of opioid analgesics and psychotropic substances was subject to special regulatory requirements and legal sanctions existed in 26 per cent for unintentional mistakes made during the handling of opioid analgesics. That legal threat was reported as a major factor in the decision of some doctors not to procure, stock or prescribe opioid analgesics, thereby contributing to limiting access to those substances.

54. In most of the countries from which replies to the questionnaire were submitted (65 per cent for opioid analgesics and 60 per cent for psychotropic substances), measures had been taken to prevent the emergence of unregulated markets, the illicit manufacture of controlled substances and the manufacture of counterfeit medicines.

55. In relation to prescription policies for opioid analgesics, information on the validity period of prescriptions was provided for 95 countries (see figure XIII). In most of the 27 countries for which a period was not specified, the competent national authority indicated that the validity was either open for the prescriber to define or that the issue was not addressed in legislation or regulations.

56. The questionnaire also included a question on whether the medical and pharmaceutical sectors were aware of new legislative and administrative measures related to controlled substances. Most (75 per cent) of the competent national authorities that replied considered the level of awareness to be either in need of some improvement or in need of significant improvement (see figure XIV).

Figure XIV. Awareness of medical and pharmaceutical sectors of new measures, assessment by competent national authorities of responding countries



Health systems

57. The procurement of opioid analgesics and psychotropic substances alone will not solve the problem of the limited access experienced in many countries. For that reason, both the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 contain recommendations on improving health systems to ensure that controlled substances are prescribed and administered in a rational and efficient manner. In relation to opioid analgesics, it is important for Governments to have a palliative care policy and an appropriate infrastructure in place. In the INCB questionnaire from 2018, competent national authorities were asked whether new palliative care policies had been introduced in response to 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". A slight majority (53 per cent) of the responding authorities indicated that new palliative care policies and measures had been introduced in their countries.

58. Another question was whether the health-care infrastructure of the country was appropriate and well resourced to ensure not only the availability of opioid analgesics but also their provision in the context of the broader delivery of palliative care. Of the competent national authorities that responded, 43 per cent reported that their country's health-care infrastructure was appropriate and 13 per cent reported that their country's health-care infrastructure was entirely appropriate; 30 per cent stated that their country's health-care infrastructure needed some improvement and 14 per cent reported that it needed significant improvement. More than two thirds of the responding competent national authorities stated that low-cost, home-based palliative care was considered a means of addressing the limitations of the national health-care systems.

Affordability

59. Another important aspect of improving availability is ensuring that opioid analgesics are affordable and easy to access by patients. In that connection, INCB has recommended that countries:

(a) Improve access to essential drugs in general, and to opioid analgesics in particular;

(b) Ensure funding for the purchase of opioid analgesics;

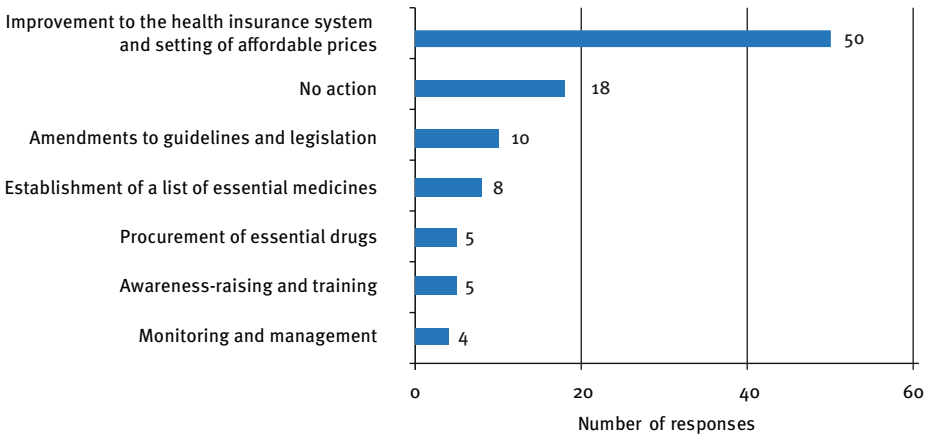
(c) Develop and improve health insurance and reimbursement schemes that guarantee access to medications.

60. Of the 104 competent national authorities that responded to the question on accessibility, 50 said that steps had been taken towards improving the health insurance system of their countries and setting affordable prices; 18 reported that no action had been taken in their countries in that regard, as the situation was satisfactory. For more detailed information on the measures taken in the countries for which responses were submitted, see figure XV.

61. Of the 115 competent national authorities that provided data on the availability of budget and resources, the majority (77 per cent) stated that they had sufficient resources for the purchase of opioid analgesics.

62. Mostly citing limited or reduced budget and a general lack of resources, 23 per cent of responding competent national authorities stated that they did not have sufficient resources for the purchase of opioid analgesics.

Figure XV. Steps taken to improve accessibility by patients to essential medicines, including opioid analgesics



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

63. Again, the procurement of pain relief drugs or psychotropic substances and the existence of appropriate health systems alone will not ensure access to medications for pain management or mental health treatment. The affordability of such drugs and substances for patients and the existence of health insurance and reimbursement schemes play a crucial role in ensuring availability. The majority of competent national authorities (76 per cent) indicated that a health insurance scheme existed in their country. Some authorities stated that the absence of health insurance schemes was because the Government provided free medicines to patients. In the countries with health insurance schemes in place, 31 per cent had reimbursement systems and 33 per cent had governmental and private health insurance systems. Some authorities (21 per cent) reported that it was obligatory for all citizens and non-citizens to have health insurance. In 15 per cent of the countries for which responses were provided, Governments encouraged companies to offer health insurance schemes for their employees.

Training of health-care professionals

64. Two of the recommendations contained in the supplement to the INCB annual report for 2015 were for palliative care to be included in the educational curricula of medical schools and for continued education, training and information on palliative care, including on rational use and on the importance of reducing prescription drug abuse, to be provided for health-care professionals.

65. The responses to the 2018 questionnaire indicated that palliative care was included in the curricula of medical schools in 71 countries (62 per cent of those for which responses were provided); palliative care was not included as a discipline of the medical education programme in 43 countries (38 per cent). In those 43 countries, palliative care education was provided in 11 countries only for a limited number of medical specialities (e.g., oncology), medical schools did not exist in 9 countries and plans to include palliative care in the curriculum of medical schools in the future existed in 4 countries. In their responses, some authorities mentioned that medical schools were responsible for organizing their own programmes, some mentioned an absence of political willingness and some mentioned a lack of financial and human resources as justification for a lack of action in that area.

66. Continued education, training and information on palliative care, including on rational use and the importance of reducing prescription drug abuse, were provided to health-care professionals in 76 countries (68 per cent); continuous education was not implemented in 36 countries (32 per cent). Doctors and health-care professionals were educated on the rational use of controlled drugs in 72 countries (63 per cent); such education was not provided in 41 countries (37 per cent) owing to a lack of resources or because it was not a priority for the Government.

67. A number of authorities responding to the questionnaire were not aware of improvements in the education curricula of medical schools in the previous five years in terms of the importance of reducing prescription drug abuse (37 per cent), the rational use of narcotic drugs and psychotropic substances (31 per cent) and prevention of misdiagnoses and inappropriate prescribing (33 per cent). About 18 per cent of the authorities responded that the curricula in the above-mentioned areas had not been updated.

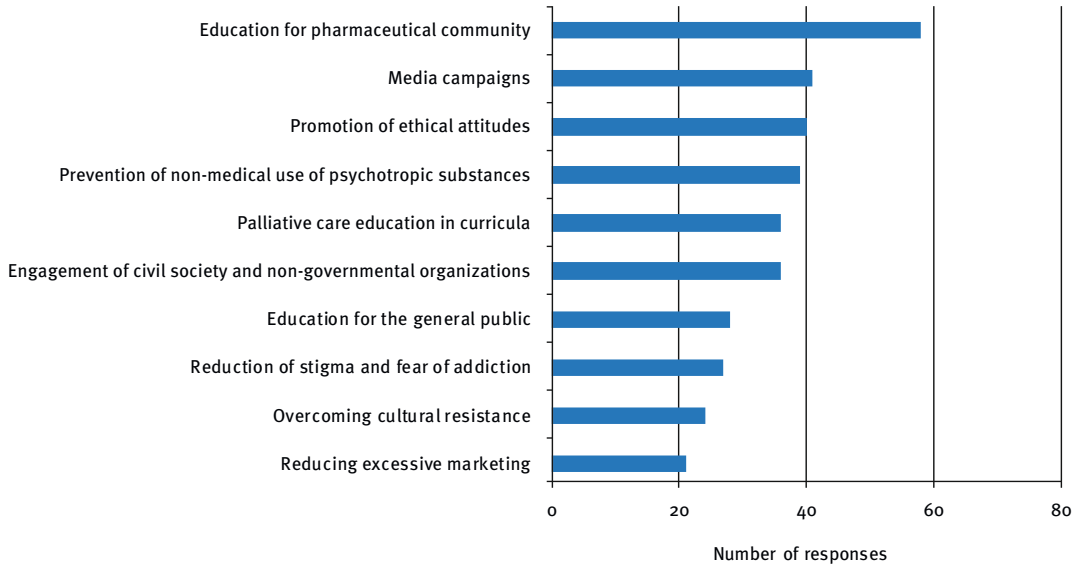
68. The majority of responding authorities (92 authorities, or 81 per cent) stated that narcotic drugs and psychotropic substances were prescribed in conformity with sound medical practice and that the rational use of such substances was promoted in their countries, alongside the need to take the measures necessary to limit their use to actual medical needs.

Education and awareness-raising

69. The analysis of the impediments to access to controlled substances shows that lack of awareness and fear of addiction are the main factors mentioned by the competent national authorities responding to the INCB questionnaire. The importance of cultural attitudes as a factor has been declining since 2014 but is still reported by some competent national authorities. For those reasons, both the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 contained recommendations on using awareness-raising campaigns and educational programmes to overcome cultural resistance and the stigma associated with the consumption of opioid analgesics or psychotropic substances.

70. Most of the competent national authorities reported that action had been taken in their countries through specific campaigns and awareness-raising programmes targeting pharmaceutical companies and involving competent national authorities and interest groups (e.g., professionals and consumers). In addition, public awareness-raising campaigns through the media and the promotion of ethical attitudes among medical doctors and pharmaceutical companies were mentioned by a significant number of competent national authorities responding to the questionnaire. A smaller number of authorities reported that specific initiatives to reduce excessive marketing and overcome cultural resistance had been carried out (see

Figure XVI. Education and awareness-raising initiatives reported by competent national authorities



Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. They could choose one or more responses.

figure XVI). The responses provided show that the majority of Governments are taking serious steps regarding education and awareness-raising. However, the information submitted on the questionnaires does not permit the impact of the various initiatives to be evaluated.

Estimates, assessments and reporting

71. In the supplement to its annual report for 2015, INCB noted that some competent national authorities were unable to properly estimate their needs for opioid analgesics and to monitor the consumption of those substances. Consequently, the Board recommended that authorities made use of the *Guide on Estimating Requirements for Substances under International Control*, developed in 2012 by INCB and WHO, and to use improved electronic tools, such as the electronic International Import and Export Authorization System (I2ES) for narcotic drugs and psychotropic substances, which had been developed by INCB in cooperation with the United Nations Office on Drugs and Crime (UNODC). As noted earlier, import and export control measures are one of the main impediments to ensuring the availability of controlled substances for medical uses reported by Member States, and the I2ES system has been developed by INCB to streamline and simplify the import and export processes and facilitate the availability of medications containing controlled substances.

72. In the 2018 survey, the vast majority of responding authorities (105) reported that they were aware of the existence of the *Guide on Estimating Requirements for Substances under International Control*. Two thirds of them found it to be extremely useful for their work and one third found it helpful to some extent.

73. Among the authorities making use of the *Guide on Estimating Requirements for Substances under International Control* to estimate their country's requirements for narcotic drugs and assess the availability of psychotropic substances, 48 reported using the consumption-based method (i.e., the average from the past three years' consumption, increased by 10 per cent to cater for possible variations in demand). That method was also used by another 30 authorities in combination with an analysis of other factors such as overall medical needs, total imports, exports and morbidity. Sixteen authorities reported establishing their estimates by compiling the requirements of pharmaceutical companies, pharmacies or hospitals; only two authorities reported calculating estimate requirements from import data.

74. Furthermore, 110 authorities reported that their estimates of requirements of narcotic drugs and assessment of the availability of psychotropic substances were appropriate and realistic. They confirmed that they considered variations in demand, including a margin for unforeseeable increases. Only 10 authorities replying to the questionnaire affirmed that their estimates and assessments were not appropriate or realistic.

75. The competent national authorities of 76 countries reported that they regularly contacted pharmaceutical companies or other stakeholders licensed to manufacture, import, export or stock controlled substances. Most of the

authorities sent out forms in order to receive information and others shared databases with licensed institutions; 28 authorities reported that they extracted estimates and assessment figures from import and export authorizations and consumption data.

76. The competent national authorities of 50 countries reported that they had established electronic tools for processing import and export authorizations. Among those, 17 countries used a national system, 14 countries used the UNODC National Database System (NDS), 4 countries used NDS combined with I2ES, 4 countries used I2ES alone and 6 countries were in the process of introducing I2ES.

77. Electronic systems to process import and export authorizations did not exist in 66 countries. The reasons for that included: *(a)* a lack of awareness of I2ES (11 countries); *(b)* a lack of resources (9 countries); *(c)* the installation of I2ES had been requested (7 countries); *(d)* a system was not needed because few authorizations were processed (4 countries); *(e)* I2ES was not used by trading counterparts (2 countries); and *(f)* paper documentation was needed by law (1 country).

B. Civil society organizations

78. The present section presents the viewpoint of civil society regarding the implementation of the recommendations contained in the supplement to the Board's annual report for 2015 and the outcome document of the special session of the General Assembly on the world drug problem held in 2016. It includes information submitted to INCB by 30 civil society organizations based in 23 countries in Asia, Africa, Europe and the Americas, with geographical representation at the local, national, regional and global levels.

79. In the context of their work, civil society organizations reported several factors that unduly limited the availability of narcotic drugs and psychotropic substances needed for medical or scientific purposes. Restrictive legislation and policies were mentioned by six organizations as impediments to availability. However, most of those replies referred to difficulties related to the use of cannabis for medical and scientific purposes. An onerous regulatory framework for the prescription of narcotic drugs for medical use was mentioned by five organizations. That included an insufficient number of doctors prescribing, a lack of prescription forms and cumbersome processes for obtaining prescription forms. A lack of financial resources was mentioned by four organizations in relation to the prices of medication and to insufficient government resources to support availability. Four organizations reported that they perceived no obstacles to availability in their countries.

Legislation and regulatory systems

80. Civil society organizations responding to the questionnaire reported positive changes in the area of legislation and regulations aimed at simplifying and streamlining processes in order to remove unduly restrictive regulations to ensure accessibility of controlled substances and maintain adequate control systems. In some cases, those changes had improved the availability of medicines for cancer pain and palliative care in particular. Approximately 57 per cent of civil society organizations that responded to the questionnaire reported having observed changes to or reviews of legislation or regulations in order to simplify and streamline processes and remove unduly restrictive regulations to ensure accessibility of controlled substances and maintain adequate control systems in their countries. Some of the organizations that reported no such action explained that their country already had a high level of availability and access to medicines containing controlled substances and that there was no need for further improvements.

81. About 40 per cent of respondents reported the introduction of new palliative care policies or measures, for example, in response to World Health Assembly resolution WHA67.19. The development of national programmes focusing on or including palliative care was frequently mentioned in the context of removing barriers to access. The creation of medical specialization programmes in pain treatment and palliative care, as well as partnerships with civil society, was also mentioned.

82. About 43 per cent of the responding organizations observed measures implemented by Governments to allow a larger base of health-care professionals (including trained general practitioners and nurses) to prescribe opioid analgesics and/or psychotropic substances to increase availability, particularly in remote or rural areas. Other measures to improve availability included the provision of opioid-substitution treatment in prisons and the prescription of controlled medication through telecommunications technology.

83. According to the civil society organizations that responded to the questionnaire, public policies on the availability of controlled substances, including national plans on palliative care, were lacking in some countries. In other countries, there are no departments or focal points appointed under national health institutions (e.g., the ministry of health) to oversee the adequacy of consumption levels together with competent national authorities. In some cases, it was reported that legislation had become more restrictive regarding access to controlled substances.

84. The responding organizations stated that legislation and punitive sanctions for accidental breaches could be so strict that they virtually prohibited the provision of care, including pain treatment and opioid-substitution treatment. The absence of clear guidelines and medical protocols created a situation of legal uncertainty that could prevent health professionals from prescribing.

85. The restrictions imposed by national legislation and regulations also affected research on the uses of controlled substances. The high prices of licences and punitive sentences for accidental breaches of regulations by researchers and universities were said to be among the elements that may be hindering research on the medical use of such substances. Those restrictions affected all controlled substances, but especially the ones for which the efficacy of medical use was still the subject of further research, such as cannabis, fentanyl analogues and ketamine analogues.

Health systems

86. Civil society organizations reported that, although, overall, national availability seemed to be adequate, in some areas, in particular rural ones, inadequate availability remained a problem, including in high-income countries. Inadequate availability was also reported to affect particular population groups, such as indigenous and rural communities, children and people living on the street.

87. Civil society organizations noted that the limited number of physicians able to prescribe, combined with geographical accessibility, was an obstacle in many countries. In such a context, the prescription of controlled medication through so-called e-prescribing might contribute to ameliorating the situation. It had already been put into practice in some countries where, for example, physicians used telecommunications technology to prescribe to patients receiving opioid-substitution treatment.

88. Other challenges reported by civil society included the relatively low number of qualified physicians to deal with the demand for palliative care and with overdose and suicide.

Affordability

89. Civil society organizations reported that, in some countries, a stronger financial commitment from Governments and donors was needed to overcome the availability gap. The recognition of the problem of a lack of awareness by authorities was often not followed up with sufficient resources to expand the provision of health services, including controlled substances, beyond pilot schemes. In many settings, patients relied solely on non-governmental organizations to access the medication they needed. Even in high-income countries, people not covered by health-care systems encountered difficulties in accessing the medications that they needed, as a result of their high costs.

90. It was reported that countries in Africa were focusing on the possibility of formulating oral morphine from morphine powder for use by patients.

Training of health-care professionals

91. About 37 per cent of the civil society organizations that responded to the questionnaire were directly engaged in education and training activities. Moreover, about 64 per cent of the organizations reported having knowledge of country-provided continued education, training and information on palliative care for health-care professionals, including on rational use and the importance of reducing prescription drug abuse.

92. However, the organizations reported that training was still much needed in various parts of the world: while controlled medicines might be available in many countries, doctors were reluctant to prescribe in some of them as a result of limited understanding of the risks and benefits of the substances. The issue of the quality of training provided, which is key to ensuring successful treatment, was also mentioned by respondents.

93. Another important factor mentioned by organizations in their replies was the training provided to health professionals by private pharmaceutical companies. It was reported that some pharmaceutical companies imparted erroneous or misleading information to doctors without being held accountable for it. Without additional training or reversal of that situation, doctors might carry on prescribing on the basis of erroneous information.

Education and awareness-raising

94. Civil society organizations reported being particularly active in the area of education and awareness-raising at the local, national, regional and international levels: about 37 per cent of organizations that responded to the questionnaire were working on advocacy and public policy areas and about 27 per cent were working with academia and in the area of research. Those were described as key areas where civil society organizations had the opportunity to mobilize decision makers with regard to availability and, in the case of research, develop and disseminate more science-based information to contribute to the debate.

95. Civil society organizations reported conducting their work on education and awareness-raising through

multi-stakeholder workshops, in which recommendations and guidelines could be developed, as well as working-level and high-level meetings, including inter-ministerial ones. Organizations reported focusing on the delivery of lectures, courses and manuals, the organization of congresses and conferences and the publication of technical reports and academic journals. They had contributed to the inclusion of palliative care and pain relief in medical and nursing curricula and were developing clinical studies on new uses of controlled substances. The launch of information campaigns and the promotion of networks were also mentioned among their main activities.

96. It was reported that the African Palliative Care Association (APCA) had developed the *APCA Atlas of Palliative Care in Africa,* which provided Africa-focused indicators for measuring progress in the provision of palliative care in the continent, as well as up-to-date country-specific information, including the availability of opioids for pain management. Africa is the continent with the lowest levels of consumption of opioid analgesics in the world.

C. International community

97. The international community has reached consensus on the need to improve availability and access to controlled substances for medical and scientific purposes, as reflected in the outcome document of the special session of the General Assembly on the world drug problem held in 2016. Although not exclusively driven by that consensus, global awareness of the need for pain management and palliative care has been steadily increasing. Specific steps in that direction include the publication by WHO of *Planning and Implementing Palliative Care Services: a Guide for Programme Managers*;[28] the addition, in 2017, of a basic palliative care package for cancer patients as a priority intervention under the WHO *Global Action Plan for the Prevention and Control of Non-Communicable Diseases 2013–2020*; and the preparation of new guidelines for the clinical management of cancer pain in adults,[29] all of which provide guidance on the appropriate use of controlled substances in pain management. Similarly, *Improving Access to and Appropriate Use of Medicines for Mental Disorders*[30] contains recommendations on the rational use of preparations containing controlled psychotropic substances.

98. Capacity-building and development support are being provided by Member States, international organizations and non-governmental organizations to countries and populations in need of support to tackle the access and availability gap. INCB, WHO and UNODC are among the organizations that have been implementing capacity-building initiatives, with the support of Member States. Those efforts need to be scaled up in order to provide sufficient and sustainable support to Governments to close the access and availability gaps in the shortest possible time span.

99. To supplement and increase the effectiveness of the support provided by INCB to Governments to ensure the availability of internationally controlled substances for medical and scientific purposes, INCB launched INCB Learning in 2016. The objective of INCB Learning is to support Governments in the implementation of the operational recommendations on ensuring access to controlled substances for medical and scientific purposes contained in the outcome document of the special session of the General Assembly held in 2016. In the period since its inception, INCB Learning has conducted regional training and awareness-raising activities in Africa, Asia, Europe, Central America and Oceania. INCB Learning has also developed a suite of e-learning courses to support the ongoing training of the staff of competent national authorities responsible for providing the estimates of and assessments for narcotic drugs and psychotropic substances needed at the national level for medical purposes, facilitating related international trade and fulfilling the reporting obligations under the drug control treaties.

100. INCB commends the international community, including Member States, international organizations and civil society, on their efforts to improve the lives of people worldwide through the facilitation of the provision of adequate treatment with appropriate medication, and encourages continued and strengthened action in that area.

[28] Geneva, 2016.

[29] WHO (forthcoming).

[30] WHO (Geneva, 2017).

V. Conclusions and the way ahead

101. The data on and analysis of the availability of opioid analgesics show that, despite a global increase in the availability of opioid analgesics for consumption, mostly in high-income countries, global disparity and imbalance remain evident. There has been an increase in the use of expensive synthetic opioids, again mostly in high-income countries, that is not matched by an increase in the use of affordable morphine.

102. For the majority of countries for which data are reported to INCB, the availability for consumption of some essential psychotropic substances (diazepam, midazolam, lorazepam and phenobarbital) has been declining, despite an increasing number of people living with anxiety disorders and epilepsy. There is also a significant global disparity in the availability of those substances for consumption: higher availability for consumption is reported by competent national authorities in high-income countries, but the morbidity associated with those disorders continues to increase in low- and middle-income countries. The difference between the highest and the lowest rates of consumption widened between 2012 and 2016, pointing to a growing consumption gap among all countries for which data were reported.

103. Not much time has passed since the recommendations formulated by INCB and those adopted at the special session of the General Assembly on the world drug problem held in 2016. For this reason, the questionnaire sent by INCB to Member States for the preparation of the present report solicited information on actions taken over the period 2012–2017.

104. It emerged from the responses of Member States that some of the impediments to the availability of controlled substances for medical and scientific purposes that are related to cultural issues and biases are progressively diminishing, while more concrete impediments (such as lack of training or awareness among health-care professionals, problems in sourcing and limited financial resources) are increasingly being reported. This gradual change in the perception of which factors are an obstacle to availability and access seems to indicate that there is more awareness of the practical factors that need to be addressed and that it may be possible to address successfully. The number of times that onerous regulation was mentioned continued to decrease, pointing to some positive developments in that area that were confirmed by the number of countries in which it was reported that changes in legislation or regulations had been implemented in the previous five years. In their responses covering a small number of countries, civil society organizations stated that they viewed legislation as an impediment.

105. About 40 per cent of the competent national authorities that responded to the questionnaire reported that, in the previous five years, there had been reviews and/or changes in their legislation and/or regulatory systems; the same percentage reported that those changes had affected the availability of controlled drugs.

106. In relation to the recommendations on increasing the base of health-care professionals able to prescribe opioid analgesics, the responses showed that nurses were allowed to prescribe them in only 2 per cent of the countries represented, leaving many people in need of palliative care and other treatments with no or limited access to opioid analgesics.

107. In 26 per cent of the countries for which responses were received, there are legal sanctions for unintentional errors in handling opioid analgesics. This situation was reported to be a factor in the decision of some doctors not to procure, stock or prescribe opioid analgesics, thereby contributing to limiting access to those substances. Similar challenges affect the number of pharmacies willing to dispense opioids. Policies in 34 countries allowed prescriptions to be valid for one month; in 17 countries, they are valid for longer than one month.

108. Most (53 per cent) of the competent national authorities responding to the questionnaire reported the introduction of new palliative care policies and 69 per cent reported that the introduction of low-cost palliative care services was being considered in their countries.

109. While the majority (almost three quarters) of the authorities reported having sufficient resources to procure the medications needed and make them available through public or private health-care systems, 23 per cent reported a lack of resources for that purpose and the same percentage also indicated the absence of a national health insurance and reimbursement scheme.

110. Palliative care was reported to be part of the curricula of medical schools in 62 per cent of the countries for which responses were received; in 68 per cent of the countries there were programmes of continued education, training and information on palliative care for health-care professionals, including on the rational use and the importance of reducing prescription drug abuse.

111. Specific campaigns and awareness-raising programmes targeting the pharmaceutical industry, with the involvement of competent national authorities and interest groups (e.g., professionals and consumers), aimed at overcoming the cultural resistance and stigma associated with the consumption of opioid analgesics or psychotropic substances, have been implemented in most countries.

112. Some 105 authorities reported making use of the *Guide on Estimating Requirements for Substances under International Control* to estimate requirements for narcotic drugs and assess the availability of psychotropic substances and all of them believed their estimates to be appropriate and realistic. While in the view of INCB and on the basis of the data submitted by Governments this assessment by Governments may not always be accurate—that is, it may not be commensurate with known morbidity rates—INCB acknowledges the efforts and increased awareness of Governments in this area. The majority of the authorities responding to the questionnaire reported having regular contact with pharmaceutical companies or other stakeholders licensed to manufacture, import, export or stock controlled substances. Electronic tools for processing import and export authorizations had been established in only 46 countries.

The way ahead

113. The analysis of the data and responses to the questionnaires by Governments and civil society organizations show promising developments in some areas; however, there are still important issues that require further action, not only by Member States but also by the international community. On the basis of this analysis, INCB urges Governments to take further action to:

- Enable a broader range of health-care professionals, in particular nurses who are specifically trained and certified, to prescribe controlled substances, especially in countries that do not have decentralized health services and where the number of available doctors is limited.
- Increase and strengthen the availability of training in the use and rational prescribing of controlled substances for health-care professionals, in particular specifically trained and certified nurses, by incorporating training modules in the training and educational programmes for health-care professionals.
- Ensure that prescriptions are appropriate to the needs of patients, while also ensuring that monitoring and dispensing arrangements are adequate to that effect.
- Mitigate the sanctions applicable in the case of unintentional errors made in the prescribing of controlled substances to reflect the lack of intent.
- Offer low-cost palliative care services to patients, including in remote areas.
- Ensure that competent national authorities prioritize public health concerns when issuing licences for the manufacture, import and export of essential medicines.
- Bolster the national and/or regional production of pharmaceuticals, in their generic forms, in order to reduce dependence on imports and increase affordability.
- Develop mechanisms to ensure that the pharmaceutical industry produces and makes available medicines containing controlled substances, such as opioid analgesics, specifically morphine, that are affordable, and enforce the regulation of the pharmaceutical industry to deal with promotional and informational campaigns on prescribing and use of high-cost formulations, including with respect to costly synthetic opioids.
- Consider banning the advertising of medical products containing narcotic drugs and psychotropic substances under international control and, where that is not constitutionally permitted, consider restricting to the largest extent possible advertising, informational and promotional campaigns for such products.
- Include palliative care in the national curricula of medical and nursing schools.

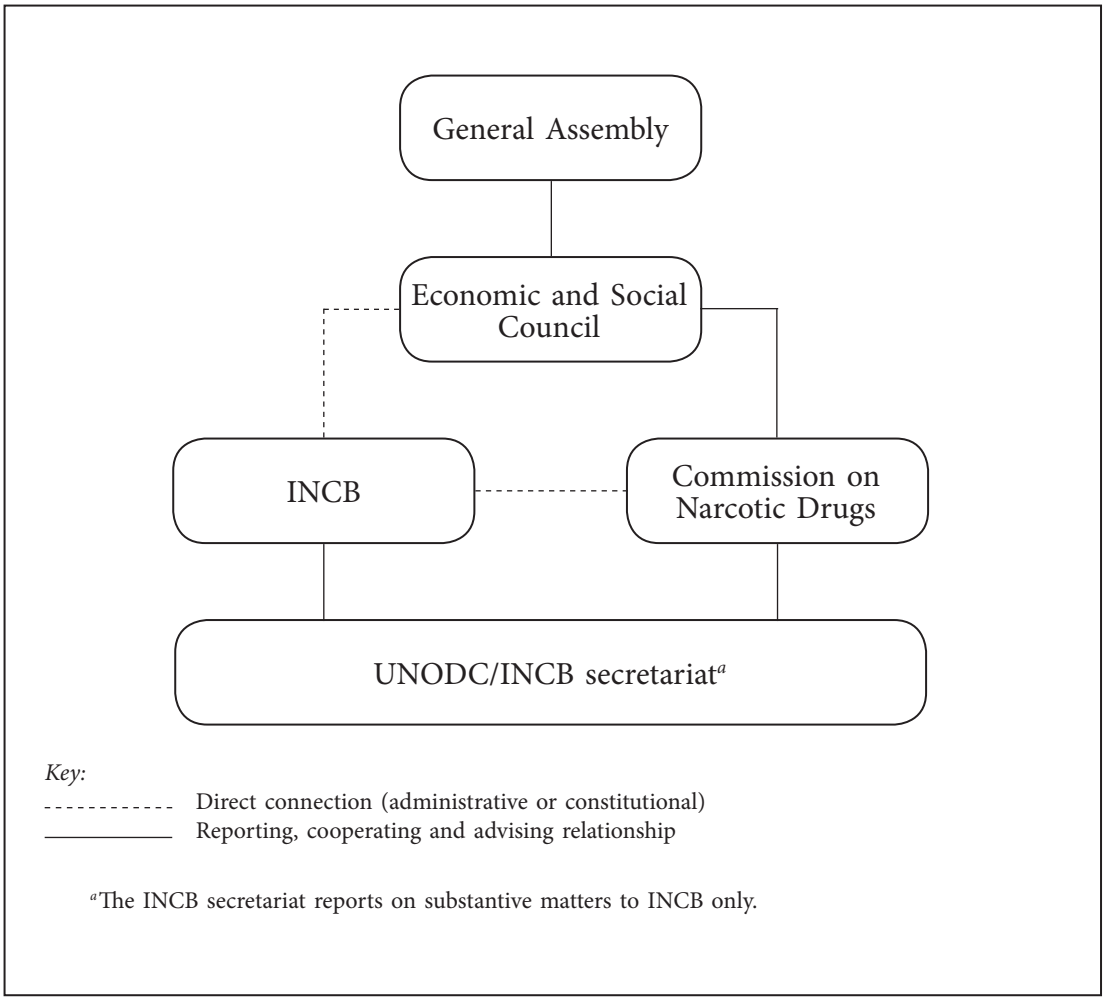
- Expand the coverage of health services and include substances in the WHO *Model List of Essential Medicines* in national lists of essential medicines.
- Periodically review their estimates and assessments for narcotic drugs and psychotropic substances with a view to ensuring that they are adequate to meet medical needs, on the basis of morbidity rates and the capacity to prescribe and dispense rationally.
- Establish tools for processing import and export authorizations, and join the electronic International Import and Export Authorization System (I2ES) developed by INCB and UNODC.

114. INCB stands ready to support Governments in their renewed efforts towards achieving those goals, which in turn will contribute towards their achievement of Sustainable Development Goal 3, on ensuring healthy lives and promoting well-being for all at all ages. The Board provides assistance through its secretariat on an ad hoc basis to Member States, and since 2016 has been implementing INCB Learning, in collaboration with WHO, UNODC and other relevant entities, with a view to strengthening the capacity of Governments in the regulatory control and monitoring of the licit trade in narcotic drugs, psychotropic substances and precursor chemicals. The ultimate goal of INCB Learning is to support Governments in ensuring the adequate availability of controlled substances for medical use. To achieve that goal and to support Governments, the Board relies on voluntary contributions from Governments for its capacity-building activities.

A final word

115. INCB is grateful to Member States for their input and for answering the questionnaire thoroughly. INCB is aware that completing the questionnaire required consulting more than one government agency, and the efforts made are appreciated. Similarly, the Board would like to recognize the contribution of civil society organizations. The time that has passed since the publication of the previous supplement to the Board's annual report and the outcome document of the special session of the General Assembly on the world drug problem held in 2016 is short, but there are clear indications that Governments are committed to the goal of ensuring adequate access to internationally controlled substances for medical and scientific purposes. That goal is at the heart of the international drug control conventions and should also be at the heart of national drug control policies.

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.

V.18-08383