Supplement to the annual report of the Board for 2022 on the availability of internationally controlled substances

No Patient Left Behind: Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes

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Supplement to the annual report of the Board for 2022 on the availability of internationally controlled substances. No Patient Left Behind: Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes (E/INCB/2022/1/Supp.1)

Narcotic Drugs: Estimated World Requirements for 2023—Statistics for 2021 (E/INCB/2022/2)


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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The text of the present report is also available on the website of the Board (www.incb.org).
Supplement to the annual report of the Board for 2022 on the availability of internationally controlled substances

No Patient Left Behind: Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes
Preface

Over half a century ago, in adopting the Single Convention on Narcotic Drugs of 1961, and later the 1972 Protocol amending the Convention, and the Convention on Psychotropic Substances of 1971, the international community made a commitment to ensure – and not unduly restrict – the availability of drugs considered indispensable for medical and scientific purposes.

Despite that commitment, there remains a significant imbalance in the availability of controlled substances globally, an imbalance which not only goes against the aim of the international drug control conventions to promote the health and welfare of humankind but also contradicts numerous human rights instruments that contain the right to health or medical care, which also encompasses palliative care.

The International Narcotics Control Board (INCB) issued supplementary reports on the availability of controlled substances for medical purposes in 1989, 1995, 2010, 2015 and 2018. In 2022, INCB has collected and analysed information from Member States and civil society to once again provide the international community with an update on the situation and to recommend remedial action. The data confirm the persistent disparities between regions in the consumption of opioid analgesics for the treatment of pain. Almost all such consumption is concentrated in Western Europe, North America, Australia and New Zealand. Consumption levels in other regions are often not sufficient to meet the medical needs of the population. These regional imbalances are not due to a shortage of opiate raw materials. Supply has been found to be more than sufficient to satisfy the demand reported to INCB by Governments, but it is evident that a large number of countries may not be accurately reflecting the actual medical needs of their populations in their reported demand, and hence the disparity in availability.

Analysis of the consumption of opioid analgesics, as reported by Governments to the Board, relative to the estimated number of people in need of palliative care in countries as provided in the Global Atlas of Palliative Care (2nd edition, 2020) by the Worldwide Hospice Palliative Care Alliance and the World Health Organization (WHO), confirmed the inequities. There is a clear need for decisive action, in particular in low- and middle-income countries. A major problem in those countries is the limited access to affordable opioid analgesics, such as morphine. One reason for this is that most of the morphine produced globally is converted into other drugs and not much is used for palliative care. In 2020, for example, 78 per cent of the morphine produced globally was converted into other drugs, mainly codeine, which in turn was mainly used in cough medicines, while only 11 per cent was consumed directly, mainly for palliative care. Furthermore, over 82 per cent of the global population had access to less than 17 per cent of the world’s morphine-based medicines.

While those imbalances show that authorities are not accurately estimating their needs for narcotic drugs used for palliative care, similar imbalances are also found with regard to the psychotropic substances used for the treatment of various mental health and neurological conditions. For example, while 80 per cent of people with epilepsy live in low- and middle-income countries, consumption of psychotropic substances used in the treatment of epilepsy is concentrated in high-income countries. Similarly, access to and availability of methadone and buprenorphine, which are used in the management of drug dependence, are still limited in some countries despite a significant prevalence of injecting drug use.

The Board’s analysis identifies some of the underlying reasons for these discrepancies, with regulatory controls often being cited as the main factor contributing to the low availability of psychotropic medicines. More studies are, however, required to determine whether regulatory controls do in fact hamper availability; and other factors, such as the low rate of diagnosis of mental health conditions and the stigma associated with use of psychotropic substances, also need to be considered.
The Board continues to encourage Governments to calculate their estimates on the basis of the methods suggested in the *Guide on Estimating Requirements for Substances under International Control*, developed by INCB and WHO. The *Guide* describes three methods and their variants that are commonly used to quantify the requirements for controlled substances: the consumption-based, service-based and morbidity-based methods. The choice of which method to use is determined by the availability of the data needed for the quantification, the availability of the necessary resources and the structure of the controlled substance supply and distribution system. The competent national authorities need to familiarize themselves with the *Guide* and identify the method that is best suited to their situation.

Countries are also encouraged, with the support of bilateral and international partners as appropriate, to strengthen their capacity to collect the best possible data and create a digital network of information collection from all stakeholders in the supply and consumption chain for the determination of an appropriate estimation of their requirements for narcotic drugs and psychotropic substances.

INCB is committed to supporting Governments in their renewed efforts to improve availability of controlled substances for medical and scientific purposes. INCB Learning was established in 2016 to build the capacity of Governments in the regulatory control and monitoring of the licit trade in narcotic drugs, psychotropic substances and precursor chemicals. Activities focus on building the capacities of Governments to implement the drug control conventions and achieve their ultimate objective of ensuring the availability of controlled substances for medical and scientific purposes while preventing diversion, trafficking, illicit manufacture and non-medical use.

Indeed, while working to ensure the availability of controlled substances for medical and scientific purposes, countries must ensure that adequate measures are in place to prevent diversion to illicit channels and non-medical use. Overprescription of fentanyl and other strong opioids is at the root of the opioid overdose epidemic that is still affecting some countries. After having increased exponentially over the past 40 years, an overall significant decline in the consumption of fentanyl has been registered since 2010, possibly related to the introduction of the more stringent control measures in some countries.

Some progress has been made since 2016 in realizing the goal of ensuring adequate availability of and access to controlled medication, which is key to achieving Sustainable Development Goal 3 on health and well-being. However, it is necessary to continue working to ensure that this goal is enshrined in all national drug control policies and practices. The Board is committed to working and assisting the international community for the greater availability of and access to controlled substances for medical and scientific purposes.

Jagjit Pavadia  
President  
International Narcotics Control Board
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Executive summary

For many years, the International Narcotics Control Board (INCB) has expressed concern about the limited availability of and access to controlled substances for medical purposes in many regions of the world. Special reports on this issue were published in 1989, 1995, 2010, 2015 and 2018. The present report is a further opportunity to provide the international community with information that may assist in the implementation of the operational recommendations specifically related to availability and access adopted by Member States in the outcome document of the special session of the General Assembly on the world drug problem, held in 2016. The data confirm the persistent disparities between regions in the consumption of opioid analgesics for the treatment of pain. For psychotropic substances, the situation is less clear, but limited access and availability, particularly in low- and middle-income countries seems to be also an issue in this case.

The relevance of the topic of availability and access was made more evident through the continued evolution and growing problem of the opioid epidemic that started in North America in the mid-1990s and, more recently, the coronavirus disease (COVID-19) pandemic.

The responses received from Member States and civil society describe an evolving situation in terms of the factors that are considered to be limiting or impeding access and availability, as well as in terms of concrete legislative, administrative and practical measures taken in the areas of the operational recommendations to address the situation.

The data on the global availability of opioid analgesics show a steep increase in the opioids available for consumption since 1978, with a significant decrease after 2018 mainly due to the reduced reported consumption of strong opioids (oxycodone and fentanyl), mainly in North America. At the same time, many countries continue to report having difficulties procuring medications containing morphine, although sufficient quantities of opiate raw materials are reported to be available. The problem is that the large majority of the morphine available is being used for the production of codeine to be used mainly for preparations in Schedule III of the 1961 Convention as amended, and only a small amount is used directly for medical purposes (such as palliative care). The limited amount used directly for pain relief is mostly used in high-income countries. This is confirmed by the data of the World Health Organization (WHO) on the availability of oral morphine in public primary care facilities, which show that there are considerable differences between the different income groups.

The consumption of opioid analgesics remains relatively high in North America, Western Europe, Australia and New Zealand. It has improved in the Russian Federation and in some countries in Eastern Europe. However, the situation remains problematic in most of Africa and parts of Asia where most countries continued to report very low consumption.

Plotting the level of consumption of opioid analgesics as reported by countries to INCB against the estimated number of people in need of palliative care (according to the Global Atlas of Palliative Care) confirms the global imbalance in the consumption of such substances: only high-income countries registered significant levels of consumption, with a corresponding number of people in need of pain relief, whereas most countries are clustered together in the lower levels as a result of the high level of consumption in a few countries.

Determining the global availability of psychotropic substances remains a challenge because only since 2011 have countries been requested to provide consumption data, and no more than half of countries provided any consumption data in 2020. Despite that situation, some key trends have emerged, namely regional disparities in the consumption of severely psychotropic substances. For example, consumption of anti-epileptic drugs, including clonazepam and phenobarbital, are low in Africa, Asia and Oceania relative to the Americas and Europe despite these substances being among the most traded psychotropic substances. Similarly, there are significant regional disparities in the consumption of
methylphenidate despite reports suggesting that prevalence levels of attention deficit hyperactivity disorder are not so different between regions.

Consumption of methadone and buprenorphine is concentrated in a limited number of countries. Even though estimates of the number of people injecting drugs are incomplete, there is evidence that in some countries, despite the existence (more or less prevalent) of that phenomenon, the consumption of buprenorphine and methadone, and also the presence of opioid agonist therapy services, are limited or not present at all.

The timely delivery of controlled substances for medical care in emergency situations is sometimes problematic, in part because there are additional administrative requirements for the international movement of such substances. The international community has long noted the urgent need for a practical solution to that administrative obstacle. The Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care, published by WHO in 1996, reflect the concerted effort to expedite the supply of controlled substances during emergency situations through simplified control measures.

In 2021, INCB also conducted with competent national authorities, international humanitarian organizations and related United Nations agencies a review and discussion of the lessons learned in the implementation of simplified control measures during emergency situations. The outcome document of those meetings, entitled “Lessons from countries and humanitarian aid organizations in facilitating the timely supply of controlled substances during emergency situations”, contains important actions that Governments can take to improve their emergency preparedness and sets out procedures that they can follow during emergency situations.

Since the beginning of 2020, the COVID-19 pandemic has created unprecedented challenges to the economies and public health systems of all countries. The lockdowns, border closures and social distancing measures adopted by most countries have put to the test the ability of the international community to ensure adequate access to and availability of internationally controlled drugs for those in need. The global supply chain of medicines has been adversely affected, as a result of both the disruption in the manufacturing of key starting materials and active pharmaceutical ingredients in some major manufacturing countries. Logistical challenges arising from border closures and other social distancing policies adopted by a number of countries also prolonged delays.

The analysis of the data and of the responses by Governments and civil society organizations to the questionnaires sent by INCB in 2022 shows that there has been some progress but that there are still important areas requiring action, not only by Member States but also by the international community.

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The Lancet Commission on Palliative Care and Pain Relief, for making available the latest data on the population in need of palliative care.

A number of civil society organizations contributed by responding to a specific questionnaire submitted to them through the Vienna NGO Committee on Drugs.

Last but not least, 96 competent national authorities provided valuable information by responding to the INCB survey.
I. Introduction

A. Availability of and access to controlled substances and the international drug control conventions

1. The drafters of the international drug control conventions on narcotic drugs (1961) and psychotropic substances (1971) gave prominence to the issue of ensuring availability of controlled substances for medical purposes, stating, in the preambles of the two conventions, that controlled narcotic drugs are indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability (Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol) and that psychotropic substances are indispensable and their availability should not be unduly restricted (Convention on Psychotropic Substances of 1971).

2. Despite the prominence given to the issue in the text of the conventions and the fact that the two conventions enjoy almost universal ratification, achieving adequate and affordable access to controlled medicines for the treatment of health conditions remains a distant goal in many countries, where people still suffer or die in pain or do not have access to the medications they need. At the same time as there is a lack of access to controlled medicines in many countries, other regions have experienced the negative health and social consequences of the non-rational prescription of controlled substances, resulting in an epidemic of opioid dependence and related overdose deaths.

3. In the past, the limited attention that Governments gave to the issue of availability of controlled substances for medical needs focused on opioid analgesics, while the problems associated with the lack of access to and availability of psychotropic substances were not always considered. Also, access to and availability of methadone and buprenorphine, which are used in the management of drug dependence, are still limited in some countries despite a significant prevalence of injecting drug use.

4. Beyond the 1961 Convention and the 1971 Convention, the importance of making internationally controlled drugs available for medical and scientific purposes has been increasingly mentioned in a number of decisions, resolutions, statements and declarations by Governments in various intergovernmental forums. This process culminated in 2015, when the gravity of the situation was recognized by the international community at the thirtieth special session of the General Assembly, on the world drug problem, at which Member States adopted the outcome document entitled “Our joint commitment to effectively addressing and countering the world drug problem”, containing, for the first time in a document on the world drug problem, a full section on access to internationally controlled drugs for medical and scientific purposes with specific operational recommendations. Those mostly reflected the recommendations formulated by the International Narcotics Control Board (INCB) in its supplement to the annual report of 2015 entitled Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes. Indispensable, adequately available and not unduly restricted.1

5. Since 2016, there have been a series of follow-up actions, in particular in the context of the Commission on Narcotic Drugs, giving continued attention to scaling up the implementation of international drug policy commitments on improving availability of and access to controlled substances for medical and scientific purposes. In 2018, INCB published a special report on the progress made by the international community in ensuring adequate access to internationally controlled substances for medical and scientific purposes. The present report is a further update on the progress made based on the information provided by Governments and civil society and on latest information provided by Governments on the consumption of opioid

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1 E/INCB/2015/1/Supp.1.
analgesics, as well as the number of people in need of palliative care (based on the latest data contained in the Global Atlas of Palliative Care published by the Worldwide Hospice Palliative Care Alliance and the World Health Organization (WHO)).

6. In 2020, in its resolution 63/3, the Commission on Narcotic Drugs called for the promotion of awareness-raising, education and training as part of a comprehensive approach to ensuring access to and the availability of internationally controlled substances for medical and scientific purposes.

7. In August 2020, INCB, WHO and the United Nations Office on Drugs and Crime (UNODC), aware of the fact that the restrictions related to the coronavirus disease (COVID-19) pandemic had, among other consequences, resulted in interruptions to the supply chain of medicines, issued a joint call on Governments to ensure that the procurement and supply of controlled medicines in countries met the needs of patients, both those infected with the COVID-19 virus and those who require internationally controlled medicines for other medical conditions.

8. That call underlined that there was a need to ensure access to controlled medicines such as sedatives and analgesics for intubation protocols for the treatment of patients with COVID-19. At the same time, it reminded Governments that non-COVID patients continued to require controlled medicines for the management of pain and palliative care, surgical care and anaesthesia, mental health and neurological conditions, and for the treatment of drug use disorders.

9. Countries were encouraged to request technical assistance and support from INCB, through its INCB Learning project, and from the UNODC-WHO-Union for International Cancer Control Joint Global Programme.

10. In 2021, the Commission on Narcotic Drugs, in its resolution 64/1, expressed its view on the impact of the COVID-19 pandemic on the implementation of Member States’ joint commitments to address and counter all aspects of the world drug problem. The Commission noted with concern the difficulties encountered by Member States in ensuring the continued access to and availability of internationally controlled substances for medical and scientific purposes throughout the world, and expressed appreciation for the work of INCB and UNODC, within their respective mandates, in supporting Member States to ensure the access to and availability of such drugs, as well as in raising awareness about the problem.

11. The Commission encouraged Member States to continue to address barriers to access to and availability of controlled substances for medical and scientific purposes while preventing their non-medical use or diversion into illicit channels, including those related to legislation, regulatory systems, health-care systems, affordability, the training of health-care professionals, education, awareness-raising, estimates, assessments and reporting, benchmarks for consumption of substances under control, and international cooperation and coordination, in particular with a view to ensuring improved responses to a possible future pandemic and other emerging threats.

12. At its sixty-fifth session, in 2022 – which also marked the forty-fifth anniversary of the WHO Model List of Essential Medicines – the Commission on Narcotic Drugs devoted attention to scaling up the implementation of international drug policy commitments on improving availability of and access to controlled substances for medical and scientific purposes (#nopatientleftbehind), as expressed in the Joint Call to Action of the Commission on Narcotic Drugs and the treaty-mandated entities of the United Nations system: INCB, UNODC and WHO.

13. Since the adoption of the outcome document of the thirtieth special session of the General Assembly, the international community has continued to follow up on the operational recommendations contained in the section devoted to ensuring access and availability to controlled substances for medical and scientific purposes.

14. The international community had been facing the twin problem of the inadequacy of access to controlled substances in some countries and the overprescription and overconsumption in other countries that led to an unprecedented epidemic. In 2020, the COVID-19 pandemic exacerbated those problems and created new ones. The COVID-19 pandemic that began in March 2020 has impacted on the availability of some medicines due to the trade and travel restrictions imposed globally. In addition, the pandemic may have worsened the epidemic of addiction and overdose. Social isolation, unemployment, fear and uncertainty throughout the pandemic are thought to have contributed to the rising number of overdoses and impaired outcomes for people living with opioid use disorder.

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falsification of medicines, have been reported. Changes in the drug market dynamics due to COVID-19 led to interruptions in the delivery of addiction treatment services, while social distancing resulted in drug use in circumstances of isolation, thus limiting the opportunity for response in the case of an overdose.

15. INCB, in its continuing effort to assist Governments and the international community, offer this second review of the progress in the implementation of the recommendations related to access to internationally controlled drugs for medical and scientific purposes. The Board reiterates the Joint Call to Action made at the sixty-fifth session of the Commission on Narcotic Drugs to ensure the achievement of one of the fundamental goals of the international drug control conventions: the safe and rational delivery of the best affordable drugs to those patients who need them while at the same time preventing the diversion of drugs for the purpose of abuse.

B. Availability and the 2030 Agenda for Sustainable Development

16. In line with its mandate, the International Narcotics Control Board, in cooperation with Governments, has the responsibility to ensure availability of controlled substances for medical and scientific purposes. Activities related to this are also linked to and assist the international efforts to achieve the 2030 Agenda for Sustainable Development.

17. The Sustainable Development Goals, adopted by the Member States of the United Nations in 2015, are a set of objectives and targets intended to guide countries in mobilizing their development efforts by addressing a range of social needs including education, health, social protection and employment, while tackling climate change and promoting environmental protection and sustainable development.

18. Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages) is at the centre of the commitments related to the availability of controlled substances. The targets under Goal 3 constitute an urgent call for a global partnership to ensure that medicines reach those in need. Those targets include achieving universal health coverage, including access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines for all (target 3.8), ending by 2030 the epidemic of AIDS (target 3.3), and strengthening the prevention and treatment of substance abuse, including narcotic drug use and harmful use of alcohol (target 3.5). Achieving universal health coverage also means that all people and communities receive health services including palliative care throughout the life course.

19. Achieving adequate availability of and access to controlled substances also implies empowerment and social inclusion for all. Reducing inequalities within and among countries (Sustainable Development Goal 10) contributes to equal opportunities to trade and in the consumption of medicines. Promoting peaceful and inclusive societies for sustainable development, providing access to justice for all and building effective, accountable and inclusive institutions at all levels (Goal 16) encourages countries to adopt non-discriminatory legislation and policies that give an effective role to competent national drug control authorities. Lastly, international cooperation and strong partnerships, as related to Goal 17, remain vital to ensuring uninterrupted licit trade and assistance between countries.

20. While the international community has committed to reaching those targets by 2030, availability of controlled substances for medical purposes remains an issue of serious concern in many parts of the world. In its special report of 2015, entitled Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes. Indispensable, adequately available and not unduly restricted, and its special report of 2018, entitled Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes, the Board concluded that notwithstanding the universally recognized medical indispensability of controlled substances, millions of people continue to suffer due to limited access to those medicines, thereby making this a major global health problem. Availability of and access to pain medication, including opioid analgesics and medicines used for opioid agonist therapy, as well as the medication required for the treatment of mental illnesses, remains low in many parts of the world. The Board has also highlighted that for people with drug use disorders, methadone and buprenorphine are either not available or not sufficiently available in many countries where there is a significant prevalence of people who use drugs, and, in that context, has recalled that the right to health of individuals dependent on opioids is also directly related to the availability and non-discriminatory access treatment.

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C. Methodology and background

21. It is the standard practice of INCB to periodically follow up with countries on the implementation of specific recommendations made by the Board. It also monitors the implementation of the general recommendations that it makes in its reports. Following up on the supplementary report for 2018, entitled Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes, in 2022, 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 those recommendations were based on those contained in the Board’s supplementary report of 2018. In total, competent national authorities from 96 countries responded, providing important information that is discussed in the present report. In addition, civil society organizations were also consulted and provided information that was also used for the preparation of this report.

22. The present report also contains an update on the availability of internationally controlled narcotic drugs, with a focus on opioid analgesics and psychotropic substances. Each year, INCB receives information on the amounts of narcotic drugs that competent national authorities estimate are required for consumption and report as having been 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 1961 Convention as amended by the 1972 Protocol, expressed in S-DDD, are calculated by dividing annual availability by 365 days; the result obtained is divided by the population, in millions (S-DDD$_{pm}$), 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$_{pm}$, INCB includes codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and tramadol. 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 information on the consumption in S-DDD$_{pm}$ has been compared with the information on the number of people in need of palliative care available in the Global Atlas of Palliative Care (2nd edition, 2020) published by the Worldwide Hospice Palliative Care Alliance and WHO, as calculated by the Lancet Commission on Palliative Care and Pain Relief.

23. The 1971 Convention does not foresee the reporting of consumption of psychotropic substances to the Board; therefore, the submission of data on the consumption of psychotropic substances is not mandatory under the 1971 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 (S-DDD$_{pt}$), during the year in question, and then by the defined daily dose.
II. Impediments to ensuring the adequate availability of controlled medicines

24. 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 2022 contained a general question, which had also appeared in previous surveys, about the factors that competent national authorities considered to be obstacles that unduly limited the availability of controlled substances for medical purposes. The analysis of the trend of the responses over the years (1995, 2010, 2014, 2018 and 2022) indicates a continuing decreasing trend in the mention of impediments associated with the requirements of the 1961 Convention and the 1971 Convention, such as onerous regulations and trade control measures. In 1995, more than 50 per cent of survey respondents cited onerous regulations as an obstacle to ensuring availability, while in 2022 fewer than 10 per cent of respondents did so. Similarly, trade control measures were first mentioned in 2014, in 22 per cent of the responses, but they were mentioned in only 14 per cent of responses in 2022. In 2022, more respondents cited limited financial resources and sourcing problems as an obstacle, and that increase is probably attributable to the COVID-19 pandemic, which resulted in varying degrees of social and economic difficulties on a global scale (see figures 1 and 2).

25. The obstacles to ensuring availability that are more closely related to cultural bias (cultural attitudes) and not necessarily based on evidence (fear of diversion, fear of addiction, fear of prosecution) had different trends. Fear of diversion and fear of addiction increased slightly in comparison with 2018, while fear of prosecution and cultural attitudes continued to decrease. Lack of training or professional awareness remained a major obstacle (26 per cent of responses), although it was cited slightly less in 2022 than in 2018.

Figure 1. Impediments to availability as mentioned by competent national authorities (2022)

Source: INCB survey of Member States, 2022.
Figure 2. Impediments to availability as mentioned by competent national authorities (1995, 2010, 2014, 2019 and 2022)

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.


26. The Board, as it did in 2018, asked civil society organizations to provide their view on the progress made. The Board received responses from 65 civil society organizations based in 36 countries. Most of the civil society organizations that answered were from Asia (22), followed by Africa (16), Europe (13), Central and South America (10), North America (3) and Oceania (1). When asked, 65 per cent of civil society organizations reported that they had first-hand data and/or knowledge of a lack of availability of controlled substances for patients, and provided relevant information in that regard. Civil society organizations reported several factors that, in the context of their work, unduly limited the availability of narcotic drugs and psychotropic substances needed for medical or scientific purposes. Among the main barriers mentioned were the lack of authorized or trained doctors to prescribe controlled substances, lack of access for patients in rural areas and the unaffordable cost of medicines (see figure 3).

Figure 3. Impediments in the availability of internationally controlled substances as reported by civil society organizations

Source: INCB survey of civil society organizations, 2022.
Implementation of recommendations

1. Member States

27. The outcome document of the thirtieth special session of the General Assembly, held in 2016, and the INCB supplementary report of 2015 on availability contain a series of operational recommendations relating to national legislation and regulatory systems, the health system, affordability, the training of health-care professionals, education and awareness-raising campaigns, and relating to estimates and the assessment of controlled substances. The questionnaire sent by INCB to countries in 2022 inquired about recent developments in those areas.

Legislation and regulatory systems

28. A total of 96 countries provided responses to the questionnaire of 2022. Of those, 60 per cent of countries reported that they had reviewed and/or changed their national legislation in the past five years, and 45 per cent had reviewed and/or changed their regulatory and administrative mechanisms in order to ensure accessibility of controlled substances and maintain adequate controls. One fifth of countries responding declared that the new or amended mechanisms affected availability of controlled substances. While competent national authorities of most countries referred to general changes, some countries referred to specific changes to measures related to cancer treatment and palliative care, electronic measures to facilitate prescription and the procurement of controlled substances or to allow the use of cannabis for medical purposes.

29. While nearly all countries do not allow for advertising of controlled substances to the general public (including on the Internet), a small number of countries stated that they had no legislation limiting advertising. In terms of sharing the promotion, information and advertising of controlled substances to the medical and pharmaceutical community, the majority of countries referred to regulatory systems in place to allow for information to be published in medical journals or other print media directed towards that community.

30. A small percentage of countries have in the past five years changed their regulations regarding the prescription of controlled substances so that a larger base of health-care professionals can prescribe opioid analgesics and psychotrophic substances. In 90 countries responding to the questionnaire only medical specialists may issue prescriptions for controlled substances, while in 68 countries general practitioners are allowed to do so without a special licence. In only 10 countries are nurses, including nurse practitioners, allowed to prescribe controlled substances (see figure 4). In addition, in 44 countries, the relevant legislation contains legal sanctions for doctors, pharmacists, nurses and other health personnel who make unintentional mistakes in the handling of opioids. Such legal sanctions are considered to be a major obstacle to rational and appropriate prescribing. Countries that have selected “others” specified practitioners such as midwives, paediatricians, anaesthesiologists and paramedics as well as dentists and dental surgeons and practitioners in private establishments requiring a special licence.

31. In 90 per cent of the countries responding, medical prescriptions for narcotic drugs and psychotropic substances were subject to more stringent regulations than were other prescription medications, including a shorter period of validity and the prohibition of automatic renewals. Three countries reported that prescriptions for medicines containing controlled substances were issued in electronic form only.
32. With regard to the validity of prescriptions for opioid analgesics, of the 90 countries that responded to the question, 12 countries had changed the period of validity of prescriptions for opioid analgesics during the last five years. Further details were provided by 68 countries (see figure 5), out of which 22 countries had a validity of one month for prescriptions and six countries had a validity longer than one month. Two countries responded that opioid analgesics could be prescribed for up to one year, and 20 countries had a maximum validity of less than one week for such prescriptions. Additionally, 17 countries responded that the validity of prescriptions depended on numerous factors, such as the classification of the opioid analgesic in domestic legislation and the medical evaluation of the individual patient.

Health system

33. The procurement of opioid analgesics and psychotropic substances alone will not solve the problem of the limited access experienced in many countries. Countries have been called upon to improve health systems to ensure that controlled substances were prescribed and administered in a rational and efficient manner. Specifically, in relation to opioid analgesics, it remains important for Governments to have a palliative care policy and an appropriate infrastructure in place. As in 2018, in the INCB questionnaire for 2022, countries were asked whether new palliative care policies had been introduced in response to resolution WHA67.19, adopted by the sixty-seventh World Health Assembly in 2014, entitled “Strengthening of palliative care as a component of comprehensive care throughout the life course”. Altogether, 53 per cent of countries responding in 2018 and 56 per cent of countries responding in 2022 indicated that palliative care measures and policies had been introduced in their countries.

Affordability

34. The questionnaire also contained a question on whether countries have an appropriate and well-resourced health infrastructure and system that ensures the availability of opioid analgesics for the delivery of pain and palliative care. In this regard, 15 per cent of countries considered that their infrastructure and system were entirely appropriate and 38 per cent considered them to be appropriate. About 35 per cent of countries consider their infrastructure and system to be in need of some improvement and 12 per cent considered them to be in need of significant improvement.

35. Competent national authorities were also asked whether, to their knowledge, their Government had implemented low-cost, home-based palliative care services. In response, a slight majority (57 per cent) responded positively. In many countries, these services are partially or fully integrated in the national health-care system and/or funded (fully or partially) by the Government. Some countries indicated that while home-based palliative care services existed in their country, they were not covered by insurance schemes and needed to be fully covered by the patient.

36. In response to a question on what steps had been taken so that the distribution of opioid analgesics and psychotropic substances could reach all areas of the country, including rural areas, some countries indicated that distribution across their country was ensured through a centralized government agency responsible for distribution, while other countries had established local distribution channels. An important measure taken was to have enough hospitals and pharmacies strategically placed throughout the territory. Some countries indicated that the system for distribution required improvement.
been included in the national list of essential medicines and steps had been taken for their procurement. Eight countries indicated that no steps in that regard had been taken in the past five years.

39. In addition, the majority of countries responding (75 per cent) reported they had sufficient resources and budget for the purchase of opioid analgesics. The remaining 25 per cent indicated that they did not have sufficient budget and resources for the purchase of opioid analgesics, most of them citing a limited or reduced budget and a general lack of resources to meet increased demand.

Training of health-care professionals

40. The training of health-care professionals, which is a fundamental requirement for patients to have access to opioid medication, continues to be lacking in many Member States, and 26 per cent of responding countries cited lack of training as an impediment to availability. Lack of training and awareness among health professionals may be a result of gaps in the educational curricula of medical schools.

41. More than 70 per cent of countries responding, a large majority, reported that pain and palliative care were included in the educational curricula of medical schools and in the training of all health professionals, although it was not mandatory in some. In 75 per cent of countries responding, health-care professionals were provided with continued education, training and information on pain and palliative care, including on the rational use and the importance of reducing prescription drug abuse.

42. When it comes to updates of the educational curricula of medical schools and other mandatory and educational health-care training related to prescribing and dispensing controlled medicines, specifically on the rational prescribing and use of narcotic drugs and psychotropic substances, 51 per cent of countries responding reported no updates to training or curricula in the past years or not being aware of any such updates. Only 17.5 per cent or countries responding reported that curricula and training on prescribing and dispensing of controlled medicines was already in place.

43. Lack of training and updated knowledge may in effect lead doctors and other health-care professionals to assign low priority to pain management as they do not trust the patients’ assessments of their pain and/or underestimate the degree of relief that can be attained through proper treatment, misjudging the need to use opioids such as morphine and overestimating the side effects of opioids, for example, the risk that a patient may become dependent.

44. In the same manner, nurses and health workers that lack proper training in the rational use of controlled substances may act as an additional obstacle between patients and the pain treatment they need, whereas well-trained nurses and other health workers can play an important role in assisting patients and families with their concerns, helping them to learn to safely manage opioid analgesics that are prescribed by the responsible health professional and to administer the correct dosages that the patient requires.

Education and awareness-raising

45. Also key to the issue of availability is ensuring that patients and communities are educated and aware of the importance of treating pain and mental health conditions, the advantages and risks of controlled substances, and the options that are available to patients.

46. Several countries have reported to the Board on the activities that have been promoted in their territories in the area of education and awareness-raising. These have benefited the general public, civil society organizations, patient groups, university students, the pharmaceutical community, doctors and pharmaceutical companies. Figure 6 shows all groups of initiatives that have been implemented by Member States in the last five years.

Figure 6. Education and awareness-raising initiatives in the last five years (2017–2022)

Source: INCB survey of Member States, 2022.

47. The largest number of activities (41 activities) reported were related to educational programmes for the pharmaceutical community involving community and
hospital pharmacists, followed by public awareness-raising through the media (37 activities). Responding countries also reported initiatives in the areas of support campaigns and efforts targeting the general public to prevent the non-medical consumption of controlled substances and encourage the active participation of the medical and pharmaceutical community in all measures related to the rational use of controlled medicines; the promotion of ethical attitudes among medical doctors and pharmaceutical companies, the provision of training and continued education for health-care professionals to encourage a better-justified and more rational use of psychotropic substances; and the inclusion of education on pain and palliative care in the curricula of medical and non-medical educational institutions.

Estimates and assessments

48. Estimates and assessments are the core of the international drug control system established by the 1961 Convention and the 1971 Convention. Nevertheless, many countries struggle to produce estimates and assessments that reflect the real need of patients in their territories. Many countries, Governments and competent national authorities are not aware of the inadequacy of the level of consumption of controlled substances in their territory or that their estimates and assessments do not adequately reflect the needs of the population.

Figure 7. Responses to the question “Are your country’s estimates of requirements of narcotic drugs and assessments of requirements of psychotropic substances appropriate and realistic in relation to the needs of patients?”

Source: INCB survey of Member States, 2022.

49. Almost all responding countries reported that their competent national authorities were aware of the Guide on Estimating Requirements for Substances under International Control, developed by INCB and WHO in 2012, and used it at least to some degree, and almost all of them (all except for two countries) considered that their estimates were, at the very least, “appropriate and realistic to some extent” (see figure 7). However, the low levels of consumption of opioid analgesics in many parts of the world, especially in low- and middle-income countries, is evidence that the needs of patients are not always appropriately reflected in the estimates of some Member States.

50. Although most countries are familiar with the Guide on Estimating Requirements for Substances under International Control and reported using it, only 28 countries reported preparing their estimates of requirements based on hospital surveys, and 26 countries based their estimates on health and morbidity surveys (with some possible overlaps in the methods employed) (see figure 8). Of those countries that indicated “Other” method used to estimate national needs for controlled substances, 26 countries specified that they used the consumption-based method, which uses recent years of consumption to estimate needs. Many of those countries also combine those data with statistics from manufacturers, wholesalers and licensed importers. Although estimates based on consumption provide the best data for decision makers and national competent authorities to define priorities and needs for controlled substances, they may often be resource-intensive, and some countries may find it difficult to conduct them often. The lack of surveys may be mitigated by periodic consultations with civil society, including non-governmental organizations supporting communities, including in rural areas, as well as patients and doctors associations.

Figure 8. Instruments used by Member States to measure needs of patients for narcotic drugs and psychotropic substances

Source: INCB survey of Member States, 2022.
Note: The results shown in the figure are based on replies submitted by countries and territories in response to a specific multiple-choice question. Respondents could choose one or more responses to the question.
II. IMPEDIMENTS TO ENSURING THE ADEQUATE AVAILABILITY OF CONTROLLED MEDICINES

2. Civil society organizations

Legislation and regulatory systems

51. Sixty-five civil society organizations answered the questionnaire and reported on progress with respect to measures taken in their respective countries to implement the recommendations adopted in the outcome document of the thirtieth special session of the General Assembly, on the world drug problem, held in 2016. They reported positive changes in the area of legislation and regulations aimed at simplifying and streamlining processes in order to remove unduly restrictive regulations and thus ensure accessibility of controlled substances and maintain adequate control systems.

52. Approximately 25 per cent of the civil society organizations responding had observed an increase in the 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 in order to increase availability, in particular in remote or rural areas. Other measures to improve availability included the prescription of controlled medication using telecommunications technology. Two organizations reported that new legislation or regulations were being developed. Three organizations mentioned changes of regulation in the specific field of palliative care.

53. On the other hand, 52 per cent of civil society organizations reported no changes in their country regarding the prescription of controlled substances that would allow a larger base of health-care professionals to prescribe opioids and/or psychotropic substances in order to increase availability, in particular in remote or rural areas. Other measures to improve availability included the prescription of controlled medication using telecommunications technology. Two organizations reported that new legislation or regulations were being developed. Three organizations mentioned changes of regulation in the specific field of palliative care.

54. In the countries allowing the legal use of cannabis for medical and scientific purposes, civil society organizations reported highly restrictive regulations to control access to the substance. This has led patients to procure the cannabis they need from illicit sources. Another issue reported was the lack of knowledge among doctors about the use of cannabis for medical purposes.

55. Fifty per cent of civil society organizations (33 of 65) were of the view that in their country no changes had been made in terms of legislation due to the COVID-19 pandemic or other political challenges that occurred in the last years. Another, 30 per cent of the civil society organizations (20 out of 65) reported that their country had been implementing legislative and administrative changes with regard to the recommendations contained in the outcome document of the special session of the General Assembly and in the supplement to the annual report of the Board for 2015 on the availability of internationally controlled substances.

56. Civil society organizations in seven countries reported new initiatives for training large numbers of health professional in the use of opioid analgesics for the treatment of pain. The development of national programmes focusing on or including palliative care was also mentioned.

57. Five civil society organizations stated that restrictive legislation and cumbersome administrative procedures still played an important role in limiting access to controlled substances, leading underresourced health-care services to avoid procuring and administering controlled substances to a preference to prescribe other medicines, such as tramadol and tapentadol, which are not internationally controlled and which civil society organizations consider to be easily accessible.

Health systems

58. About half (34) of the civil society organizations that responded to the questionnaire reported that although availability may seem to be adequate when seen at the national level in some countries, in the rural areas, including in some high-income countries, inadequate availability remained a problem. It was also reported that inadequate availability affected particular population groups, such as indigenous people, children and people living on the street.

59. Approximately 50 per cent of the civil society organizations noted that it continued to be the case that only a limited number of physicians were able to prescribe. That situation, combined with issue of accessibility throughout the national territory, is considered a main obstacle in several countries.

60. Other challenges reported by civil society include the concern of some medical professionals, sometimes unfounded, about the risk of dependence related to opioid use. It is reported that some medical practitioners from various countries express hesitation to prescribe controlled substances despite demand from patients and the supporting scientific evidence from research about the proper and rational use of opioids.

61. Also, the prescription of cannabis for medical purposes has been a matter of concern because of differing views within the medical community, resulting in inconsistent prescription practices, with patients reporting dissatisfaction about the treatment options offered.
Affordability

62. Approximately 30 per cent of civil society organizations (21 in total) reported the price of some medicines to be an impediment to accessibility. Two of them reported that there was lower utilization and adherence to prescribed medication regimens owing to the cost and financial barriers. They reported that patients frequently turned to the illicit market to procure their medications, often buying falsified products that posed considerable risk to their health. The loss of purchasing power due to the COVID-19 pandemic has led some families to reduce or suppress their purchases of medicines. Additionally, treatment and rehabilitation for drug dependence in prison settings, including the availability of controlled substances such as methadone and buprenorphine for medically assisted therapy, were further limited due to budgetary restrictions.

Training of health-care professionals

63. About 52 per cent of the civil society organizations were directly engaged in education and training activities related to access to controlled substances. Also, about 75 per cent reported having undertaken educational and awareness-raising initiatives in that area. Seven of the responding civil society organizations mentioned educational and awareness-raising initiatives specifically in the area of palliative care. Most organizations reported that training was still much needed because while controlled medicines might in theory be available in many countries, some doctors were reluctant to prescribe in some of those countries as a result of partial understanding of the risks and benefits of the substances.

64. With respect to the effects of the lack of knowledge among doctors, civil society organizations reported inappropriate prescribing of medicines containing controlled substances. The doctors’ lack of knowledge also related to the possible legal use of cannabis and cannabis-derived substances for medical purposes.

Role of civil society organizations

65. Civil society organizations were asked whether they were consulted in the process of preparing national estimates for the consumption of narcotic drugs and/or psychotropic substances. Only 35 per cent (23 out of 65) answered that they were part of the process. Some civil society organizations responding were not specialized in the area of ensuring availability of controlled substances for medical purposes and therefore could not legitimately be consulted by competent national authorities.

66. While 35 per cent of the responding organizations were aware of the simplified control measures in the import and export of controlled substances in emergency situations, only 3 civil society organizations (or 5 per cent) out of 65 in total provided narcotic drugs and/or psychotropic substances to countries with insufficient availability. Again, this may be a result of the limited number of civil society organizations directly involved in the specific area of ensuring availability.
III. Narcotic drugs

67. Since the publication of the supplement to the annual report of the Board for 2018, entitled *Progress in Ensuring Adequate Access to Internationally Controlled Substance for Medical and Scientific Purposes*, the issue of ensuring adequate access has continued to be analysed and studied by experts, researchers and policymakers. The analysis of the inadequacy of access to and availability of pain medications was helped by the ground-breaking report of the Lancet Commission on Palliative Care and Pain Relief, which visualizes in innovative ways the reality of the global divide in access to opioid analgesics by plotting the data on the availability of opioid analgesics for consumption as reported to INCB by competent national authorities against the estimated amount needed for health conditions most associated with serious health-related suffering (an indicator developed by the Commission on the basis of existing health data and statistics).

Opioid crisis

68. The North American opioid crisis is the result of a number of factors but started when limited regulations allowed the exponential increase of opioid prescribing, particularly of potent opioids, such as oxycodone and fentanyl, and the expansion of their use for a broad range of chronic pain conditions. The result was an enormous increase in overdose deaths and the number of people addicted to opioids. When Governments introduced measures to control the prescription of opioids, people who had become dependent turned to heroin, which was often laced with fentanyl, making the situation even more tragic in terms of overdose deaths.

69. The Stanford–Lancet Commission on the North American Opioid Crisis underlined the need to reform regulatory systems to avoid profit-driven overprovision of addictive controlled substances. It also recommended continuous financial support for the care of people with substance use disorder and for social programmes for safe disposal of opioid pills and substance use prevention. The Commission also noted that while preventing overprescription of controlled substances was essential, it was also necessary to provide generic morphine to low- and middle-income countries for adequate pain and palliative care management. There are indications that some of the patterns of the opioid epidemic experienced in North America may be being replicated in other regions, but it seems that this is not driven by the overprescription or non-medical use of prescription opioids but by the trafficking of illicitly manufactured synthetic opioids.

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

70. Opiates consumed by patients for medical treatment are obtained from opiate raw materials (opium, poppy straw and concentrate of poppy straw). Adequate availability of opiate raw materials for the manufacture of opiates is therefore a precondition for ensuring the adequate availability of opiates used for medical and scientific purposes. Assisting Member States in ensuring this availability is one of the key functions of the Board and is enshrined in the preamble of the 1961 Convention.

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

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5 The latest data available at the time of writing of this report were for 2020. Since then, data for 2021 have been received and are available in the technical report of the Board for 2022 on narcotic drugs (E/INCB/2022/2).

year to ensure the availability of opiates used for medical and scientific purposes in the event of an unexpected decline in production resulting from, for example, adverse weather conditions in producing countries.\(^7\)

72. The inadequate global distribution in the consumption of opiates does not seem to be the result of a lack of supply of raw materials and opioids. On the contrary, the data received by the Board in at least the past decade has shown that the supply of opiate raw materials at the global level is more than sufficient to cover the global demand as expressed by competent national authorities. However, this is established on the basis of the estimates expressed by government authorities and many of them seem not to be able to properly assess the needs of their populations. The Board had also on several occasions shared its concerns with major producers and major importers of opiate raw materials about the possible excessive accumulation of stocks and the need to prevent diversion of controlled substances into illicit channels. However, the data available to the Board indicate that there are significant disparities between countries in the availability of narcotic drugs because many countries do not accurately estimate their medical needs for opioid analgesics or have limited access to them. Consequently, in its annual and technical reports the Board has called upon those countries with greater resources to assist other countries in their efforts to ensure access to and the availability of substances for the treatment of pain.

73. At the end of 2020, global stocks of opiate raw materials rich in morphine were sufficient to cover global demand for 21 months. Global stocks of opiate raw materials rich in thebaine were sufficient to cover global demand for 18 months. In 2020, the global production of opiate raw materials rich in morphine was greater than the utilization of those materials. The global supply (stocks and production) of opiate raw materials rich in morphine was fully sufficient to cover global demand. As at the time for which data were available (end of 2021), the plans of producing countries indicated that global production of opiate raw materials rich in morphine was to increase in 2021 and 2022, as was the demand for those raw materials. Total stocks of opiate raw materials rich in morphine were expected to decrease notably in 2021 compared with 2020, but were then expected to increase slightly in 2022. The global supply (stocks and production) of opiate raw materials rich in morphine would continue to be sufficient to cover fully the global demand at the projected levels.

74. Figure 9 presents data on the manufacture, stocks, consumption and utilization\(^7\) of morphine during the period 2001–2020. Global manufacture of morphine was increasing considerably from 2001 until 2012, when it peaked at 475 tons, after which it started decreasing and in 2020 it was lower than in 2001 (309 and 316 tons respectively). However, it needs to be taken into account that the sharp decline in manufacture in 2020 compared with 2019 (when it was 380 tons) may be due in part to the difficulties posed by the COVID-19 pandemic.

75. Until the 1990s, thebaine, the other main alkaloid obtained from opium poppy, was manufactured mainly from opium; since 1999, it has been obtained primarily from poppy straw. Thebaine may also be obtained through the conversion of oripavine or from semi-synthetic opioids, such as hydrocodone. Thebaine itself is not used therapeutically, but it is an important starting material for the manufacture of a number of opioids, mainly codeine, dihydrocodeine, etorphine, hydrocodone, oxycodone and oxymorphone (all of which are controlled under the 1961 Convention) and buprenorphine (which is controlled under the 1971 Convention). Global manufacture of thebaine has increased sharply since the late 1990s, as a consequence of the growing demand for oxycodone and other drugs and substances that may be derived from it, but it has been declining since 2016, possibly as the result of stricter local regulations for controlled substances.

\(^7\)E/INCB/2014/1, para. 90.

\(^8\)“Consumption” indicates the quantity of the drug to be consumed directly for domestic medical and scientific purposes, while “utilization” refers to quantity of the drug to be utilized for the manufacture of other drugs, preparations included in Schedule III of the 1961 Convention or substances not covered by the 1961 Convention.

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**Figure 9. Morphine: global manufacture, stocks, consumption and utilization,\(^a\) 2001–2020**

Source: International Narcotics Control Board.

\(^a\) Stocks as at 31 December of each year.
control measures on strong opioids, such as oxycodone, that were manufactured from thebaine (see figure 10).

76. Codeine is a natural alkaloid of the opium poppy plant, but most of the codeine currently manufactured is obtained from morphine through a semi-synthetic process. There has been an increase in the cultivation of the opium poppy variety that is rich in codeine and in the manufacture of concentrate of poppy straw rich in codeine, which is used for the extraction of codeine. Codeine is used mainly for the manufacture of preparations in Schedule III of the 1961 Convention. Utilization of codeine for this purpose amounted to 212.5 tons in 2020, or 98.9 per cent of the global consumption of codeine, while the remaining quantity of approximately 1 per cent of the global total was used for the manufacture of other narcotic drugs, such as dihydrocodeine and hydrocodone. The trends relating to global manufacture, consumption, utilization and stocks of codeine during the period 2001–2020 are shown in figure 11.

77. Global demand for opiate raw materials rich in mor-
phine and rich in thebaine may rise in the future because of the expected increase in the demand from countries that consume low levels of opioid analgesics. It is anticipated that global demand for opiates and opiate raw materials will also continue to rise. Figure 12 presents the global level of consumption of opiates and synthetic opioids, including buprenorphine and pentazocine, which are opioids controlled under the 1971 Convention, during the period 2001–2020. To allow the aggregation of consumption data for substances that have different potencies, the levels of consumption are expressed in billions of S-DDD.

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*Global consumption* is a term used by INCB to reflect the total of the amount of a drug that is directly consumed and the amount that is utilized for the manufacture of preparations listed in Schedule III of the 1961 Convention as amended.
78. Over the past 20 years, global consumption of opioids has more than doubled. The share of consumption of opiates in total consumption of opioids fluctuated, rising from 51 per cent in 2008 (the lowest share) to 65 per cent in 2014 (the highest share). In 2020, the share of opiates decreased to 61 per cent, compared with 63 per cent in 2019. This indicates that the use of synthetic opioids, which are used for the same indications as opiates, increased in 2020 to 39 per cent, compared with 37 per cent share in 2019. The overall trend indicates that the demand for opiates might increase in the future, but it is not clear whether their share in total consumption of opioids will increase or decrease in relation to the consumption of synthetic opioids.

B. Adequacy and trends in the consumption of opioid analgesics

79. According to the data available to INCB, in the 20-year period 2001–2020, the manufacture\(^{10}\) of morphine increased considerably, from 315.8 tons manufactured in 2001 to 475.3 tons in 2012, when the global morphine manufacture reached its peak. In 2020, the global production of morphine was 308.8 tons, a considerable decrease from the 380 tons manufactured in 2019. In 2020, 77.6 per cent of the morphine manufactured globally was converted into other narcotic drugs or into substances not covered by the 1961 Convention as amended. The rest was used directly for medical purposes (for direct consumption and for the utilization to manufacture preparations listed in Schedule III), mainly for palliative care.

80. In 2001, morphine used for direct consumption amounted to 23.4 tons, or 7.4 per cent of the total morphine manufactured; 20 years later, in 2020, it stood at 35.3 tons, or 11.4 per cent – the greatest percentage used for direct consumption in recent years. Nevertheless, many countries continue to report having difficulties procuring morphine although opiate raw materials are reported to be available in sufficient quantities. The problem is that almost all the morphine available is being used for the production of codeine that is then mainly used for the manufacturing of Schedule III preparations, with only a small amount being used directly for medical purposes (such as palliative care).

81. In the 20 years from 2001 to 2020, of the total amount of morphine utilized globally, on average only 9.5 per cent was reported to have been used for palliative care directly. Smaller amounts have been used for the manufacture of other narcotic drugs (3.9 per cent), Schedule III preparations containing morphine (2.4 per cent) and substances not covered by the 1961 Convention (1.6 per cent). The majority (82.7 per cent on average) has been converted into codeine (see figure 13).

Figure 13. Utilization of morphine, average 2001–2020

\[\text{Source: International Narcotics Control Board.}\]

82. The share of morphine used for direct consumption has not changed considerably in the past 20 years and the disparity in the consumption of narcotic drugs for palliative care continues to be a matter of concern, particularly in relation to access and availability of affordable opioid analgesics such as morphine. In 2020, nine countries, mainly in North America and Western Europe, accounted for 82.1 per cent of the morphine used for the management of pain and suffering: those countries reported consumption between 1.3 tons and 13.1 tons (see figure 14).

83. The patterns of consumption of opioid analgesics as expressed in S-DDD\(_{\text{pm}}\) provide a picture of the different levels of consumption in various countries, but they do not provide information on the adequacy of the consumption in relation to the medical needs.

84. Information from the Global Atlas of Palliative Care (2nd edition, 2020) by the Worldwide Hospice Palliative Care Alliance and WHO provides an overview of the global need for palliative care. In the Global Atlas, it is stated that despite modest improvements in the development of palliative care services, significant inequities remain both between and within countries. Data from the Lancet

\(^{10}\)In Australia, China, Italy, Norway, Türkiye and the United Kingdom of Great Britain and Northern Ireland, concentrate of poppy straw is used in continuous industrial processes for the manufacture of other narcotic drugs, without first separating morphine. For statistical and comparative purposes, the theoretical quantity of morphine involved in such conversions is calculated by INCB and included in the present publication in the statistics on global manufacture and utilization of morphine.
Commission on Palliative Care and Pain Relief and the Global Atlas show that worldwide, over 65 million people are estimated to require palliative care every year and that palliative care services are still not accessible by most people in need, especially in low- and middle-income countries. The Western Pacific region, Africa and South-East Asia account for over 64 per cent of all adults in need of palliative care, while Europe and the Americas accounts for 30 per cent, and the Eastern Mediterranean region accounts for 4 per cent.

85. The Global Atlas reports on similar inequities as drawn from the WHO survey to assess the capacity of countries for the prevention and control of non-communicable diseases. The 2019 survey included questions about the level of palliative care policy and development. In relation to the capacity of countries to deliver palliative care services, the survey found that just 48 per cent of Governments of low-income countries funded them, while 91 per cent of Governments of the high-income group of countries provided funding for palliative care services. Also, in relation to the availability of oral morphine in public primary care facilities, it found considerable differences between the different income groups (see figure 15).

86. The data available to INCB indicate that in the period 2018–2020, in various countries there was an overall increase in the level of reported consumption in S-DDDpm compared with previous decades (comparing with data for the periods 1998–2001 and 2008–2010) (see map 1). In particular, there was visible progress made with regard to the availability in Latin America, as gradually more and more countries reported falling within the categories of more than 200 S-DDDpm or more than 1,000 S-DDDpm. Actual consumption of opioid analgesics in Latin America could be even greater than reported because methadone, which is not included in the global S-DDDpm calculation because of its prevalent use in opiate agonist therapy, is used for pain relief in this region more frequently than in others. Very little methadone is used for opioid agonist therapy in Latin America since the prevalence of heroin abuse is relatively low.

87. In addition, the amount of codeine reported is only that reported as direct consumption. There are some preparations mixing paracetamol and codeine that are used in some countries to treat pain, but those quantities are reported to INCB as Schedule III preparations and therefore are not accounted for in the calculation of consumption for pain relief because it is not possible to distinguish the quantities used for that purpose from preparations used as cough suppressants. In addition, there are some opioid analgesics, such as tramadol, that are used for the treatment of pain that are not under international control. Their use is quite extensive in some countries, and a lower consumption of internationally controlled substances may to a small extent be due to the use of tramadol and tapentadol as a substitute for pain treatment.

88. Over the years, there have been significant increases in the overall consumption of opioid analgesics in Western Europe, with more countries reporting consumptions levels
between 5,000 and 10,000 S-DDD pm or between 10,000 and 20,000 S-DDD pm. In North America, the United States of America continued to report consumption above 20,000 S-DDD pm while reported consumption in Canada decreased below 20,000 S-DDD pm in the period 2018–2020. The decrease may be the result of control measures introduced in Canada to address the opioid epidemic. Similar measures introduced in the United States seem to have reduced the consumption of strong opioids, but those measures did not significantly diminish overall consumption of opioid analgesics in the country. The consumption of opioid analgesics in the Russian Federation and in Eastern Europe rose, with more countries reporting consumption over 200 S-DDD pm or 1,000 S-DDD pm. However, the situation remains problematic in most of Africa and parts of Asia: most countries in those regions continued to report consumption in the categories of below 200 S-DDD pm or below 100 S-DDD pm.

Availability of opioids for pain management, average for the period 1998–2000

Availability of opioids for pain management, average for the period 2008–2010

Availability of opioids for pain management, average for the period 2018–2020

Source: International Narcotics Control Board.

Note: 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. A 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).
89. A longitudinal analysis of the data on the global availability of opioid analgesics shows a steep increase in the opioids available for consumption, from an average of 202 S-DDD in the period 1978–1980 to an average of 2,827 S-DDD in the period 2008–2010, after which there was a significant decrease to 2,025 S-DDD in the period 2018–2020 (see figure 16). The decrease was mainly due to the reduced reported consumption of strong opioids (oxycodone and fentanyl), mainly in North America, (see figure 17), while consumption in Europe and Oceania (Australia and New Zealand) remained stable at a lower level. In the rest of the world, there seems to be a slight increase on top of a much lower level of consumption. Figure 18 shows the same data as figure 17 but uses a semi-logarithmic scale in order to display trends in all regions in a more compact view. South Asia, Africa, Central America and the Caribbean and East and South-East Asia remain the regions with the lowest levels of reported consumption. Eastern Europe, West Asia, South America and South-Eastern Europe have improved, gradually but significantly, the levels of their consumption over the years. The values for regional S-DDD are calculated on the basis of the total population of the countries reporting consumption and the overall amounts of opioid analgesics reported as consumed.

90. The inadequate distribution of the consumption of opioid analgesics is also evident if, instead of considering consumption by regional grouping, the income classification used by the World Bank ranking countries based on gross national income per capita, in United States dollars, is considered (see, in this regard, figures 19 and 20).
A comparison of the consumption of individual substances is based on the consumption of the main opioid analgesics (codeine, fentanyl, hydrocodone, hydromorphone, morphine and oxycodone), expressed in S-DDD (see figure 21), shows the predominance of fentanyl over the past two decades. However, after peaking in 2018 at 285,959 S-DDD, global consumption of fentanyl decreased to 235,074 S-DDD in 2019 and remained relatively stable, with a slight decrease in 2020, declining to 233,636 S-DDD. The consumption of oxycodone has been increasing, although remaining at a lower level, and, since 2009, has replaced morphine as the second most-consumed opioid (after fentanyl). Like fentanyl, consumption of oxycodone reached an all-time high in 2018 (45,726 S-DDD), decreasing to 44,821 S-DDD in 2019 and fell further, to 42,099 S-DDD in 2020. The trend in the use of morphine, on the other hand, remained relatively stable between 2004 (25,644 S-DDD) and 2019 (27,957 S-DDD), but in 2020 it increased to 31,824 S-DDD, the highest level of consumption since 2002. After decreasing steadily starting in 2014, hydrocodone consumption (almost exclusively in the United States) increased from 14,161 S-DDD in 2018 to 20,415 S-DDD in 2019 but decreased to 18,366 in 2020. The consumption of codeine for pain management decreased from 5,720 S-DDD in 2018 to 4,591 S-DDD in 2019 but increased to 4,665 S-DDD in 2020. Hydromorphone consumption decreased from 11,834 S-DDD in 2018 to 7,713 S-DDD in 2019, the lowest level since 2008, but increased to 8,528 S-DDD in 2020.
92. Figures 22 and 23 show consumption of opioid analgesics in total S-DDD$_{pm}$ per day, by region. The figures show once again the predominance of fentanyl in most regions of the world. Oxycodone consumption is highest in North America, Oceania, Western and Central Europe and West Asia, although it is also consumed in other regions. Hydrocodone consumption is significant in the Americas. The share of morphine is less pronounced in most regions, except for Africa and South America.

93. Another way to present the situation is to plot the level of consumption of opioid analgesics as reported by countries to INCB against the estimated number of people in need of palliative care (according to the Lancet Commission on Palliative Care and Pain Relief and the Global Atlas of Palliative Care) confirms the global imbalance in the consumption of such substances, as only high-income countries reported levels of consumption adequate for the estimated number of people requiring pain relief. Figure 24 shows the result of the comparison: most countries are clustered together at a low level of consumption compared with the high level of consumption in a few countries. However, if a semi-logarithmic scale is used (see figure 25), it is possible to see the differences between the various income groups in a more compact view.

94. Figure 26 below shows the ratio between the number of defined daily doses for statistical purposes per million inhabitants (S-DDD$_{pm}$) per day and the number of people in need of palliative care. The resulting ratios have been plotted on a logarithmic scale for a compact display of the wide range of values between the different income groups. The vertical length of the boxes in the figure depict the difference between the ratio of reported consumption per million inhabitants and estimated number of people in need per million inhabitants. Figure 26 confirms that the inequalities are related not only to the levels of consumption but more importantly to the level of consumption in relation to medical need, with low-income countries at the bottom of the scale and high-income countries at the top. The inequality in access to opioids is also evident when the trends in consumption are presented according to the income groups of the various countries. Consumption in high-income countries is well above the rest of the world (see figure 19).
Figure 24. Relationship between palliative care need (2017) and consumption of narcotic drugs in defined daily doses for statistical purposes per million inhabitants per day (average, 2018–2020)

Source: International Narcotics Control Board and Lancet Commission on Palliative Care and Pain Relief, as reported in Worldwide Hospice Palliative Care Alliance and WHO, Global Atlas of Palliative Care, 2nd ed. (2020).

Figure 25. Relationship between palliative care need (2017) and consumption of narcotic drugs in defined daily doses per million inhabitants per day (average, 2018–2020) (semi-logarithmic scale)

Source: International Narcotics Control Board and Lancet Commission on Palliative Care and Pain Relief, as reported in Worldwide Hospice Palliative Care Alliance and WHO, Global Atlas of Palliative Care, 2nd ed. (2020).
Figure 26. Ratio between defined daily doses for statistical purposes per million inhabitants (average, 2018–2020) and number of people in need of palliative care per million inhabitants (2017) (logarithmic scale)

Source: International Narcotics Control Board and Lancet Commission on Palliative Care and Pain Relief, as reported in Worldwide Hospice Palliative Care Alliance and WHO, Global Atlas of Palliative Care, 2nd ed. (2020).

Map 2. Number of people in need of palliative care per million, 2017


Note: 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. A 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).
Map 3. Availability of opioids for pain management, average for the period 2018–2020

Source: International Narcotics Control Board.

Note: 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. A 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. Psychotropic substances

A. Supply of psychotropic substances controlled under the 1971 Convention

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

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

99. The licit market for internationally controlled psychotropic substances has historically been and continues to be dominated, in terms of gross weight, by sedatives, in particular those from the benzodiazepine and barbiturate substance families. As can be seen in figure 27, sedatives comprised more than 80 per cent of the manufacture of all internationally controlled psychotropic substances from 2011 to 2020, except in 2017, when it dipped to 77.8 per cent. In the same period, stimulants comprised 10 to 18 per cent of all manufacture. Other psychotropic substances have never exceeded a 4 per cent share of total global manufacture in that time frame.

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

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

The latest data available at the time of writing of this report were for 2020. Since then, data for 2021 have been received and are available in the technical report of the Board for 2022 on psychotropic substances (E/INCB/2022/3).
101. Most of the global supply of internationally controlled psychotropic substances comes from a handful of countries. Since 2010, the manufacture of psychotropic substances, in terms of gross weight, has been led by China, Germany, India, Italy, Switzerland and the United States. In 2020, those countries manufactured over 831 tons of internationally controlled psychotropic substances, approximately 88 per cent of the 943.4 tons of psychotropic substances manufactured that year (see figure 29). Consequently, these countries are also the lead exporters of psychotropic substances providing a majority of the world’s supply of these substances. For 2020, these countries exported 546.1 tons of psychotropic substances, approximately 72 per cent of the 762.2 tons exported globally.

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

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

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

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

106. Broadly speaking, nearly all countries and territories regularly provide updated assessments to the Board within the suggested three-year time frame or modify existing assessments. Between 2011 and 2020, at least 91 countries and territories provided updated assessments or modifications to assessments each year with a high of 104 countries in 2017 (see figure 30). One hundred and
ninety-seven countries and territories have provided assessments for psychotropic substances at least once during that 10-year period, which reflects near universal adherence by countries and territories to the assessment system. Not reflected in the figure is that in 2011 the Board established assessments for psychotropic substances on behalf of South Sudan following that country’s independence.

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

Source: International Narcotics Control Board.

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

108. The quantity of a specific psychotropic substance that a country assesses is, in fact, an aggregate value relating to several specific needs. For example, a country that assesses that it needs 1,000 kg of phenobarbital annually may have determined that quantity because it intends to manufacture that entire quantity to meet domestic demand. Conversely, another country may assess that it needs 500 kg of methylphenidate because it intends to import that full quantity for domestic consumption as it is unable to manufacture the substance itself. It is important to underscore that the assessment system does not take into account consumption.

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

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

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

111. For the four select psychotropic substances, their gross annual assessment is represented by the red line designating 100 per cent in figure 31 below. As can be seen, the aggregate licit use – manufacture, imports and utilization for manufacture of non-psychotropic and other psychotropic substances – reported by countries of clonazepam exceeded its global assessment in 2011 and 2012, which was also the case for methylphenidate in 2012 and 2013.
112. Since 2014, the total licit use of the four select psychotropic substances did not exceed their respective aggregate global assessment. In fact, countries have used no less than 84 per cent of the aggregate global assessment for methylphenidate from 2011 to 2020. Usage levels of clonazepam, phenobarbital and zolpidem have varied significantly during the same time period. The highest rate of use of phenobarbital relative to its aggregate global assessment was 74 per cent in 2019 but under 50 per cent in 2013 and 2017.

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

114. It is difficult to draw conclusions based on these data. As the calculation of an assessment is not based directly on the consumption of a specific substance, it is difficult to know if an assessment reflects a country’s actual need. In any case, the ideal assessment use rate should track as close to 100 per cent as possible without going over. Using less than the entire amount in the assessment for a psychotropic substance does not necessarily indicate that the needs in the region or a particular country are not being met. In some cases, it may simply be necessary for countries to more carefully evaluate their assessments and update the Board as necessary. On the other hand, a lack of statistical reporting by countries adversely affects the accuracy of what quantity of an assessment is used. For example, the sharp decline in use for the Americas in 2020, as seen in figure 32, is due to key countries in the region not having provided their statistical reports for that year.

C. Availability of psychotropic substances

1. Consumption data and psychotropic substances

115. A key challenge in determining the availability of psychotropic substances for medical and scientific purposes is that the 1971 Convention does not mandate the States parties to provide consumption data as part of their annual statistical reports. Acknowledging that this data gap hinders the ability of the Board and the international community to determine adequate levels of availability for psychotropic substances, the Commission on Narcotic Drugs adopted resolution 54/6 of 2011, in which it encouraged Member States to provide consumption data in their annual statistical reports on psychotropic substances. Since the adoption of that resolution, a growing number of countries have been providing those data, reaching a high of 99 countries and territories in 2018. Ever since, nearly half of all countries and territories include consumption data on psychotropic substances as part of their annual statistical report.
116. The growing number of countries and territories providing consumption data is encouraging, but the lack of data, in particular from less developed countries, makes it difficult to have a complete picture at the global level regarding the availability of psychotropic substances for medical and scientific purposes. This can be seen when looking at submissions by region. From 2011 to 2020, Europe has led in having the highest proportion of countries and territories that submit consumption data, as 71 per cent of all countries and territories in the region provide consumption data (see figure 33). With the exception of the Americas in 2018, no other region has had more than half of their countries and territories provide consumption data as part of their annual statistical report during the same time period.

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


118. While considerable progress has been made since 2018 in quantifying the level of availability of psychotropic medicines, much less has been done in identifying the underlying reasons for low or high availability and measuring the impact of different levels of availability. Regulatory control is often cited as a factor contributing to the low availability of psychotropic medicines, but more studies are required to determine whether regulatory control does in fact hamper the availability of psychotropic medicines (and if it does, to what extent), alongside other factors such as the low rate of diagnosis of the corresponding mental health conditions and the stigma associated with use of psychotropic substances.

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

120. Other studies have focused on measuring the level of availability of different psychotropic medicines in low-income settings. Sengxeu and others, in their 2020 study,13 assessed the availability, affordability and quality of long-term anti-epileptic drugs in Lao People’s Democratic Republic. Of all the outlets that researchers visited in the three main provinces, only one in every five had at least one anti-epileptic drug available, and the level of availability in urban areas (24.9 per cent) was considerably different from rural areas (10.0 per cent). Phenobarbital (in tablets of 100 mg) was the most available medication (14.3 per cent), followed by non-controlled substances such as sodium valproate in 200 mg tablets (9.7 per cent), phenytoin in 100 mg tablets (9.7 per cent) and carbamazepine in 200 mg tablets (12.3 per cent).
tablets (8.9 per cent). Possible reasons for the low availability of anti-epileptic drugs include the strict regulatory control of psychotropic and narcotic substances at the national and international levels, the lack of regular assessment of the current need for anti-epileptic drugs, low rates of diagnosis and the uneven distribution of delivery structures between urban and rural areas.

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

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

**Anti-epileptics (clonazepam and phenobarbital)**

123. As clonazepam and phenobarbital are commonly used for the treatment of persons with epilepsy or seizures a combined analysis of their consumption as anti-epileptics can be done. A regional comparison of the consumption trends of these substances – from countries that provided consumption data – for the period 2011–2020 is presented in figure 34. A few trends become immediately apparent, the first being the difference between the level of consumption in the Americas and the level in the other regions. The sharp drop in consumption for the Americas in 2020 is due to a lack of data from Brazil, which is generally a very high per capita consumer of phenobarbital. European consumption fluctuated in the earlier part of the decade but has been consistent in the last several years, staying around 3.0 S-DDDpt. Finally, consumption levels in Africa, Asia and Oceania are consistently low, relative to the other regions, with only Asia exceeding 2.0 S-DDDpt in 2012 and 2017.

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

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

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

Methylphenidate

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

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

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

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

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129. United States, Centers for Disease Control and Prevention, Data and statistics, “ADHD throughout the years”. Available at www.cdc.gov/ncbddd/adhd/timeline.html.
ADD and ADHD, the differences between regions in consumption levels reflect either gaps in treatment, alternative treatment protocols or other inhibitors to access of methylphenidate. For example, some countries have invoked article 13 of the 1971 Convention banning the importation of methylphenidate into their territory.

Zolpidem

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

132. Levels of consumption of zolpidem vary widely between the regions. Europe has led in consumption since 2015, sustaining rates well above 4 S-DDDpt. Consumption in the Americas has been on the decline, particularly in 2015 as consumption levels in Canada dropped significantly. The sharp drop in consumption for the Americas in 2020 is due to a lack of data from Brazil, another major consumer of the drug in the region. Consumption in Africa and Asia has grown since 2014 although neither region has reported more than 1.15 S-DDDpt. Consumption in Oceania has been very low and for many years never exceeded 0.02 S-DDDpt. Australia and New Zealand do not report consumption of zolpidem. Consumption rose in 2020 owing to consumption data on zolpidem being reported in New Caledonia for the first time.
V. Availability of internationally controlled drugs for the treatment of opioid dependence

133. Methadone and buprenorphine are used in the management of pain, but they are also extensively used in the treatment of opioid dependence. Even though the data reported by countries to INCB do not precisely indicate the purpose of the use of methadone and buprenorphine, they mostly mention programmes for the treatment of opioid dependence as the reason for submitting estimates to INCB.

134. Over the last decades, there has been a gradual increasing trend in the manufacture and consumption of both methadone and buprenorphine. The global manufacture of buprenorphine started to increase gradually in the late 1990s as the substance began to be used in higher doses. After a significant drop in 2010, global manufacture recovered, reaching 17.2 tons in 2018. After declining to 10.5 tons in 2019, the global total rose to 13.0 tons in 2020. Most reported consumption of buprenorphine is in Europe and North America.

135. Methadone is sometimes used for pain management, but it is primarily used in the treatment of opioid dependence. As shown in figure 38, the trends related to the consumption, manufacture and stocks of methadone show a steady increase over the 20-year period 2001–2020, albeit with some fluctuations, reaching 44.1 tons of manufacture in 2020.

136. Global consumption stood at 59 tons in 2020, up from 45.5 tons in 2019 and a further increase from the level of 36.7 tons in 2018. Consumption of methadone was concentrated in a few countries, and there were large differences in global consumption patterns. The countries of greatest consumption were the United States (25.8 tons, or 43.7 per cent of global consumption), followed by Spain (13.6 tons, or 23.1 per cent), the Islamic Republic of Iran (4.9 tons, or 8.3 per cent), the United Kingdom of Great Britain and Northern Ireland (1.5 tons, or 3.3 per cent), France and Canada (each with 1.4 tons, or 2.5 per cent), Germany (1.2 tons, or 2 per cent) and Italy (1.1 tons, or 1.9 per cent).

Figure 37. Reported manufacture and stocks of buprenorphine, 2011–2020

Figure 38. Methadone: global manufacture, consumption and stocks, a 2001–2020

aStocks as of 31 December of each year.
137. The data available to INCB show that consumption of both substances is concentrated in a limited number of countries. Even though the estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS) of people injecting drugs are not complete, it is evident that generally the different levels of consumption for both buprenorphine and methadone are related to the presence or absence of people who inject drugs. However, in some countries with a significant prevalence of people injecting drugs, the consumption of buprenorphine and methadone, and also the presence of opioid agonist therapy services, are limited or not present at all. This is sometimes because of political and cultural resistance, or simply inaction by the responsible authorities or incapacity to recognize the problem. Some Governments do not recognize the use of these substances and the provision related opioid agonist therapy services as effective in the treatment of opioid dependence.

138. In responding to the 2022 INCB survey, 14 per cent of the 96 countries responding stated that they do not have opioid agonist therapy services in place and 9 per cent provide treatment services that do not include methadone or buprenorphine. Thirty-two countries (33 per cent) reported the use of both buprenorphine and methadone in the opioid agonist therapy provided by their health-care services; 27 per cent of countries use only methadone; and 13 per cent use only buprenorphine. The majority of countries using methadone and/or buprenorphine within their opioid agonist therapy health-care services are in the Americas and Europe.
VI. Ensuring the availability of internationally controlled drugs in emergency situations

A. Background on simplified control measures during emergency situations

139. Defined as "a disaster requiring international support (humanitarian assistance) to meet the basic needs of the affected population", an international humanitarian emergency may be caused by a natural disaster or a human-made event and can occur suddenly or gradually. According to the estimates of the Office for the Coordination of Humanitarian Affairs of the United Nations Secretariat, 274 million people are facing hunger, armed conflict, displacement and the impacts of climate change and the COVID-19 pandemic in 2022, and require immediate humanitarian assistance.

140. A number of internationally controlled substances, for instance, morphine, diazepam and phenobarbital, which are listed by WHO as essential medicines and often included in emergency health kits, are vital for pain management, palliative care, surgical care and anaesthesia, and the treatment of mental health and some neurological conditions. Others, such as fentanyl and midazolam, are also used in many countries to treat patients with COVID-19 admitted to intensive care units. Additionally, ketamine, although not under international control but often subject to national control, is also commonly found in the emergency kits dispatched by non-governmental organizations to countries that require emergency humanitarian assistance.

141. Ensuring the availability of these controlled substances during emergency situations is critical to satisfy the sudden and acute needs of the receiving countries, in particular at the onset of emergencies.

142. Humanitarian relief agencies have found it difficult to rapidly obtain controlled substances for medical care in emergency situations, partly because of the additional administrative requirements for their international movement. Some of these controlled medicines were even taken out of emergency health kits in order to minimize the possible delays that their presence might cause to the provision of humanitarian assistance. This problem is compounded if competent national authorities in the importing countries are no longer functioning.

143. The international community has long noted the urgent need for a practical solution to this obstacle. The Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care, published by WHO in 1996, represented the concerted effort to expedite the supply of controlled substances during emergency situations through simplified control measures.

144. During emergency situations such as the humanitarian crisis in Afghanistan starting in 2021 and that in Ukraine in 2022, the earthquake in Haiti in 2021 and the explosion in Beirut in 2020, competent national authorities may permit the export of controlled substances in the absence of the corresponding import authorizations and/or estimates. Furthermore, estimates for controlled substances in urgent deliveries may be submitted by the exporting country instead of by the recipient country.

145. In responding to these humanitarian emergencies, the Board has taken active steps to remind all countries that, in accordance with article 21 of the 1961 Convention, simplified control procedures are permissible in exceptional cases where the Government of the exporting country is of the view that the export of the controlled substances is essential for the treatment of the sick. The Board also facilitates communication between exporting and receiving countries and informs providers of humanitarian assistance about the simplified regulations, to hasten the supply of controlled medicines.
B. Impact of COVID-19 on the availability of controlled substances

146. Since the beginning of 2020, the COVID-19 pandemic has created unprecedented challenges for the economies and public health systems of all countries. The lockdowns, border closures and social distancing measures adopted by most countries have put to the test the ability of the international community to ensure adequate access to and availability of internationally controlled drugs for those in need.

147. The global supply chain of medicines has been adversely affected as a result of both the disruption in the manufacturing of key starting materials and active pharmaceutical ingredients in some major manufacturing countries. Logistical challenges arising from border closures and other social distancing policies adopted by a number of countries also prolonged delays.

148. On top of challenges in sourcing active pharmaceutical ingredients and generic medicines, the surge in demand for the treatment of patients with COVID-19 further reduced the availability of some medicines containing controlled substances. In particular, the Board was aware of and concerned about news regarding shortages of substances such as fentanyl and midazolam in some countries, largely driven by significant increases in the need to provide pain relief and sedation for patients with COVID-19 admitted into intensive care units.

149. In the face of lower supply and greater demand, a number of contingency measures have been put in place by some countries, including increasing stocks to provide a greater buffer, resorting to alternative medicines, implementing temporary export bans (which have in turn led to shortages of certain medicines in other countries), and importing medicines containing controlled substances that in other countries are registered. The heightened demand for certain substances is partly due to a number of requests by Governments to increase their estimates and assessments and to a greater number of countries deciding to switch to issuing electronic import and export authorizations instead of hard copies since March 2020.

150. To facilitate the international movement of controlled substances during such emergencies, not only were the increased number of supplementary estimates for narcotic drugs and modifications to assessments for psychotropic substances processed expeditiously, the INCB secretariat also facilitated communication between importing and exporting countries and assisted in the verification of the legitimacy of import and export authorizations.

151. Meanwhile, the Board has repeatedly expressed its commitment to supporting Governments in using the International Import and Export Authorization System (I2ES) and enhancing their knowledge of the international drug control framework through INCB Learning. Such activities have taken on heightened importance during the COVID-19 crisis, as paperless trade and online training have become the norm.

152. Governments have been encouraged to share, through the I2ES forum, updates on contingency measures taken as a result of the COVID-19 pandemic so that trading partners are informed in a timely manner in order to minimize disruptions to trade. Furthermore, the INCB secretariat conducted several webinars to strengthen the operational capacity of the I2ES community.

153. Alongside the difficulties faced by most countries in the procurement and sourcing of controlled substances, disruption in the treatment and service delivery for people with mental health problems and substance use disorders since the onset of COVID-19 warrants specific attention. Based on the rapid assessment of WHO, more than 40 countries experienced disruption in their services for people with mental health problems and substance use disorders, including those related to life-saving emergencies. Community-based outpatient services, services to raise awareness of and prevent mental health problems, and services for older adults and children were among the most adversely affected. The lack of access to such essential treatment services as a result of the COVID-19 pandemic were extremely worrisome, as prolonged social distancing and the associated social isolation placed greater emotional strain on people with mental health problems and substance use disorders and may have further increased the number of people suffering from such conditions.

154. Research from UNODC has further confirmed the impact and health consequences of the COVID-19 pandemic on people who use drugs. Specifically, the mobility restrictions imposed by most Governments caused considerable disruption to access to drug treatment services, clean drug-using equipment and substitution therapy. The lack of access to treatment services and safe practices increased the risk of aggravating drug use disorders, as well as risks related to the health and survival of drug users. For instance, heroin users who could not access opioid-assisted therapy were reported to have suffered severe withdrawal symptoms. Meanwhile, shortages in the supply of drugs also led to the use of alternative means of administration (e.g. injection) by some users, incurring additional risks such as the spread of blood-borne diseases (e.g. HIV/AIDS and hepatitis C).
The impact of COVID-19 on availability of controlled substances in Brazil

Special times call for special measures

In Brazil, a state of public health emergency was declared on 3 February 2020, after the identification of the first case of COVID-19. The subsequent rise in the number of COVID-19 patients, especially those admitted into the intensive care unit, generated considerable demand and pressure on the timely supply of controlled medicines.

Resolution RDC 483/2021, introduced in March 2021 and which remained in effect until 12 November 2021, outlined some extraordinary and temporary requirements related to the import of controlled substances used in the treatment of COVID-19, for example, alfentanil, diazepam, fentanyl, midazolam, morphine, remifentanil and sufentanil. For instance, hospitals could directly import those controlled substances, including those not registered in other countries. In addition, the Brazilian National Health Regulatory Agency (ANVISA), the competent national authority of Brazil, was requested to prioritize the processing of import requests of these substances and authorize their imports in the absence of the corresponding estimates.

Other temporary legislative measures, including the opening of additional entry and exit points for substances subject to special control due to the health emergency related to COVID-19 (resolution RDC No. 402/2020) and permission for home delivery of drugs subject to special control (resolution RDC No. 357/2020) also aimed to increase availability of and access to controlled drugs during the pandemic.

On 29 April 2021, INCB sent a circular letter to all competent national authorities to encourage them to implement simplified control measures for urgent deliveries to Brazil. Governments may permit the export of controlled substances to Brazil, even in the absence of corresponding import authorizations and/or estimates.

C. Implementation of simplified control measures during emergency situations

155. A review and discussion of the lessons learned in the implementation of the simplified control measures during emergency situations, held among competent authorities, international humanitarian organizations and related United Nations agencies were conducted by INCB during two online meetings held in March 2021. The outcome document of those meetings, entitled “Lessons from countries and humanitarian aid organizations in facilitating the timely supply of controlled substances during emergency situations”, contains important actions that Governments can take to improve their emergency preparedness and sets out procedures that they can follow during emergency situations.

Simplified control measures to facilitate export in the legislation of Belgium

A small legislative change that yields great help during an emergency

The competent national authorities of Belgium, the Federal Agency for Medicines and Health Products (FAMHP) has a long experience in the implementation of simplified control measures on controlled medicines during emergency situations.

A legislative change on the export of controlled substances was introduced in the narcotics law of Belgium in September 2017. The amendment was aimed at enhancing the implementation of simplified control measures during emergency situations, and providing better support to the Médecins sans frontières European supply centre, which is responsible for ensuring the supply of quality drugs and medical devices to 30 humanitarian missions of Médecins sans frontières around the world.

As outlined in article 34, section 5, of the royal decree of 06.09.2017 on regulating narcotic and psychotropic substances, in the case of emergency, no foreign import authorization or prior Belgian export authorization is required for the export of controlled substances, as defined in the WHO Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care by a wholesaler with a humanitarian purpose. The wholesaler, however, must inform FAMHP a posteriori as soon as possible using the notification form (in lieu of import authorization) contained in the Model Guidelines.

A posteriori export authorization, specifying the “WHO emergency procedure” was applied, and the date of the shipment is then registered in the FAMHP database, facilitating the monitoring by FAMHP. A copy of the export authorization is printed and sent to the competent authorities of the recipient country (if possible), who shall then be informed about the names and quantities of controlled substances shipped through the simplified control procedures.

Médecins sans frontières welcomed that legislative change and considered it to be of great help for their emergency operations, in particular in acute emergency phases when the competent authorities of receiving countries became temporarily unavailable or absent. MSF further noted that smooth implementation of the simplified control measures relies on transparency, that is, clear specification of (a) the nature of emergency and (b) the availability of control authorities in the receiving country, because that information is entered on the WHO model form, which is passed on to FAMHP after the urgent shipment took place.

156. Specifically, Governments are strongly encouraged to review existing national legislation on controlled substances and make amendments and/or adopt new provisions that allow for greater flexibility in the import and export of controlled substances during emergency situations, with clear specifications of the conditions under which such flexibility can be exercised. All relevant front-line workers responsible for the delivery of controlled substances should also be made aware of the emergency procedures and be trained in their use.
157. In an increasingly complex and uncertain world, for instance, the conflicts in Ukraine and the dire humanitarian situations in Afghanistan and many other countries, in which controlled substances remain vital in the provision of quality essential care to affected populations, the Board reminds all States that, under international humanitarian law, parties to armed conflicts have an obligation not to impede the provision of medical care to civilian populations located in territories under their effective control. This includes access to necessary narcotic drugs and psychotropic substances.

Receiving donations in times of crises

**Communication and flexibility are key**

On 4 August 2020, a huge explosion occurred at the port of Beirut in Lebanon, causing at least 200 deaths and 6,000 injuries, and extensive infrastructure damage up to 8 km away. The explosion also resulted in considerable loss of medications and significant damage to several port entries, which further complicated the logistical situation faced by the authorities in receiving international assistance.

A national emergency of two weeks was immediately declared by the Government, after which the Ministry of Public Health swiftly drew up a corresponding emergency plan to overcome the logistical challenges and address the pressing medical needs of the injured. As the first step of the emergency plan, the Ministry conducted an analysis of the situation to lay out immediate actions. It then strived to save as many medications, including controlled substances, as possible. Meanwhile, alternative entry sites (the port of Tripoli, the Beirut airport and the intact, functional parts of the port of Beirut) were also designated for receiving humanitarian assistances.

As several exporting countries that implemented simplified control measures during emergency situations had not informed the competent national authorities of Lebanon about their shipments, the simultaneous influx of donations from different parts of the world within a short time, although they were a strong sign of goodwill and support from the international community, posed additional challenges to the receiving authorities. A delicate balance between expediting the movement of controlled substances for urgent medical needs and preventing their diversion became particularly hard to achieve amid the chaos and competing priorities.

As all activities concerning controlled substances in Lebanon are governed by Narcotics Law 673/98, the Narcotics Department of the Ministry of Public Health continued to issue import authorizations for all imports of controlled substances. Exemption for such issuance, however, had been granted to donations containing controlled substances, in order to expedite their supply to the injured.

To ensure that only credible operators handled controlled substances – a legal requirement for controlled substances in Lebanon – all donations were delivered only to the Lebanese military or eligible non-governmental organizations, for further distribution to the hospitals. Furthermore, all donations were checked by the Pharmaceutical Inspection Department before entering the country. Medications past their expiry dates or with other quality issues that failed to comply with national standards were also rejected in order to safeguard the health of the injured.

158. The Board invites Governments and humanitarian relief agencies to bring to its attention any problems encountered in exporting and/or receiving controlled substances during emergency situations. Together with the help of international humanitarian organizations and other United Nations agencies, INCB will continue to monitor and assist in the implementation of the simplified control measures during emergency situations, so as to ensure the timely supply of controlled substances to alleviate the pain and suffering of the most vulnerable.
VII. Conclusions and recommendations

159. The thirtieth special session of the General Assembly, on the world drug problem, held in 2016, is considered by many to have been a watershed moment for the international approach to drugs. One of the major innovations of the outcome document adopted at the special session was that for the first time a document of its kind contained a section on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes while preventing their diversion, with concrete operational recommendations on actions to be taken to address the problem.

160. In 2018, INCB sent a questionnaire to Member States and civil society organizations soliciting information on actions taken in the period 2012–2017. The information was the basis for the preparation of the supplementary report of INCB in 2018 entitled *Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes*. Four years later, the Board has once again asked Member States and civil society organizations for their views on the factors that are impeding access to and availability of controlled substances for medical purposes and actions taken to address the issue in line with the operational recommendations contained in the outcome document of the thirtieth special session of the General Assembly, on the world drug problem.

161. The analysis of the data available and the responses to the questionnaires by Governments and civil society organizations indicate that there has been some progress, but important areas still require action not only by Member States but also by the international community. On the basis of that analysis, INCB urges Governments, civil society organizations and the broad international community to take further steps in the following areas.

162. Global trends. The analysis of the availability of opioid analgesics shows 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 wider use of affordable morphine.

163. Comparing the reported consumption of opioid analgesics with the estimated number of people in need of palliative care, it is confirmed that the problem is related to the level of economic and social development of countries. High-income countries have more resources and better health systems, and they are more capable of reaching people in need, while low- and lower-middle-income countries have health systems with limited capacity to prescribe and administer opioid analgesics to patients. The COVID-19 pandemic has seriously affected the capacity of many countries to deliver health services. The pandemic has claimed the lives of many health and care workers worldwide. Limited available resources were redirected to address the emergency. Progress achieved so far in universal health coverage was reversed, and there was an increase in anxiety and depression, in particular among young people, which increased the need for psychotropic substances to respond to those conditions. The international community must unify in solidarity with countries with limited resources and take the COVID-19 pandemic as an opportunity to address the inequities and disparities in the level of health services provided, including access to and availability of controlled substances for medical purposes. INCB, within its mandate, contributes to the Sustainable Development Goals, in particular Sustainable Development Goal 3. The Sustainable Development Goals were adopted by the Member States of the United Nations in 2015 to address a range of social needs, including education, health, social protection and employment, which are at the centre of the social and economic development of countries. INCB urges Governments to continue to pursue the achievement of the Sustainable Development Goals by 2030 because in so doing they will also be addressing the main underlying impediments to access to and availability of medicines containing controlled substances.

164. Impediments and obstacles. Impediments reported by Governments seem to indicate that compliance with the requirements of the conventions (onerous regulations and
trade control measures) is perceived to be less and less of a problem. In the perception of authorities, factors such as fear of diversion, fear of addiction, fear of prosecution and cultural attitudes remained relatively stable or decreased in importance as impediments. The lack of training and the awareness of health professionals with respect to the prescribing and dispensing of opioid analgesics remains a major issue. This, together with the increase in the mentions of problems in sourcing and limited financial resources, both possibly related to the problems created by the COVID-19 pandemic, indicates that there are structural problems that limit access to controlled substances which need to be addressed so that those obstacles are removed.

Civil society organizations have confirmed the importance of training health professionals and have pointed out the limited access for patients living in rural or remote areas. INCB recommends that Governments continue to prioritize training health professionals in the rational prescribing and safe administration of controlled substances while at the same time ensuring that administrative and budgetary measures are put in place to address the problems of the procurement and the affordability of medicines containing controlled substances that need to be accessible for all people in need, including those living in rural areas.

165. Legislative and regulatory systems. The responses from Governments indicate that there is a broad effort to review or change national legislation and regulatory systems to improve access to controlled substances while maintaining adequate control. However, still only a few countries (10 of 96 countries) allow nurses, including nurse practitioners, to prescribe controlled substances. Also, the time that a prescription for controlled substances is valid varies by country and, in some cases, is relatively short, making it difficult for patients to procure medicines that are needed on a continuous basis. Another factor that limits access is the presence of legal sanctions for health professionals who unintentionally mishandle opioids. INCB urges Governments to continue to review their legislation and regulations with the aim of increasing access for patients while maintaining the essential controls to prevent diversion. INCB urges Governments to make use of technological possibilities, such as mobile phone applications, that can help to ensure the safe and controlled prescribing and administering of controlled substances.

166. Health systems. The procurement of opioid analgesics and psychotropic substances alone will not solve the problem of access to and availability of the medicines for patients. The majority of Governments responding indicated that palliative care policies and measures had been implemented in their country, including low-cost and home-based services. About half of national authorities responding considered their health infrastructure to be appropriate to the needs of their people. Not many authorities reported that in their country there was a problem of accessibility to controlled substances for patients in rural and remote areas. However, civil society organizations considered that such accessibility was a major issue. The Board urges Governments, together with other stakeholders, to continue working towards the improvement of their health systems in the area of the safe and rational delivery of medications containing controlled substances and to ensure that all patients are reached by the health services and no patient is left behind.

167. Affordability. Tackling the issue of availability of and access to controlled substances for medical purposes necessarily involves addressing the issue of affordability. Some competent national authorities (24 per cent) mentioned that among the main impediments to availability was the lack of financial resources to procure medicines containing controlled substances. In response to a specific question, 75 per cent of competent national authorities reported that they had sufficient resources to purchase the needed medicines, while the remaining 25 per cent cited a limited budget and lack of resources. The Board invites Governments to consider allocating sufficient resources to ensure the sufficient availability of controlled substances and encourages countries to review pricing and production policies of medicines for low- and middle-income countries. In particular, INCB invites major morphine-producing countries to increase the amount destined for palliative care use and to give low- and middle-income countries the possibility of purchasing affordable morphine instead of expensive synthetic opioids.

168. Training of health-care professionals. A major issue for many countries continues to be that health professionals lack training and awareness of the proper prescription and administration of controlled substances. A large number of countries reported that training in the area of pain and palliative care is part of the educational curricula of medical and nursing schools but is not always mandatory. INCB reiterates the need for Governments to introduce mandatory training on pain and palliative care management in the curricula of medical and nursing schools, as well as in the continuing medical education programmes, to ensure proper rational prescribing and administering of opioid analgesics.

169. Education and awareness-raising. Cultural attitudes towards the use of controlled substances for medical purposes have contributed to the impedance of access for patients. INCB notes that a large number of countries have reported educational and awareness-raising activities targeting the general public and the pharmaceutical
community and encourages them to continue their programmes in this area.

170. **Estimates and assessment.** Even though almost all countries stated that they were aware of the *Guide on Estimating Requirements for Substances under International Control* published by INCB and WHO, only about one quarter of those countries used the service- or morbidity-based methods to estimate their needs. INCB recognizes that those two methods are resource-intensive but urges countries to use them so that they have a more precise idea of their needs for medicines containing internationally controlled substances.

171. **Controlled substances for opioid agonist therapy.** Consumption of methadone and buprenorphine is concentrated in a limited number of countries (mostly in Western and Central Europe), while people injecting drugs are present in many additional countries. INCB urges Governments and medical authorities to consider using methadone and buprenorphine for the treatment of opioid dependence where that problem exists, given that there is scientific evidence indicating the effectiveness of opioid agonist therapy programmes.

172. **Emergency situations.** In the light of the many ongoing humanitarian emergencies, as well as the COVID-19 pandemic, which has disrupted the supply chain for controlled medicines in several parts of the world, the Board has been working with Governments to address the urgent need to ensure availability of controlled medicines during emergency situations. In 2021, INCB published a factsheet entitled “Lessons from countries and humanitarian aid organizations in facilitating the timely supply of controlled substances during emergency situations”. The document provides recommendations to Governments on how to improve access to medicines containing controlled substances in emergencies, including pandemics and climate-related disasters. INCB invites countries to review the recommendations contained in that factsheet and consider incorporating them into their own legislative and administrative systems.

173. INCB stands ready to support Governments in their renewed efforts to achieve the above-stated goals. The Board provides assistance through its secretariat to Member States on an ad hoc basis, 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.

174. An efficient and successful regulatory system that ensures that medicines containing controlled substances are available and accessible for the population requires the involvement of the entire community, as well as the commitment of the Government. The analysis contained in the present report provides information for a better understanding of the global situation and highlights the different impediments to access to medicines containing controlled substances. Recommendations made in this report are designed to assist Governments as they review national legislation and regulatory and administrative mechanisms, and design policies, to simplify processes and remove unduly restrictive regulations.

175. 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 recognizes the contribution of civil society organizations. The information provided shows 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. No patient should be left behind.
United Nations system and drug control organs and their secretariat

Key:

Direct connection (administrative or constitutional)
Reporting, cooperating and advising relationship

United Nations Office on Drugs and Crime.
The INCB secretariat reports on substantive matters to INCB only.
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.