

# 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*.<sup>1</sup>

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

<sup>1</sup>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.<sup>2</sup> Since the onset of the COVID-19 pandemic, increases in the price of medicines and their decreased availability, as well as the

<sup>2</sup>Keith Humphreys and others, "Responding to the opioid crisis in North America and beyond: recommendations of the Stanford–Lancet Commission", *The Lancet*, vol. 399, No. 10324 (February 2022), pp. 555–604.

falsification of medicines, have been reported.<sup>3</sup> 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*,<sup>4</sup> 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.

<sup>3</sup>Sameer Imtiaz and others, "The impact of the novel coronavirus disease (COVID-19) pandemic on drug overdose-related deaths in the United States and Canada: a systematic review of observational studies and analysis of public health surveillance data", *Substance Abuse Treatment, Prevention, and Policy*, vol. 16, art. No. 87 (November 2021), pp. 1–14.

<sup>4</sup>E/INCB/2018/1/Supp.1.

## 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<sub>pm</sub>), 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<sub>pm</sub>, INCB includes codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine. Methadone and buprenorphine are not included because of the impossibility of distinguishing, on the basis of the information provided to the Board, their use for pain relief from their use for the treatment of drug dependence. The information on the consumption in S-DDD<sub>pm</sub> 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<sub>pt</sub>), during the year in question, and then by the defined daily dose.