

## Executive summary

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

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

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

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

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

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

<sup>1</sup>E/INCB/2015/Supp.1.

<sup>2</sup>General Assembly resolution S-30/1, annex.

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

## Background

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

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

Every year, INCB receives information on the amounts of narcotic drugs that competent national authorities estimate are required for consumption and report as consumed or, more precisely, the amount distributed by wholesalers that is available for consumption. INCB evaluates those data in terms of defined daily doses for statistical purposes (S-DDD). S-DDD are used by INCB as a technical unit of measurement for the purpose of statistical analysis and are not a recommended prescription dose. The availability levels of narcotic drugs, excluding those listed in Schedule III of the Single Convention on Narcotic Drugs of 1954 as amended by the 1972 Protocol,<sup>4</sup> expressed in S-DDD, are calculated by dividing annual availability by 365 days; the result obtained is divided by the population, in millions, of the country or territory during the year in question, and then by the defined daily dose. In the analysis of the availability of opioid analgesics by S-DDD, INCB includes codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine. Methadone and buprenorphine are not included because of the impossibility of distinguishing, on the basis of the information provided to the Board, their use for pain relief from their use for the treatment of drug dependence.

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

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

<sup>3</sup>20th ed. (Geneva, 2017).

<sup>4</sup>United Nations, *Treaty Series*, vol. 976, No. 14152.

<sup>5</sup>*Ibid.*, vol. 1019, No. 14956.