Executive summary

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

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

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

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

Narcotic drugs

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

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

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

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

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

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

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

Psychotropic substances

Insufficient or inadequate access to psychotropic substances seems to be particularly pronounced in low- and middle-income countries, where it is estimated that about four out of five people who need mental, neurological or substance abuse treatment do not receive such treatment. Regarding the supply and consumption of substances controlled under the 1971 Convention that the World Health Organization lists as essential drugs (buprenorphine, diazepam, lorazepam, midazolam and phenobarbital), diverse patterns emerge. The reported global manufacture and calculated levels of consumption of buprenorphine used for pain relief and opioid dependence treatment have increased significantly in the past decade. While some countries (especially in Europe) show very high levels of consumption, the calculated level of consumption of the majority of countries and regions still remains below 0.1 S-DDD[8] per 1,000 population per day, indicating insufficient access to this medicine.

[8]Defined daily doses for statistical purposes.

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

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

Availability of internationally controlled drugs for the treatment of opioid dependence

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

Ensuring adequate availability of internationally controlled drugs in emergency situations

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

Recommendations

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

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

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

Acknowledgements

Many individuals contributed to the preparation of the present report. The International Narcotics Control Board extends its deep appreciation to all those who in various ways provided inputs, suggestions, ideas, information and data that enabled the Board to have a better understanding of the situation.

The Board would like to acknowledge the contribution of the following individuals and organizations:

Stefano Berterame, Beate Hammond, Juliana Erthal, Levent Canturk, Nabil Katkhouda, Francis Chazhoor, Johny Thomas, Janna Shrestha and Mina Balooch of the Narcotics Control and Estimates Section of the INCB secretariat. Vera Skruzny and Sarah Fellner, interns in that Section.

Eva Fernandez-Santis, Hanifa Rebbani, Ha Fung Cilla Ng, Darmen Zhumadil, Paramita Doubek and Lilian Sandouk of the Psychotropics Control Section of the INCB secretariat. Daniela Ettehad and Stefano Ricci, interns in that Section.

United Nations Office on Drugs and Crime: HIV/AIDS Section of the Drug Prevention and Health Branch; Prevention, Treatment and Rehabilitation Section of the Drug Prevention and Health Branch; and Statistics and Surveys Section/Research and Trend Analysis Branch.

World Health Organization: Noncommunicable Diseases and Mental Health Cluster; Department of Mental Health and Substance Abuse; Essential Medicines and Health Products; and International Agency for Research on Cancer.

United Nations Joint Programme on HIV/AIDS.

Union for International Cancer Control, Worldwide Palliative Care Alliance, International Association for Hospice and Palliative Care, McCabe Centre for Law and Cancer, Pain and Policies Study Group and Human Rights Watch.

The Board would also like to acknowledge the contribution of past members of the Board who devoted time and energy to the development of this report: Dr. Galina Korchagina, Dr. Lochan Naidoo and Dr. Rajat Ray.

The present members of the Board are:
Werner Sipp, President
Sri Suryawati, First Vice-President
Jagjit Pavadia, Second Vice-President and Chair of the Standing Committee on Estimates
Bernard Leroy, Rapporteur