

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.