

# Chapter VI.

## Conclusions and recommendations

266. Ensuring the availability of internationally controlled substances for medical and scientific purposes while preventing their illicit trafficking and abuse is the role of the control system as established by the international drug control conventions. An efficient and successful drug regulatory system that maintains this balance requires the involvement of the entire community, as well as the commitment of Governments.

267. The issue of ensuring the availability of narcotic drugs and psychotropic substances for medical purposes is a complex one. The previous chapters have discussed the unequal distribution of these drugs, as well as the barriers and impediments that cause this inequality. Apart from the data on consumption and prevalence of health conditions requiring palliative care, and the information presented by Member States, the Board has also reviewed information provided by international organizations (WHO, UNODC and UNAIDS), academia, research centres and civil society organizations. The analysis of this entire set of information suggests that there are some key areas that require action at the national and international levels.

### A. Legislation and regulatory systems

268. The regulatory machinery that countries have established to implement the provisions of the international drug control conventions needs to be reviewed. Most studies and analyses indicate that some countries, when developing legislation and regulations, were concerned mostly with the need to avoid diversion and abuse rather than the need to ensure availability and make adequate provisions to that end. In fact, concerns about the risk of addiction

are still reported to be a major impediment by countries. However, in the three surveys carried out by the Board over the past 20 years, the percentage of countries indicating this as an impediment has dropped from over 70 per cent in 1995 to 34 per cent in 2014. This unbalanced or asymmetrical view of the conventions has, in a number of countries, generated regulatory systems that make it difficult or almost impossible for people in need to obtain opioid analgesics.

269. The Board has in the past expressed concerns in this regard and issued recommendations. It seems that some countries have taken action, but there are still countries that need to address this issue. The Board recommends that they take the following actions:

- Review national legislation and regulatory and administrative mechanisms, as well as procedures, including domestic distribution channels, with the aim of simplifying and streamlining those processes, and removing unduly restrictive regulations and impediments to ensure accessibility while maintaining adequate control systems.
- Allow a larger base of health-care professionals (including trained general practitioners, nurses and others, as appropriate) to prescribe opioids to increase availability, particularly in remote or rural areas.
- Take measures to prevent the emergence of unregulated markets and illicit or counterfeit manufacture of narcotic drugs and psychotropic substances.
- Ensure adequate prescription policies, including, where appropriate, by increasing the validity

period of prescriptions to enable patients to procure medications when they need them.

- Remove legal sanctions for unintentional mistakes in the handling of opioids.
- Improve inter-agency and interministerial cooperation and coordination at the national level, particularly between health and drug control agencies.
- Provide the medical and pharmaceutical community with updated information on all new legislative and administrative measures enacted in connection with controlled substances and on modalities of distribution and prescription of psychotropic substances to ensure and sustain the requisite availability that would satisfy requirements with regard to both quantity and quality.

## B. Health system

270. The availability of pain relief drugs or psychotropic substances alone will not solve the problem of pain management or mental health treatment. There is broad consensus that it is important for countries to give appropriate attention to the improvement of the health system. To that end, the Board recommends that countries:

- Implement the recommendations contained in resolution WHA67.19, adopted by the sixty-seventh World Health Assembly on 24 May 2014, entitled “Strengthening of palliative care as a component of comprehensive care throughout the life course”.
- Develop an appropriate and well-resourced health infrastructure that not only ensures the availability of opioid analgesics but also provides for such availability in the context of the broader delivery of palliative care.
- Consider, where appropriate, the option of low-cost, home-based palliative care services.
- Improve the distribution of opioid analgesics and psychotropic substances to all areas of the country, including rural areas.

## C. Affordability

271. Another important aspect of improving availability is ensuring that opioid analgesics are affordable. In this connection, the Board recommends that countries:

- Improve access to essential drugs in general and to opioid analgesics in particular.
- Ensure funding for the purchase of opioid analgesics.
- Develop and improve health insurance and reimbursement schemes that guarantee access to medications.

272. With respect to affordability, pharmaceutical companies have an important role to play. The Board will, as part of its ongoing efforts to improve the situation, commence consultations with pharmaceutical industry groups about the lack of controlled medications in many regions, involving relevant international organizations (e.g. WHO), and relevant international professional groups and interested Governments in these discussions, which will focus on the availability and accessibility in developing countries of affordable, effective monotherapies, such as morphine for pain, especially cancerous pain. The Board recommends that the pharmaceutical industry:

- Manufacture high-quality opioid preparations that are more affordable.
- Manufacture generic pharmaceutical preparations that are bioequivalent and cost effective.

## D. Training of health-care professionals

273. Patients have the right to be treated and to receive medications that are rationally prescribed. Lack of training and lack of awareness among health-care providers concerning the rational use of narcotic drugs and psychotropic substances, and the resulting reduced levels of prescription, will limit the use of such substances. Furthermore, certain cultural attitudes towards the management of mental health disorders and palliation are acting as an impediment to the use of narcotic drugs and psychotropic substances. To this end, health-care professionals need to be properly educated and trained. It is recommended that countries:

- Include palliative care in the educational curricula of medical schools and in the mandatory training of all health professionals.
- Provide continued education, training and information on palliative care to health-care professionals, including on rational use and on the importance of reducing prescription drug abuse.

- Provide education and training to doctors and other health-care professionals on the rational use of psychoactive drugs, since this is of paramount importance for the prevention of the abuse of such drugs. Health actors must exercise vigilance to prevent possible misdiagnoses and inappropriate prescribing.
- Ensure that psychotropic substances are prescribed in conformity with sound medical practice as set forth in the 1971 Convention (art. 9, para. 2), promote the rational use of such substances and take the necessary measures to limit their use to actual medical needs.

## E. Education and awareness-raising

274. Opioid analgesics and palliative care in general are also limited in some countries by social and cultural norms. In some societies and cultures, there is resistance to dealing with things related to the end of life or associated with the fear of addiction. Also, the use of psychotropic substances faces considerable resistance because of the stigma associated with the mental health conditions that may require their use. The Board recognizes that it is necessary for Governments in cooperation with civil society to:

- Develop and implement educational programmes for the general public and the pharmaceutical community involving competent national authorities, interest groups (e.g. professional and consumer interest groups) and the media.
- Organize workshops to disseminate information on palliative care to overcome cultural resistance to it.
- Ask educational institutions to include education on palliative care in their curricula.
- Engage civil society organizations representing patients, families and other relevant groups to advocate for palliative care and for the acceptability of the medical use of opioid analgesics.
- Educate the public to reduce stigma and unreasonable fear of addiction.
- Reduce excessive marketing by industry and improve consumer awareness.
- Promote ethical attitudes among medical doctors and pharmaceutical companies, together

with appropriate information for the general public and continued education and training of health-care professionals to encourage a better-justified and more rational use of psychotropic substances.

- Support campaigns and efforts to prevent the non-medical consumption of psychotropic substances, and encourage the active participation of the medical and pharmaceutical community in all measures related to the rational use of controlled medicines.

## F. Estimates, assessments and reporting

275. One of the problems that the Board has noted over the past several years is that some countries are not able to properly estimate their needs for opioid analgesics and to monitor the consumption of those substances. Furthermore, many countries still find it difficult to identify with precision their requirements for psychotropic substances. Consequently, they are unable to establish and provide the Board with adequate assessments for their legitimate use. In addition, in its resolution 53/4 and 54/6, the Commission on Narcotic Drugs encouraged Governments to provide the Board with data on the consumption of psychotropic substances, in the same manner as for narcotic drugs. Finally, the punctuality of the submission of reports and their comprehensiveness and reliability are important aspects of each Government's cooperation with INCB. The Board recommends that countries:

- Improve their method of assessing their needs by making use of the *Guide on Estimating Requirements for Substances under International Control* developed in 2012 by INCB and WHO for use by competent national authorities.
- Submit appropriate and realistic estimates that take into consideration possible variations in demand.
- Establish proper and feasible monitoring mechanisms at the national level and make use of improved technical systems such as the electronic International Import and Export Authorization System (I2ES) for narcotic drugs and psychotropic substances, which was developed by INCB in close cooperation with UNODC.

- Establish a procedure and develop mechanisms that will allow their competent national authorities to more accurately assess the actual requirements for psychotropic substances and submit such data to the Board.
- Develop adequate systems that will enable the collection of reliable data that would be essential in enabling the Board to better analyse trends in the consumption of psychotropic substances and, ultimately, to promote their adequate availability for medical and scientific purposes while preventing their diversion and abuse.

## G. Benchmarks for consumption of substances under international control

276. The results of the analysis of the data on availability and consumption reported to INCB, and the answers to the questionnaire on availability provided by Governments demonstrate the complexity of this analysis. In particular, the levels of consumption of psychotropic substances calculated by the Board on the basis of statistics on manufacture and trade provided to the Board by Governments cannot reflect with precision the levels of consumption of these substances.

277. Furthermore, in the absence of thresholds for per capita consumption in S-DDD, the Board is not in a position to evaluate and assess levels of consumption of psychotropic substances, and therefore cannot estimate whether in some countries or regions the level of

consumption of such substances is adequate, too high or too low. The Board recommends that WHO work with INCB to:

- Establish benchmarks for the consumption of psychotropic substances.

This would greatly support the work of INCB and of the national Governments, as standards would serve as indicators when assessing the availability for legitimate medical and scientific purposes of psychotropic substances. This can be achieved only by using reliable morbidity data, and prevalence rates that include geographical distribution and the medical practice with regard to specific psychotropic substances for a related medical condition.

## H. International community

278. Some Governments are not in a position to implement the above recommendations on their own. They need advice, training and resources to address the limitations of their systems. For this reason, the international community has a role to play. The Board believes that the international community should:

- Improve cooperation among Governments, international organizations (INCB, WHO, UNODC, UNAIDS and UNDP, among others), the donor community and civil society organizations to ensure the sharing of expertise and the coordinated delivery of resources and technical support to countries in need of assistance.