Chapter I.

Introduction

1. “Pharmakon” is the ancient Greek word for drug. It has been commonly translated as “remedy” or “poison”, even though it has other meanings that do not correspond exactly with the two main ones.

2. This double meaning represents well the problem that many cultures and societies have faced in the course of history in relation to drugs. Several substances that are available in nature, or that more recently have been synthesized from natural substances or artificially produced, have the capacity to treat or alleviate certain health conditions. For this reason, they are widely used. If taken beyond certain limits, however, they can have negative effects and can damage the health of the persons using them. In addition, there may also be negative consequences for the families of such persons and the broader community.

3. Dealing with the difficult balance between “remedy” and “poison” has been a longstanding problem in many societies. It was at the heart of the development of the international drug control system as outlined in the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971. In the preambles to those conventions, Parties indicated the primary interest of the international community in protecting the health and welfare of mankind by making such indispensable substances available for medical and scientific purposes while ensuring that there was no diversion or abuse. The conventions established a control regime to serve this dual purpose.

A. Role of the international drug control conventions

4. In particular, parties to the 1961 Convention, while recognizing that addiction to narcotic drugs constituted a serious evil for the individual and was fraught with social and economic danger to humankind, also recognized “that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes”.

5. Similarly, parties to the 1971 Convention, while noting with concern the public health and social problems resulting from the abuse of certain psychotropic substances and expressing their determination to prevent and combat abuse of and trafficking in psychotropic substances, recognized “that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted”.

6. Since the entry into force of the three international drug control conventions, these principles have been reiterated in a number of resolutions adopted by the Commission on Narcotic Drugs and then by the Economic and Social Council. More recently, the Commission adopted resolutions 53/4 and 54/6, with a view to promoting adequate availability of internationally controlled...
substances for medical and scientific purposes while preventing their diversion and abuse. In its resolution 53/4, the Commission decided, among other things, to establish a specific agenda item to examine impediments to adequate availability and efforts to prevent the diversion and abuse of narcotic drugs and psychotropic substances.

7. The importance of making internationally controlled drugs available for medical and scientific purposes is also mentioned in the 2009 Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem and in the Joint Ministerial Statement of the 2014 High-Level Review by the Commission on Narcotic Drugs of the Implementation by Member States of the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem.

B. Availability of and access to internationally controlled drugs as a health and human right

8. The need to have access to essential drugs is also prominent in other international legal instruments under the concept of the right to health set out in article 25 of the Universal Declaration of Human Rights:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

9. The preamble to the Universal Declaration of Human Rights refers also to the “recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family”. An earlier formulation of the right to health as a fundamental part of human rights was first articulated in the 1946 Constitution of the World Health Organization (WHO), the preamble to which defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The preamble further states that:

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

10. Additionally, the right to health was recognized as a human right in the 1966 International Covenant on Economic, Social and Cultural Rights.

11. In his report to the Human Rights Council at its seventh session, the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment stated that:

The de facto denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman or degrading treatment or punishment.

Further, he added that:

Given that lack of access to pain treatment and opioid analgesics for patients in need might amount to cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome current regulatory, educational and attitudinal obstacles to ensure full access to palliative care.

12. Similarly, in a report published in 2011, Human Rights Watch argued that under international human rights law, “Governments have an obligation to address the widespread and unnecessary suffering caused by the poor availability of palliative care worldwide.”

13. In addition to the international drug control conventions and the international human rights instruments, the international community has developed a series of legal instruments in the context of the World Health Assembly.

14. Furthermore, WHO has compiled a list of essential medicines that are designed to “satisfy the priority healthcare needs of the population” and are selected “with due regard to disease prevalence, evidence on efficacy and

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17General Assembly resolution 217 A (III).
18General Assembly resolution 2200 A (XXI), annex.
19A/HRC/10/44, paras. 72 and 74 (e).
safety, and comparative cost-effectiveness. Several narcotic drugs and psychotropic substances under international control are part of the list and are therefore considered essential to satisfying the priority health-care needs of the population.

15. In its resolution WHA55.14 of 2002, on ensuring accessibility to essential medicines, the World Health Assembly urged Member States:

16. Also in that resolution, the World Health Assembly requested the Director-General of WHO "to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicines, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them".

17. In its resolution WHA58.22 of 2005, on cancer prevention and control, the World Health Assembly urged Member States "to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system". In addition, it requested the Director-General of WHO "to examine jointly with the International Narcotics Control Board the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics".

18. More recently, on 24 May 2014, the World Health Assembly adopted resolution WHA67.19, on strengthening of palliative care as a component of comprehensive care throughout the life course. In that resolution, it emphasized that the need for palliative care services would continue to grow, partly because of the rising prevalence of non-communicable diseases and the ageing of populations everywhere.

19. In relation to palliative care services, Human Rights Watch, in Global State of Pain Treatment, stated that:

20. Furthermore, the WHO Global Action Plan for the Prevention and Control of Non-Communicable Diseases 2013-2020, endorsed by the World Health Assembly in May 2013, includes palliative care among the policy options proposed to Member States as a means of reducing the suffering caused by non-communicable diseases.

21. The World Cancer Declaration of 2013, elaborated by the global cancer community under the leadership of the Union for International Cancer Control, which is building on the Global Action Plan, is aimed at achieving major reductions in premature deaths from cancer, as well as improvements in quality of life and cancer survival rates. The Declaration contains nine targets to be achieved by 2025. One of them is to make effective pain control and distress management services universally available.

22. The Declaration also identifies a series of actions for all stakeholders, in particular Governments, to advance progress towards the targets. The Declaration urges them to:

\[\text{\footnote{The World Health Organization defines palliative care as "an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual." Available from www.who.int/cancer/palliative/definition (accessed 22/09/2014).}}\]
• Take steps to remove the many barriers to optimal pain control.
• Work with all stakeholders, including Governments, civil society and relevant private sector players, to address the overregulation of pain medicines.
• Cooperate with international agencies, including WHO, the United Nations Office on Drugs and Crime (UNODC) and the International Narcotics Control Board, to ensure that global implementation of the international drug control conventions strikes an appropriate balance between ensuring availability of pain medicines for cancer patients in pain and preventing their misuse.

23. A number of regional organizations have also emphasized the importance of the availability of internationally controlled drugs for medical purposes. The European Union Drugs Strategy for the 2013-2020 period highlighted the need to ensure and improve access to prescribed controlled medications as one challenge that had been identified in recent years. In 2012, the African Union Conference of Ministers of Drug Control adopted the African common position on controlled substances and access to pain management drugs. That position was translated into the African Union Plan of Action on Drug Control (2013-2017), which lists among its key objectives capacity-building to facilitate the licit movement of narcotic drugs and psychotropic substances for medical and scientific purposes. It also describes some outputs related to this objective, such as the removal of barriers limiting availability of internationally controlled drugs for medical and scientific purposes. The Inter-American Drug Abuse Control Commission of the Organization of American States, at its forty-seventh session, adopted a hemispheric drug strategy that states the following:

In applying control measures to limit the use of narcotic drugs exclusively to medical and scientific purposes, the availability of adequate supplies should be ensured. Availability exists when sufficient quantities are on hand and are accessible in accordance with international treaties.

24. The goal of ensuring adequate, not unduly restricted, availability of internationally controlled drugs for medical purposes has been pursued for over 50 years. It is fair to say that not all countries, in implementing the provisions of the 1961 and 1971 Conventions at the national level, have been able to ensure that this fundamental goal has informed the development of policies and administrative procedures for the distribution of narcotic drugs and psychotropic substances.

25. By becoming parties to the international drug control conventions, Governments have accepted the obligation to introduce the provisions of those treaties into their national legislation and to implement them. The International Narcotics Control Board (INCB) is the body established by the 1961 Convention that is responsible for monitoring the compliance of Governments with the international drug control treaties and for providing support to Governments in that regard.

26. The Board, under article 9 of the 1961 Convention, has the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes. It is in a unique position to monitor the cultivation, production, manufacture, import, export and consumption of narcotic drugs and psychotropic substances.

27. Over the years, the Board has reminded Governments of their obligations in this regard. It has repeatedly voiced its concern about the disparate and inadequate levels of access to controlled substances for medical and scientific purposes worldwide. It has raised this problem repeatedly in its annual reports and devoted a number of special reports to the topic.

28. The Economic and Social Council, in its resolution 1989/15 of 22 May 1989, requested the International Narcotics Control Board to “assess legitimate needs for opiates in various regions of the world, hitherto unmet because of insufficient health care, difficult economic situations or other conditions”. Pursuant to that resolution, INCB prepared a special report entitled Demand for and Supply of Opiates for Medical and Scientific Needs.

29. In that report, the Board concluded that the medical need for opiates, particularly those related to the treatment of cancer pain, were not being fully satisfied. The report further recommended that Governments should:

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• Critically examine their methods for assessing domestic medical needs for opiates and collecting and analysing data to ensure that estimates reflected actual needs.
• Examine the extent to which their health-care systems and laws and regulations permitted the use of opiates for medical use.
• Identify impediments to such use.
• Develop plans of action to facilitate the supply and availability of opiates for all appropriate indications.

30. The Economic and Social Council, in its resolutions 1990/31 and 1991/43, requested the Board to give priority to monitoring the implementation of those recommendations. In 1994, the Board examined the effectiveness of the international drug control treaties in a supplement to its annual report, entitled Effectiveness of the International Drug Control Treaties. In its evaluation, the Board concluded that the treaty objective of ensuring an adequate supply of narcotic drugs, especially opiates used for medical purposes, had not been universally achieved.

31. In 1995, the Board prepared another special report, entitled Availability of Opiates for Medical Needs. In that report, the Board noted that most Governments had not responded to its questionnaire aimed at determining the progress made in the implementation of the recommendations, but concluded that the recommendations of 1989 were far from being implemented, although there had been efforts by some Governments. The Board provided a new set of recommendations for the consideration of Governments; the United Nations Drug Control Programme; the Commission on Narcotic Drugs; WHO; international and regional drug control, health and humanitarian organizations; and educational institutions, as well as non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives.

32. Furthermore, chapter I of the annual report of the Board for 1999 was dedicated to the issue of the availability of narcotic analgesics. As internationally controlled drugs were overused in some countries, leading to prescription drug abuse and related problems, chapter I of the annual report of the Board for 2000 dealt with overconsumption of internationally controlled drugs and recommended a balanced approach in their use.

33. One tool to determine whether countries improve availability levels, or at least are aware of the problem and show the intention to improve, is an analysis of their assessments of annual estimated requirements for narcotic drugs, which all countries are required to submit to the Board. The Board regularly contacts countries with missing or particularly low estimates in order to ensure adequate availability of opioids for the treatment of pain. This practice was formalized in November 1999, when the Board started selecting certain groups of countries with low levels of consumption of opioid analgesics (mainly morphine) and with common characteristics. The matter was repeatedly brought to the attention of Governments in circular letters to all countries and specific letters to individual countries. In August 2001, a joint letter from the President of the Board and the Chair of the United Nations Development Group was sent to all resident coordinators of the United Nations system at the country level, urging them, inter alia, to be aware of underconsumption and the lack of medicaments available for the treatment of severe pain in many developing countries.

34. This request was confirmed in February 2005, in a follow-up joint letter from the President of the Board and the Chair of the United Nations Development Group. In April 2006, in a letter to all countries, the President of the Board emphasized the difficulties regarding access to narcotic drugs and psychotropic substances for patients in need, and encouraged Governments to take measures to ensure the inclusion of the subject of rational use of drugs in the curricula of the appropriate university faculties.

35. In 2010, INCB launched its 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, broadening the scope of the report to include also psychotropic substances.

36. The 2010 report identified once more the main impediments to adequate availability and provided detailed recommendations to various stakeholders. INCB noted that, in response to previous recommendations concerning the availability of narcotic drugs, a significant number of Governments had increased their annual estimated requirements to meet medical demand, issued national policies to improve medical use of narcotic drugs, supported educational programmes and examined their health-care systems, laws and regulations to see if they created impediments to availability.

37. INCB noted improvements in the adequacy of supply of certain narcotic drugs and psychotropic substances in many countries, but expressed concern about setbacks in
others. While the most significant improvements were recorded in highly developed countries, the setbacks had occurred mostly in the regions with the lowest levels of availability of internationally controlled substances. The report concluded that, in spite of the progress made towards meeting treaty objectives, relatively few countries had an adequate drug supply management system and working mechanisms that ensured reliable, needs-based assessments, equitable availability and cost-effectiveness.

38. The report pointed to the deficiencies in drug supply management that remained attributable to a lack of financial resources, inadequate infrastructure, the low priority given to health care, weak government authority, inadequate education and professional training, and outdated knowledge, which together affected the availability of not only controlled drugs but all medicines.

39. In 2012, a publication entitled Guide on Estimating Requirements for Substances under International Control was launched with the aim of providing competent national authorities with concrete tools to improve the assessment of their national needs.

40. At its 108th session, in November 2013, the Board decided to prepare a special report to be published in 2016 as a supplement to the INCB annual report for 2015. The Board decided that the report should focus on the implementation by Governments of the recommendations contained in its 2010 report on Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes.

41. Pursuant to that decision, the present report is aimed at providing an updated overview of the situation with regard to the availability of narcotic drugs and psychotropic substances for medical and scientific purposes as compared with the situation presented in 2010.

D. Methodology

1. Data on consumption

42. The data provided by countries to INCB show one aspect of the issue of availability, i.e. the amounts that the competent national authorities estimate and report as consumed. This information is available for a large number of countries for several years. However, since the quality of reporting varies from country to country, such information is not always reliable, even though INCB has the ability to verify reported consumption by using data from export and import notifications. The Board evaluates these consumption data in terms of “defined daily doses for statistical purposes” to ascertain the degree of overprescription or underprescription.

43. The term “defined daily doses for statistical purposes” (S-DDD) has replaced the term “defined daily doses”, which had previously been used by the Board. The defined daily doses for statistical purposes is used by INCB as a technical unit of measurement for the purpose of statistical analysis and is not a recommended prescription dose. This definition, which is not free of a certain degree of arbitrariness, recognizes that there are no internationally agreed standard dosages for narcotic drugs and psychotropic substances, that they are used in certain countries for different treatments or in accordance with different medical practices, and that therefore S-DDD should be considered an approximate measure to rank consumption in different countries. For narcotic drugs, levels of consumption, expressed in S-DDD per million inhabitants per day, are calculated by using the following formula: annual consumption, excluding the manufacture of the preparations in Schedule III of the 1961 Convention, divided by 365 days. The result obtained is divided successively by the population, in millions, of the country or territory during the year in question, and then by the defined daily dose of each substance.

44. Since the 1971 Convention does not foresee reporting on consumption of psychotropic substances to the Board, the rates of consumption are calculated by the Board every year, based on statistics reported by Governments on manufacture, industrial use, stocks and international trade. The rate of consumption of psychotropic substances is measured in S-DDD per 1,000 inhabitants per day. In addition, for the purposes of the present report, three-year averages were used, in order to account for the occasional non-submission of annual statistics, and in view of the practice by some Governments of intermittent manufacture and import of psychotropic substances when stocks cover domestic requirements for several years.

45. The analysis of the availability of psychotropic substances contained in the present report is based on the levels of consumption of groups of psychotropic substances.


30For some countries, the S-DDD calculated for the period 2001-2003 may be higher than the successive periods because of the difficulty at that time of distinguishing the quantities of opioids consumed for pain relief and the opioids utilized for the manufacture of preparations, listed in Schedule III of the 1961 Convention.
Levels of consumption of psychotropic substances expressed in S-DDD are calculated by using the following formula: manufacture plus imports plus stocks at the end of the previous year, minus exports minus quantities used for industrial purposes, minus stocks at the end of the current year, divided by 365 days. The result obtained is divided by the population, in thousands, of the country or territory during the year in question and by the defined daily dose. Some cases of high calculated use of psychotropic substances could be related to increasing manufacture for exports, with a possible lack of reporting of exports and/or a non-reporting of stocks of manufacturers and/or elevated stocks kept by wholesalers.

46. The Board has identified levels of consumption that it considers to be inadequate (consumption of opioid analgesics in quantities between 100 and 200 S-DDD per million inhabitants per day) or very inadequate (consumption of opioid analgesics in quantities equal to or less than 100 S-DDD). However, the Board has not yet defined comparable levels of adequate or inadequate consumption for psychotropic substances.

47. In the analysis of consumption of opioid analgesics expressed in S-DDD, the Board did not include methadone and buprenorphine because of the impossibility of distinguishing their use for pain relief from their use for the treatment of drug dependence.

2. Survey of Member States

48. In the summer of 2014, the Board sent questionnaires to competent national authorities asking for information on the availability of controlled drugs for medical and scientific purposes. One questionnaire was devoted to narcotic drugs, and a separate one to psychotropic substances. A total of 107 countries and territories, with 75 per cent of the world’s population, responded, providing important information that is discussed in the present report.

3. Other sources of information

49. While INCB data are important in measuring (through S-DDD) the performance of countries in ensuring the availability of internationally controlled drugs for medical use, it is important to also consider other sources of information when evaluating the situation. To that end, the Board also analysed information on health conditions for which internationally controlled drugs are required in order to compare reported consumption against the prevalence of the specific health conditions.

50. The World Health Organization and the Worldwide Palliative Care Alliance provided information on health conditions requiring palliative care and the level of palliative care development. The International Agency for Research on Cancer of WHO provided fundamental information on the prevalence of cancer through its GLOBOCAN database. Information on the prevalence of AIDS was made available by the Joint United Nations Programme on HIV/AIDS (UNAIDS). The United Nations Office on Drugs and Crime provided information on the number of people who inject drugs, which was then used to measure the specific availability of internationally controlled drugs (methadone and buprenorphine) used in the treatment of opioid dependence in relation to the prevalence of people who would be in need of such treatment.

51. In addition, various civil society organizations representing patients, families, health professionals and other stakeholders have also contributed data and information, and offered their views. A number of researchers have provided relevant analyses and insights.