



**UNODC**

United Nations Office on Drugs and Crime



# **Ensuring availability of controlled medications for the relief of pain and preventing diversion and abuse**

Striking the right balance to achieve  
the optimal public health outcome

DISCUSSION PAPER  
based on a scientific workshop



UNITED NATIONS OFFICE ON DRUGS AND CRIME  
Vienna

**Ensuring availability of controlled medications  
for the relief of pain and  
preventing diversion and abuse**

**Striking the right balance to achieve  
the optimal public health outcome**

Discussion paper based on a scientific workshop

January 18 – 19, 2011  
UNODC, Vienna



UNITED NATIONS  
New York, 2011



## Acknowledgements

This draft discussion paper has been prepared by UNODC Drug Prevention and Health Branch in collaboration and as a result of the deliberations of a group of international experts and INCB as observer, who attended a preliminary technical consultation held in Vienna in January 2011: “Access to controlled medicines for the treatment of pain”.

Mr. Alberto Groff  
Mr. Alexander David  
Mr. Almehdi Akari  
Dr. Andrea Trescot  
Ms. Asra Husain  
Mr. Ayoola L Olukani  
Dr. Bruna Brands  
Dr. Carlos Fabián Damin  
Ms. Daria Goncharova  
Mr. David Joranson  
Dr. Deborah Haller  
Ms. Denise Curry  
Ms. Elza Gustanti  
Ms. Engko Sosialine  
Mr. Ekpebike S. Agbana  
Dr. Éva Luxnè-Gecsö  
Ms. Fátima Costa  
Dr. Gisela Weiser- Herbeck  
Mr. Hashim Ubale Yusuf  
Dr. Hedvig Zajzon-Boruzs  
Mr. Heyam Ibrahim  
Mr. Jonathan Liberman  
Mr. José Romão  
Mr. Joseph Jody Suhendra  
Ms. Liliana De Lima  
Ms. Margaret Ogundipe  
Ms. Maureen Ebigbeyi  
Ms. Mila Fransisco Ferrada  
Mr. Mustafa Badr  
Ms. Ngozi Oguejiorfor  
Mr. Óscar Carvalho  
Dr. Paul Orhi  
Dr. Philip Emafo  
Mr. S. D. Umar  
Dr. Willem Scholten  
Mr. Yasuhiro Araki

The authors would like to thank Mr. Jonathan Liberman for his role as rapporteur throughout the meeting as well as co-drafter of the document. Furthermore the authors would like to thank Ms. Cristina Mesa who during her internship conducted a literature review on the topic and contributed to the initial drafts of this document.



# Contents

	<i>Page</i>
Purpose of this Discussion Paper .....	1
Background—the indispensability of controlled medicines.....	1
UNODC’s informal technical consultation on pain treatment.....	3
Appropriate pain treatment .....	4
Developmental aspects of access to controlled medicines .....	6
Convention control measures to ensure safety and availability.....	7
Impediments to availability of opioid analgesics.....	8
Regulatory impediments.....	8
Attitude and knowledge impediments.....	9
Economic and procurement impediments .....	10
Action to enhance access to opioid analgesics and to prevent diversion and abuse .....	11
Recommendations .....	11
Role of UNODC .....	12
A joint UNODC-WHO programme on access to controlled medications ...	12
Areas for immediate action .....	14





## Purpose of this Discussion Paper

This Discussion Paper has been prepared as a conference room paper for the 54<sup>th</sup> session of the Commission on Narcotic Drugs at which the adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes in accordance with the international drug control treaties will be on the agenda. It aims to complement two other major documents on availability of controlled medicines, namely the INCB's 2010 Annual Report, and particularly its supplement "Availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes",<sup>1</sup> and the World Health Organization (WHO) revised "Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines".<sup>2</sup>

It is hoped that these documents can collectively assist Member States in moving forward with practical action in this area involving cooperation and coherence at both national and international levels.

This Discussion Paper has been developed with an understanding that country experiences, capacities, cultures and needs vary widely. What is required to achieve the optimum public health outcome in any particular country will depend on the particular circumstances of that country.

## Background—the indispensability of controlled medicines

At the 53<sup>rd</sup> session of the Commission on Narcotic Drugs (CND) held in March 2010, the Commission adopted Resolution 53/4 "Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse".<sup>3</sup>

The Commission recalled the recognition of parties to the Single Convention on Narcotic Drugs 1961<sup>4</sup> as amended by the 1972 Protocol<sup>5</sup> that the medical use of narcotic drugs continued to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability for such purposes. It also recalled the recognition of parties to the Convention on Psychotropic Substances 1971<sup>6</sup> 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.

---

<sup>1</sup>International Narcotics Control Board, "Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes", New York 2011.

<sup>2</sup>World Health Organization, "Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines", Geneva 2011.

<sup>3</sup>"Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse".

<sup>4</sup>United Nations, Treaty Series, vol. 520, No. 7515.

<sup>5</sup>United Nations, Treaty Series, vol. 976, No. 14152

<sup>6</sup>United Nations, Treaty Series, vol. 1019, No 14956.

The rational use of controlled medicines—i.e. medicines controlled under the international drug treaties—is essential to health. Their rational prescription and administration are essential aspects of good medical practice for pain treatment and other clinical interventions.<sup>7</sup>

Notwithstanding the universally recognized medical indispensability of narcotic drugs and psychotropic substances, the World Health Organization (WHO) estimates that every year tens of millions of people suffer disease, moderate to severe pain and death because they do not have access to controlled medicines.<sup>8</sup> This lack of availability of controlled medicines represents a major global health problem.

In Resolution 53/4, the Commission noted its concern that “although there is sufficient supply of licit opiate raw materials to meet global requirements” as highlighted in the annual reports of INCB for 2008 and 2009, “access to opioid-based medications is non-existent or almost non-existent in many countries and regions”.<sup>9</sup> The Commission’s concern is confirmed in the International Narcotics Control Board’s (INCB) Supplement to its 2010 Annual Report, “Availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”,<sup>10</sup> with the Board underlining the “urgent need” for some Governments to take measures to ensure that their populations have adequate access to opioid-based medications in accordance with the international drug control Conventions.<sup>11</sup>

Opioids are recognized to have a number of medical uses, including as analgesics for the treatment of mild, moderate and/or severe pain with, for example buprenorphine, oxycodone, fentanyl, hydromorphone, methadone and morphine, to induce or supplement anaesthesia (fentanyl and fentanyl analogues such as alfentanil and remifentanyl), as cough suppressants (codeine and some other substances), and for the treatment of opioid dependence syndrome (buprenorphine and methadone).

Member States are referred to WHO publications for clinical treatment guidelines on the rational use and management of adverse effects, based on scientific evidence. Currently available are:

- WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illness<sup>12</sup>
- WHO Guidelines on Psychosocially Assisted Pharmacological Treatment of Opioid Dependence<sup>13</sup>

While the rational use of opioids is essential to health, they can produce negative health consequences and secondary effects that can be particularly serious in cases of misuse and abuse, such as sleep apnoea, constipation, decreased sexual hormone levels leading to osteoporosis, sedation (car and workplace accidents), nausea, loss of judgement and sometimes

<sup>7</sup>World Health Organization, “Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines” Geneva 2011, p.10.

<sup>8</sup>Ibid

<sup>9</sup>“Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse”.

<sup>10</sup>International Narcotics Control Board, “Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”, New York 2011, para 40.

<sup>11</sup>Ibid

<sup>12</sup>WHO Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illness. Geneva, 2011.

<sup>13</sup>World Health Organization. WHO Guidelines on Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Geneva, 2009.

fatal overdose (respiratory depression and death). Health professionals must monitor the adverse effects and indications of misuse especially amongst patients with a history of misuse.

While in most countries there is little or no access to opioids, in some countries, the misuse of controlled medicines represents a significant public health problem. In resolution 53/4, the Commission acknowledged that an increase in the licit supply of internationally controlled substances may raise the risk of diversion and abuse.<sup>14</sup>

The reason that opioids are controlled under the international drug control Conventions is the harm associated with misuse and abuse. As the Commission affirmed in Resolution 53/4, the Conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse.<sup>15</sup> Both sides of this balance—ensuring availability and preventing diversion and abuse—are concerned with the protection and promotion of health and public safety. As WHO states, the public health outcome is “at its maximum” when “the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use”.<sup>16</sup>

This recognition of the international drug control Conventions as concerned primarily with health was articulated by the former Executive Director of the United Nations Office on Drugs and Crime (UNODC), in his report to the review of the twentieth special session of the General Assembly, in which he said “we most bring public health—the first principle of drug control—back to centre stage” and “drug control, and the implementation of the drug Conventions, must proceed with due regard to health and human rights”.<sup>17</sup>

## UNODC’s informal technical consultation on pain treatment

In Resolution 53/4, the Commission requested the UNODC “to continue its efforts to ensure the adequate availability of internationally controlled drugs and psychotropic substances for medical and scientific purposes, cooperating, as appropriate, through the Access to Controlled Medications Programme of the World Health Organization, while continuing its activities to prevent diversion and abuse”.<sup>18</sup>

Pursuant to this request, the UNODC convened an informal technical consultation in January 2011 on “Access to controlled medicines for the treatment of pain”. The purpose of the consultation was to discuss further actions to be taken on the already established scientific basis for a necessary response to acute and unnecessary pain endured by patients when opioid-based medications are unavailable and to develop a document on the progress

---

<sup>14</sup>“Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse”.

<sup>15</sup>Ibid.

<sup>16</sup>World Health Organization, “Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines”. Geneva 2011, p.16.

<sup>17</sup>“Making drug control “fit for purpose”: Building on the UNGASS decade”. Report by the Executive Director of the United Nations Office on Drugs and Crime as a contribution to the review of the twentieth special session of the General Assembly.

<sup>18</sup>“Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse”.

of activities to be submitted to the 54<sup>th</sup> session of the CND for further discussion. UNODC has previously released two discussion papers dealing with the use of opioid medication for drug treatment: “Reducing the adverse health and social consequences of drug abuse: a comprehensive approach”;<sup>19</sup> and “Principles of drug dependence treatment”.<sup>20</sup>

The tragedy of the inadequate availability of opioid analgesics is well expressed by the INCB: “Although medical science has the capacity to provide relief for most forms of moderate to severe pain, over 80 per cent of the world population will have insufficient analgesia, or no analgesia at all, if they suffer from such pain.”<sup>21</sup> WHO estimates that each year 5.5 million terminal cancer patients and 1 million end-stage HIV/AIDS patients as well as many other people with chronic, non-malignant pain suffer un- or under-treated moderate to severe pain, including 800,000 patients with lethal injuries caused by accidents and violence, patients with chronic illnesses, patients recovering from surgery, women in labour (110 million births each year) and paediatric patients.<sup>22</sup> Altogether, WHO estimates that annually tens of millions of people are not treated adequately for their moderate to severe pain.<sup>23</sup>

Unrelieved pain affects the quality of life of individuals and their families, friends and communities, and can cause wider losses to society, such as through reduced productivity of both patients and their caregivers. Inadequate pain treatment may also lead to the seeking of additional medical intervention.<sup>24</sup>

Global inequalities in access to pain relief are stark, with, for example, 90 per cent of the global consumption of morphine, fentanyl and oxycodone registered in 2009 occurring in Australia, Canada, New Zealand, the United States and several European countries.<sup>25</sup>

## Appropriate pain treatment

Pain was defined by the International Association for the Study of Pain (IASP) in 1979 as an “unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage”.<sup>26</sup> Data from WHO identified the worldwide prevalence of significant, persistent pain in about 22 per cent of primary care patients.<sup>27</sup>

The source of the pain signal dictates the rational use of medications for its treatment. Pain can be considered nociceptive or neuropathic or a combination of both. Nociceptive pain is most well-known to the clinician and originates from damage to the body (skin, bones, muscles

---

<sup>19</sup>United Nations Office on Drugs and Crime, “Reducing the adverse health and social consequences of drug abuse: a comprehensive approach”. Vienna 2009.

<sup>20</sup>United Nations Office on Drugs and Crime and World Health Organization, “Principles of drug dependence treatment”. Vienna, 2008.

<sup>21</sup>International Narcotics Control Board, “Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”, New York 2011, para 5.

<sup>22</sup>World Health Organization, “Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines”. Geneva 2011, p.19.

<sup>23</sup>Ibid.

<sup>24</sup>World Health Organization, “Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines”. Geneva 2011, p.19

<sup>25</sup>International Narcotics Control Board, “Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”. New York 2011, para 5.

<sup>26</sup>International Association for the Study of Pain. *Pain* 1979;6:249-252

<sup>27</sup>Gureje O., Von Korff M, Simon G.E., Gater R. Persistent pain and well-being: a World Health Organization Study in Primary Care. *JAMA*. 1998 Jul 8;280(2):147-51.

and viscera) other than to the peripheral or central nervous system. This kind of pain generally responds to nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids. Neuropathic pain refers to “all pain initiated or caused by a primary lesion or dysfunction of the nervous system”.<sup>28</sup> A subgroup of patients with neuropathic pain responds to opioid medicines.

Rational use of medication, therefore, requires an understanding of the type of pain, matching the pain to the most appropriate treatment. The initial approach to the patient in pain includes physical modalities such as ice and heat as well as mild analgesics such as acetaminophen/paracetamol. Pain associated with inflammation is rationally treated with anti-inflammatory medicines, both nonsteroidal (NSAIDs) as well as steroid. Opioid analgesics have an essential role in the treatment of moderate to severe pain, particularly in patients not responding to other analgesic medication. A rational use of opioids as analgesics would integrate them into a complex treatment schedule.

Opioid analgesics are essential for sufficient pain management, but should never be the only available substance type for the treatment of pain, particularly for the treatment of mild to moderate pain. Both opioid and non-opioid analgesics should be made available for appropriate pain management and their rational use should follow an appropriate clinical assessment, criteria for proportional interventions and pharmacological rules for the integration in a complex therapeutics approach. If appropriately used, opioid medicines are safe and the patients rarely become dependent on opioid analgesia.<sup>29</sup>

It is also clear that not all opioids work the same way in the same dose for all patients.<sup>30</sup> Although still not well defined, some of the differences appear to be genetic, with changes in opioid receptors leading to differing levels of analgesia.<sup>31</sup> Genetics also control the metabolism of opioids, leading to low or elevated blood levels depending on whether the patient is a fast or slow metabolizer.<sup>32</sup> Other differences in response to opioids may be due to concomitant medications that influence the metabolism of opioids. As an example, multiple medications, especially several antidepressants, will block the metabolism of certain opioids. This evidence indicates how important it is for the management of pain to be driven on a case-by-case basis, with personalized therapeutic programmes, including personalized dosage and frequency of administration.

Knowledge of the use of appropriate pain medications,<sup>33</sup> their metabolism,<sup>34</sup> and the management of their side effects<sup>35</sup> (including addiction<sup>36</sup>) are all critical to the safe and effective use of these medicines, and the investment in training programmes must therefore be part of any attempt to increase pain relief efforts.

<sup>28</sup>Merskey H., Bogduk N (eds). *Classification of Chronic Pain*. Seattle, IASP Press 1994.

<sup>29</sup>Noble M., Treadwell JR, Tregear S.J., Coates V.H., Wiffen P.J., Akafomo C., Schoelles K.M. Long-term opioid management for chronic noncancer pain. *Cochrane Database Syst Rev*. 2010 Jan 20;(1):CD006605.

<sup>30</sup>Smith H.S. Variations in opioid responsiveness. *Pain Physician*. 2008;11:237-48.

<sup>31</sup>Bayerer B., Stamer U., Hoeft A., Stuber F. Genomic variations and transcriptional regulation of the human mu-opioid receptor gene. *Eur J Pain*. 2007 May;11(4):421-7.

<sup>32</sup>Samer C.F., Daali Y., Wagner M., et al. Genetic polymorphisms and drug interactions modulating CYP2D6 and CYP3A activities have a major effect on oxycodone analgesic efficacy and safety. *Br J Pharmacol*. 2010;160(4):919-30.

<sup>33</sup>Trescot A.M., Helm S., Hansen H., et al. Opioids in the management of chronic non-cancer pain: an update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines. *Pain Physician*. 2008;11(Opioid Suppl):S5-S62.

<sup>34</sup>Trescot A.M., Datta S., Lee M., Hansen H. Opioid pharmacology. *Pain Physician*. 2008;11(Opioid Suppl):S133-S53.

<sup>35</sup>Benjamin R., Trescot A.M., Datta S., et al. Opioid complications and side effects. *Pain Physician*. 2008;11(Opioid Suppl):S105-20.

<sup>36</sup>Manchikanti L., Atluri S., Trescot A.M., Giordano J. Monitoring opioid adherence in chronic pain patients: tools, techniques, and utility. *Pain Physician*. 2008 Mar;11(Opioid Suppl):S155-80.

The issue of opioid dependence related to the treatment of pain remains controversial. On the one hand, the fear of opioid dependence is discouraging public opinion and also health-care personnel in respect to the use of opioid analgesics. On the other hand, the evidence concerning dependence in patients affected by pain should be expanded. All persons exposed continuously to opioids develop tolerance and withdrawal, two important, but by themselves not sufficient characteristics to diagnose dependence. Dependence is understood as a bio-psycho-social condition which clusters physiological, behavioural and cognitive phenomena and their related vulnerability factors. In most cases, patients treated with opioid analgesics for pain do not present the vulnerability characteristics that contribute to inducing a condition of dependence, although they develop tolerance and withdrawal symptoms<sup>37</sup>.

Although the risk of opioid dependence is really low among people treated for pain, it could be more significant in some individuals with a specific history of vulnerability. Therefore, close clinical monitoring and an individualized approach for each patient are needed to provide adequate pain treatment while preventing unintended consequences such as dependence or diversion.<sup>38,39,40</sup> However, dependence alone is not a contraindication for use of opiates in the treatment of pain.

## Developmental aspects of access to controlled medicines

Access to medicines is a key part of the international development agenda, which recognizes the essential role that health plays in social and economic development, and the indispensability of medicines to good health. It is specifically addressed in Target 8.E of the Millennium Development Goals (MDGs): “In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries”.<sup>41</sup> At the September 2010 United Nations General Assembly Millennium Development Goals Review, the General Assembly committed to “accelerating progress in promoting global public health for all”, by strengthening international cooperation in improving access to medicines.<sup>42</sup>

In September 2011, the United Nations General Assembly will hold a high-level meeting on the prevention and control of non-communicable diseases, with a focus on the four most prominent non-communicable diseases, namely cardiovascular diseases, cancers,

<sup>37</sup>Webster L.R., Webster R.M. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. *Pain Med.* 2005 Nov-Dec;6(6):432-42.

<sup>38</sup>Ballantyne J.C., Shin N.S. Efficacy of opioids for chronic pain: a review of the evidence. *Clin J Pain.* 2008 Jul-Aug;24(6):469-78. DuPen A., Shen D., Ersek M. Mechanisms of opioid-induced tolerance and hyperalgesia. *Pain Manag Nurs.* 2007 Sep;8(3):113-21. Ueda H., Ueda M. Mechanisms underlying morphine analgesic tolerance and dependence. *Front Biosci.* 2009 Jun 1;14:5260-72. Koch T., Höllt V. Role of receptor internalization in opioid tolerance and dependence. *Pharmacol Ther.* 2008 Feb;117(2):199-206. Epub 2007 Nov 17.

<sup>39</sup>Passik S.D. Issues in long-term opioid therapy: unmet needs, risks, and solutions. *Mayo Clin Proc.* 2009 Jul;84(7):593-601.

<sup>40</sup>Chou R., Fanciullo G.J., Fine P.G., Miaskowski C., Passik S.D., Portenoy R.K. Opioids for chronic noncancer pain: prediction and identification of aberrant drug-related behaviors: a review of the evidence for an American Pain Society and American Academy of Pain Medicine clinical practice guideline. *J Pain.* 2009 Feb;10(2):131-46.

<sup>41</sup>United Nations General Assembly, “Follow-up to the outcome of the Millennium Summit” A/RES/56/95 (adopted 14 December 2001).

<sup>42</sup>United Nations General Assembly, “Keeping the promise: united to achieve the Millennium Development Goals” (adopted 22 September 2010), para 73(m).



chronic respiratory diseases and diabetes.<sup>43</sup> The General Assembly Resolution deciding to hold this high-level meeting “underscored the need for concerted action and a coordinated response at the national, regional and global levels in order to adequately address the developmental and other challenges posed by non-communicable diseases”.<sup>44</sup> The General Assembly noted with concern that access to medicines remains a distant goal for millions of people throughout the world and reaffirmed the need to strengthen international cooperation in the production of and increased access to affordable, safe, effective and high-quality medicines.<sup>45</sup> This should be seen to apply equally to access to opioid analgesics for the treatment of pain as to preventive and curative medicines.

In Resolution 53/4, the Commission invited Member States to consider ways to leverage existing health and development programmes in countries without adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes, including by building the capacity of those countries through training.<sup>46</sup>

## Convention control measures to ensure safety and availability

The objective of the international drug Conventions—balance between ensuring availability and preventing diversion and abuse—is promoted by an international regulatory system that provides the framework for national drug regulation. Pursuant to the international regulatory system, States agree to adopt certain regulatory requirements.

The control provisions of the Conventions are designed to (a) ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and (b) combat illicit manufacture, trade and distribution. They are designed to serve what the INCB has described as the overall goal of a “well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances” namely “to provide relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, to prevent the diversion of drugs for the purpose of abuse”.<sup>47</sup>

Measures which parties to the Conventions agree to implement include:

- Government licensing of manufacture<sup>48</sup>
- Government licensing of trade and distribution<sup>49</sup>
- Government licensing of international trade<sup>50</sup>

<sup>43</sup>United Nations General Assembly, “Prevention and Control of Non-Communicable Diseases” A/RES/64/265 (adopted 13 May 2010).

<sup>44</sup>Ibid

<sup>45</sup>Ibid

<sup>46</sup>Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse”.

<sup>47</sup>International Narcotics Control Board, “Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”. New York 2011, para 132.

<sup>48</sup>Article 29, Single Convention 1961 and Article 8, Convention on Psychotropic Substances 1971.

<sup>49</sup>Article 30, Single Convention 1961 and Article 8, Convention on Psychotropic Substances 1971.

<sup>50</sup>Article 31, Single Convention 1961 and Article 8, Convention on Psychotropic Substances 1971.

- Government import-export authorization<sup>51</sup>
- Provision to the INCB annually of estimates of medical and scientific needs for narcotic drugs<sup>52</sup>
- Record-keeping by governmental authorities and persons engaged in manufacture, trade and distribution, and conduct of inspections by government<sup>53</sup>
- Requirement of medical prescriptions for supply or dispensation to individuals<sup>54</sup>
- Prohibition of advertising to the general public with due regard to constitutional provisions<sup>55</sup>
- Requirement of adequate labelling<sup>56</sup>
- Requirements for commercial documents<sup>57</sup>
- Suppression of use of the mails in accordance with basic principles of domestic legal systems<sup>58</sup>
- Prohibition of export to post office box<sup>59</sup>
- Establishment of penal provisions for contraventions of the above requirements.

## Impediments to availability of opioid analgesics

While the availability of opioid analgesics for legitimate treatment of pain in many countries is unacceptably low, the major impediments to availability are widely known, and progress is being made in some countries.<sup>60</sup> Further global progress can be made if there is sufficient will and if resources are adequately mobilized.

The WHO divides the causes of underuse of controlled medicines into three categories: regulatory impediments; attitude and knowledge impediments; and economic and procurement impediments.<sup>61</sup>

### Regulatory impediments

While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare,<sup>62</sup> efforts to limit the use of narcotic drugs and psychotropic substances

<sup>51</sup>Article 31, Single Convention 1961 and Article 12, Convention on Psychotropic Substances 1971.

<sup>52</sup>Articles 12 and 19, Single Convention 1961.

<sup>53</sup>Article 34, Single Convention 1961 and Articles 11 and 15 Convention on Psychotropic Substances 1971.

<sup>54</sup>Article 30.2(b), Single Convention 1961 and Article 9, Convention on Psychotropic Substances 1971.

<sup>55</sup>Article 10, Convention on Psychotropic Substances 1971.

<sup>56</sup>Articles 30.4 and 30.5, Single Convention 1961, Article 10, Convention on Psychotropic Substances 1971 and Article 16.2, Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

<sup>57</sup>Article 16.1, Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

<sup>58</sup>Article 19, Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

<sup>59</sup>Article 31, Single Convention 1961 and Article 12, Convention on Psychotropic Substances 1971.

<sup>60</sup>Joranson D.E., Ryan K.M., Maurer M.A. (2010) Opioid policy, availability and access in developing and non-industrialized countries. In: Fishman S.M., Ballantyne J.C., Rathmell J.P., eds. *Bonica's Management of Pain*. Baltimore, M.D.: Lippincott Williams & Wilkins, pp. 194-208.

<sup>61</sup>World Health Organization, "Access to controlled medications programme framework" Geneva 2007, pp. 7-8.

<sup>62</sup>Article 39, Single Convention 1961 and Article 23, Convention on Psychotropic Substances 1971.



to medical and scientific purposes “must not adversely affect their availability for such purposes”.<sup>63</sup> A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability.<sup>64</sup>

Examples of measures that may impede availability and that are not required by the Conventions include:

- Limitations on the number of days’ supply that may be provided in a single prescription (with too short a period of time allowed);
- Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low);
- Excessive limitations on prescription authority, such as only to some categories of medical doctors;
- Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain, and/or a requirement that multiple copies of the prescription be maintained;
- Requirements that patients receive special permission or registration to render them eligible to receive opioid prescriptions;
- Excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids;
- Arbitrary restrictions on the number of pharmacies permitted to dispense opioid medications; and
- Unreasonable requirements relating to the storage of opioid medications.

These measures, not required by the Convention, do not significantly improve control, but may interfere significantly with accessibility to and availability of essential medicines.

### **Attitude and knowledge impediments**

The recent INCB survey referred to above found that<sup>65</sup> a majority of Governments identified attitude and knowledge-related impediments among health-care professionals and patients and insufficient training for health-care professionals as the main factors contributing to the underuse of opioids.

#### ***Health-care professionals***

In many countries, health-care professionals are insufficiently trained in the recognition and management of pain. Many do not know how to ask patients about pain or how to understand patients’ descriptions of pain, do not appreciate the need to ease pain, and underestimate the extent to which pain can be relieved through treatment that includes the use of opioid analgesics.

<sup>63</sup>International Narcotics Control Board, “Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”. New York 2011, para 131.

<sup>64</sup>International Narcotics Control Board, “Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes”. New York 2011, para 97.

<sup>65</sup>Ibid

Many are overly concerned about the side effects of opioid treatment and hold exaggerated fears of the potential for the development of dependence or of depression of the central nervous system.

These attitudes and knowledge impediments are often the result of medical schools and other health-care related programmes inadequately teaching pain management and also not including pain management in continuing health affiliated professional education programmes. These shortcomings can commonly result in health professionals not treating a patient's pain or using ineffective medicines that are not suitable for the treatment of moderate to severe pain.

### ***Patients, their families and the general public***

In many countries, patients—often acting in the context of family values and influence—do not report pain or refuse to be treated with opioid analgesics. They may have internalized social stigma relating to opioid use, hold exaggerated fears of the side effects of opioid use, or worry about the effects of opioid use on their awareness.

The suffering of pain can undermine human dignity and the failure to relieve pain can conflict with health-care professional treatment standards and values. From an ethical perspective, health-care professionals must take account of and respect patients' personal conceptions of pain and their treatment wishes. Health-care professionals should strive to strike a balance that provides patients with the support and treatment they need and deserve, and respects their beliefs and their autonomy.

### **Economic and procurement impediments**

In many countries, particularly low- and middle-income countries, a range of barriers which affect the availability of medicines generally may be in place. As INCB notes, there may be deficiencies in drug supply management due to lack of financial resources, inadequate infrastructure, the low priority given to health care, weak government authority, inadequate education and professional training, and outdated knowledge.<sup>66</sup> In some cases, medicines may be available in large cities, but supply chains do not reach smaller cities or towns or rural areas. In these circumstances, substantial progress in the availability of opioid analgesics cannot be achieved in isolation from broader efforts to enhance the availability of medicines generally in the context of work to strengthen health systems (including the accessibility of treatment and rehabilitation facilities) and national infrastructure as a whole.

In addition, though opioid analgesics can, being off-patent, be produced and sold cheaply, they often cost significantly more in low- and middle-income countries than in high-income countries. In several countries, the limited use of opioids means that the current market for them is small and uncertain. This type of market for products with a small profit margin is unattractive for local pharmaceutical companies to begin manufacturing and also discourages foreign pharmaceutical companies from paying the fees to register their products. The result is very limited competition and monopolistic pricing and frequently no supply available in the entire country.

---

<sup>66</sup>International Narcotics Control Board, "Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes". New York 2011, para 128.

## Action to enhance access to opioid analgesics and to prevent diversion and abuse

This section is divided into two parts: recommendations for actions that can be taken to enhance access to opioid analgesics and prevent diversion and abuse; and the role of UNODC in enhancing access and preventing diversion and abuse.

### Recommendations

- Improve data collection mechanisms used for Governments' estimation of requirements through the collection of data about unmet needs for opioid analgesics by surveying professionals and non-governmental organizations, hospices, palliative care programmes, pharmacies, medical centres, emergency rooms and primary care;
- Review and revise national legislation, regulation and policies, in order to ensure that they reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability;
- Increase the awareness of policymakers and national regulatory authorities about the necessity, including unmet needs, for opioid analgesics, through training and the dissemination of informational materials;
- Stimulate inter-agency coordination and cooperation between relevant government ministries and agencies, including health, drug regulation, law enforcement, justice and customs, to facilitate the sharing of information and to ensure the implementation of balanced laws, regulations, policies and programmes;
- Establish national committees and workshops on pain treatment and palliative care that bring together relevant government personnel, medical and pharmaceutical stakeholders, and patients' and families' representatives, to facilitate the sharing of information and better coordination of regulatory, medical and pharmaceutical practices affecting access to and control of opioid analgesics;
- Provide training to medical doctors, nurses, pharmacists and health-care professionals concerning the treatment of pain, methods to prevent the misuse of opioid analgesics, the balance between ensuring availability and preventing diversion and abuse, and the most common misunderstandings about the use of opioid analgesics. Such training should be included in both health-care professional university curricula and ongoing professional education;
- Allow appropriately trained and qualified medical practitioners to prescribe opioid analgesics without requiring an additional licence specific to opioids;
- Educate the public about the appropriate role of opioid analgesics, addressing outdated beliefs, and removing prejudices that present barriers to rational use; promote the view of pain treatment as an essential part of an individualized therapeutic relationship, respecting the specific needs, expectations and beliefs of the individual patient and trust in the provider;

- Provide Member States, particularly low- and middle-income countries, with the necessary technical assistance, and the necessary instruments including model laws, to facilitate the implementation of a better balance between ensuring availability of opioid analgesics and preventing diversion and abuse;
- Reinforce existing monitoring mechanisms, and assist low- and middle-income countries to develop systematic supervision systems—including electronic monitoring systems—enabling the detection of illegal manufacture, over-prescription, unjustified sale or supply, and diversion;
- Establish mechanisms facilitating the availability in low- and middle-income countries of opioid analgesics at affordable prices, in cooperation, as appropriate, with pharmaceutical companies (as has occurred with respect to anti-retroviral therapy for HIV/AIDS);
- Increase the monitoring of internet trading and delivery of controlled medications by mail and dismantle illegal delivery channels;
- Engage civil society and relevant non-governmental organizations, as appropriate, in activities designed to enhance availability of opioid analgesics and prevent their diversion and abuse.

### **Role of UNODC**

A central aspect of the work of the UNODC is its normative work assisting States to implement relevant international treaties, including through the development of domestic legislation. UNODC thus has a clear mandate and responsibility to work to assist Member States to implement balanced laws and policies taking into account that different cultures, attitudes, knowledge and experience require individual guidance in such processes.

UNODC will commence a process of examination of its model laws to ensure that they reflect an appropriate balance between the measures to ensure availability of controlled medications for medical and scientific purposes and the measures to reduce illicit manufacture, illicit trade, and diversion. If required, revisions will be made to remove or modify provisions that create impediments to medical and scientific use and do not advance the objectives of the Conventions.

UNODC has long worked proactively to assist Member States to implement the diversion and abuse prevention aspect of their obligations under the drug Conventions. This should be, and will remain, an essential element of UNODC's work, but the Office will also focus equally on all elements necessary to guarantee availability and accessibility with particular attention to avoiding any control measures unintentionally impeding high quality medical treatment.

## **A joint UNODC-WHO programme on access to controlled medications**

UNODC and WHO are already partners in a “Joint Programme on Drug Dependence Treatment and Care”, which was launched in March 2009 with the aim of promoting and supporting worldwide, with a particular focus on low- and middle income countries,

evidence-based and ethical treatment policies, strategies and interventions to reduce the health and social burden caused by drug use and dependence.

UNODC and WHO have complementary mandates, experience, competencies and networks. Through the Joint Programme, UNODC and WHO work to strengthen their collaboration on drug dependence treatment and care at the global, regional and country levels, sharing their networks of intervention and interacting with Member States and other intergovernmental organizations on a common basis. The Joint Programme aims to start or facilitate dialogues with Member States through their Ministry of Health, National Drug Secretariat, Ministry of Interior, Ministry of Justice and other relevant ministries. Activities at the country and regional levels are implemented through UNODC's network of Regional and Country Offices, in close collaboration with WHO Regional and Country Offices.

In a similar way, a large scale initiative and interagency cooperation between UNODC and WHO would make a real difference to enhance the accessibility of controlled medicines for the treatment of pain. Within this framework, Member States, both donors and recipients, should perform their responsibilities in supporting the development of appropriate legislation and regulatory systems, the training of health professionals, drug policy and law enforcement officials, the conducting of public awareness and education programmes, and the procurement of medicines, in cooperation with public health agencies, NGOs and civil society organizations.

In the light of developments over the last decade in better understanding the impediments to the availability of opioid analgesics and the need for balanced laws and policies, and the Commission's request to UNODC in Resolution 53/4, the time has come for UNODC and WHO to enter into such a partnership on "Access to controlled medicines". The purpose of such a partnership—building on WHO's existing Access to Controlled Medications Programme—would be to jointly support Member States' efforts to ensure availability of controlled medicines for medical and scientific purposes while implementing appropriate control mechanisms to prevent the potential abuse and diversion of these substances.

A joint UNODC/WHO programme on "Access to controlled medicines" would have an enormous impact in alleviating pain and other conditions suffered by millions of people around the world.

### **WHO's Access to Controlled Medications Programme**

At the request of the Economic and Social Council and the World Health Assembly, WHO developed with INCB the Access to Controlled Medications Programme (ACMP). This was announced to the Commission on Narcotic Drugs in its 51st session by the Director-General of WHO and the President of INCB in a joint declaration.

The ACMP is operated by WHO. The ACMP develops policy and treatment guidance related to the medical and scientific use of controlled substances, as well as other technical guidance. Together with INCB it develops a manual on establishing estimates and statistics on controlled substances. The programme provides country support for the implementation of guidelines and for the review of pertinent policies and legislation.

## Areas for immediate action

There are three areas in which UNODC can immediately take action in order to assist Member States to implement the availability aspect of their obligations under the drug conventions:

1. UNODC will review and revise its model laws to ensure that they fully reflect the Convention obligations concerning both ensuring availability and preventing diversion and abuse and make necessary revisions.
2. This is a particularly important matter in the light of the Commission's encouragement to Member States in Resolution 53/4 States to consider working with INCB and UNODC to update policies and legislative frameworks, as appropriate, to ensure adequate availability and prevent diversion and abuse, in line with the provisions of the international drug control treaties.
3. UNODC will conduct awareness-raising activities and training for UNODC personnel through Regional and Country Offices to ensure that efforts to ensure adequate availability of controlled medicines are fully integrated into their work with Member States on the implementation of the international drug control treaties.
4. Initiate formal and practical mechanisms aimed at joining efforts by the three incumbent bodies, in securing appropriate availability of controlled substances for medical and scientific purposes, emphasizing INCB in its regulatory and quasi-judicial role, WHO as directing and coordinating authority on global health matters and, UNODC as the executive organization translating the Conventions into operational strategies by means of providing technical assistance to Member States through its consolidated network of Field Offices.





# UNODC

United Nations Office on Drugs and Crime

Vienna International Centre, PO Box 500, 1400 Vienna, Austria  
Tel.: (+43-1) 26060-0, Fax: (+43-1) 26060-5866, [www.unodc.org](http://www.unodc.org)