Joint Submission on Controlled Medicines Policy and Human Rights

Office of the High Commissioner for Human Rights

May 2015

In response to your letter of April 16, 2015, we are pleased to make the following submission to the Office of the High Commissioner of Human Rights (OHCHR) for consideration in the preparation of the study mentioned in Resolution A/HRC/28/L.22 for the UN General Assembly Special Session on the World Drug Problem.

As organizations active in the field of palliative care, our submission focuses on the need for countries to ensure people have access to controlled substances for medical purposes. As you may know, controlled substances play a critical role in the provision of healthcare around the world. At present, 12 medicines that are made of or contain controlled substances are on the World Health Organization (WHO) Model List of Essential Medicines which are used such diverse fields of medicine as analgesia, anesthesia, drug dependence, maternal health, mental health, neurology, and palliative care. In this submission we focus on access to opioid analgesics for pain management and palliative care.

The Human Rights Council (HRC) resolution recalls the international drug control conventions and notes the "need to promote adequate availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes," echoing a core objective of the UN drug conventions. Under both the international drug control conventions and international human rights law, countries have a legal obligation to ensure patients with a medical need for these medicines have access to them.

A wealth of research from countries around the world, however, suggests that controlled substance regulations often interfere with the availability and accessibility of this group of medicines, especially strong analgesics. Regulations are frequently far more restrictive than required by the UN drug conventions, deterring their use. These kinds of regulations raise important questions about the fulfillment by countries of their obligations under the right to health as well as the obligation to protect individuals from exposure to cruel, inhuman, or degrading treatment.

Background

With life expectancy increasing worldwide, the prevalence of non-communicable diseases (NCDs), such as cancer, lung, and heart disease, is rising rapidly.[1] These and other chronic illnesses are often accompanied by pain and other distressing symptoms.[2] Palliative care focuses on relieving these symptoms and ensuring that people with life-limiting illnesses and their loved-ones can enjoy the best possible quality of life throughout the course of their disease up until their last moments.

An important aspect of palliative care is addressing chronic, severe pain. Pain has a profound impact on quality of life and can have physical, psychological, and social consequences. It can lead to reduced mobility and consequent loss of strength; compromise the immune system; and interfere with a person's ability to eat, concentrate, sleep, or interact with others.[3]

Most pain in palliative care patients can be controlled well.[4] The mainstay medication for the treatment of moderate to severe pain is morphine, an inexpensive opioid that is made of an extract of the poppy plant. For moderate to severe pain, the WHO has recognized that strong opioids, such as morphine, are "absolutely necessary".[5]

Human Rights Standards

The obligation of states to respect, protect, and fulfill the right to health includes an obligation to ensure access to pain medicines and palliative care.[6] Notably, the United Nations Committee on Economic, Social and Cultural Rights has identified providing essential medicines, as defined by the WHO, as a core obligation under the right to health.[7] The WHO has included morphine in its Model List of Essential Medicines, a list of the medications that should be available to all persons who need them, since it was first established.[8] The right to be free from torture, cruel, inhuman, or degrading treatment or punishment also creates a positive obligation for states to protect persons in their jurisdiction from unnecessary pain related to a health condition.[9]

In 2008, the U.N. Special Rapporteur on The Right to the Highest Attainable Standard of Health and the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment jointly recognized that a failure to address barriers to palliative care and pain treatment can be a violation of human rights:

> The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel, inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines—which include, among others, opioid analgesics—as part of their minimum core obligations under the right to health.[10]

Since 2008, there has been an increasing body of statements supporting the right to pain treatment and palliative care, including statements by the Committee on Economic, Social and Cultural Rights,[11] the Committee on the Elimination of all Forms of Discrimination Against Women,[12] and the Committee on the Rights of the Child.[13]

In 2011, in her opening statements at the Human Rights Council Panel on the Right to Health of Older Persons, Navi Pillay, the UN High Commissioner on Human Rights stated: “Adequate access to palliative care is essential to ensure that these people can live and—ultimately—die with dignity.”[14] In that same year, in the Report of the Secretary General on the rights of older persons, the Secretary General noted: “The challenges to Member States, particularly low- and middle-income countries, include: … [a] lack of specific measures to avoid pain and provide palliative care that allow the terminally ill to die with dignity.”[15]

Impact of Controlled Substance Regulations on Access to Palliative Care and Pain Treatment

Opioid pain medicines are subject to control under the 1961 Single Convention on Narcotic Drugs.[16] Under the system set up by the Single Convention, states must monitor and regulate their distribution and use.[17]

Under international human rights law and drug control treaties, however, countries have a dual obligation with respect to these medicines: They must ensure their adequate availability for medical and scientific use while preventing their misuse and diversion.[18] The 1961 Convention specifically declares the medical use of narcotic drugs indispensable for the relief of pain and requires their adequate availability.[19]

As noted, however, despite the obligations outlined above, many states fail to properly ensure the availability of opioid pain medicines. According to the International Narcotics Control Board (INCB)—the body responsible for monitoring the 1961 Convention— "approximately 5.5 billion people, or three quarters of the world's population, live in countries with… inadequate access to treatment for moderate to severe pain…."[20] Due to limited access to essential medicines, the WHO estimates that tens of millions of people around the world, including around 5.5 million end-stage cancer patients and one million people with AIDS, suffer from moderate to severe pain each year without treatment.[21]

One reason for the limited availability of opioid pain medicines is the failure of countries to strike a balance between ensuring the availability of controlled medicines for legitimate purposes and preventing their abuse and diversion. Indeed, many states severely restrict access through onerous regulations.[22] In a 2011 discussion paper, the UN Office on Drugs and Crime enumerated the following examples of regulations that, among others, may impede medicines availability and are not required by international drug conventions:

> (a) Limitations on the number of days' supply that may be provided in a single prescription (with too short a period of time allowed);
> (b) Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low);
> (c) Excessive limitations on prescription authority, such as only to some categories of medical doctors;
> (d) Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain….[23]

These unduly strict regulations frequently create complex procedures for procuring, stocking, and dispensing opioid pain medicines. The result is that pharmacies and health facilities do not procure or stock opioid pain medicines; doctors are deterred from prescribing them; and obtaining opioids is so impractical that patients cannot realistically hope to obtain a sufficient, continuous supply. Where these regulations unnecessarily impede the procurement and dispensing of these medications for medical purposes, they are incompatible with the right to health.

In our organizations' work, we routinely see the impact of these regulatory restrictions on patients. Human Rights Watch, for example, has found that people with untreated severe pain often describe their pain in exactly same terms as victims of torture—that is, as so intense that they would do anything to make it stop. These individuals often want to commit suicide to end the pain, pray for death, or tell doctors or relatives that they want to die.[24]

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We respectfully urge OHCHR to include access to opioid analgesics for pain management and palliative care in its study, giving voice to the millions of people who require controlled medicines for the relief of pain and suffering.

African Palliative Care Association
Asia Pacific Hospice Palliative Care Network
European Association for Palliative Care
Hospice Palliative Care Association of South Africa
Human Rights Watch
International Association for Hospice and Palliative Care
International Children's Palliative Care Network
Kenya Hospice and Palliative Care Association
Latin American Palliative Care Association
Pallium India
Union for International Cancer Control
Worldwide Hospice and Palliative Care Alliance

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[1] UNDESA Population Division, "World Population Prospects: The 2012 Revision," 2013, p. 4 http://esa.un.org/wpp/Documentation/pdf/WPP2012_%20KEY%20FINDINGS.pdf (accessed March 31, 2015).
[2] Katrien Moens, MSC, et al., "Are There Differences in the Prevalence of Palliative Care-Related Problems in People Living With Advanced Cancer and Eight Non-Cancer Conditions? A Systematic Review," *Journal of Pain and Symptom Management,* vol. 48, No. 4, (2014), pp. 667-669.
[3] F. Brennan, D.B. Carr, and M.J. Cousins, "Pain Management: A Fundamental Human Right," *Anesthesia & Analgesia*, vol. 105, no. 1 (2007), pp. 205-221.
[4] WHO, "Achieving Balance in Opioid Control Policy: Guidelines for Assessment," 2000, p. 1, http://whqlibdoc.who.int/hq/2000/who_edm_qsm_2000.4.pdf (accessed April 28, 2014).
[5] Ibid.
[6] International Covenant on Economic, Social and Cultural Rights (ICESCR), G.A. res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993; Convention on the Rights of the Child, adopted Nov. 20, 1989, G.A. Res. 44/25, Annex, 44 U.N. GAOR, Supp. No. 49, U.N. Doc. A/44/49, at 167 (Sept. 2, 1990); Convention on the Elimination of All Forms of Discrimination against Women, adopted Dec. 18, 1979, G.A. Res. 34/180, 34 U.N. GAOR, Supp. No. 46, U.N. Doc. A/34/46, at 193 (Sept. 3, 1981); International Convention on the Protection and Promotion of the Rights and Dignity of Persons with Disabilities, G.A. Res. 61/106, Annex, U.N. GAOR, 61st Sess., Supp. No. 49, U.N. Doc. A/61/49, at 65, entered into force May 3, 2008.
[7] UN Committee on Economic, Social and Cultural Rights, "Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights," General Comment No. 14, The Right to the Highest Attainable Standard of Health, E/C.12/2000/4 (2000), para. 43, http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/40d009901358b0e2c1256915005090be?Opendocument (accessed April 28, 2014).
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[9] Human Rights Council, Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez, A/HRC/22/53, February 1, 2013, para. 54, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf (accessed April 28, 2015); International Covenant on Civil and Political Rights (ICCPR), adopted December 16, 1966, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, entered into force March 23, 1976, art. 7; Universal Declaration of Human Rights (UDHR), adopted December 10, 1948, G.A. Res. 217A(III), U.N. Doc. A/810 at 71 (1948); Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (Convention against Torture), adopted December 10, 1984, G.A. res. 39/46, annex, 39 U.N. GAOR Supp. (No. 51) at 197, U.N. Doc. A/39/51 (1984), entered into force June 26, 1987, art. 16.
[10] United Nations Special Rapporteur on the Prevention of Torture and Cruel, Inhuman, or Degrading Treatment or Punishment & Special Rapporteur on Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, "Letter to Chairperson of the Commission on Narcotic Drugs," U.N. Doc. G/SO 214 (52-21) (Dec. 10, 2008), p. 4, http://www.hrw.org/sites/default/files/related_material/12.10.2008%20Letter%20to%20CND%20fromSpecial%20Rapporteurs.pdf (accessed April 28, 2015).
[11] UN Committee on Economic, Social and Cultural Rights, General Comment No. 14: The right to the highest attainable standard of health, November 8, 2000, para. 34.
[12] UN Committee on the Elimination of Discrimination Against Women (CEDAW), General recommendation No. 27 on older women and protection of their human rights, CEDAW/C/GC/27, December 16, 2010, para. 45, http://www2.ohchr.org/english/bodies/cedaw/docs/CEDAW-C-2010-47-GC1.pdf (accessed April 28, 2015).
[13] UN Committee on the Rights of the Child (CRC), General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), CRC/C/GC/15, April 17, 2013, para. 25, http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRC%2fC%2fGC%2f15&Lang=en (accessed April 28, 2015).
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[18] INCB, "Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes," 2011, http://www.incb.org/documents/Publications/AnnualReports/AR2010/Supplement-AR10_availability_English.pdf (access July 11, 2014); INCB, "Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995," http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf (accessed June 28, 2014), p. 1.
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