



## **Access to Controlled Substances for medical and scientific purposes: Ensuring and Restoring Balance**

Balanced access to controlled substances for medical and scientific purposes is critical both to ensuring rational access to these medicines, and preventing and reducing their diversion and abuse. Access for pain treatment and palliative care is lacking in the majority of the world (e.g. Asia, Gulf States, Africa, Latin America), while diversion and abuse are increasingly prevalent in a few countries with higher consumption (e.g. within North America).

*Palliative care organisations from around the world are issuing this joint statement to promote the universal development of balanced prescription opioid consumption systems.*

**The central principle of “balance”** represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meet those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care.<sup>1</sup>

The World Health Organisation (WHO) recommends that government policies regarding these medicines strive for the maximum public health outcome, which is “balanced” when 1) access for rational medical use is maximized, and 2) substance misuse and diversion are minimized. Countries such as, Austria, Germany, and United Kingdom are among those reporting higher opioid consumption to the International Narcotics Control Board (INCB) while reporting low rates of non-medical use,<sup>2</sup> suggesting their systems are close to balanced. States parties to the Single Convention are obliged to implement a comprehensive, balanced and coordinated approach that encompasses supply control, demand reduction, and access to controlled medicines. Partnerships with civil society organisations can assist them in this.

### **Examples of Unbalanced systems:**

#### **1. Those reporting low consumption of controlled substances for rational medical use.**

Unrelieved pain from advanced cancer, traumatic injury, AIDS, and other life-limiting illnesses impacts all dimensions of quality of life, including patients’ ability to participate in family, social, and spiritual activities. Relief of severe pain is contingent upon evidence-based education and practice.

According to the International Narcotics Control Board (INCB) and the WHO:

- Opioid analgesics are essential medicines for the relief of pain and palliative care<sup>3</sup>
- Under-treatment of severe pain is reported in more than 150 countries, accounting for about **75%** of the world’s population. At least 5 billion people live in countries affected by the crisis of *under-consumption*, and more than 18 million annually die with treatable pain.<sup>4</sup>
- Studies show that up to 84% of patients with cancer and HIV and suffer severe pain .<sup>5</sup>
- INCB reports barriers to adequate availability of opioid analgesics include lack of training/ awareness among health professionals, fear of addiction, limited resources, problems in sourcing opioids, cultural/societal attitudes, fear of diversion, control measures for international trade, fear of prosecution/sanction, and onerous regulatory framework.<sup>6</sup>
- The INCB reports that most countries under-utilise opioids for legitimate medical purposes; the Board particularly notes this in Africa, Asia, the Caribbean, and the Middle East.

#### **2. Systems with significant diversion from legal supply chain and substance abuse.**

Currently, a small number of countries (e.g., Australia, Canada, and the US) have unbalanced systems characterized by higher consumption of prescribed opioids for medical purposes *and* increased abuse and diversion of prescription opioids and other drugs. There has been extensive

reporting of the US “opioid overdose epidemic.” The US Centers for Disease Control and Prevention (CDC)<sup>7</sup> reported that in 2015 over 15000 deaths in were associated with prescription opioids. Facts about US opioid use include:

- Most US physicians have little or no education in pain management and opioid prescription.
- 60% of deaths associated with prescription opioids involve alcohol and/or benzodiazepines.
- Up to 30% of deaths have been associated with methadone, an opioid requiring increased provider training, when used in the pain management.
- Patients with mental health issues are at greater risk of prescription associated opioid overdose.
- The US consumes 100% of the world's hydrocodone as it is the only country that uses it medically.
- Several cities and states across the U.S. are suing opioid manufacturers, alleging that aggressive and fraudulent marketing fuelled the opioid epidemic.<sup>8</sup>
- The US has identified other sources of diverted prescription opioids such as pharmacy thefts, pill mills, and illegal internet pharmacies.<sup>9</sup> The US accounts for this as "licit" consumption.
- Experts are unable to establish a causal relationship between increased rates of opioid prescription, and increased heroin use or spiking overdose rates.

We recommend that, to **ensure and restore balanced systems, countries should**

- Evaluate their drug control systems, using the WHO *Ensuring Balance in National Policies on Controlled Substances* guideline, and follow recommendations for improving balance.
- Implement, in collaboration with WHO, INCB, and UNODC, the recommendations from the WHA Palliative Care Resolution 67/19<sup>10</sup> and the UNGASS 2016 Outcome Document<sup>11</sup> on the safe and effective use of controlled medicines for pain and palliative care, including enhanced data collection throughout the controlled medicines supply chain to better detect diversion in real time.
- Strengthen measures, in collaboration with the WHO, to ensure that policy makers and health professionals are not unduly influenced by pharmaceutical companies with financial interests in opioid production and marketing.
- Ensure collaboration between global, regional, and national pain and palliative care organisations such as ours to train healthcare providers to prescribe opioids safely.
- Promote inter-professional collaboration between providers in countries with higher opioid consumption rates and little or no abuse, and those in countries with low consumption rates, to prevent the development of unbalanced situations similar to that in the US.

#### Further reading

- The Pendulum Swings for Opioid Prescribing, Charles F. von Gunten
- Pain Treatment Continues To Be Inaccessible for Many Patients Around the Globe: Second Phase of Opioid Price Watch, a Cross-Sectional Study To Monitor the Prices of Opioids, De Lima et. al. IAHP
- Evolving Government Policy on Opioid Availability and Use Is a Double-edged Sword, Arthur G. Lipman
- City devastated by OxyContin use sues Purdue Pharma, claims drug maker put profits over citizens' welfare

<sup>1</sup> WHO. Ensuring balance in national policies on controlled substances. [http://www.who.int/medicines/areas/quality\\_safety/guide\\_nocp\\_sanend/en/](http://www.who.int/medicines/areas/quality_safety/guide_nocp_sanend/en/)

<sup>2</sup> Häuser The opioid epidemic and the long-term opioid therapy for chronic non-cancer pain revisited: a transatlantic perspective

<sup>3</sup> WHO Model Lists of Essential Medicines <http://www.who.int/medicines/publications/essentialmedicines/en/>

<sup>4</sup> Worldwide Hospice Palliative Care Alliance. [www.thewhpc.org](http://www.thewhpc.org)

<sup>5</sup> <https://www.incb.org/incb/en/publications/annual-reports/annual-report-supplement-2015.html>

<sup>6</sup> INCB Annual Report Suppl. Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes. <https://www.incb.org/incb/en/publications/annual-reports/annual-report-supplement-2015.html>

<sup>7</sup> CDC Injury Prevention & Control: Opioid Overdose <https://www.cdc.gov/drugoverdose/>

<sup>8</sup> <http://www.simmonsfirm.com/news/item/simmons-hanly-conroy-files-suffolk-county-n-y-lawsuit-drug-companies-opioids-epidemic-addiction/>

<sup>9</sup> [http://www.jpmsjournal.com/article/S0885-3924\(05\)00477-X/fulltext?referrer=&priority=true&module=meter-Links&pgtype=Blogs&contentId=&action=click&contentCollection=meter-links-click&version=meter+at+null&mediaId=](http://www.jpmsjournal.com/article/S0885-3924(05)00477-X/fulltext?referrer=&priority=true&module=meter-Links&pgtype=Blogs&contentId=&action=click&contentCollection=meter-links-click&version=meter+at+null&mediaId=)

<sup>10</sup> World Health Assembly Resolution WHA67.10 Strengthening of palliative care as a component of comprehensive care throughout the life course. Accessed 3 February 2017 at: <http://apps.who.int/medicinedocs/en/d/Js21454en/>

<sup>11</sup> United Nations General Assembly. Resolution adopted by the General Assembly on 19 April 2016. S-30/1: Our joint commitment to effectively addressing and countering the world drug problem. Accessed 3 February 2017 at: <http://www.un.org/Docs/journal/asp/ws.asp?m=A/RES/S-30/1>