



Submission of the International Association for Hospice and Palliative Care to OHCHR

In response to the CESCR call for inputs to inform the OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13), the [International Association for Hospice and Palliative Care](#) (IAHPC) is pleased to make the following submission concerning barriers to access and availability of internationally controlled essential medicines (ICEMs) for the treatment of severe pain, palliative care, mental health, treatment of substance use disorder, and many other conditions.

The IAHPC is a non-governmental organization in consultative status with the United Nations Economic and Social Council (ECOSOC) and a non-state actor in official relations with the World Health Organization.

Background: Internationally controlled essential medicines

ICEMs are those included both in the schedules of the three international drug control conventions *and* in the World Health Organization Model List of Essential Medicines (for adults and children). States parties to the three drug control treaties, the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; the Convention on Psychotropic Substances, 1971, and the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988), are legally obligated to ensure availability for medical and scientific purposes.

The purpose of these treaties is to establish internationally applicable control measures with the aim of ensuring that psychoactive substances are available for medical and scientific purposes, while preventing them from being diverted into illegal channels. The treaties also include general provisions on the trafficking and use of psychoactive substances. The 1961 and 1971 Conventions classify controlled substances in four lists or Schedules, according to their perceived therapeutic value and potential risk of abuse. Included in an annex to the 1988 Convention are two tables listing precursor chemicals, reagents and solvents which are frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. This treaty also significantly reinforced the obligation of countries to establish criminal offences in order to combat all aspects of the illicit production, possession and trafficking of psychoactive substances.

Adequate availability of, and affordable access to these medicines supports the rights to life and personal security, to medical care, to the highest attainable standard of physical and mental health, and to participation in political, social, family, economic and civic life, among others.

Morphine, fentanyl, hydromorphone, oxycodone, and methadone are included in the WHO Model List of Essential Medicines for the treatment of moderate to severe pain and dyspnea in advanced disease. They are also listed, or ‘scheduled’, for extra regulatory control under the international drug control conventions. These conventions mandate governments to promulgate regulatory controls to prevent harmful non-medical use that many regulatory bodies have translated into unduly restrictive national policies and social attitudes



that prevent rational opioid availability for medical purposes and result in preventable suffering that violates, *inter alia*, the right to the highest attainable standard of physical and mental health.

Palliative care and global unavailability of ICEMs

ICEMs are the cornerstone of global palliative care practice. Palliative care (PC) is the active holistic care of individuals across all ages with serious health-related suffering (SHS) due to severe illness, including those near the end of life. It aims to improve the quality of life of patients, their families, and their caregivers. The World Health Organization estimates that only 14% of people in the world with palliative care needs, mostly in upper income countries, receive it. Palliative care is included as an essential service in the 2018 Astana Declaration on Primary Healthcare as well as the 2019 and 2023 Political Declarations on Universal Health Coverage.

Experts estimate that SHS, and thus the need for PC will increase in all regions of the world, with the largest proportional rise in low-income countries (155% increase between 2016 and 2060). By 2060, an estimated 48 million people (47% of all deaths globally) will die experiencing SHS, which represents an 87% increase from 26 million people in 2016. 83% of these deaths will occur in low-income and middle-income countries. Globally, SHS will increase most rapidly among older persons (aged 70 years and above --183% increase between 2016 and 2060). In absolute terms, it will be driven by rises in cancer deaths (16 million people, 109% increase between 2016 and 2060). The condition with the highest proportional increase in SHS will be dementia (6 million people, 264% increase between 2016 and 2060).¹

According to the International Narcotics Control Board, INCB, more than **80%** of the world population, more than 5.5 billion people, mainly in low- and lower middle-income countries, has no access to internationally controlled essential medicines to address SHS associated with severe pain, palliative care needs, treatment of substance use disorder, and other conditions.² Morphine, particularly oral morphine, a generic medicine derived from opium, a traditional medicine used for millennia, is the gold standard of pain management according to WHO, yet remains unavailable to an estimated 75 per cent of the global population.³

IAHPC responses to OHCHR questionnaire.

- (a) Major obstacles at the national, regional, and international levels to ensure equitable access to medicines, vaccines and other health products.

¹ Sleeman, K. E., De Brito, M., Etkind, S., Nkhoma, K., Guo, P., Higginson, I. J., ... & Harding, R. (2019). The escalating global burden of serious health-related suffering: projections to 2060 by world regions, age groups, and health conditions. *The Lancet Global Health*, 7(7), e883-e892.

² Supplement to the annual report of the Board for 2022 on the availability of Internationally Controlled Substances: No Patient Left Behind: Progress in Ensuring Adequate Access to Internationally Controlled Substances for Medical and Scientific Purposes

³ Left Behind in Pain, WHO 2023. <https://iris.who.int/bitstream/handle/10665/369294/9789240075269-eng.pdf?sequence=1>.

The INCB reports that lack of training of the health workforce, unduly restrictive national regulations, and “fear of addiction” are the main impediments to opioid availability. Other barriers include lack of training of National Competent Authorities in estimating amounts of ICEMs needed to meet population needs. Submitting annual estimated amounts for patient care is a treaty obligation of all States parties to the Single Convention on Narcotic Drugs. Historical prejudice, stigma, and lack of education in 21st century medical and regulatory sciences essential for the treatment of conditions requiring ICEMs is lacking in many countries with weak health systems.

- (b) Specific barriers, that women and girls, older persons, children, persons living in poverty, or other persons or groups in situations of vulnerability or marginalization face in accessing medicines, vaccines and other health products.

Specific barriers pertaining to women and girls, older persons, persons living in poverty and other structurally vulnerable groups are the *cost* at point of disbursement of ICEMs when generics are not available, the fact that ICEMs if stocked in pharmacies at all, are usually only available in urban centers and hospitals that are often distant from the homes of residents of rural areas and informal settlements, and can only be reached by expensive automobile trips or long public transport journeys. Older persons and women are often marginalized in health systems in countries of all income levels and given suboptimal care as a result of ageist and sexist perspectives.

- (c) Legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines, and other health products?

Legal and regulatory challenges that impact accessibility and affordability include marketing by the pharmaceutical industry of expensive, brand-name opioids rather than generic oral morphine; unduly restrictive regulations that result from misinterpretation of the Single Convention on Narcotic Drugs requirements, and multiple regulatory regimes within health systems that include variations between hospitals and districts within the same national regime.

Lack of palliative care policies and prescribing guidelines at the national and sub-national levels, including regulations about safe and effective prescribing of ICEMs has been identified as a major barrier in most regions of the world where the INCB has flagged ICEM availability as “low to inadequate.”

- (d) Impact of research and development models for pharmaceuticals and other health technologies, including emerging digital technologies, on the access to medicines, vaccines, and other health products?

N/A

- (e) Main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products?

A global normative framework commits states parties of the drug control treaties to ensure availability of ICEMs. This includes a number of WHO, HRC, and CND resolutions that mandate adequate availability of as a component of the right to the highest attainable standard of health, and the recent development of WHO and UNODC technical guidelines and recommendations. Governments have yet to fund programs that teach states parties the necessary steps to draft, implement, and monitor enabling policies and human resource training. Funding for civil society advocacy, which has been extremely successful at the multilateral level in securing the normative framework, is now non-existent for CSOs working at all levels of governance. This leaves national civil society and professional organizations without the support they need to advocate with their governments for implementation of the global normative framework and application of existing technical guidelines.

- (f) Impact of existing intellectual property rights regime on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines, and other health products?

The pharmaceutical industry markets, distributes, and provides temporary subsidies for expensive opioid formulations in health systems and declines to manufacture and distribute generic oral morphine because doing so is not profitable.

- (g) Main challenges to ensure the quality, safety and efficacy of medicines and vaccines?

The main challenge is the existence of an unregulated illicit and grey market for ICEMs. When availability is limited in the licit market, patients will turn to the illicit market, thereby fueling the production of substandard and counterfeit medicines.

- (h) Obstacles do you see to ensuring the affordability of medicines, vaccines, and other health products?

Lack of political will in the face of the North American “opioid crisis”, which is in fact a governance crisis; stigma attaching to ICEMs and cultural prejudices not based in 21st century science about the dangers of opioids, even when used by properly trained and accredited prescribers. Lack of funding for advocacy, education, and training of workforces, including pharmacists and primary care practitioners. Unavailability of affordable generic oral morphine in LMICs and a workforce trained to prescribe it.

- (i) Concrete recommendations to enhance access to medicines, vaccines and other health products.

Encourage states parties to the drug control and human rights conventions to

- Implement the recommendations they adopted in the 2016 UNGASS Outcome Document.
- Fund the International Narcotics Control Board Learning Programme to train competent national authorities in the estimates and reporting process.
- Invest in a primary palliative care, mental health, and harm reduction workforce.

- Strengthen ICEM supply chains to ensure safe and rational availability that prevents diversion and non-medical use to allay fears of policymakers.
- Provide funding for supply chain systems convenings at the national and sub-national levels of all affected actors, including national competent authorities, manufacturers, prescribers, and narcotics control agents.

(j) Other information or data. Relevant documents include

- ‘Left Behind in Pain’ WHO June 2023 Report
<https://iris.who.int/bitstream/handle/10665/369294/9789240075269-eng.pdf?sequence=1>
- Table of Authorities, Palliative Care and Essential Medicines
<https://hospicecare.com/uploads/2022/9/table-of-authorities-and-resources.pdf>
- Three International Drug Control Conventions, UN Office of Drugs and Crime.
https://www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Ebook/The_International_Drug_Control_Conventions_E.pdf
- WHO. The selection of essential drugs. Geneva. 1977
<https://list.essentialmeds.org/files/trs/sC1L9Ib4I8o8cDqlyfhnKyoa8MGm7XUFDffFVNUc.pdf>
- Scheduling of Substances
https://www.unodc.org/unodc/en/commissions/CND/Mandate_Functions/Scheduling.html
- UNGASS Outcome Document, 2016
<https://www.unodc.org/documents/postungass2016/outcome/V1603301-E.pdf>
- WHO guidelines for the pharmacological and radiotherapeutic management of cancer pain in adults and adolescents.; World Health Organization; 2018. Available from:
<https://www.who.int/publications/i/item/9789241550390>.
- Bhadelia A, De Lima L, Arreola-Ornelas H, Kwete XJ, Rodriguez NM, Knaul FM. Solving the Global Crisis in Access to Pain Relief: Lessons From Country Actions. *Am J Public Health*. 2019 Jan;109(1):58-60. doi: 10.2105/AJPH.2018.304769. Epub 2018 Nov 29. PMID: 30495996; PMCID: PMC6301382.
- Knaul FM, Farmer PE, Krakauer EL, et al Alleviating the access abyss in palliative care and pain relief—an imperative of universal health coverage: the Lancet Commission report. *The Lancet*, Volume 391, Issue 10128, 1391 - 1454
- Resolution WHA67.19 on Strengthening of palliative care as a component of comprehensive care throughout the life course. https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R19-en.pdf