

Challenge of Ministerial Declaration to which this submission applies:

The availability of internationally controlled substances for medical and scientific purposes, including for the relief of pain and palliative care, remains low to non-existent in many parts of the world

I. Definitions

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). ICEMs are the cornerstone of palliative care practice. The International Narcotics Control Board (INCB) estimates that more than 80% of the world's people live in countries where access to ICEMs is low to inadequate.¹

Morphine, fentanyl, hydromorphone, oxycodone, and methadone are the cornerstones of palliative and addiction medicine and treatment for opioid use disorder. They are also routinely used by anesthesiologists and surgeons to treat moderate to severe pain from operations and trauma injuries. The INCB has recommended that, in countries where ICEMs are largely unavailable for medical and scientific purposes, national regulatory bodies review unduly restrictive national policies that stigmatize these medicines and the people who need them in order to improve availability. The combination of stigma and regulatory ringfencing prevents rational availability of ICEMs for medical purposes and results in preventable suffering for millions of people with cancer and other diseases.

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.² The World Health Organization estimates that only 14% of people in the world with palliative care needs, mostly in upper income countries, receive it.³

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 Organisation (WHO).

II. Background: global unavailability and serious health related suffering

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

¹International Narcotics Control Board Supplement 2022

https://www.incb.org/documents/Publications/AnnualReports/AR2022/Supplement/E_INCB_2022_1_Supp_1_eng.pdf

²IAHPC definition of palliative care 2018 <https://hospicecare.com/what-we-do/projects/consensus-based-definition-of-palliative-care/definition/>

³World Health Organization Fact Sheet <https://www.who.int/health-topics/palliative-care>

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).⁴

According to the [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. Morphine, particularly oral morphine, is the gold standard of pain management according to WHO, and is unavailable to 75 per cent of the global population. The INCB also reports that lack of training of the health workforce, unduly restrictive regulations, and “fear of addiction” are the main impediments to opioid availability.

The [Lancet Commission on Palliative Care and Pain Relief](#), which studied the health economics of the global abyss in access to internationally controlled essential medicines such as morphine, calculated that improving access to medical morphine would cost the global community around USD145 million per year, [a fraction of the USD100 billion the world spends every year on drug control](#).

Education of regulators, health workers, and supply chain professionals is key to ensuring availability of controlled medicines. National legal frameworks, which can be updated through multi-sectoral and inter-ministerial collaborations, configure professional education norms in safe use of opioids. Unduly restrictive regulations on availability place a stranglehold on medical education, rendering the majority of health workers, even at tertiary facilities in urban areas, unfamiliar with the safe use of medical opioids. The resulting low demand for strong analgesia in the public sector generates a spiral of market failure that disincentivizes private production of effective generics such as morphine that yield no profit margin. Industry’s response is to resort to marketing and subsidizing expensive brand-name opioids, whose price discourages public sector procurement and parallel markets supply diverted or counterfeit products to meet demand.^{5,6}

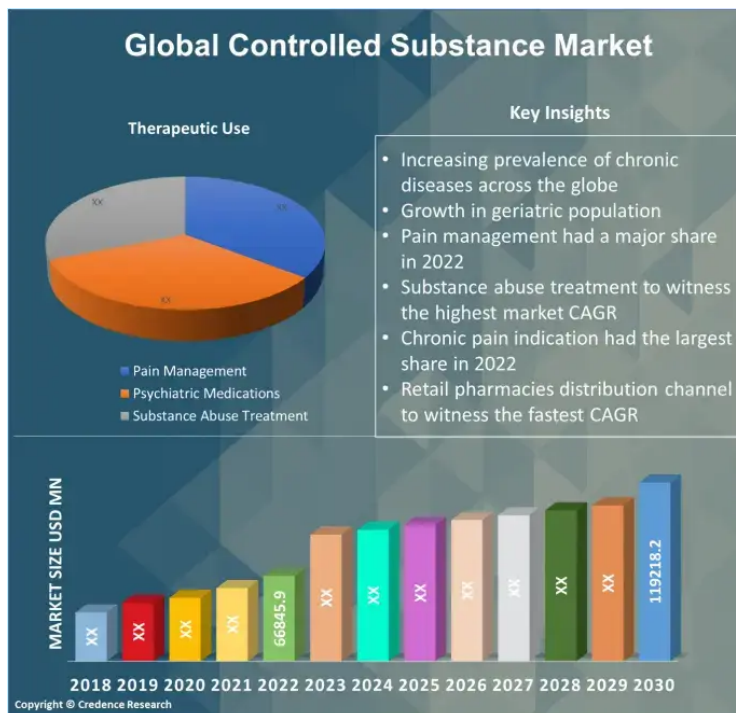
⁴ Sleeman, K. E., De Brito, M., Etkind, S., Nkhoma, K., Guo, P., Higginson, I. J., ... & Harding, R. (2019). The escalating global burden of serious health-related suffering: projections to 2060 by world regions, age groups, and health conditions. *The Lancet Global Health*, 7(7), e883-e892.

⁵ De Lima, L., Arias Casais, N., Wenk, R., Radbruch, L., & Pastrana, T. (2018). Opioid medications in expensive formulations are sold at a lower price than immediate-release morphine in countries throughout the world: third phase of opioid price watch cross-sectional study. *Journal of palliative medicine*, 21(10), 1458-1465. <https://www.ffisp.org/sites/default/files/documents/Opioides-Monde.2018.pdf>

⁶ WHO, 2023 Left behind in pain: Extent and causes of global variations in access to morphine for medical use and actions to improve safe access. <https://www.who.int/publications/i/item/9789240075269>.

Public sector cultivation, manufacture, and distribution of opium for domestic use -- allowed under the drug control conventions -- and shorter supply chains, are one solution recommended by the UN agencies that member states could explore to counteract the market failure of essential generics. Medical, nursing, pharmacy and regulatory curricula that routinely include evidence-based modules on safe prescribing and dispensing, opioidphobia (culturally based fear of opioids) can begin to mitigate the epistemic gap underlying the preventable suffering that prevails in the vast majority of settings, multiplied exponentially in health emergencies.

Unduly restrictive regulations for medicines containing narcotic drugs configure and feed parallel markets for opioids that may be counterfeit or poisonous.



The legitimate medical demand for ICEMs is essentially *inelastic and in fact growing*. If patients in severe pain or in need of treatment for substance use disorder cannot find their prescribed medicines in pharmacies, they turn to the parallel markets. Parallel markets can be dangerous, carry the risk of criminal sanctions for those who access them, and are often the source of counterfeit or dangerous substances that lack the requisite therapeutic value. In this, states parties are failing to fulfil the right to protect the health and welfare of their

citizens and undermining the aims of the three international drug control conventions.

IAHPC has taken the Pledge for Action to provide for support CND member states who want to address this challenge. Our global membership of practitioners is well situated to participate in multi-sectoral consultations with ministries to review regulations and provide education for the health workforce per INCB recommendation.
