

Position Statement on the Decision by WHO to Withdraw Guidance Documents

On the 22nd of May 2019, Congresswoman Katherine Clark and Congressman Hal Rogers, two members of the US House of Representatives, published a report claiming (falsely) that the development of two World Health Organization (WHO) guidance documents (*Ensuring Balance in National Policies on Controlled Substances* and *Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses*), was influenced by the interests of Purdue Pharma. This influence was, according to the report, achieved through organizations and individuals serving the interests of the company (Purdue Pharma is the maker of OxyContin, a commercial brand of oxycodone). The report argued that by developing, distributing and promoting these guidelines, the WHO was helping the pharmaceutical company increase its market share and putting other countries at risk of replicating the US “opioid crisis.” No staff member of the offices of the US representatives contacted any of the organizations or individuals mentioned in the document to verify or confirm the claims in their report.

On June 19, WHO Director-General Dr. Tedros Adhanom Ghebreyesus sent a letter to the US Representatives informing them that the WHO had taken the Report’s concerns very seriously and that the agency had decided to withdraw the two guidelines, published in 2011 and 2012. The WHO has now published the statement in its website https://www.who.int/medicines/areas/quality_safety/guide_nocp_sanend/en/

The WHO decision took all the academic, civil society, experts and organizations involved in the development of these guidance documents by surprise. Both documents were developed in order to improve the situation of millions of patients worldwide who suffer from lack of, or inadequate access to medications, including pain medications. The guidelines were not commercially initiated, funded or influenced. Our primary focus has been, continues to be and will always be the patients and their families. We have seen and experienced how unrelenting, excruciating pain affects individuals and families and the magnitude of the suffering it engenders.

Ensuring Balance in National Policies on Controlled Substances provides WHO Member States guidance on how to adopt balanced policies to ensure availability to, and rational use of all controlled medicines for legitimate medical needs, including opioids while preventing harm from non-medical use and dependence. The research leading to the results of these guidelines was funded by the European Community’s 7th Framework Programme. Additional support was provided by Foundation Open Society Institute, the Ministry of Health, Welfare and Sport of The Netherlands; the Mission Interministérielle de la Lutte Contre la Drogue et la Toxicomania of the Government of France; and the International Association for the Study of Pain (USA).

The *WHO Paediatric Pain Guidelines* were an important step towards better treatment of persistent pain in children. The paediatric pain guidelines did not focus on any specific potent opioid analgesic. However, in these guidelines, codeine is no longer recommended because of the way it is metabolized in children and is often ineffective. The paediatric pain guidelines were funded by grants from The Diana Princess of Wales Memorial Fund (UK), Open Society Institute (now Open Society Foundations), (Switzerland); the International Association for the Study of Pain (USA); the International Children’s Palliative Care Network (S. Africa); Mayday Fund (USA); the Ministry of Health, Welfare and Sport of the Netherlands; the Rockefeller Foundation (USA); The True Colours Trust (UK) and the US Cancer Pain Relief Committee (USA).

We welcome WHO’s statement that the agency remains fully committed to ensuring that people suffering severe pain have access to effective pain relief medication, including opioids. The organization has reiterated its concern that there is very limited access to medication for moderate and severe pain, particularly in low and middle-income countries. However, as representatives of the organizations, institutions and experts working in

pain relief and palliative care, we are extremely concerned that the withdrawal of these guidance documents will lead to confusion and possible extreme measures that will hinder access to patients with legitimate medical needs.

Global Situation

Millions of patients, the vast majority of whom live in low- and middle-income countries, have limited or no access to treatment for moderate and severe pain. The Lancet Commission on Palliative Care and Pain Relief estimated that less than 2% of the opioids needed for palliative care patients are provided in low income countries.¹ Under-treatment of severe pain is reported in more than 150 countries, accounting for about 75% of the world's population. The UN's International Narcotics Control Board (INCB) reports that most countries under-utilize opioids for legitimate medical purposes; in particular in countries in Africa, Asia, the Caribbean, and the Middle East². At least 5 billion people live in countries affected by the crisis of under-consumption, and more than 18 million annually die with untreated, excruciating pain³.

Opioid analgesics are needed for the relief of moderate to severe pain and for palliative care. Of these, WHO considers morphine an essential analgesic with oxycodone as one of its alternatives. In 2017, the WHO added transdermal fentanyl patches and methadone for the relief of cancer pain to the WHO Model List of Essential Medicines⁴. Lack of availability and limited access to these medications for legitimate medical treatment is a human rights violation, is unethical, creates a situation of deep global health inequity and affects the countries' capacity to achieve Universal Health Coverage and the promise to not leave anyone behind.

Principle of Balance

The central principle of “balance” represents the 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 their non-medical use, diversion, and trafficking. These obligations are the two primary goals of the international control system.

Although widespread non-medical use of controlled substances poses a public health risk, the system of control is not intended to be a barrier to their rational availability for medical and scientific purposes, nor to interfere in patient care. 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.

The 2016 UNGASS Outcome Document⁵ obliges member states to implement a comprehensive, balanced and coordinated approach that encompasses supply control, demand reduction, *and* adequate access to controlled medicines including opioids such as morphine.

¹ 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. *Lancet* 2018; **391**(10128): 1391-454.

² INCB. Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purpose. New York: UN2016. Available from https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/Supplement-AR15_availability_English.pdf

³ Connor SR, Sepulveda Bermedo MC, eds. 2014. Global Atlas of Palliative Care at the End of Life. London: UK/Geneva CH: WHPCA/WHO. Available from <http://www.who.int/cancer/publications/palliative-care-atlas/en/> WHPCA/WHO.

⁴ WHO. WHO Model List of Essential Medicines 2017 [September 16, 2017]. 20th list. Available from: http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017_FINAL_amendedAug2017.pdf?ua=1

⁵ United Nations. Thirtieth Special Session. Outcome document of the 2016 United Nations General Assembly Special Session (UNGASS). Our joint commitment to effectively addressing and countering the world drug problem (2016). Available from <http://www.unodc.org/documents/postungass2016//outcome/V1603301-E.pdf>

The INCB, the Human Rights Council and other UN agencies recommend that governments adopt policies regarding these medicines that strive for the best possible public health outcome, which is “balanced” when, a) access for rational medical use is maximized, and b) non-medical use and diversion are minimized. Countries such as Austria, Germany, and the United Kingdom are among those reporting higher consumption of prescription opioids to the INCB while reporting low rates of non-medical use, suggesting their systems are almost balanced.

The problem of non-medical use in some countries underscores the importance of implementing basic mandatory training for all health-care personnel in safe management and evidence-based prescribing of opioid analgesics. However, we disagree that the particular situation of a few countries should drive decisions that may have a negative impact on global health, especially when such inequity already exists in access to controlled medicines for the relief of serious health related suffering in low income settings. The recently released 2019 World Drug Report confirms that “most of the morphine found on illicit markets originates from illicitly produced opium, and only small quantities of morphine are likely to be diverted from licit manufacture to illicit markets”.⁶

We stand by our commitment to continue working with the WHO and other UN agencies, government representatives, academia and organizations to improve appropriate pain treatment and palliative care. And we will continue to serve as a voice of millions of patients, their families and caregivers who will be affected by WHO’s decision to withdraw these guidelines.

As representatives of the organizations listed below, we urge:

- The WHO to revise and update the guidelines they have withdrawn with all deliberate speed, and until this task has been completed, to reinstate both the *Ensuring Balance in National Policies on Controlled Substances* and *Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses* to fill the normative and technical vacuum left by their withdrawal.
- Heads of State to continue to collaborate with palliative care and pain experts, health care workers and policy makers to develop and restore balanced drug control systems to ensure adequate access to internationally controlled essential medicines necessary for the relief of suffering, while preventing diversion and non-medical use. We also suggest that policymakers and implementation teams use the Technical Guidance on Promoting Access developed by the United Nations Office on Drugs and Crime (UNODC) in 2018. A PDF of the Guidance is available on the UNODC website [here](#).

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⁶ UNODC. https://wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_3_DEPRESSANTS.pdf

List of Organizations and Institutions endorsing this statement:

African Palliative Care Association (APCA)

Asociación Latinoamericana de Cuidados Paliativos (Latin American Association for Palliative Care)

Care for the Hopeless Impact Missions (CHIMISSIONS – Cameroon)

Chronic Illness Advocacy and Awareness Group (CIAAG – USA)

European Association for Palliative Care (EAPC)

Fundacion Tomatelo a Pecho (Mexico)

Global Drug Policy Observatory (UK)

International Association for Hospice and Palliative Care (IAHPC)

Indian Association for Palliative Care (IAPC)

International Federation on Ageing (IFA)

Palliative Care in Humanitarian Aid Situations and Emergencies network (PalCHASE)

Pallium India (India)

Regional Clinical Palliative Care Centre (Ukraine)

Ukrainian League of Hospice and Palliative Care (ULHPC - Ukraine)

Worldwide Hospice Palliative Care Alliance (WHPCA)