Summary report on the

Intercountry meeting on controlled medicines

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1. Introduction

Pharmaceutical preparations containing internationally controlled substances play an essential role in medical treatment to relieve pain and suffering. Psychotropic substances such as benzodiazepine-type anxiolytics, sedative-hypnotics and barbiturates are indispensable medications for the treatment of neurological and mental disorders. Most narcotic medicines and psychotropic substances controlled under international drug control treaties are indispensable in medical practice. Opioid analgesics, such as codeine and morphine, as well as semi-synthetic and synthetic opioids, are essential medicines for the treatment of pain and are listed on the WHO’s Model List of Essential Medicines.

It is estimated that 83% of the world’s population lives in countries with low or non-existent access to controlled medicines for the treatment of patients with advanced HIV disease, with terminal cancer, suffering injuries caused by accidents and violence, patients recovering from surgery, women in labour and paediatric patients with painful conditions.

The WHO Eastern Mediterranean Region has extremely low consumption of controlled medicines as compared with other regions. This reflects a reality observed in various settings, where patients suffer from moderate to severe pain which remains untreated, partly due to limited access to strong analgesics. To understand better the situation in the Region, a survey will be undertaken to document in detail the barriers faced in countries in order to build a sound regional strategy on improving access to controlled medicines.

An intercountry meeting on controlled medicines was hosted by the WHO Regional Office for the Eastern Mediterranean in Cairo from 17 to 19 May 2016. The meeting involved 17 participants from 8 countries: Egypt, Islamic Republic of Iran, Jordan, Lebanon, Oman, Saudi Arabia, Kuwait and Tunisia. Participants included representatives
from ministries of health involved in: 1) inspection of controlled medicines in health facilities; and 2) international drug control conventions, as well as a senior representative from the Ministry of Interior (Saudi Arabia) involved in drug control legislation enforcement. The meeting was facilitated by WHO staff from headquarters and the Regional Office and with two international experts in the field of controlled medicines, namely Dr Jim Cleary and Dr Martha Maurer of the WHO collaborating centre for pain policy and palliative care (University of the Wisconsin Carbone Cancer Center).

The overall objective of the meeting was to address the very low consumption of controlled medicines for medical use in the Region. The specific objectives were:

- to present results and lessons learnt of global and studies to access to controlled medicines in countries;
- to identify main barriers to access to controlled medicines in countries;
- to understand the methodology for estimating requirements for narcotic drugs;
- to discuss and agree on using WHO country assessment checklist with teams from selected countries; and
- to agree on additional information to be collected for the survey.

The meeting was inaugurated with welcome remarks made by Dr Mohammad Assai Ardakani, acting Director of the Department of Health System Development. Dr Marthe Everard, Coordinator, Essential Medicines and Technologies, introduced the workshop objectives and expectations.

The first day of the meeting focused on the global and regional situation of access to controlled medicines. It included a presentation
on the international estimates system for narcotic drugs, which was developed to ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse. In this system, each government estimates annually the amount of narcotic drugs that will be needed to satisfy all medical and scientific requirements in the country for the next year. The International Narcotic Control Board (INCB) evaluates, confirms and publishes the amount of narcotic drugs for each government. Then each government may manufacture or import narcotic drugs within that amount, and distribute them to medical facilities for the treatment of patients. The presentation was followed by a group exercise on estimating the requirements for narcotic drugs.

On the second day, guidelines for ensuring balance in national policies on controlled substances were discussed. Group work included exercises to train the participants in the use of the WHO country assessment checklist, which reflects each guideline. On the last day of the meeting, group work focused on developing national action plans to improve availability and accessibility of controlled medicines.

2. Conclusions

Participants emphasized the importance of addressing the low availability and accessibility of narcotic medicines and psychotropic substances which are critical for pain management of cancer, AIDS, injuries, surgical interventions and obstructed labour, and for neurological and mental disorders. Ministries of health alone have limitations regarding access to information and impact on policy formulation. This is because the responsibility for overseeing law enforcement lies within different government bodies.

It was understood that policy change alone does not bring about increased access. There is a need to address the low priority of pain management
within health care services, inadequate education on narcotic medicines and psychotropic substances, exaggerated fear of opioids and addiction, and problems in the supply chain for obtaining narcotic medications.

Participants recognized the barriers to opioid medication availability, which are multifactorial in nature. Therefore tackling the problem from the health side only will not address the issue entirely. The main barriers identified by the participants were legal and regulatory barriers, policy barriers, knowledge and societal attitudes, and economic aspects, including affordability.

Participating countries confirmed that governments need to enable and empower health care professionals to prescribe, dispense and administer opioid medications in line with WHO policy directions and treatment guidelines to meet the individual medical needs of patients. They must also ensure that sufficient supply is available to meet those needs.

It was well understood by the participants that their governments have a dual obligation to improve access based on legal, political, public health and moral grounds and have the obligation to have a “balanced policy” in order to ensure opioid availability for medical purposes and research and to protect populations against abuse and dependence. Therefore, a national policy should include the establishment of a drug control system that prevents diversion and ensures adequate availability for medical use.

Participating countries understood the importance of accurate estimates as it is essential to ensure adequate supply because underestimation can lead to a distortion of demand and consequent shortages and inappropriate prescribing, dispensing and use. At the same time, overestimation can lead to surpluses, waste, leakage and increased risk of diversion.
The participants developed action plans for conducting country assessments using WHO country assessment checklist. The main components of the action plans included the establishment of a multisectoral committee for narcotics and psychotropics, mapping of the current status, revising and updating laws and guidelines concerned with the medical use and research of controlled medicines, integration of palliative care services as part of the national health strategy, the inclusion of palliative care in the curricula of health personnel and in continuous medical education, raising awareness among patients through campaigns, and improving accuracy in estimation controlled medicine needs in comparison with current requirements reported to INCB.

The meeting concluded that WHO should provide guidance and support to countries to assist them in achieving balance in national policies on controlled substances and in ensuring availability and accessibility of controlled medicines.

3. Next steps

- Participating countries should send to WHO their assessment reports on the availability and accessibility of controlled medicines using WHO country checklist by Thursday, 25 August 2016.
- Participating countries should discuss further the national action plan for improving access to narcotic medicines with the Minister of Health and other government entities involved in narcotic medicines.
- WHO should bring the topic of access to controlled medicines in the Region to the attention of the health delegations attending the forthcoming Regional Committee.
- Based on the findings of the assessment reports, WHO should organize an expert consultation to draft a regional strategy on improving access to controlled medicines by the end of the year.