World Health Organization Briefing Note — April 2012

Access to Controlled Medications Programme

Improving access to medications controlled under international drug conventions

- **Providing normative guidance relating to the use of controlled medicines**
- **Policy analysis and review of legislation to identify possible means for improving access**
- **Training and practical assistance to governments and healthcare workers**

Access to many medicines controlled under international drug control treaties is lacking around the world, with the exception of a few industrialized countries. Even in some highly industrialized countries access is limited. The realization of the Millennium Development Goal 8e,"Provide access to affordable essential drugs in developing countries", is likely to be further away for opioid analgesics than for any other class of medicines.

These controlled medicines are used to treat conditions including:

- Moderate to severe pain
- Opioid dependence
- Obstetric complications

Pain Management

The World Health Organization (WHO) estimates that 5.5 billion people (83% of the world's population) live in countries with low to non-existent access to controlled medicines and have inadequate access to treatment for moderate to severe pain.[1]

In these countries, each year tens of millions of patients are suffering without adequate treatment:

- 1 million end-stage HIV/AIDS patients
- 5.5 million terminal cancer patients
- 0.8 million patients suffering injuries, caused by accidents and violence
- Patients with chronic illnesses
- Patients recovering from surgery
- Women in labour (110 million births each year)
- Paediatric patients

Opioid dependence treatment and HIV-prevention

Despite strong evidence of efficacy, treatment of opioid dependence such as therapy with long-acting opioid agonists is frequently unavailable.

There are 16 million people who inject drugs in the world.[2] Of the new HIV infections in Eastern Europe and Central Asia in 2005, 67% were due to injection drug use.[3] It is estimated that if pharmacological treatment of opioid dependence was to be made readily available, such access could result in the prevention of up to 130,000 new HIV infections from needle sharing outside sub-Saharan Africa annually. A meta analysis of four studies showed a reduction of annual HIV-seroconversion by 64% (C.I. 34 - 81 %).[4]

Maternal death

Each year, half a million women die during childbirth[5], about 120,000 of them from post-partum bleeding.[6] Many of these lives could have been saved if medicines to stop the bleeding were available.

Treatment is simple and inexpensive

Moderate to severe pain can be easily controlled with opioid analgesics such as morphine. Opioid dependence can be effectively treated with long-acting opioid agonists such as methadone or buprenorphine. While post-partum bleeding can be treated by either ergometrine or oxytocin, these medicines are both not readily available. Of the two medicines, ergometrine is a controlled substance.

Lack of access affects all controlled medicines on the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children. Because of their status as essential medicines, their availability for medical treatment is a human right, as defined in the International Covenant on Economic, Social and Cultural Rights (article 12, the Right to Health).

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Balancing prevention and medical availability

Many factors contribute to the lack of access to controlled medicines. There is a need for greater awareness among policy makers, healthcare professionals and the general public to dispel the myth that opioid analgesics (i.e. pain relievers derived from opium, such as morphine) will do harm to patients and cause dependence. The fear of dependence upon pain treatment is largely unfounded, as almost all pain patients are able to stop their opioid medication at the end of their treatment with no long-lasting effects.

The World Health Organization (WHO) promotes governments, civil society and other interested individuals to strive for the maximum public health outcome of policies related to these medicines. WHO considers the public health outcome to be at its maximum (or "balanced") when the optimum is reached between maximizing access for rational medical use and minimizing substance abuse. All countries have a dual obligation with regard to these medicines based on legal, political, public health and moral grounds. The dual obligation is to ensure that these substances are available for medical purposes *and* to protect populations against abuse and dependence. Countries should aim at a policy that ultimately achieves *both* objectives; in other words, a "balanced policy".

What has been done so far?

In response to the World Health Assembly and the United Nations' Economic and Social Council in 2005[7], WHO developed the Access to Controlled Medications Programme (ACMP) in consultation with the International Narcotics Control Board (INCB) and a number of NGOs. The strategy was presented to and accepted by the UN's Commission on Narcotic Drugs (CND) and the World Health Assembly in 2007. In 2010, the CND adopted a resolution in support of the ACMP's objectives.[8] The ACMP focuses on lifting barriers that impede access to controlled medicines, including opioids - the most important category of these medicines.

Over the past years, ACMP has raised awareness about the problem of access to these medicines through presentations at conferences, publications and the media. It published policy guidelines entitled *Ensuring Balance in National Policies on Controlled Substances: Guidance for availability and accessibility of controlled medicines,*[9] *Guidelines on the Pharmacological Treatment of Persisting Pain in Children with Medical Illnesses*[10] and it published a study on the global and country needs for opioids for pain management.[1] Jointly with the INCB, WHO published the *Guide on Estimating Requirements for Subtances under International Control* for use by the Competent National Authorities.[11]

The ACMP supported and is supporting various countries in assessing their pertinent policies and legislation.

What needs to be done?

The ACMP addresses all aspects that act as barriers to obtaining controlled medicines for medical treatment including legislative and administrative procedures, as well as knowledge among policy makers, healthcare workers, patients and their families.

Further ACMP's activities will include:

Normative guidance

- Further development and dissemination of internationally recognized standards for treatment of pain

Policy analysis

- Workshops for healthcare professionals, legislators and law enforcers to analyse and discuss the problem and draft national action plans for its resolution
- Improving access to effective treatment by reviewing legislation and administrative procedures

Training and practical assistance

- Supporting implementation of action plans at the national level
- Training healthcare professionals through workshops on rational prescribing, provision of information materials and curriculum review support to universities
- Training workshops for civil servants to make realistic estimates of future needs for opioid analgesics and to

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compile reliable statistics, and

Further study

- Performing surveys on accessibility, availability, affordability and use of the medicines and substances involved.

Who are our partners?

The ACMP supports governments in identifying and overcoming obstacles that hinder the procurement and distribution of controlled medicines to help ensure adequate availability of opioid analgesics for pain treatment and opioid dependence. WHO will work with national authorities, including regulatory authorities, public health administrators and law enforcement officials. WHO also draws on the expertise of relevant WHO departments and units involved in diseases related to pain, international and national experts, WHO Collaborating Centres, the INCB, the United Nations Office on Drugs and Crime and healthcare professionals, such as medical practitioners, nurses with special training and pharmacists.

Work in countries will be implemented in close collaboration with WHO regional offices and WHO Representatives in the countries.

" The ACMP is an extremely important development which will have a similar major impact on the management of severe unrelieved pain world wide as the 1986 WHO initiatives on the management of cancer pain."

International Association for the Study of Pain

The ACMP's current partners and endorsers include national and international healthcare experts, the WHO Collaborating Centre for Pain and Palliative Care at the University of Wisconsin, the WHO Collaborating Centre for Training and Policy on Access to Pain Relief at the Trivandrum Institute for Palliative Sciences, Trivandrum, India, and national and international professional associations, such as the African Palliative Care Association (APCA), the European Association for Palliative Care (EAPC), Human Rights Watch, the International Association for the Study of Pain (IASP), the Harm Reduction International (HRI), the International Association for Hospice and Palliative Care (IAHPC) and the International Observatory for End of Life Care.[12]

To develop activities in twelve East European countries, ACMP formed the *ATOME-consortium* (Access to Opioid Medicines in Europe; www.atome-project.eu) which includes: EAPC, the Eurasian Harm Reduction Network, Help the Hospices UK, Hospice Casa Sperantei, the International Observatory for End of Life Care at the University of Lancaster, Ministry of Interior and Administrative Reform - Government of Romania, National Anti-Drugs Agency, Utrecht University and University of Bonn.

The governments of France, the Netherlands and Switzerland as well as the European Commission, The Diana, Princess of Wales Memorial Fund, the International Association for the Study of Pain; the International Childrens Palliative Care Network, the Mayday Fund, the Rockefeller Foundation, The True Colours Trust, and the US Cancer Pain Relief Committee contributed to the Programme.

What will happen as a result?

Expected outputs of the ACMP include internationally recognized standards for clinical treatment with controlled medicines, tools and national capacity to assess trends in opioid availability and future needs of controlled medicines, reviews of national policies and legislation on controlled medicines, national healthcare workers trained in rational use of controlled medicines, and curriculum developed on the use of controlled medications.

The direct beneficiaries of the ACMP will be national authorities such as regulatory authorities, national healthcare administrators, healthcare professionals and law enforcement officials in developing countries where access to pain medication is severely limited. The indirect and ultimate beneficiaries of the ACMP will be people in need of controlled medication, particularly

patients suffering from cancer, chronic pain, diabetic neuropathy, HIV neuropathy, sickle-cell disease, pre-and post-operative surgery pain, traumatic pain, women in delivery, neonates, children, particularly paediatric patients in developing countries, as well as patients with opioid dependence and their communities.

The ACMP is the first and only global initiative in this field adding value to *national* processes through the provision of evidence-based treatment guidelines, policy guidelines, policy and legal analysis, training and practical assistance. The clinical guidelines, tools and training materials developed under the programme will provide universal and internationally recognized standards for the clinical use of controlled medicines for use by national governments.

Proposed budget

The ACMP's action plan has a projected budget of US$ 55.5 million over six years (inclusive 13% Programme Support Cost). Two-thirds of the budget will focus on policy development and support activities to improve access to opioids for pain management. The remaining third will be directed towards efforts on therapy of opioid dependence with long-acting opioid agonists. It is expected that half of the budgeted activities will be delivered through the regional and country offices[13], while the remainder of the budget will support ACMP work at WHO headquarters (including 11% for staff).

Contributions from governments as well as NGOs are urgently needed.

Further information

More information on the Framework of the *Access to Controlled Medications Programme,* the nature of access barriers for controlled medicines, as well as literature references, is available on the WHO Medicines web site: http://www.who.int/entity/medicines/areas/quality_safety/sub_Int_control/en/index.html

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[4] World Health Organization, Guidelines for the Pharmacologically Assisted Treatment of Opioid Dependence, Geneva 2009.

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[6] WHO, Emergency and surgical procedures at the first referral health facility, accessed at: www.who.int/eht/en/SurgicalProcedure.pdf

[7] Resolutions WHA58.22 and ECOSOC 2005/25

[8] Commission on Narcotic Drugs, Resolution 53/4

[9] World Health Organization, Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines, Geneva 2011, ISBN 978 92 4 156417 5

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[11] International Narcotics Control Board and World Health Organization, Guide on Estimating Requirements for Subtances under International Control, Developed by the International Narcotics Control Board and the World Health Organization for use by the Competent National Authorities, Vienna/Geneva, 2012, ISBN English: 978-92-4-150328-0, Arabic: 978-92-4-650328-5, Chinese: 978-92-4-450328-X, French: 978-92-4-250328-9, Russian: 978-92-4-450328-7, Spanish: 978-92-350328-8.

[12] Many of these organizations have written letters of support. to the ACMP

[13] The ACMP will go to over 150 countries world-wide eventually. For the moment, priority countries are: Cameroon, Ethiopia, Ghana, Ivory Coast, Kenya, Malawi, Nigeria, Rwanda, Senegal, Sierra Leone, Tanzania and Zambia (all AFRO Region); Egypt, Iran, Morocco, Oman, Pakistan and Sudan (all EMRO Region), Bosnia-Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, Serbia, Slovenia, Slovakia and Turkey (all EURO Region); Argentina, Colombia and Panama (all AMRO Region), Indonesia, Bangladesh and India (all SEARO Region) Vietnam, China and the Philippines (all WPRO Region).

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