

Access to Controlled Medications Programme

Improving access to medications controlled under international drug conventions

- Providing normative guidance relating to the use of controlled medications
- 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 billion people live in countries with low or no access to controlled medicines and have no or insufficient 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, adequate treatment of opioid dependence such as oral substitution therapy 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 Such treatment would also reduce the spread of hepatitis C and other blood-borne diseases as well as decrease deaths from opioid overdose by 90%.⁵ Finally, it is estimated that every dollar invested in treatment of opioid dependence has a 3 to 13-fold return to society.

Maternal death

Each year, half a million women die during childbirth⁶, about 120,000 of them from post-partum bleeding.⁷ 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 oral substitution therapy using 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. 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).

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 killers 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 patients are able to stop their opioid medication at the end of their treatment with no long-lasting effects. Although substitution treatment does not terminate dependence, it removes most of the detrimental health effects for the patient as well as the harmful impact of drug dependency on a society. Ergometrine, a medicine used in obstetrics, is often unavailable for use in childbirth. Although not a drug of abuse it can be used as a starting material for the synthesis of such drugs.

Of course, the risk of dependence through non-medical use is real and society needs to protect against these drugs being diverted from appropriate medical use. This can and should be done in a balanced way that does not affect their availability for appropriate medical treatment.

What has been done so far?

In response to the World Health Assembly and the United Nations' Economic and Social Council in 2005⁸, WHO developed the Access to Controlled Medications Programme (ACMP) in consultation with the International Narcotics Control Board and a number of NGOs. The strategy was presented to and accepted by the UN's Commission on Narcotic Drugs and the World Health Assembly in 2007. The ACMP focuses on lifting barriers that impede access to controlled medicines, including opioids - the most important category of these medicines.

The ACMP has participated in activities of other organizations directed at

lifting these barriers and started the development of pain treatment guidelines. Over the past years, ACMP has raised awareness about the problem of access to these medicines through presentations at conferences, publications and the media.

What needs to be done?

The ACMP will address 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.

During the first phase (six years) of its implementation, the ACMP focus is on identifying the most effective assistance mechanisms and further developing tools to be used in the programme. The ACMP's activities will include:

Normative guidance

- Development and dissemination of internationally recognized standards for treatment and policy guidelines

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 compile reliable statistics, and
- Training workshops on procurement for pharmaceutical inspectors and law enforcement

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 medication 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 will also draw on the expertise of relevant WHO departments and units involved in diseases related to pain, international and national experts in the area of opioid medication, WHO Collaborating Centers, the International Narcotics Control Board 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, *WHO Collaborating Centre for Policy and Communications in Cancer Care* at the University of Wisconsin and national and international professional associations, such as the United States' Cancer Pain Relief Committee, the International Harm Reduction Association (IHRA), the International Association for the Study of Pain (IASP), the European Association for Palliative Care (EAPC), the African Palliative Care Association (APCA), the International Association for Hospice and Palliative Care (IAHPC) and the International Observatory for End of Life Care.⁹

To develop activities in twelve East European countries, ACMP formed the *ATOME-consortium* (Access to Opioid Medicines in Europe) which includes: the European Association for Palliative Care (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 and NautaDutilh NV.

The governments of France and the Netherlands as well as the US Cancer Pain Relief Committee, the Open Society Institute and IASP, are donors to the Programme. The European Commission (Directorate-General for Research) is a donor to the *ATOME* consortium through its 7th Framework Programme.

What will happen as a result?

Expected outputs of the ACMP include internationally recognized standards for clinical treatment with controlled medications, tools and national capacity to assess trends in opioid availability and future needs of controlled medicines, a review of national policy 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 guidelines, policy 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 for its first 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 substitution therapy efforts. It is expected that half of the budgeted activities will be delivered through the regional and country offices¹⁰, 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

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

⁵ Dr Patrizia Carrieri, INSERM, Marseille, France (oral communication, 28 March 2006)

⁶ Maternal Mortality in 2005, Estimates developed by, WHO, UNICEF, UNFPA and The World Bank, Geneva 2007, ISBN 978 92 4 159621 3, accessed at http://www.who.int/reproductive-health/publications/maternal_mortality_2005/mme_2005.pdf

⁷ WHO, Emergency and surgical procedures at the first referral health facility, accessed at: www.who.int/eht/en/SurgicalProcedure.pdf

⁸ Resolutions WHA58.22 and ECOSOC 2005/25

⁹ Many of these organizations have written letters of support. to the ACMP

¹⁰ 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).

¹ The countries with low or no access are defined as countries where the consumption of opioid analgesics is lower than 30% of the adequate per capita consumption. The adequate consumption is defined as the average per capita consumption in the top 20 countries in the Human Development Index.

² Bradley M, Louisa D et al. Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. *Lancet* 2008; DOI:10.1016/S0140-6736(08)61311-2

³ UNAIDS, AIDS Epidemic Update 07, accessed at http://data.unaids.org/pub/EPISlides/2007/2007_epiu_pdate_en.pdf