WHO Briefing note

Access to Controlled Medications Programme

Improving access to medications controlled under the international drug conventions through:

- **providing guidance on improving accessibility, availability and affordability of controlled medications**
- **improved access to effective treatment by review of legislation and administrative procedures**
- **education of health-care professionals, law enforcement staff and others regarding current best practices and scientific evidence and encouraging their adherence to these**
- **development of relevant clinical guidelines**
- **promotion of a better understanding of the international drug control treaties**
- **assistance in ensuring an uninterrupted supply of controlled medications at affordable prices**
- **assisting governments to make realistic estimates of future needs for opioid analgesics and to compile reliable statistics on past consumption**
- **performing surveys on the accessibility, availability, affordability and use of the medicines and substances involved**

In many countries pain management is poorly addressed. Patients suffering severe pain as a result of diseases such as cancer face immense challenges in obtaining pain relief, even though eliminating it is clinically possible. It is estimated that over 80% of the world's population is inadequately treated. This is because the opioid medicines that could provide such relief have been categorized as "controlled substances", because of concerns about their possible abuse. They are therefore subject to strong international control and rendered inaccessible.

Unrelieved severe and prolonged pain causes immense suffering and has devastating effects on individuals, their families and the communities to which they belong.

Furthermore, opioids for substitution therapy (to treat opioid dependence) are frequently not available, despite strong evidence of treatment efficacy. Among drug users, lack of access to controlled substances contributes to the spread of HIV and hepatitis C, and even death from overdose.

In addition, over half a million women die every year during childbirth. It is, therefore, a matter of concern that access to ergometrine and ephedrine, used in emergency obstetric care, is reportedly difficult in some countries.

What is the extent of the problem?

Severe undertreatment is reported in more than 150 countries. In these countries, hardly anybody who is eligible for treatment will be treated. Combined, these countries cover about 80% of the world's population. It is assumed that

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undertreatment is even more severe in another 30 countries. For these countries, no data are yet available. Generally, the governing bodies who are responsible for submitting the relevant data are the same as those responsible for importing the substances, but often they are not functioning as intended.

Preliminary estimates show that 4.8 million people who are suffering from moderate to severe pain caused by cancer do not receive treatment. For moderate to severe pain in end-stage HIV, 1.4 million are not treated. For other pain causes, we can only guess that they are in the millions.

Substitution therapy brings down the mortality rate of opioid-dependent patients considerably (in France there was over a 90% reduction after its introduction in the 1990s) and also brings down the transmission of blood-borne diseases. Transmission by the use of contaminated needles is known to be the cause of new infections in 30% of all new HIV cases outside sub-Saharan Africa (420 000 cases annually).

With regard to the medicines used in emergency obstetric care no accurate figures are currently at our disposal.

An even more forthright way to express this impact is: of all the people living now, at least 600 million will see their health negatively affected during their lifetime by not having access to medicines controlled under the international drug control treaties.

In the countries affected, everybody has at least one friend or relative who will suffer unnecessarily because these medicines are not available. Therefore, developing more balanced policies on opioid use is urgently needed.

Which medicines and diseases are involved?

A large number of controlled medicines are used regularly to treat many conditions. Each of these controlled medicines should be readily accessible for those patients who are in need of them, especially those medicines placed on the *WHO Model List of Essential Medicines*.

The most important categories are opioid analgesics and opioids for substitution therapy. The relevant medicines are morphine, buprenorphine, methadone. For many conditions — e.g. cancer pain, chronic pain, diabetic neuropathy, HIV neuropathy, sickle-cell disease, surgery pain (both pre-operative medication and post-operative pain) and traumatic pain — adequate analgesia means opioid analgesics.

Other controlled medicines on the *WHO Model List of Essential Medicines* are ephedrine and ergometrine (as used in obstetrics), benzodiazepines (as used in mental health care) and phenobarbital (an antiepileptic).

Which professions are involved?

Almost all general practitioners and almost all medical specializations need controlled medicines for professional use. They should be able to prescribe these substances when needed. The principal need relates to patients with cancer or HIV/AIDS, or those who require surgical anaesthesia and/or post-operative pain control.

In some cases, where the shortage of physicians is severe, nurses with special training are authorized to provide pain medication.

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The pharmaceutical industry and pharmacists are responsible for making the medicines available.

Governments, the regulations they develop and enforce, and civil servants, are responsible for creating the conditions whereby availability is facilitated. Regulations should be appropriate in order to facilitate prescribing and dispensing, as needed by patients.

Causes for underuse

The causes of underuse of controlled medicines for pain relief have been fully documented. See, for example, the homepage of the Pain & Policy Studies Group at:
http://www.painpolicy.wisc.edu/

A short summary is given below.

1. Regulatory impediments

Controlled substances must be regulated. If these regulations are applied in an inappropriately restrictive manner, they become impediments to access to adequate patient care.

In some countries, regulations prevent doctors from prescribing the appropriate substance and in sufficient amounts. Regulations sometimes mean that doctors fear arrest if they carry controlled medicines with them for treating their patients. Regulatory impediments can make it difficult to obtain and use prescription forms, while restrictions on the number of pharmacies that are allowed to dispense controlled substances may serve to significantly reduce the availability of controlled substances in pharmacies. The administrative burden related to the manufacture, import, trade and distribution of controlled medicines can be prohibitive.

2. Impediments relating to attitude and knowledge

Impediments relating to attitude and knowledge are very much interrelated. For example, beliefs on the part of regulators, politicians, doctors, patients and their families. One such misconception is that a patient will become dependent once prescribed a dose of an opioid painkiller. As *withdrawal symptoms* and *tolerance* alone are not sufficient for a diagnosis of dependence syndrome, but other symptoms are also required, the mere presence of physical dependence on opioids prescribed for pain control usually does not constitute drug dependence syndrome or "*addiction*".[1]

In fact, becoming dependent when using a controlled medicine, after prescription for a legitimate medical purpose, is rare. If it does occur, it should be treated as would any other side-effect. Indeed, in countries where analgesia is only rarely prescribed, health-care professionals tend to be unaware that the use of opioids is an element of current good medical practice.

Improved understanding and hence rational prescribing of controlled medicines can be achieved only through professional education and training.

3. Economic and procurement impediments

[1] The word "addiction" is not in use any more by WHO, because it is regarded as stigmatizing.

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A strategy to improve access to controlled medicines should distinguish the impediments mentioned above from those related to procurement issues in general. Although these impediments can be significant, they are not specific to controlled medicines and cannot be addressed by this programme. (But they are being addressed by other WHO medicines activities.)

Conditions surrounding control of these medicines can create economic impediments, and such impediments can be addressed by this programme.

For the patient, accessibility is highly dependent upon affordability. It is not the programme's aim to subsidize any medicines, but it could be instrumental with structural measures that would make controlled medications affordable.

What will WHO do?

World Health Assembly and ECOSOC adopted resolutions on improving access to opioid analgesics. Because of these resolutions WHO created the *Access to Controlled Medications Programme*. However, the programme will go beyond the request contained in the resolutions, by including access to all those medicines that are controlled under the United Nations' drug conventions[1] as far as they are listed on the *WHO Model List of Essential Medicines*.

The *Access to Controlled Medication Programme* will enhance the access to the following medicine categories:

- opioid analgesics
- opioids for substitution therapy of opioid dependence
- ephedrine and ergometrine
- benzodiazepines
- phenobarbital

Proposed programme objectives and deliverables

Objectives

The *Access to Controlled Medications Programme*'s general objective is to promote the availability, affordability and rational use of, and the accessibility to the medicines on the *WHO Model List of Essential Medicines* that are under the international control of the UN's drug conventions.

To achieve this general objective, the programme has the following specific objectives:

- improving access to effective treatment by review of legislation and administrative procedures
- education of health-care professionals, law enforcement staff and others regarding current best practices and scientific evidence and encouraging their adherence to these
- development of relevant clinical guidelines
- promotion of a better understanding of the international drug control treaties
- assistance in ensuring an uninterrupted supply of controlled medications at affordable prices.

[1] The United Nations' drug conventions are: the Single Convention on Narcotic Drugs (1961); the Convention on Psychotropic Substances (1971) and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)

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- assisting governments to make realistic estimates of future needs for opioid analgesics and to compile reliable statistics on past consumption
- performing surveys on the accessibility, availability, affordability and use of the medicines and substances involved

Deliverables

The programme will produce the following deliverables:

- workshops at which health-care professionals, legislators and law enforcers will analyse and discuss the problem and draft action plans for its resolution
- training workshops and symposia on rational prescribing and information material, including e-learning tools, on rational prescribing
- support to universities in the development of a curriculum containing the use of controlled medications
- public education activities
- treatment guidelines and updates of treatment guidelines
- reviewed legislation relating to controlled substances
- training workshops for civil servants on drafting and submission of estimates for and statistics of controlled substances
- training workshops on procurement for pharmaceutical inspectors and law enforcers
- provision of pricing, supplier and quality information
- study reports on the availability and use of the medicines involved

Full programme text

Once available, the full text of the *Access to Controlled Medications Programme* will be published on the WHO Medicines website http://www.who.int/medicines/ (expected spring 2007).

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