

Access to Controlled Medications Programme

Improving access to medications controlled under international drug conventions by:

- providing guidance on improving accessibility, availability and affordability of controlled medications
 - providing assistance on making realistic estimates of future needs for opioid analgesics and ensuring an uninterrupted supply
- reviewing legislation and administrative procedures relating to controlled medications
 - educating health-care and law enforcement professionals on best practices and scientific evidence
 - developing clinical guidelines

Severe pain is commonly experienced by individuals suffering from diseases such as cancer. The majority of them — an estimated 80% — do not receive adequate treatment for this pain, even though eliminating it is clinically possible. The opioid medicines that could provide relief have been categorized as "controlled substances", because of concerns about their possible abuse. They are therefore subject to strong control and often 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.

Similarly, opioids for substitution therapy (to treat opioid dependence) are also frequently unavailable, 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.

A third area of concern relates to ergometrine and ephedrine, used in emergency obstetric care. They too are subject to strict control, in this instance because of fears that they will be used as starting materials for drug synthesis. Obtaining ergometrine and ephedrine is reportedly difficult in some countries. Each year, half a million women die during childbirth. Some of these deaths could be prevented if these medicines were more widely available.

What is the extent of the problem?

Severe undertreatment is reported in more than 150 countries, containing about 80% of the world's population. In these countries, hardly anybody who is eligible for treatment will be treated. It is assumed that undertreatment is even more severe in another 30 countries, for which no data are yet available.

More precisely, preliminary estimates show that, every year, 4.8 million people suffering from moderate to severe pain caused by cancer, do not receive treatment. For moderate to severe pain experienced during end-stage HIV, an estimated 1.4 million are not treated annually. For other causes of pain, we can assume that those estimated are in the millions.

Substitution therapy brings down the mortality rate of opioid-dependent patients considerably. (In France, a reduction of more than 90% was observed after its introduction in the 1990s.) It also brings down the transmission of blood-borne diseases since it reduces the use of contaminated needles, which 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 have yet been collected.

An even more forthright way of expressing the health impact of the lack of access to



controlled medicines is: of all the people living now, at least 600 million will experience negative health impacts during their lifetime as a result of not being able to obtain medicines controlled under 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. Clearly, policies on opioid use, that carefully balance concerns about abuse and the need for access, are urgently needed.

Which medicines and diseases are involved?

A large number of controlled medicines should be 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 placed on the *WHO Model List of Essential Medicines*¹.

The most important categories are opioid analgesics and opioids for substitution therapy.

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.

The key medicines therefore, are opioids such as morphine, for analgesia, and methadone and buprenorphine, both used mainly for substitution therapy.

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. Health professionals should

be able to prescribe these substances as and when necessary.

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

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. But if these regulations are overly restrictive or are applied in an inappropriately restrictive manner, they prevent adequate patient care.

For example in some countries, regulations prevent doctors from prescribing the appropriate substance and in sufficient amounts. Doctors may even fear arrest if they carry controlled medicines for treating their patients.

Regulations can make obtaining prescription forms difficult, while restrictions on the number of pharmacies that are allowed to dispense controlled substances may serve to significantly reduce the availability of controlled substances.

The administrative burden related to the manufacture, import, trade and distribution of controlled medicines can also be prohibitive.

¹ This list defines medicines essential to satisfying priority health needs.



2. Impediments relating to attitude and knowledge

Impediments relating to attitude and knowledge are very much interrelated. For example, regulators, politicians, doctors, patients and their families often wrongly believe that a patient will become dependent once prescribed a dose of an opioid painkiller. However, *withdrawal symptoms* and *tolerance* are not sufficient for a diagnosis of dependence syndrome. Other symptoms must also be present. The mere presence of physical dependence on opioids prescribed for pain control usually does not constitute drug dependence syndrome or “*addiction*”.²

In fact, becoming dependent when using a controlled medicine, after its prescription for a legitimate medical purpose, is rare. If this does occur, dependence 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

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, most of them 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 will be addressed by this programme.

² The word “addiction” is no longer used by WHO, because it is regarded as stigmatizing.

For controlled medicines, good procurement starts at country level, with the collection of data for making the estimates of future needs and the submission of these estimates to the International Narcotics Control Board (INCB). However, some countries do not submit their estimates in a timely and adequate manner.

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

What will WHO do?

World Health Assembly and ECOSOC have each adopted resolutions that request that WHO and INCB work to improve access to opioid analgesics. To follow up on 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 conventions³, provided they are listed on the *WHO Model List of Essential Medicines*.

The ***Access to Controlled Medication Programme*** will work to enhance access to:

- 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*

³ 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).



general objective is to promote the availability, affordability and rational use of, and accessibility to those 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 reviewing legislation and administrative procedures
- educating health-care professionals, law enforcement staff and others regarding current best practices and scientific evidence, and encouraging their adherence to these
- developing normative clinical guidelines
- promoting a better understanding of the international drug control treaties
- helping to ensure 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.
- training workshops and symposia on rational prescribing and information materials, including e-learning tools, on rational prescribing
- support to universities to develop a curriculum that includes a component on 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 estimates for and statistics on 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

Deliverables

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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

Full programme text

More information, including the text of Framework of the *Access to Controlled Medications Programme* is available on the WHO Medicines web site⁴.

⁴ http://www.who.int/medicines/areas/quality_safety/sub_Int_control/en/index.html

