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Access to Controlled Medications Programme

Framework

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Programme abstract

The Framework for the Access to Controlled Medications Programme has been prepared by the Secretariat of the World Health Organization (WHO) in cooperation with the International Narcotics Control Board (INCB) in response to resolutions of the World Health Assembly (WHA) and the Economic and Social Council of the United Nations (ECOSOC) (WHA58.22 and ECOSOC 2005/25).

The Programme distinguishes the causes of underuse of controlled substances[1] as regulatory impediments; attitude and knowledge impediments; and economic and procurement impediments. The activities of the Programme will address all these impediments, with a focus on the first two groups.

When the Programme was developed, INCB and WHO were aware of differences in their mandate, which differences are reflected in the present Framework. The INCB derives its mandate for the Programme from the international drug control treaties and the Resolutions mentioned above. It finds itself restricted to what was requested in these Resolutions. WHO's objective is the attainment by all peoples of the highest possible level of health. Therefore WHO finds itself obliged to widen the scope of the activities to be undertaken with regard to availability of controlled medicines. For these reasons INCB and WHO agreed to divide the Framework into two Parts.

Part I includes activities that aim at improving access to opioid analgesics. This part is supported by INCB, which monitors the compliance of governments with the international drug control treaties and assists governments in this respect. INCB will provide its expertise to this part of the Programme.

Part II envisages activities developed in response to other related WHA and ECOSOC resolutions, also taking into account WHO's general responsibilities and ongoing activities and programmes conducted by WHO. This part also focuses on the classes of opioids for treatment of opioid dependence, medications for mental and neurological disorders and medicines for obstetrics. It also includes certain activities not included in part I.

Part III describes the organization of the Programme and its evaluation. Annexes 1–7 are provided for information only.

The Access to Controlled Medications Programme will be implemented by the World Health Organization.

[1] This programme includes in controlled substances those substances listed in the following conventions: Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; Convention on Psychotropic Substances, 1971; United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Part I: Opioid analgesics

Introduction

In many countries pain management is poorly addressed and it is estimated that over 80% of the world's population is inadequately treated for moderate to severe pain, although medical science has the capacity to relieve most such pain.[1]

The elaboration of this framework was prompted by the resolutions of ECOSOC and the WHA, adopted in 2005, in which the INCB and WHO were invited to examine the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics.[2]

The priority objective of this part of the framework is to propose an assistance programme that would facilitate access to opioid analgesics for the adequate treatment of pain. It was prepared by WHO and INCB and is to be further elaborated and implemented by WHO in the coming years, in cooperation with INCB, governments, WHO partners and collaborating centres, in order to facilitate access to opioid analgesics that are under international control and on the WHO Model List of Essential Medicines.

This part of the framework of the programme is intended to give technical assistance on a voluntary basis to the countries and their governments in complying with their responsibility to ensure the availability of opioid analgesics for medical purposes. It will be flexible and provide tailor-made solutions as far as possible.

I.1. Access to opioid analgesics: a problem for many

The Single Convention on Narcotic drugs, as amended by the 1972 Protocol emphasizes that adequate provision of narcotic drugs for the relief of pain and suffering must be made (see Annex 6).

In spite of adequate supply of opioids raw materials worldwide, in many parts of the world, patients suffering severe pain as a result of diseases such as cancer face immense challenges in obtaining pain relief. In many countries opioid medicines that could provide effective relief are not available in sufficient quantities. In other words, severe pain is often left untreated, although eliminating it is clinically possible. Unrelieved severe and prolonged pain causes immense suffering and has devastating effects on individuals, their families and the communities to which they belong.

[1] There are a number of safe and effective methods to treat pain. Opioid analgesics continue to be the mainstay for the relief of moderate to severe pain.

[2] Economic and Social Council Resolution 2005/25. Treatment of pain using opioid analgesics (Annex 1), and Resolution WHA58.22. Cancer prevention and control. In: *Fifty-eighth World Health Assembly*, Geneva, 25 May 2005 (Annex 2).

Statistical data reported by governments to INCB on consumption of opioids under international control indicate significant disparities in consumption levels among countries, as can be seen in Table 1.

Table 1. Average medical consumption of opioids under the control of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, in the period 2002–2004, expressed in defined daily doses for statistical purposes (S-DDDs) per million inhabitants per day

No. of S-DDDs	*No. of countries/territories*
> 10 000	12
1000–9999	32
< 1000	146
data not available	20

The countries and territories from which statistical data are not available belong to the group of countries and territories with very low opioid consumption. Pain treatment specialists maintain that there is some undertreatment[1] of pain with opioid analgesics even in the countries with the highest consumption. Consequently, and taking into account the data in Table 1, it can be concluded that in over 160 countries or territories undertreatment exists and that this undertreatment might be severe in the majority of these countries.

Global consumption of opioid analgesics has increased substantially over the past two decades.[2] However, the bulk of that increase has occurred in some countries which are home to only a small part of the world's population. "In 2003, six countries accounted for 79 percent of global consumption of morphine. Developing countries which represent about 80 percent of the world's population, accounted for only about 6 percent of global consumption of morphine" (*The Report of the International Narcotics Control Board for 2004*, document E/INCB/2004/1, paragraph 143).

Which medications and diseases are involved?

The primary field for inclusion in the strategy is medication to relieve moderate to severe pain. For a wide variety of conditions, patients do not receive adequate analgesia without controlled medicines, e.g. cancer pain, HIV neuropathy, diabetic neuropathy, chronic pain, surgery pain (both pre-operative medication and post-operative pain), traumatic pain and sickle-cell disease.

Although oral morphine is the gold standard for pain relief, there are other opioids that can be used. Individuals differ in their response to opioids, opioids have differing potency and can differ in side-effect profiles. Consequently, although availability of oral morphine is essential, physicians should have access to other opioids in other dosage

[1] Undertreatment is used in this document to indicate a situation at the country level where there is less treatment of patients than required by medical standards. It includes situations of non-treatment at the individual level.

[2] Global consumption of morphine rose from 3 tonnes in 1984 to almost 29 tonnes in 2004 (based on data reported by governments to INCB).

forms in order to respond to individual differences in patient needs. It should also be noted that some substances belonging to the class of opioids give only a weak analgesic effect and often cannot be used for the adequate treatment of moderate to severe pain. The Programme will address all opioid analgesics including those on the WHO Model List of Essential Medicines.

Table 2. Opioid analgesics on the WHO Model List of Essential Medicines[a]

Explicitly listed[b]

Codeine tablet 30 mg
Morphine injection 10 mg = 1-ml ampoule
Morphine oral solution 10 mg/5 ml
Morphine tablet 10 mg

Implicitly listed[c]

The WHO Expert Committee on the Selection and Use of Essential Medicines recommended that all the medicines mentioned in the WHO publication *Cancer pain relief: with a guide to opioid availability*, 2nd ed., are considered essential. The medicines are included in the relevant sections of the Model List, according to their therapeutic use, e.g. analgesics.

[a] This list includes all opioid analgesics included in the fourteenth WHO Model List of Essential Medicines that are placed under the international control of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.
[b] An application has been made to the Expert Advisory Committee on the Selection and Use of Essential Medicines to add morphine modified release tablets, 10 mg, 30 mg and 60 mg to the list.
[c] The opioids mentioned in the WHO publication *Cancer pain relief: with a guide to opioid availability*, 2nd ed., 1996, include standardized opium, tramadol, hydromorphone, methadone, levorphanol, pethidine, oxycodone and buprenorphine.

Causes of underuse

The causes of underuse of controlled substances have been described comprehensively in various studies and documents.[1] For the purpose of this part of the framework of the Programme they are categorized as follows:

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.

[1] See for instance Freedom from pain and suffering. In: *Report of the International Narcotics Control Board for 1999*. Chapter I, paragraph 30; *Achieving balance in national opioids control policy*. Geneva, World Health Organization, 2000:2; and information on the Pain & Policy Studies Group Homepage (www.painpolicy.wisc.edu).

2. Attitude and knowledge impediments

Attitude and knowledge impediments are strongly interrelated. There are attitude impediments among regulators, politicians, doctors, patients and their families due to misconceptions**. I**n countries where provision of adequate analgesia is an uncommon or even a rare practice, health-care professionals do not realize that the use of opioids conforms with current medical standards.

Knowledge impediments are clearly the basis of attitude impediments, and for this reason a shift to a more rational attitude to prescribing controlled medicines can only be achieved by professional education and training.

*3. Economic and procurement impediment*s

A strategy to improve access to controlled medicines should distinguish the impediments mentioned above from impediments due to economic factors and issues relating to the procurement of medicines in general, including insufficient medical infrastructure, limited resources for the purchase of medicines and barriers from the supply system capacity. Although these impediments can be significant, they are not specific to controlled medicines and cannot be addressed by this Programme, but instead, by other specific activities of WHO.

Specific information on suppliers and pricing can be collected and made available through the Programme in collaboration with the United Nations Children's Fund (UNICEF). In collaboration with the WHO Prequalification Programme the quality of relevant products can be verified.

Availability and accessibility are not enough to meet the needs of the individual patient who would also need the medicines to be affordable. It is not the Programme's aim to subsidize any medicine, but the Programme could be helpful with structural measures that would make controlled medications available at affordable prices.

I.2. Description of the Programme

Objectives

Part I of the Programme will focus on the following objectives:

- promotion of a better understanding of relevant provisions under the international drug control treaties;
- providing guidance to national authorities on improving the accessibility, availability and affordability of controlled medications;
- assistance in the review of national legislations and administrative procedures in order to improve access to effective treatment;
- assisting governments to help them to establish more realistic estimates of future needs for substances included in controlled medications and to compile more reliable statistics on their past consumption;

— promotion of rational use of controlled medications by health-care professionals in compliance with current best practices and scientific evidence;
— education of regulatory and law enforcement authorities on the need for availability of controlled medications while meeting regulatory requirements;
— formulation of main principles of treatment with controlled medicines that will provide a framework for the development of relevant clinical guidelines;
— collection and analysis of information relevant to availability, accessibility, affordability and use of controlled medications;
— assistance in ensuring an uninterrupted supply of controlled medications at affordable prices.

Beneficiaries of the Programme

The Programme will support governments in ensuring adequate availability of opioid analgesics for pain treatment to the population of their countries. It will support national authorities to identify and counter obstacles hindering the procurement and distribution of controlled medication. National authorities to be addressed include regulatory authorities, public health management administrators and law enforcement officials. The Programme will also work with WHO partners, collaborating centres and health-care professionals, such as medical practitioners, nurses with special training as well as pharmacists, and their educators and organizations. The ultimate beneficiaries of the Programme are patients in need of controlled medication.

Programme activities

The following activities, and the relevant tasks and expected outcomes have been identified for this Programme.

1. Process initiating workshops

Process initiating workshops will be organized to raise awareness of the problem and provide assistance with country-specific analysis.

The workshops will be attended by representatives from four to seven countries. Participants will be national regulatory authorities,[1] concerned law enforcement authorities, health care representatives and others in relevant positions. Expertise will be provided by medical and public health management specialists, national and international control authorities, and legal advisers.

Pre-meeting activities involve a review of national laws and policies, health infrastructure and preparation of country reports. During the workshop, relevant drug control policies and regulations will be discussed. Participating countries will identify impediments to procurement, including ineffective supply systems or budgetary constraints of national health and social security systems. National social security systems should, where possible, aim to include in their list of reimbursable medications

[1] Relevant regulatory authorities could include the ministries of health, the divisions of noncommunicable diseases, communicable diseases, and pharmaceutical affairs; the drugs control department; the ministry of finance; and the ministry responsible for the police. Coordination between authorities will be encouraged.

all controlled medications in the WHO Model List of Essential Medicines. Technical assistance will be provided for developing national action plans and follow-up activities.

Encouragement will be given for the development of national action plans to promote the inclusion of access to controlled medications into the national medicines policy plans and in disease-specific policy plans such as those that include treatment of pain in cancer care, palliative care and HIV/AIDS care. In countries where such plans do not yet exist, their development will be promoted.[2]

The advocacy workshops will be followed up by other activities, which will, *inter alia*, support the country teams in implementing their national action plans. Selected countries, identified as being ready for extended activities, will receive assistance with a national initiative. This support will be adapted as far as possible to the countries' needs and their specific situation; more details on such issues are provided in section I.3.

Specific induction courses to train and re-train trainers will be organized during the preparation for the workshops so as to establish a pool of qualified trainers.

2. Review and development of treatment guidelines

For the promotion of rational use of controlled medications the appropriate evidence-based guidelines for health-care professionals should be available. Revisions and updates of the guidelines should take into account the results of their implementation on the country level, particularly in low and middle income countries.

The WHO Guidelines *Cancer pain relief* and *Cancer pain relief and palliative care in children* should be updated, as they were last reviewed in 1996 and 1998, respectively.

As some aspects of treatment are not covered sufficiently by the present recommendations, new WHO guidelines will be developed, including guidelines on the treatment of other types of pain.

The chapter on opioid analgesics in the WHO Model List of Essential Medicines and other WHO documents (e.g. Interagency Emergency Health Kit) should be adapted to reflect current good practice and WHO guidelines as required.

3. Review of legislation and regulations

Countries participating in the advocacy workshops will be offered a review of their legislation and regulations, such that they are consistent with international drug control treaties and such that they will provide good access to legitimate medical use of the substances under control. Upon request such a review should also be offered to other countries not represented at the workshops. Reviews can extend to existing legislation, including international model legislation (in order to assess which parts need to be changed) as well as to draft legislation (in order to assess whether a draft would allow rational access to controlled medications). In general, the review will focus exclusively on the legislation regarding controlled substances, but in cases where other legislation (e.g. legislation on pharmaceutical affairs, professional qualifications or practice affairs) may impede rational use of controlled medications, such other laws should receive equal attention in the review. Proportionality of sanctions (i.e. the principle that the punishment

[2] Care should be taken to ensure that the development of disease-specific policy plans does not lead to patients with other diseases being discriminated against and not getting access to these medications.

should be in proportion to the severity of the crime) following offences regarding drug regulations – committed both inadvertently and intentionally – should be examined.

The WHO guidelines *Achieving balance in national opioids control policy* will be reviewed and extended to include health care aspects.

4. Training workshops for national authorities on estimates and statistics

Training workshops will be held for national authorities in groups of eight to ten countries (two participants per country), in order to improve availability of controlled medications while maintaining adequate control. Training will focus on the establishment of rational estimates of annual requirements for the substances contained in controlled medications and on the preparation of annual statistics on the consumption of the substances contained in controlled medications, as applicable. Specific preparatory workshops to train and re-train trainers will be organized so as to establish a pool of qualified trainers.

5. Workshops and symposia on promotion of rational prescribing

Workshops and symposia will be organized to promote rational prescription and adequate control of controlled medications in accordance with scientific medical standards and regulatory requirements. Participants will include representatives from the health care field, including prescribers, dispensers and nurses from the medical side, and regulatory authorities and law enforcement agencies.

6. Training and information material on promotion of rational prescribing

The Programme will initiate a review of training materials developed for health care professionals by WHO departments as well as by other competent organizations and include information on the rational use of controlled medicines as appropriate. These training materials are directed at:

— training of those who prescribe, dispense and administer medicines: medical doctors, pharmacists and nurses;
— training, assistance and workshops on prevention and treatment of drug dependence.

Draft articles for national scientific journals and for magazines directed to the target groups will be offered to ensure maximum coverage among health care workers.

E-tools and e-learning tools for prescribers, dispensers, nurses and regulators and national authorities will be developed and made available on the Internet and made available in CD or DVD format. They will include information on the practical use of the medications involved. The development of other e-tools is proposed to generate feedback information that would be useful to prescribers and institutions.

7. Support to health education institutions

Technical support will be provided to institutions and organizations involved in education and training of health-care professionals to ensure that rational use of controlled medications will be adequately covered in their curricula.

8. Public education activities

Technical support will be provided to institutions and organizations involved in public education to promote knowledge about appropriate use of controlled medications, while also drawing attention to the risks associated with those medications.

9. Studies on impact analysis and consumption of controlled medications

In order to establish the extent of the problem at the national level, to set priorities and measure progress, a study programme will be developed for the assessment of country needs for controlled medications. Part of this study programme will concentrate on the development of a method to determine more precisely the specific country needs for controlled medications, based on country-specific morbidity data.

Part II: Other controlled medicines and aspects not covered by Part I

Introduction

Pharmacological treatment is effective for improving the health, well-being and social functioning of people dependent on opioids, and preventing the transmission of HIV and other blood-borne diseases. It also provides a platform for antiretroviral (ARV) treatment and treatment of tuberculosis (TB) and other diseases highly prevalent among injecting drug users (IDUs). While several countries have decided to include this treatment option into their national treatment strategies, access to this form of treatment remains difficult in many countries.

In addition, over half a million women die every year during childbirth. It is, therefore, a matter of concern that access to medications[1] containing ergometrine and ephedrine, used in emergency obstetric care, is reportedly difficult in some countries, even though reducing maternal death is part of the Millennium Development Goals. (World Health Organization. *The new emergency health kit 98,* 2nd ed., Geneva, 1998:61.)[2]

It was considered that many of the activities needed to assist countries in improving access to opioid analgesics, as well to other controlled medicines are very similar. The right to health (i.e. "the right to the enjoyment of the highest attainable standard of health") includes access to necessary treatment and care and to all essential medicines. It is expected that WHO will take a leading role in the realization of this right. Therefore, it would be inefficient not to take into account the need for other controlled essential medicines when taking action to improve access to analgesia.

It is in view of this overall responsibility of WHO regarding the use of medicines, and recognizing that major barriers to access to controlled medicines are common for different health conditions, that activities under the Programme will also address the adequate use of controlled substances for other medical purposes. These additional activities under the exclusive responsibility of WHO are described in this part of the framework of the Programme.

This part of the Programme framework was prepared by WHO and is to be further elaborated and implemented by WHO in the coming years, in cooperation with governments and nongovernmental organizations (NGOs). It consists of aspects that are not covered by Part I.

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[1] For access, no barrier may be left in place. Even if there is no formal barrier to access to controlled medicines, the patient will benefit only if they are administered. To express this, the Programme uses the word "medications" where applicable. This includes the process of administering the medicines to the patient.

[2] This publication was issued on behalf of the following agencies: WHO, Ecumenical Pharmaceutical Network, the International Committee of the Red Cross, International Dispensary Association (IDA) Foundation, the International Federation of Red Cross and Red Crescent Societies, International Organization for Migration, Médecins sans Frontières, Merlin, United Nations Population Fund, the United Nations' High Commissioner for Refugees and UNICEF.

Like Part I, Part II will also be enabling to the countries addressing comprehensively, within WHO's mandate, the issue of legitimate access to all medications made from substances controlled under the three drug Conventions.

This second part of the framework of the Programme is intended to give technical assistance on a voluntary basis to the countries and their governments in complying with their responsibility to ensure the availability of controlled medicines for medical purposes not yet covered in Part I. Like the first part of the framework, it will be flexible and provide tailor-made solutions as far as possible.

II.1. Access to other controlled medicines: not a lesser problem

In most countries, access to many medicines which contain narcotic drugs and psychotropic substances controlled under the international drug control treaties, is much more difficult than to other prescription medicines. The need to apply additional control measures to those medicines is a result of their liability to abuse and to produce ill effects. This is not only the case for opioid analgesics, but it is reported for other controlled medicines as well. The international drug control treaties not only emphasize the need to ensure that there is adequate provision of narcotic drugs for the relief of pain and suffering but also state that the availability of psychotropic substances for medical purposes should not be unduly restricted (see Annex 6). Controlled substances are often not available as required by current good medical practice, thus contributing to the spread of disease or to avoidable death.

In Part I of this framework, statistical data were reported on the consumption of opioids under international control. These data indicate significant disparities in consumption levels among countries. Although much more is known about the consumption of opioids than that of other controlled medicines, there are reports showing that other controlled medicines are also not always accessible for medical use.

Which other medications and diseases are involved?

Aside from opioid analgesics, a large number of controlled medicines are used regularly for medical treatment and for a large number of conditions. All these controlled medicines should be easily accessible to patients who are in need of them.

Part II covers all controlled substances on the WHO Model List of Essential Medicines. In addition to those mentioned in Table 2, this includes the following categories (Table 3):

- opioids for substitution therapy of opioid dependence
- ephedrine and ergometrine, as used in obstetrics
- benzodiazepines
- phenobarbital.

Table 3. Additional controlled medicines covered by Part II of the Programme framework

Controlled medicines on the WHO Model List of Essential Medicines[a]	
buprenorphine	
diazepam	injection 10 mg = 2 ml ampoule tablets 2 mg and 5 mg (and other benzodiazepines that can replace diazepam)
ephedrine	30 mg/ml ampoule
ergometrine	injection 200 microgram = 1 ml ampoule
methadone	oral solution 5 mg/5 ml oral solution 10 mg/5 ml concentrate for oral solution 5 mg/5 ml concentrate for oral solution 10 mg/5 ml
phenobarbital	tablet 15–100 mg elixir 15 mg/5 ml

[a] This list includes all medicines for other use than analgesia included in the fourteenth WHO Model List of Essential Medicines that are placed under the international control of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol and the Convention on Psychotropic Substances, 1971, as well as medicines made from substances controlled as precursors under the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Causes of underuse

The causes of underuse of controlled substances have already been described in Part 1 and are essentially the same for opioid analgesics and other controlled medications.

In addition to what was noted in Part 1, it should be mentioned here that regulatory impediments include various administrative and legal restrictions on access to controlled medicines, such as regulatory provisions inappropriately limiting the right of doctors to prescribe certain substances or undue limitations on the quantities of substances to be prescribed. Depending on the circumstances, regulatory impediments may also include:

- the requirement to use special prescription forms and limits on the quantities of controlled medicines that may be kept by medical personnel in connection with their therapeutic functions;
- restrictions on the number of pharmacies that are allowed to dispense controlled medicines; and
- the administrative burden related to the manufacture, import, trade and distribution of controlled medicines.

Strong sanctions for unintentional errors made by those handling controlled substances also contribute to their limited availability, since they deter medical personnel from distributing and/or prescribing those substances.

Economic and procurement impediments are sometimes related to the controlled status of these medicines. An example is the safety measures for storage, which require investments that are regarded by pharmacists in some countries as too high. Therefore, they do not invest in safety lockers and decide not to dispense controlled medicines. Such specific impediments will be addressed by this programme.

Mandate for WHO action

WHO constitution

WHO has a constitutional task to make recommendations with respect to international health. Many of WHO's *constitutional tasks* relate to activities directed to improved accessibility of controlled medicines, *inter alia*:

- to promote cooperation among scientific and professional groups which contribute to the advancement of health;
- to promote maternal health;
- to foster activities in the field of mental health and substance abuse; and
- to assist governments, upon request, in strengthening health services to provide information, counsel and assistance in the field of health.

Millennium Development Goals related to the access to controlled substances

WHO plays an important role in the realization of the Millennium Development Goals, as set in September 2000 in a declaration endorsed by 189 countries[1] These goals need to be reached by 2015.

Access to affordable, essential medicines in developing countries is one target of the Millennium Development Goals (target 17). This target does not make any exemption for controlled medicines, which are in principle available, but which may not be accessible due to attitude and regulatory impediments. Target 7 is to have halted and begun to reverse the spread of HIV/AIDS by 2015. The reduction in the number of IDUs and reduction in risk of HIV transmission among IDUs as a result of treatment will contribute to reaching this target. Target 6 is to reduce by three quarters, between 1990 and 2015, the maternal mortality ratio. This reduction would be facilitated by the availability of the essential medicines that are used during delivery.

Resolutions by international bodies

The *World Health Assembly*, the *WHO Executive Board*, the *Commission on Narcotic Drugs* and the *Economic and Social Council (ECOSOC)* have adopted several resolutions on, *inter alia*, the subject of access to opioids for medical purposes. These resolutions reiterate the importance of medically appropriate use of opioids in pain relief as advocated by WHO. Copies of the most relevant resolutions can be found in Annexes 1-5.

[1] *WHO and the Millennium Development Goals*. Geneva, World Health Organization, 2005. Fact sheet 290.

The right to health

The WHO Constitution recognizes "the enjoyment of the highest attainable standard of health" as "one of the fundamental rights of every human being…". More than 45 WHA resolutions adopted since the first WHA (1948) to the most recent 59th WHA (2006) refer explicitly to human rights. Today, every WHO Member State is party to at least one human rights treaty that endorses health as a human right and/or other health-related rights; thus, WHO's public health guidance needs to be consistent with these human rights obligations.

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) sets out the scope and content of the right to health. To clarify and operationalize this right further, the UN Committee on Economic, Social and Cultural Rights, which monitors compliance with the ICESCR, adopted General Comment 14 in 2000. General Comment 14 set out that the right of health includes the availability of essential medicines, as defined by the WHO Action Programme on Essential Drugs. It also set out that the right to health includes access to pre-and postnatal care, emergency obstetric services, and mental health care as well as urgent medical care in case of accidents and epidemics.

An overarching principle of human rights law, integral to the realization of the right to health, is equality. In this context, General Comment 14 sets out that health facilities, goods and services must be accessible without discrimination on any of the prohibited grounds, including physical or mental disability and health status. To safeguard the principle of equality, and prevent covert preferential treatment of one group of patients in access to health care and health services, the medicines and activities that are addressed by Part I of this Framework cannot be disconnected from the medicines and activities addressed by Part II.

Conclusion

Since the mandate for WHO to address the issue of access to essential medicines, including controlled medications, stems from the constitution of WHO and the above-mentioned resolutions, and the WHO Secretariat and its Member States should act in ways that promote and protect the right to health as enshrined in WHO's constitution, the activities under the Programme should be implemented as an integral programme that includes both Parts I and II.

II.2. Description of the Programme

Objectives

Part II of the programme will focus on the same objectives as Part I.

Beneficiaries of the Programme

Part II of the programme will focus on the same beneficiaries as Part I.

Programme activities

Part II of the Programme will comprise the activities covered in Part I for opioid analgesics, but applied to the remaining controlled medicines on the WHO Model List of Essential Medicines. In addition to those activities already described in Part I, the following remarks and further activities are relevant with regard to Part II:

1. Process initiating workshops

Besides the points on process initiating workshops made under Part I of the Programme, additional process initiating workshops will be organized under Part II to cover the evidenced-based pharmacological treatment of substance dependence in conformity with the right to health.

2. Review, development and dissemination of treatment guidelines

As already mentioned in Part I, for promotion of the rational use of controlled medications, the appropriate evidence-based guidelines for health-care professionals should be available. Revision and updating of the guidelines should take into account the results of their implementation on the country level, particularly in low and middle income countries.

Under Part II, the Guidelines on "Psychosocially assisted pharmacotherapy of opioid dependence", which are under development, will be disseminated to the countries and their use will be encouraged, supported and evaluated.

3. Training workshops on procurement, pharmacy inspection and law enforcement for controlled medications

Part II of the Programme will comprise training workshops on procurement for groups of four to five countries which will be organized to develop and maintain secure medicines distribution systems and to establish best practices in procurement. Such medicines distribution systems need to be efficient in making medications available to patients in different settings including at home, while ensuring rational security, including full implementation of the provisions of the Conventions, such as licensing, record-keeping, reporting and inspection. Guidance will be provided to regulatory authorities, pharmacy inspectors and law enforcement officials on how to prevent and investigate diversion of controlled medications without impeding availability of medicines and medical care of patients and to eliminate parallel markets. Specific preparatory workshops to train and re-train trainers will be organized so as to establish a pool of qualified trainers.

4. Provision of pricing, supplier and quality information

Under Part II of the Programme, information will be collected on suppliers and pricing of relevant products. This information will be made available to the Programme's partners and others. In collaboration with the WHO Prequalification Programme the quality of relevant products can be verified.

5. Public education activities

Technical support will be provided to institutions and organizations involved in public education to promote knowledge about appropriate use of controlled medications, while also drawing attention to the risks associated with those medications.

6. Survey on availability of ergometrine and ephedrine medications in obstetrics, and controlled medications for psychiatric and neurological disorders

The evaluation of the adequacy of the access to medications containing ephedrine and ergometrine (which are scheduled as precursors under the 1988 Convention) used in emergency obstetric care, is more complicated than an evaluation of the availability of other controlled medications. An inventory of countries where the availability of these medications is a problem will be made. Problems identified will be analysed to identify their cause. (Which follow-up activities need to be developed will be decided after the survey.)

Many medications used in psychiatric care are scheduled under the 1971 Convention on Psychotropic Substances. Most of the substances contained in these controlled medications are included in Schedule IV of the 1971 Convention, such as benzodiazepines and phenobarbital, which are also medicines included on the WHO Model List of Essential Medicines. A survey will determine whether the availability of these substances is adequate and whether diversions of these substances do occur. An inventory will list countries where the availability of these substances is a problem. Problems identified will be analysed in order to identify their cause. (Which follow-up activities need to be developed will be decided after the survey.)

Part III: Planning for action

The Programme as a joint effort

Many governments and organizations are already involved in improving access to controlled medications. This Programme will utilize, integrate and build upon the accumulated experience from the numerous activities implemented.

Collaborative and coordinated action of governments, UN agencies, other relevant international bodies and NGOs has to be reinforced in order to implement the Access to Controlled Medications Programme. The Programme is envisaged as assisting governments in complying with their responsibility to ensure availability of controlled substances for medical purposes.

The exact roles and responsibilities of stakeholders in the Programme need to be determined for each specific activity.

WHO[1] will be responsible for the implementation and coordination of the Programme, including fundraising. WHO Regional Offices and Country Offices will identify opinion leaders among professionals and key persons in national administrations and recruit trainers; furthermore, they will implement project modules (such as workshops, distribution of newsletters and e-learning tools) at the regional and country levels.

Furthermore, the Programme will seek the expertise and support of the WHO Expert Advisory Panels, the WHO Expert Committee on Drug Dependence, WHO Collaborating Centre, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Office on Drugs and Crime (UNODC), and NGOs[2] including associations of health-care professionals and patient/consumer organizations.

Conditions which will affect the outcome on the country level:

- adequate medical and control infrastructure;
- adequate political will and commitment of the government and the national administration;
- adequate support to related programmes and initiatives dealing with the health conditions requiring controlled medicines;
- adequate resources for implementing regulatory controls to prevent diversion and to ensure availability;
- socioeconomic situation and the presence of a well-functioning social security system; and

[1] Department of Medicines Policies and Standards (PSM) in WHO Headquarters, Unit of Quality and Standards: Medicines (QSM), in collaboration with the departments and programmes of NMH (Programme on Cancer control, Department of Mental Health and Substance Abuse), HTM (HIV/AIDS) and HTP (Surgery, Access to Medicines (PAR)).

[2] For example: the National Hospice and Palliative Care Organization (NHPCO; Alexandria, VA, USA), the African Palliative Care Association (Entebbe, Uganda), the International Association for Hospice and Palliative Care (IAHPC; Houston, TX, USA) and the International Association for the Study of Pain (IASP; Seattle, WA, USA).

— sufficient implementation capacity in the country.

Implementation modalities

- Implementation will be in several phases. During the first phase, which will last approximately six years, the Programme will concentrate on selected activities to find the most effective assistance mechanisms and to develop tools to be used in the Programme.
- Pilot projects will be undertaken in individual countries and groups of countries. Lessons learned from those pilot projects will be used in extending the project to other countries in the region and to other regions.
- A regional approach will be used wherever possible, since many conditions for success (e.g. socioeconomic situation, present consumption level, health infrastructure and social security systems) are similar in countries within a region.
- The activities of this Programme will be integrated or linked with other relevant WHO activities and programmes, such as the Cancer Control Programme and programmes implemented by the department of HIV/AIDS and Mental Health and Substance Abuse.
- Activities may be outsourced (coordinated by WHO, but implemented by other organizations) to increase effectiveness.

Priority setting

The extent to which the Programme can be implemented will depend on financial and other support. For this reason, assistance given to countries to improve access to controlled medications will depend on available resources.

In the setting of priorities with regard to the selection of countries, the following factors will be given particular consideration:

— low and middle income countries;
— governments that have already started action to improve access;
— governments of countries and territories where medical infrastructure would allow wider access to controlled medicines;
— countries and territories where controls are or can be applied successfully to prevent diversion; and
— governments that have demonstrated the political will to make controlled medications more available.

On the regional and country level, particular attention will be given to activities with a significant impact on the disease burden and the quality of life of patients.

Pilot and demonstration projects could be helpful to show that the Programme is effective, and successful implementation in one country in the region may cause a domino effect.

Monitoring and evaluation

A distinction should be made between monitoring of the process indicators and of the outcome indicators of the Programme.

Monitoring the process indicators of programme implementation

To ensure and measure achievements it is important to set clearly identified targets and establish a mechanism to monitor implementation of activities and their outcomes at the national and international levels. In order to improve performance, activities should be regularly evaluated.

Monitoring the progress and outcome of Programme implementation will include:

- Setting and monitoring measurable progress implementation targets, including on the country level as appropriate, such as:
  - number of targeted countries where the Programme is being implemented;
  - numbers of training workshops and of trained professionals;
  - quantity of training and information materials;
  - initiated and completed surveys and studies; and
  - number of countries that submitted estimates and statistics to INCB adequately and before the deadline.
- Setting and monitoring measurable outcomes, including on the country level as appropriate, such as:
  - consumption levels in participating countries, based on data available to INCB, to be analysed annually, to measure overall progress made by countries;
  - actual disease-specific consumption levels in countries to which activities are directed;
  - levels of diversion and abuse of controlled medications will be monitored and appropriate actions taken, if necessary;
  - effectiveness of specific components of the programme, for example case studies or surveys, to identify policies and activities which were successful in achieving the desired results and to determine the way forward for the next phase of the Programme;
  - number of countries in which barriers in the laws and regulations, which impede availability of and access to rational use of controlled medicines, have been removed.

Results should be measured against the objectives as mentioned in Parts I and II.

Programme evaluation

Towards the end of the first phase, starting early in the fifth year, the first phase as a whole will be evaluated externally under the responsibility of WHO general management. The findings of this evaluation will be reported to WHO governing bodies and to other relevant international bodies as appropriate.

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Further reading

Beck SL, Falkson G. Prevalence and management of cancer pain in South Africa. *Pain*, 2001, 94:75–84.

Blengini C, Joranson DE, Ryan KM. Italy reforms national policy for cancer pain relief and opioids. *European Journal of Cancer Care*, 2003, 12:28–34. (http://www.medsch.wisc.edu/painpolicy/publicat/03ejcc/index.htm).

De Lima L. The use of opioid analgesics to alleviate cancer pain. *Rev Panamericana de Salud Publica/Pan American Journal of Public Health,* 1997, 2:142–145.

De Lima L et al. Opioid availability in Latin America: The Santo Domingo Report. Progress since the Declaration of Florianopolis. *Journal of Pain and Symptom Management*, 1997, 13:4.

De Lima L. Opioid availability in Latin America as a global problem: a new strategy with regional and national effects. In: A Model for Improving Access to Opioids: The Latin American Experience. *Innovations in End of Life Care*, 2003, 5 (http://www2.edc.org/lastacts/archives/archivesJan03/editorial.asp).

De Lima L, Sweeney C, Palmer JL, Bruera E. Potent analgesics are more expensive for patients in developing countries: a comparative study. *Journal of Pain and Palliative Care Pharmacotherapy*, 2004, 18:59–70.

Ghooi RB, Ghooi SR. Freedom from pain – a mirage or a possibility? Experience in attempts to change laws and practices in India. *Journal of Pain Palliative Care Pharmacotherapy*, 2003, 17:1–9.

Ghooi RB, Ghooi SR, Charturvedi HK. Pain relief in India. *Lancet*, 1999, 353:677.

Gilson AM et al. Progress to achieve balanced state policy relevant to pain management and palliative care: 2000–2003. *Journal of Pain & Palliative Care Pharmacotherapy*, 2005, 19:7–20 (http://www.medsch.wisc.edu/painpolicy/publicat/05jppcp/05jppcp.pdf).

Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997–2002. *Journal of Pain and Symptom Management.* 2004, 28:176–188 (http://www.medsch.wisc.edu/painpolicy/publicat/04jpsm/04jpsm.pdf).

International Narcotics Control Board. *Availability of opiates for medical needs, report of the International Narcotics Control Board for 1995 (Special report prepared pursuant to Economic and Social Council resolutions 1990/31 and 1991/43)*. New York, United Nations, 1996 (www.incb.org).

International Narcotics Control Board. *Report of the International Narcotics Control Board for 1999, Chapter I. Freedom from pain and suffering.* New York, United Nations (United Nations publication, sales no. E.00.XI.1) (www.incb.org).

International Narcotics Control Board. *Report of the International Narcotics Control Board for 2000, Chapter I. Overconsumption of internationally controlled drugs*. New York, United Nations (United Nations publication, sales no. E.01.XI.1) (www.incb.org).

International Narcotics Control Board. *Narcotic drugs: estimated requirements for 2006; statistics for 2004, E/INCB/2005/2.* New York, United Nations (United Nations publication, sales no. E.06.XI.3) (www.incb.org).

International Narcotics Control Board. *Psychotropic substances: statistics for 2004; assessments of annual medical and scientific requirements for substances in schedules ii, iii and iv of the convention on psychotropic substances of 1971, E/INCB/2005/3.* New York, United Nations (www.incb.org).

International Narcotics Control Board. *Report of the International Narcotics Control Board for 2005, Chapter II. Operation of the international drug control system*. New York, United Nations, paras. 83–103 (United Nations publication, sales no. E.06.XI.2) (www.incb.org).

Joranson DE. Improving availability of opioid pain medications: testing the principle of balance in Latin America. *Innovations in End-of-Life Care*, 2003, 5 (http://www2.edc.org/lastacts/archives/archivesJan03/featureinn.asp).

Joranson DE, Gilson AM, Dahl JL, Haddox JD. Pain management, controlled substances, and state medical board policy: A decade of change. *Journal of Pain and Symptom Management*, 2002, 23:138–147 (http://www.medsch.wisc.edu/painpolicy/publicat/02jpsm1/index.htm).

Joranson DE, Rajagopal MR, Gilson AM. Improving access to opioid analgesics for palliative care in India. *Journal of Pain and Symptom Management.* 2002; 24:152–159 (http://www.medsch.wisc.edu/painpolicy/publicat/02jpsm3/index.htm).

Kerr T et al. Opioid substitution and HIV/AIDS treatment and prevention. *Lancet*, 2004, 364:1918–1919.

Logie DE, Harding R. An evaluation of a morphine public health programme for cancer and AIDS pain relief in Sub-Saharan Africa. *BMC Public Health*, 2005, 5:82.

Pain & Policy Studies Group. *Improving cancer pain relief in the world: report for 2004.* Madison, WI, University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Centre for Policy and Communications in Cancer Care, 2005 (http://www.medsch.wisc.edu/painpolicy/publicat/04report/04report.pdf).

Pain & Policy Studies Group. *Global opioid use trends: resources for Africa, Asia, Europe, India, and Latin America. 2005.* Madison, WI, University of Wisconsin Pain & Policy Studies Group (http://www.medsch.wisc.edu/painpolicy/publicat/monograp/globaltrends.htm).

Pain & Policy Studies Group. *On-line Eastern Europe Resource Center. 2005.* Madison, WI, University of Wisconsin Pain & Policy Studies Group (http://www.medsch.wisc.edu/painpolicy/internat/E.Europe/Eastern_Europe.htm).

Rajagopal MR, Joranson DE, Gilson AM. Medical use, misuse, and diversion of opioids in India. *Lancet*, 2001, 358:139–143 (http://www.medsch.wisc.edu/painpolicy/publicat/01lancet/contents.htm).

Sepulveda, C et al. Quality care at the end of life in Africa. *BMJ*, 2003, 327:209–213.

Stjernsward J et al. Opioid availability in Latin America: The Declaration of Florianopolis. *Journal of Pain and Symptom Management*, 1995, 10:233–237.

Wenk R, Bertolino M, De Lima L. Analgésicos Opioides en Latinoamérica: La Barrera de Accesibilidad Supera la de Disponibilidad. [Analgesic opioids in Latin America: the barrier of accessibility surpasses the one of availability.] *Medicina Paliativa*, 2004, 11:148–151.

World Health Organization. *Pharmacotherapy of opioid dependence in Central and Eastern Europe: the practices and context of pharmacotherapy of opioid dependence in Central and Eastern Europe.* Geneva, World Health Organization (WHO/MSD/MSB/04.1 2004).

World Health Assembly. *Cancer prevention and control. WHA 58.22*. Geneva, World Health Organization, 2005 (http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_22-en.pdf).

World Health Organization. *Achieving balance in national opioids control policy: guidelines for assessment*. Geneva, World Health Organization, 2000 (http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm).

World Health Organization. *Cancer pain relief: with a guide to opioid availability,* 2nd ed. Geneva, World Health Organization, 1996 (http://whqlibdoc.who.int/publications/9241544821.pdf).

World Health Organization. *Cancer pain relief and palliative care in children*. Geneva, World Health Organization, 1998.

World Health Organization. *National Cancer Control Programmes: Policies and Managerial Guidelines*, 2nd ed. Geneva, World Health Organization, 2002 (http://www.who.int/cancer/nccp/nccp/en/)

Annex 1: Resolution ECOSOC 2005/25 on Treatment of pain using opioid analgesics

36th plenary meeting

22 July 2005

The Economic and Social Council,

Recalling its resolutions 1995/19 of 24 July 1995, 1996/19 of 23 July 1996, 1997/38 of 21 July 1997, 1998/25 of 28 July 1998, 1999/33 of 28 July 1999, 2000/18 of 27 July 2000, 2001/17 of 24 July 2001, 2002/20 of 24 July 2002, 2003/40 of 22 July 2003 and 2004/43 of 21 July 2004, in which it reiterated the importance of medically appropriate use of opiates in pain relief therapy as advocated by the World Health Organization,

Bearing in mind the report of the International Narcotics Control Board for 1999[3] especially its chapter I, "Freedom from pain and suffering", in which the Board reminded all Governments that the medical use of narcotic drugs continued to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,

Recalling the document entitled "Achieving balance in national opioids control policy: guidelines for assessment",[4] prepared in 2000 by the World Health Organization in consultation with the International Narcotics Control Board to help Governments to achieve better pain management by identifying and overcoming the barriers to opioid availability, in which it was emphasized that opioids such as morphine were the drugs of choice in the treatment of severe pain and that they should be available at all times in adequate amounts and in the appropriate dosage forms to satisfy the health care needs of the majority of the population,

Recalling also that, in May 2004, the Executive Board of the World Health Organization recommended for adoption by the Fifty-eighth World Health Assembly, to be held in May 2005, a draft resolution on cancer prevention and control, in which the Assembly would urge member States to ensure the medical availability of opioid analgesics according to international treaties and recommendations of the World Health Organization and the International Narcotics Control Board and subject to an efficient monitoring and control system,

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[3] Report of the International Narcotics Control Board for 1999 (United Nations publication, Sales No. E.00.XI.1).
[4] WHO/EDM/QSM/2000.4.

Welcoming the fact that the World Health Organization is developing a strategy to integrate the availability of opioid pain medication into palliative care for HIV/AIDS, cancer and other chronic diseases,

Calling attention to the assessment of the International Narcotics Control Board in its report for 2004 according to which low consumption of opioid analgesics for the treatment of moderate to severe pain, especially in developing countries, continued to be a matter of great concern to the Board,[5]

Noting, on the basis of that report, the disparities in the consumption of such medicines existing between developing and developed countries, and recalling that, in 2003, six countries together accounted for 79 per cent of global consumption of morphine, while developing countries, representing about 80 per cent of the world's population, accounted for only about 6 per cent of global consumption of morphine,

Bearing in mind that, in its report for 2004, the International Narcotics Control Board encouraged Member States that had not yet done so to examine the extent to which their health-care systems and laws and regulations permitted the use of opioids for medical purposes, to identify possible impediments to such use and develop plans of action for the development of long-term pain management strategies, with a view to facilitating the supply and availability of narcotic drugs for all appropriate indications,[6]

Recalling that, in its report for 1999, the International Narcotics Control Board stated that the development of a new, non-profit mechanism for the use of otherwise unused narcotic products should be considered[7] and observed that the impediments to opioid availability that were frequently reported by government authorities were impediments originating in the regulatory and drug control system, medical/therapeutic impediments, economic impediments and social and cultural impediments,[8]6

1. Recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics, as advocated by the World Health Organization, especially in developing countries, and calls upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use;

2. Invites the International Narcotics Control Board and the World Health Organization to examine the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics and to inform the Commission on Narcotic Drugs at its forty-ninth session of the results of that examination;

[5] Report of the International Narcotics Control Board for 2004 (United Nations publication, Sales No. E.05.XI.3), para. 143.
[6] Ibid., para. 197.
[7] Report of the International Narcotics Control Board for 1999 (United Nations publication, Sales No. E.00.XI.1), para. 45.
[8] Ibid., para. 30.

3. Requests the Secretary-General to transmit the text of the present resolution to all Member States for their consideration and implementation and to report on the implementation of the resolution to the Commission on Narcotic Drugs at its forty-ninth session.

Annex 2: Resolution WHA 58.22 on Cancer prevention and control

Ninth plenary meeting,
25 May 2005 – Committee B, third report

The Fifty-eighth World Health Assembly,

Having examined the report on the prevention and control of cancer;
Recalling resolutions WHA51.18 and WHA53.17 on the prevention and control of noncommunicable diseases, WHA57.17 on the Global Strategy on Diet, Physical Activity and Health, WHA56.1 on tobacco control, WHA57.12 on the reproductive health strategy, including control of cervical cancer, and WHA57.16 on health promotion and healthy lifestyles;
Recognizing the suffering of cancer patients and their families and the extent to which cancer threatens development when it affects economically active members of society;
Alarmed by the rising trends of cancer risk-factors, the number of new cancer cases, and cancer morbidity and mortality worldwide, in particular in developing countries;
Recognizing that many of these cases of cancer and deaths could be prevented, and that the provision of palliative care for all individuals in need is an urgent, humanitarian responsibility;
Recognizing that the technology for diagnosis and treatment of cancer is mature and that many cases of cancer may be cured, especially if detected earlier;
Recognizing that tobacco use is the world's most avoidable cause of cancer and that control measures, such as legislation, education, promotion of smoke-free environments, and treatment of tobacco dependence, can be effectively applied in all resource settings;
Recognizing that among all cancer sites cervical cancer, causing 11% of all cancer deaths in women in developing countries, has one of the greatest potential for early detection and cure, that costeffective interventions for early detection are available and not yet widely used, and that the control of cervical cancer will contribute to the attainment of international development goals and targets related to reproductive health;
Recognizing the value of multidisciplinary management and the importance of surgery, radiotherapy, chemotherapy, palliative care and other approaches in the treatment of cancer;
Recognizing the contribution of IARC, over 40 years, to research on cancer etiology and prevention, providing evidence on global cancer prevalence and incidence, the causes of cancer, mechanisms of carcinogenesis, and effective strategies for cancer prevention and early detection;
Mindful of the need for careful planning and priority-setting in the use of resources in order to undertake effective activities to reduce the cancer burden;
Recognizing the importance of adequate funding for cancer-prevention, control and palliative care programmes, especially in developing countries;
Encouraged by the prospects offered by partnerships with international and national

organizations within the Global Alliance for Cancer Control, and other bodies such as patient organizations;
Recognizing the support given by IAEA to combat cancer, and welcoming the initiative of the Agency to establish the Programme of Action for Cancer Therapy, and research efforts of national cancer institutes in various Member States,

1. URGES Member States:
(1) to collaborate with the Organization in developing and reinforcing comprehensive cancercontrol programmes tailored to the socioeconomic context, and aimed at reducing cancer incidence and mortality and improving the quality of life of cancer patients and their families, specifically through the systematic, stepwise and equitable implementation of evidence-based strategies for prevention, early detection, diagnosis, treatment, rehabilitation and palliative care, and to evaluate the impact of implementing such programmes;
(2) to set priorities based on national burden of cancer, resource availability and health system capacity for cancer-prevention, control and palliative-care programmes;
(3) to integrate national cancer-control programmes in existing health systems that set out outcome-oriented and measurable goals and objectives for the short, medium and long term, as recommended in the Annex to the present resolution, to identify evidence-based, sustainable actions across the continuum of care, and to make the best use of resources to the benefit of the entire population by emphasizing the effective role of primary health care in promoting prevention strategies;
(4) to encourage and to frame policies for strengthening and maintaining technical equipment for diagnosis and treatment of cancer in hospitals providing oncology and other relevant services;
(5) to pay special attention to cancers for which avoidable exposure is a factor, particularly exposure to chemicals and tobacco smoke in the workplace and the environment, certain infectious agents, and ionizing and solar radiation;
(6) to encourage the scientific research necessary to increase knowledge about the burden and causes of human cancer, giving priority to tumours, such as cervical and oral cancer, that have a high incidence in low-resource settings and are amenable to cost-effective interventions;
(7) to give priority also to research on cancer prevention, early detection and management strategies, including, where appropriate, traditional medicines and therapies, including for palliative care;
(8) to consider an approach in the planning, implementation and evaluation phases of cancer control that involves all key stakeholders representing governmental, nongovernmental and community-based organizations, including those representing patients and their families;
(9) to ensure access to appropriate information in relation to preventive, diagnostic and treatment procedures and options, especially by cancer patients, and to palliative care;
(10) to develop appropriate information systems, including outcome and process indicators, that support planning, monitoring and evaluation of cancer-prevention, control and palliativecare programmes;
(11) to assess periodically the performance of cancer prevention and control programmes, allowing countries to improve the effectiveness and efficiency of their programmes;

(12) to participate actively in implementing WHO's integrated health promotion and prevention strategies targeting risk factors for noncommunicable diseases, including cancer, such as tobacco use, unhealthy diet, harmful use of alcohol and exposure to biological, chemical and physical agents known to cause cancer, and to consider signing, ratifying, accepting, approving, formally confirming or acceding to the WHO Framework Convention on Tobacco Control;
(13) to improve access to appropriate technologies, with support from WHO, for the diagnosis and treatment of cancer, in order to promote its early diagnosis and treatment, especially in developing countries;
(14) to determine cost-effective minimum standards, adapted to local situations, for cancer treatment and palliative care that use WHO's strategies for nationwide provision of essential drugs, technologies, diagnostics and vaccines, taking into consideration in the case of palliative care the recommendations of the Second Global Summit of National Hospice and Palliative Care Associations (Seoul, 2005);
(15) to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system;
(16) to ensure, where appropriate, the documented, scientific, evidence-based safety and efficacy of available traditional medicines and therapies;
(17) to develop and strengthen health system infrastructure, particularly related to human resources for health, in order to build adequate capacity for effective implementation of cancerprevention and control programmes, including a cancer registry system;
(18) to accord high priority to cancer-control planning and implementation for high-risk groups, including relatives of patients and those having experienced long-duration and highintensity carcinogen exposure;

2. REQUESTS the Director-General:
(1) to develop WHO's work and capacity in cancer prevention and control and to promote effective, comprehensive cancer prevention and control strategies in the context of the global strategy for the prevention and control of noncommunicable diseases, the Global Strategy on Diet, Physical Activity and Health, and resolution WHA57.16 on health promotion and healthy lifestyles, with special emphasis on less developed countries;
(2) to provide technical support to Member States in setting priorities for cancer prevention, control and palliative-care programmes;
(3) to strengthen WHO's involvement in international partnerships and collaboration with Member States, other bodies of the United Nations system and actors from a wide variety of related sectors and disciplines in order to advocate, mobilize resources, and build capacity for, a comprehensive approach to cancer control;
(4) to continue developing WHO's strategy for the formulation and refinement of cancer prevention and control programmes by collecting, analyzing and disseminating national experiences in that regard, and providing appropriate guidance, upon request, to Member States;
(5) to contribute to drawing up recommendations on early diagnosis of cancer, especially in order to define and reach the target populations that should benefit from such diagnosis;

(6) to consider allocating additional resources so that the knowledge provided by research is translated into effective and efficient public-health measures for cancer prevention and control;
(7) to promote research on cost-effectiveness of different strategies for prevention and management of various cancers;
(8) to promote and support research that evaluates low-cost interventions that are affordable and sustainable in low-income countries;
(9) to promote research on development of an effective vaccine against cervical cancer;
(10) to support the further development and expansion of a research agenda in IARC and other bodies that is appropriate to the framing of integrated policies and strategies for cancer control, and to promote and support technical and medical programmes in cancer treatment;
(11) to promote guiding principles on palliative care for cancer patients, including ethical aspects;
(12) to provide adequate resources and leadership support to the International Programme on Chemical Safety for its active role in international multisectoral mechanisms for chemical safety, including support for capacity building in chemical safety at country level;
(13) to support and strengthen mechanisms to transfer to developing countries technical expertise on cancer prevention and control, including surveillance, screening and research;
(14) to advise Member States, especially developing countries, on development or maintenance of a national cancer registry containing the type, location of the cancer and its geographical distribution;
(15) to collaborate with Member States in their efforts to establish national cancer institutes;
(16) to explore appropriate mechanisms for adequately funding cancer-prevention, control and palliative-care programmes, especially in developing countries;
(17) to explore the feasibility of initiating the development of a joint programme between WHO and IAEA for cancer prevention, control, treatment and research;
(18) to examine jointly with the International Narcotics Control Board the feasibility of a possible assistance mechanism that would facilitate the adequate treatment of pain using opioid analgesics;
(19) to explore all opportunities to improve the accessibility, affordability and availability of chemotherapy drugs, particularly in developing countries, for the treatment of HIV/AIDS related cancers;
(20) to report regularly on implementation of this resolution to the Health Assembly.

ANNEX to RESOLUTION 58.22

NATIONAL CANCER CONTROL PROGRAMMES:
RECOMMENDATIONS FOR OUTCOME-ORIENTED OBJECTIVES
National health authorities may wish to consider the following outcome-oriented objectives for their cancer control programmes, according to type of cancer:
• preventable tumours (such as those of lung, colon, rectum, skin and liver): to avoid and

reduce exposure to risk factors (such as tobacco use, unhealthy diets, harmful use of alcohol, sedentariness, excess exposure to sunlight, communicable agents, including hepatitis B virus and liver fluke, and occupational exposures), thus limiting cancer incidence;
• cancers amenable to early detection and treatment (such as oral, cervical, breast and prostate cancers): to reduce late presentation and ensure appropriate treatment, in order to increase survival, reduce mortality and improve quality of life;
• disseminated cancers that have potential of being cured or the patients' lives prolonged considerably (such as acute leukaemia in childhood): to provide appropriate care in order to increase survival, reduce mortality and improve quality of life;
• advanced cancers: to enhance relief from pain and other symptoms and improve quality of life of patients and their families.

Annex 3: Resolution ECOSOC 2004/40 on Guidelines for psychosocially assisted pharmacological treatment of persons dependent on opioids

47th plenary meeting

21 July 2004

The Economic and Social Council,

Recognizing the existence of a large number of persons dependent on opioids,[9] who are either receiving or in need of treatment for their opioid dependence,

Respecting the sovereign right of Member States to establish and implement effective treatment strategies,

Noting the evidence on the effectiveness of various treatments, inter alia abstinence therapy,

Recognizing the existence of a wide range of evidence-based treatment options, Emphasizing that psychosocially assisted pharmacological treatment is one of the treatment options available for improving the health, well-being and social functioning of persons dependent on opioids, and for preventing the transmission of HIV and other blood-borne diseases,

Acknowledging that the present resolution may be applicable only to Member States that are providing or planning psychosocially assisted pharmacological treatment for opiate addiction,

Recalling the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol,[10] in particular article 38, on measures against the abuse of drugs,

Recalling also the Declaration on the Guiding Principles of Drug Demand Reduction,188 adopted by the General Assembly at its twentieth special session,

Taking into account the conclusions and recommendations adopted by the World Health Organization in 1993 after the twenty-eighth meeting of the Expert Committee on Drug Dependence, on the need to increase access to effective

[9] "Dependent" is used in the present resolution to mean addicted.
[10] United Nations, Treaty Series, vol. 976, No. 14152.

treatment,

Taking note of the report of the International Narcotics Control Board for 2003,189 in particular paragraphs 222 and 328 of that report,

Taking note also of the position paper of the World Health Organization, the United Nations Office on Drugs and Crime and the Joint United Nations Programme on HIV/AIDS on substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention,

Acknowledging that work has been undertaken on psychosocially assisted pharmacological treatment in different regions,

Invites the World Health Organization, in collaboration with the United Nations Office on Drugs and Crime, subject to the availability of voluntary funds, which might be either from general-purpose funds, in accordance with the Commission on Narcotic Drugs guidelines for the use of general-purpose funds,185 or from earmarked funds, to develop and publish minimum requirements and international guidelines on psychosocially assisted pharmacological treatment of persons dependent on opioids,190 taking into account regional initiatives in this field, in order to assist the Member States concerned.

Annex 4: Resolution WHA 55.14 on Ensuring accessibility to essential medicines

Ninth plenary meeting,
18 May 2002
Committee A, second report

The Fifty-fifth World Health Assembly
Welcoming adoption of the "Declaration on the TRIPS agreement and public health" at the Fourth WTO Ministerial Conference (Doha, 14 November 2001), supportive of the rights of countries to protect public health and, in particular, to promote access to medicines for all;

Recalling discussions and proposals reported by Member States in their regional meetings before the Fifty-fifth World Health Assembly, mainly at the 53rd session of the Regional Committee for the Americas (September 2001) and the Forty-eighth session of the Regional Committee for the Eastern Mediterranean (October 2001) and, additionally, the thorough discussion of the Executive Board at its 109th session;

Reaffirming resolution WHA54.11, emphasizing WHO's medicines strategy and its requests to Member States and the Director-General of WHO;

Having considered the report on WHO's medicines strategy: expanding access to essential drugs;

Aware of the need to assure the continuity of updating WHO's Model List of Essential Drugs in light of evidence-based, scientific information;

Underlining the feasibility of addressing comprehensively the impact of international trade agreements on equitable access to all drugs, particularly essential drugs;

Conscious of the responsibility of Member States to support solid scientific evidence, excluding any biased information or external pressures that may be detrimental to public health;

1. URGES Member States:
(1) to reaffirm their commitment to increasing access to medicines, and to translate such commitment into specific regulation within countries, especially enactment of national drug policies and establishment of lists of essential medicines based on evidence and with reference to WHO's Model List, and into actions designed to promote policy for, access to, and quality and rational use of, medicines within national health systems;
(2) to establish the necessary mechanisms for essential medicines lists that are science-based, independent of external pressures, and subject to regular reviews;

(3) in addition to health policies and actions, to implement complementary measures to ensure that national lists of essential medicines are supported by standard clinical guidelines, preferably national therapeutic formularies, with the aim of promoting rational prescription;
(4) to reaffirm, within the national drug policies, WHO's concept of essential medicines as those medicines that satisfy the priority health care needs of the population, reflecting also availability, quality, price and feasibility of delivery, and re-emphasizing the evidence base for overall national discussions;
(5) to continue monitoring the implications on access to medicines of recent patent-protection laws and compliance with WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);

2. REQUESTS the Director-General:
(1) to strengthen the Expert Committee on the Use of Essential Drugs, ensuring its independence from external pressures at all times, the use of science-based criteria for revision and updating, and receipt, when appropriate and as required, of the necessary inputs from all relevant stakeholders;
(2) to ensure that WHO's medicines strategy addresses the important issue of the impact of international trade agreements on access to medicines and to reflect, in the relevant reports to WHO's governing bodies, progress in its comprehensive endeavour;
(3) to advocate the necessary action worldwide to promote market-based differential pricing for essential medicines between high-, middle-, and low-income countries, and to provide technical support, especially to developing countries, to establish drug-pricing policies;
(4) to advocate the concept and policies of essential medicines as a tool for implementing rational prescription of medicines;
(5) to continue to work on the methodology for computerized databases on reference prices of essential medicines worldwide;
(6) to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicines, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them;
(7) to join with and support nongovernmental organizations in the process of implementing initiatives that are compatible with public health priorities.

Annex 5: Resolution ECOSOC 2005/26 on Demand for and supply of opiates used to meet medical and scientific needs

36th plenary meeting

22 July 2005

The Economic and Social Council,

Recalling its resolution 2004/43 of 21 July 2004 and previous relevant resolutions,

Recognizing that the medical use of narcotic drugs, including opiates, is indispensable for the relief of pain and suffering,

Emphasizing that the need to balance the global licit supply of opiates against the legitimate demand for opiates used to meet medical and scientific needs is central to the international strategy and policy of drug control,

Noting the fundamental need for international cooperation with the traditional supplier countries in drug control to ensure universal application of the provisions of the Single Convention on Narcotic Drugs of 1961[11] and that Convention as amended by the 1972 Protocol,[12]

Reiterating that a balance between consumption and production of opiate raw materials was achieved in the past as a result of efforts made by the two traditional supplier countries, India and Turkey, together with established supplier countries,

Expressing deep concern at the level of licit global production of opiate raw materials and the significant accumulation of stocks over the past few years as a consequence of the operation of market forces, which has the potential to upset the delicate balance between the licit supply of and demand for opiates for medical and scientific purposes,

Emphasizing the importance of adhering to the estimates, based on actual consumption and utilization of narcotic drugs, furnished to and confirmed by the International Narcotics Control Board on the extent of cultivation and production of opiate raw materials, especially in view of the current oversupply,

[11] United Nations, Treaty Series, vol. 520, No. 7515.
[12] Ibid., vol. 976, No. 14152.

Recalling the Joint Ministerial Statement adopted during the ministerial segment of the forty-sixth session of the Commission on Narcotic Drugs,[13] in which ministers and other government representatives called upon States to continue to contribute to the maintenance of a balance between the licit supply of and demand for opiate raw materials used for medical and scientific purposes and to cooperate in preventing the proliferation of sources of production of opiate raw materials,

Considering that opiate raw materials and opiates derived there from are not just ordinary commodities that can be subjected to the operation of market forces, and that, therefore, market economy considerations alone should not determine the cultivation of opium poppy,

Reiterating the importance of medically appropriate use of opiates in pain relief therapy, as advocated by the World Health Organization,

Noting that countries differ significantly in their level of consumption of narcotic drugs and that in most developing countries the use of narcotic drugs for medical purposes has remained at an extremely low level,

1. Urges all Governments to continue to contribute to maintaining a balance between the licit supply of and demand for opiate raw materials used for medical and scientific purposes, the achievement of which would be facilitated by maintaining, insofar as their constitutional and legal systems permit, support to the traditional and established supplier countries, and to cooperate in preventing the proliferation of sources of production of opiate raw materials;

2. Urges Governments of all producer countries to adhere strictly to the provisions of the Single Convention on Narcotic Drugs of 1961[14] and that Convention as amended by the 1972 Protocol,[15] and to take effective measures to prevent the illicit production or diversion of opiate raw materials to illicit channels, and welcomes the study carried out by the International Narcotics Control Board on the relative merits of different methods of producing opiate raw materials and encourages improvements in practices in the cultivation and production of opiate raw materials;

3. Urges Governments of consumer countries to assess their licit needs for opiate raw materials realistically on the basis of actual consumption and utilization of opiate raw materials and opiates derived there from and to communicate those needs to the International Narcotics Control Board in order to ensure easy supply, calls on Governments of countries producing opium to limit the cultivation of opium poppy, taking into account the current level of global stocks, to the estimates furnished to and confirmed by the Board, in accordance with the requirements of the 1961 Convention,

[13] A/58/124, chap. II, sect. A.
[14] United Nations, Treaty Series, vol. 520, No. 7515.
[15] Ibid., vol. 976, No. 14152.

and urges that, in providing estimates of such cultivation, producer countries consider the actual demand requirements of importing countries;

4. Urges all the Governments of countries where opium poppy has not been cultivated for the licit production of opiate raw materials, in the spirit of collective responsibility, to refrain from engaging in the commercial cultivation of opium poppy, in order to avoid the proliferation of supply sites;

5. Commends the International Narcotics Control Board for its efforts in monitoring the implementation of the relevant Economic and Social Council resolutions and, in particular:

(a) In urging the Governments concerned to adjust global production of opiate raw materials to a level corresponding to actual licit requirements and to avoid unforeseen imbalances between the licit supply of and demand for opiates caused by the exportation of products manufactured from seized and confiscated drugs;

(b) In inviting the Governments concerned to ensure that opiates imported into their countries for medical and scientific use do not originate in countries that transform seized and confiscated drugs into licit opiates;

(c) In arranging informal meetings, during the sessions of the Commission on Narcotic Drugs, with the main States that import and produce opiate raw materials;

6. Requests the International Narcotics Control Board to continue its efforts in monitoring the implementation of the relevant Economic and Social Council resolutions in full compliance with the Single Convention on Narcotic Drugs of 1961 and with that Convention as amended by the 1972 Protocol;

7. Requests the Secretary-General to transmit the text of the present resolution to all Member States for consideration and implementation and to report to the Commission on Narcotic Drugs at its forty-ninth session on progress made in the implementation of the present resolution.

Annex 6: Treaty provisions and statements in official commentaries on the treaties regarding availability of controlled medications

Single Convention on Narcotic Drugs, 1961

Preamble to the Single Convention:
"*Recognizing* that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes …."

Single Convention, Article 9, paragraph 4:
" The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavour to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs."

Commentary on the Single Convention on Narcotic Drugs, 1961

Art. 3 – Changes in the Scope of Control, Paragraph 1, section 4
"An amendment to a Schedule is "required" if it is needed to combat the abuse of "narcotic" drugs, or to facilitate the availability of the drugs for the relief of pain and suffering without endangering the basic aim of the Single Convention, i.e. that of fighting drug abuse."

Art. 3 – Changes in the Scope of Control, Paragraph 3, subparagraph (iii), section 16
"The WHO has very wide discretion in selecting the Schedule. …. It will be guided in this choice by the interest of public health in each case, as it appears not only from the degree of danger which the substance in question presents but also from the need to make useful medicines as easily available as may be compatible with the requirements of their control."

Convention on Psychotropic Substances, 1971

Preamble to the 1971 Convention:
"*Recognizing* that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted, …."

Commentary on the 1971 Convention

Art. 2 – Scope of control of substances, paragraph 1, section 5

"An amendment in a Schedule may not only be 'required' for the purpose of fighting drug abuse, but sometimes also to facilitate the availability of very useful psychotropic substances for therapeutic purposes. In determining the question of control of a substance or of the strictness of régime to which it should be subjected, its dangerous properties must very often be weighed against its usefulness in medical practice. Not only the problem of drug abuse but more general considerations of public health are to be taken into account. …."

Annex 7: ICDRA recommendations

The 12th International Conference of Drug Regulatory Authorities (ICDRA), which was held from 3–6 April, 2006 in Seoul, Republic of Korea adopted the following recommendations:

- Regulators should make efforts to ensure that national regulatory frameworks do not impose an excessive (i.e. not prescribed by the respective international conventions) administrative and legal burden on achieving access to internationally controlled narcotic painkillers.
- To achieve better access to narcotic painkillers (first of all those that belong to Essential Medicines List) regulators are encouraged to working closely together with international organizations such as the International Narcotics Control Board and World Health Organization, as well as with national and local bodies involved in palliative care. All severe pain needs to be appropriately addressed therapeutically and especially severe pain in life-limiting illnesses (cancer, HIV/AIDS).
- Regulators should seek proactive ways to collaborate with other national health authorities to improve access to painkillers controlled under international conventions from importation/manufacture through secure distribution chains, rational prescribing and dispensing to patients. To cover the population in need, it is necessary to widen patient access to legitimate prescribers, taking into account the national specific situation, e.g. consideration should be given to allowing specialized palliative care nurses or clinical officers to prescribe oral morphine.
- WHO should support countries in improving their regulatory systems in order to identify potential administrative and legal hurdles to access of narcotic painkillers and find ways to eliminate them without compromising control functions prescribed by international conventions.
- WHO should contribute to organizing respective regional and national training courses and exchange information on effective interventions carried out by countries that have achieved improvement in making narcotic painkillers more accessible to patients in need.