



African Palliative Care Association  
**Guidelines for Ensuring Patient  
Access to, and Safe Management  
of, Controlled Medicines**



## Notice

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## Foreword

The 59th Session of the World Health Assembly of the UN adopted resolution 58.22, thereby recognising the importance of improving pain relief using opioid analgesics and calling on member states to remove barriers to their medical use and availability.

While advances have been made pursuing this agenda in Africa (e.g. legalisation of oral morphine prescription rights for nurses and clinical officers in Uganda, approval of access to morphine for hospices in Zambia, and advocacy progress in Malawi and Kenya), challenges remain.

A key challenge that hinders access to opioids is the fact they are controlled medicines and therefore only available under tight regulations. Controlled medicines are legally classified by their benefit when used in medical treatment and their harm if misused. In this regard, a balanced access to controlled medicines is needed to maximise their availability for the safe treatment of medical conditions and minimise their availability for abuse and dependency. However, achieving this balance is often problematic. Indeed, in many countries access to controlled medicines is impacted on by overly restrictive regulations and a lack of enabling policies.

National legislation in many countries includes provisions that are beyond the requirements of the international drug

conventions. Several countries make the importation, storage, distribution and dispensing of controlled medicines more restrictive than is needed. Additionally, it is a requirement for countries to provide detailed annual estimates and reports for narcotic substances to the International Narcotic Control Board to procure or produce controlled medicines. However, formulating reliable estimates is often a barrier to accessing controlled medicines, while the procurement of opioids is subject to complex and lengthy exportation and importation systems of licences and certificates

In an attempt to provide straightforward information with regard to these regulations and supply chain issues, the African Palliative Care Association (APCA) has developed these guidelines. It is intended to be a signpost for palliative care providers, palliative care national associations and other stakeholders to the relevant legislation and guidance from competent authorities, narcotic control boards, the World Health Organisation, governments, professional bodies and other agencies with regard to the safe use and management of controlled medicines.

In developing the guidelines, APCA recognises the need to increase awareness of the existing obligations for governments and providers in the management of controlled medicines and the expectation that such obligations will not hinder



patients from accessing the treatment they need. APCA is also aware that there are national laws and regulations that exist to guide the use and management of controlled substances. It is our hope, therefore, that these guidelines will be adapted in accordance to existing country-specific guidelines for the handling of Schedule I and II medicines.

It is also intended that key country players, such as national palliative care associations, will use these guidelines to support their advocacy work with governments around drug availability.

We believe that, if properly used, these guidelines will preserve the Central Principle of Balance – in other words, they will provide robust safeguards against abuse, while at the same time allowing controlled medicines to address the real and often unmet needs of patients requiring effective pain management and relief.

**Dr. Faith Mwangi-Powell**  
**Executive Director**

African Palliative Care Association

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## Acknowledgements

The African Palliative Care Association  
Model Guidelines for Patient Access to, and  
Safe Management of, Controlled Medicines

### Editors

**David Joranson, MSSW**  
**Distinguished Scientist**

Founder, Pain & Policy Studies Group  
(PPSG) / WHO Collaborating Center for  
Policy and Communications in Cancer Care  
School of Medicine and Public Health  
University of Wisconsin  
Carbone Cancer Center

**Martha Maurer, MSSW, MPH, PhD**  
**Associate Researcher**

Pain & Policy Studies Group / WHO  
Collaborating Center for Policy and  
Communications in Cancer Care  
School of Medicine and Public Health  
University of Wisconsin  
Carbone Cancer Center

**Faith Mwangi-Powell, Ph.D.**  
**Executive Director**

African Palliative Care Association  
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## Table of Contents

FOREWORD .....	3
ACKNOWLEDGEMENTS. ....	5
Table of Contents.....	6
DEFINITION OF TERMS AND ABBREVIATIONS .....	8
Abbreviations .....	8
Definition of Terms .....	9
INTRODUCTION.....	11
PURPOSE OF THE GUIDELINES .....	11
INTERNATIONAL REGULATIONS .....	11
The International Control Organs.....	12
Estimating the Required Amount of Schedule I/II Drugs.....	13
Supplementary Estimates .....	14
Statistical Returns to INCB .....	15
Inspection and Supervision .....	15
IMPORTATION, MANUFACTURING AND WHOLESALE GUIDELINES .....	16
PROCEDURE FOR IMPORTATION OF SCHEDULE I/II MEDICINES.....	16
MANUFACTURING .....	18
Licensing .....	18
Record keeping .....	18
Storage.....	18
Packaging and Labelling.....	21
WHOLESALE SUPPLY .....	22
Licences .....	22
Records .....	22
What happens on receipt of an order: .....	23

---

DISTRIBUTION OF SCHEDULE I/II MEDICINES:..... 25

REGULATIONS WITH REGARD TO TRANSPORTATION..... 25

POSSESSION OF SCHEDULE I/II MEDICINES..... 25

    Who can prescribe Schedule I/II medicines? ..... 26

    The prescription details:..... 26

    Dispensing of Schedule I/II medicines ..... 28

WARD SUPPLIES OF SCHEDULE I/II MEDICINES..... 30

GUIDE FOR HOSPITAL WARD STAFF..... 31

    Ward supplies of scheduled medicines..... 31

A GUIDE FOR HOME CARE TEAMS ..... 35

    Patient records ..... 35

    Prescribers of Schedule I and II medicines ..... 35

    Who can dispense Schedule I and II medicines ..... 36

    How these medicines should be stored:..... 36

    On the first home visit ..... 36

    Following visits..... 37

APPENDIX I: ..... 39

APPENDIX II. .... 44

APPENDIX III: ..... 51



## Definition of Terms and Abbreviations

### Abbreviations

<b>AIDS</b>	Acquired Immunodeficiency Syndrome
<b>APCA</b>	African Palliative Care Association
<b>NCA</b>	National Competent Authority
<b>CID</b>	Criminal Investigations Department
<b>CPCN</b>	Clinical Palliative Care Nurse
<b>DEA</b>	Drug Enforcement Agency
<b>DRA</b>	Drug Regulatory Agency
<b>ECOSOC</b>	Economic and Social Council (Commission) of the U.N
<b>HIV</b>	Human Immunodeficiency Virus
<b>INCB</b>	International Narcotics Control Board
<b>MOH</b>	Ministry of Health
<b>PCCO</b>	Palliative Care Clinical Officer
<b>SCND</b>	Single Convention on Narcotic Drugs
<b>UNODC</b>	United Nations Office on Drugs and Crime
<b>WHO</b>	World Health Organisation

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## Definition of Terms

<b>Board</b>	Refers to the International Narcotics Control Board (the international Competent Authority)
<b>Commission</b>	Refers to the UN Commission on Narcotic Drugs of the Economic and Social Council
<b>Drug Regulatory Authority</b>	Refers to a body established by an Act of Parliament to ensure the availability, at all times, of essential medicines in a country. The drug regulatory authority is usually charged with the implementation of the national drug policy.
<b>National Competent Authority</b>	Refers to the principal national authority for ensuring that opioid analgesics are adequately available for medical and scientific purposes. This authority is also responsible for submitting required drug procurement documents and consumption estimates to the International Narcotics Control Board. This office, designated by each government (that is Party to the Single Convention on Narcotic Drugs, 1961), is also responsible for carrying out functions required by the international drug control treaties. The office may be located in a country's pharmaceutical department within the Ministry of Health, or in the national drug regulatory authority.
<b>Scheduled Drug</b>	A drug whose use and distribution is controlled because of its potential for abuse
<b>Convention:</b>	Refers to the 1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol.
<b>Drug</b>	Refers to any of the substances in Schedule I and II of the Single Convention on Narcotic Drugs whether natural or synthetic. Use of the word 'Drug' has been associated with abuse; it is sometimes preferable to use 'Medicine'.



**Manufacturing**

Refers to all processes other than production by which drugs may be obtained; including refining and transformation of drugs into other formulations e.g. morphine sulphate to elixir.

**Narcotic Drugs**

Refers to substances listed in Schedules I and II see below

**Production**

Refers to cultivation of the poppy plant and collection of sap from the poppy head that is manufactured into morphine.

**Schedule I**

As identified by the Single Convention on Narcotic Drugs, Schedule 1 includes substances that have a high abuse liability, or are convertible into drugs that are similarly liable to abuse. This includes cannabis and cannabis resin (and extracts and tinctures), narcotic raw materials (coca leaf, concentrate of poppy straw, opium), the stronger opiate analgesics (morphine, oxycodone), the drugs of the ecgonine-cocaine group and a large number of synthetic drugs (fentanyl and its analogues, methadone).

**Schedule II**

As identified by the Single Convention on Narcotic Drugs, Schedule II includes substances that are less liable to abuse than those in Schedule I, such as codeine and its derivatives.

**Yellow Forms**

Refers to statistical return forms supplied to UN member countries by INCB

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## Introduction

These guidelines have been developed in simple, user-friendly language and they explain the procedures for patients' access to and the safe management of Schedule I and II drugs<sup>1</sup> that are necessary for the treatment and relief of moderate to severe pain. They provide both procedures for acquisition and information on records or documents that are necessary to ensure that these medicines are made available and accessible to patients across the entire health care delivery system (i.e. from tertiary institutions to primary level) and ensuring prevention of illicit non-medical use.

### Purpose of the Guidelines

These guidelines are intended to supplement information available in the national laws and regulations governing the use and handling of Schedule I and II drugs (see examples of Schedule 1 and 11 drugs in Appendix 1) for some of the Schedule I and II drugs).

It is anticipated that should there be conflicting guidance between the national laws or regulations and these guidelines, consideration should be given to achieving a balance between ensuring accessibility of drugs and maintaining controls against diversion and abuse.

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<sup>1</sup> 'Drug' means any of the substances in Schedules I and II, whether natural or synthetic. Use of the word: Drug: has been associated with abuse; it is preferable to use 'Medicine'

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Palliative care providers, national stakeholders and associations can use these guidelines to support their advocacy work with governments around drug availability. In addition it is expected that the national associations will adapt the information in these guidelines to develop their own country-specific guidelines for handling of Schedule I/II medicines in accordance with the national regulations.

### International Regulations

These guidelines are underpinned by international regulations and conventions to which many countries are party.

The 1961 Single Convention on Narcotic Drugs as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961(referred to in further text as 'Single Convention') regulates the use of opioids. The Convention recognises that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that it is a government obligation to ensure that adequate provision is made to ensure the availability of narcotic drugs for such purposes.

One of the main purposes of this treaty is to ensure the availability of opioids for medical use and scientific research while at the same time preventing illicit use based on the Central Principle of Balance. The central principle of balance represents a dual imperative of governments to



establish a system of control to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time ensuring their medical availability.

Hence this treaty stipulates basic requirements regarding production of, importation, manufacture, trade and distribution of internationally controlled drugs.

For the purposes of the Single Convention, a drug is regarded as ‘consumed’ when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research; and ‘consumption’ shall be construed accordingly [Article 1 (2)].

## The International Control Organs

The parties to the Convention agreed to entrust the Commission on Narcotic Drugs of the Economic and Social Council (Commission), and the International Narcotics Control Board (INCB) to the international control of drugs under the Convention.

The **Commission** is authorised to consider all matters pertaining to the aims of the Convention, and in particular:

- a) To amend the Schedules in accordance with Article 3 of the Convention;
- b) To call the attention of the Board to any matters which may be relevant to the functions of the Board;

- c) To make recommendations for the implementation of the aims and provisions of the Convention, including programmes of scientific research and the exchange of information of a scientific or technical nature.

The **INCB**, on the other hand and in cooperation with national governments, has the function of limiting the cultivation, production, manufacture and use of drugs in adequate amount as required for medical and scientific purposes.

The Convention requires governments to control narcotic drugs in order to prevent their diversion and non-medical use, but also to ensure their adequate availability for medical and scientific needs. To accomplish the drug availability objectives, the Convention established two principle mechanisms for ensuring adequate availability of controlled medicines, which are to be administered by the INCB:

1. The estimates system for narcotic drug requirements
2. The statistical returns system for narcotic drugs



## Estimating the Required Amount of Schedule I/II Drugs<sup>2</sup>

Under Article 19 of the Convention, governments are required to furnish to the Board, each year in the manner and form prescribed by INCB, ***estimated requirements of controlled medicines*** in respect of the following matters:

- a) Quantities of drugs to be consumed for medical and scientific purposes;
- b) Quantities of drugs to be utilised for the manufacture of other drugs, or preparations in Schedule III.

Stocks of drugs to be held as at 31 December of the year to which the estimates relate. Governments have an obligation to establish a system to collect information from medical facilities that care for patients with pain, from organisations working to improve the rational use of opioids and from manufacturers, distributors, etc. and to use this information to determine the country's opioid consumption estimates.

The National Competent Authority (NCA) should be designated to oversee or manage the opioid consumption estimation process; the national consumption estimates are then confirmed by the INCB before the government can permit the manufacture or importation of opioids.

Quantification of requirements for controlled medicines can be carried out using one or a combination of the methods below:

### a) Population-based:

This method determines the theoretical ideal need for the population and tends to be generous in the quantities of narcotics estimated. It is based on:

- an epidemiological assessment of the country's most important diseases and health problems.
- accepted or devised treatment norms for the diseases in question.

The population-based method takes into account the entire population; however, if resources for purchasing medicines are limited this method may not be the most appropriate.

### b) Consumption-based:

This method is based on consumption demands. In absence of government statistics on previous narcotic utilisation, information may be gathered from commercial sources, if available, and private voluntary organisations. The following are needed:

- Good historical data on medicines consumption
- Steady demand for health services.

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<sup>2</sup> [http://www.incb.org/pdf/e/estim/trainmat/NAR\\_2%20English%202005.pdf](http://www.incb.org/pdf/e/estim/trainmat/NAR_2%20English%202005.pdf)

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The average of recently observed values is used to predict consumption. The problem with this method is that where no previous consumption information exists (e.g. about newly registered drugs) this method cannot be used.

In situation where there are rapidly changing health needs or health care systems, estimates based on past demand will be inaccurate.

c) Service-based:

This method targets the health services available in the country. The estimates are based on:

- capacity of the health services
- health resources available (the number and types of health providers, and the diseases they will be likely to treat)
- the financial and administrative constraints in the country.

This method does not take into account the needs of patients for whom the current health system is inaccessible for geographical, financial or cultural reasons.

d) Morbidity-based:

The morbidity method calculates the requirements for controlled substances based on an assessment of the frequency of health problems (morbidity) and on accepted treatment norms for the health problems in question.

It is based on:

- an epidemiological assessment of the country's most important diseases and health problems
- accepted or devised treatment norms for the diseases in question.

To record the country consumptions estimates and requirements, Yellow Form B (see Appendix II) should be completed by the NCA with data on the estimated requirements on narcotic drugs for the following year and submitted to INCB.

### Supplementary Estimates

It worth noting however that should there be a case where the estimated requirements do not meet the needs, the country may (during the year) furnish supplementary estimates, provided there is a simple explanation of the circumstances necessitating such additional requirements. The INCB has a positive attitude about receiving supplementary estimates, as it is their responsibility to work with governments to ensure that adequate provision is made.

## Statistical Returns to INCB<sup>3</sup>

Under Article 20 of the Single Convention, Governments are obliged to furnish to INCB, in the manner and form prescribed by the Board, statistical returns on forms supplied by it (Yellow Form C, downloadable at:

[http://www.incb.org/incb/yellow\\_list.htm](http://www.incb.org/incb/yellow_list.htm)) in respect of the following matters:

- a) Production or manufacture of drugs
- b) Utilisation of drugs for manufacture of other drugs, of preparations in Schedule III and of substances not covered by this Convention, and utilisation of poppy straw for the manufacture of drugs
- c) Consumption of drugs
- d) Imports and exports of drugs and poppy straw
- e) Seizures of drugs and disposal thereof
- f) Stocks of drugs as at 31 December of the year to which the returns relate
- g) Ascertainable area of cultivation of opium poppy.

In order to do this proper and accurate records of imports, supplies, use and manufacture need to be maintained to help Drug Regulatory Agencies (DRA) provide proper accountability.

## Inspection and Supervision

Article 34 of the Convention refers to measures of supervision and inspection. Governments of countries that are signatories to the Convention have a responsibility to ensure that all persons who obtain licences, or who have managerial or supervisory positions in a government enterprise, have adequate qualifications for the effective and faithful execution of the provisions of such laws and regulations.

Inspection may be carried out in accordance with requirements in national laws or regulations.

Governmental authorities, manufacturers, traders, scientists, scientific institutions and hospitals are required to keep records to show the quantities of each drug manufactured and of each individual acquisition and disposal of drugs.

Records need to be well kept and preserved for a minimum period of two years.

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<sup>3</sup> [http://www.incb.org/pdf/e/estim/trainmat/NAR\\_3%20English%202005.pdf](http://www.incb.org/pdf/e/estim/trainmat/NAR_3%20English%202005.pdf)

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## Importation, Manufacturing and Wholesale Guidelines

### Procedure for importation of Schedule I/II medicines

A country obtains its supply of Schedule I/II substances for medical purposes by either importing from another country, manufacturing the medicine in country, or both. The amount to be imported needs to be within the estimated quantities of the submitted annual requirements that were confirmed by the INCB. The medicines are then distributed by manufactures or wholesalers to hospitals and pharmacies, and subsequently dispensed to patients by health workers.

It is a requirement of the Single Convention that all individuals and enterprises in the distribution system be licensed or otherwise appropriately authorised by the government to handle controlled medicines.

### Steps in the Importation of Schedule I/II Drugs<sup>4</sup> (fig. 1)

1. The entity<sup>5</sup> wishing to import a Schedule I/II substance applies to the Regulatory Authority (national competent authority) for an Import Certificate.

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<sup>4</sup> Cancer Pain Relief: with a Guide to Opioids Availability, 2nd edition (<http://whqlibdoc.who.int/publications/9241544821.pdf>)

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<sup>5</sup> Entity may be a manufacturer obtaining raw materials such as morphine powder, or a medical institution (public or non-governmental) or pharmaceutical organisation (public or private) obtaining finished products, or the government itself (central or national medical stores) that serves as an opioid distributor.

### The Import Certificate

#### Information that should appear on an Import Certificate:

- The certificate number
- The name of the drug
- The international non-proprietary name (INN) of the drug
- The exact description and quantity of the drug, including strength(s) and dosage form(s)
- The name and address of the importer
- The name and address of the exporter
- The period of validity of the certificate

2. The regulatory authority considers whether the entity is properly licensed and whether the drug and amount are within the national estimate; if approved, an original import certificate and one copy are issued.
3. The importer sends the original copy of the import certificate to the entity proposing to export the Schedule I/II substance, including (sometimes) the arrangements for payment.

4. The exporter applies to its drug regulatory authority for an export certificate.
5. The regulatory authority in the exporting country checks that an import certificate has been issued and that the exporter is properly licensed; if the application is approved, an export certificate is issued. *Note: In accordance with the Single Convention, the competent authorities of the exporting country also need to verify whether the estimates for narcotic drugs of the importing country are sufficient for the intended import.*
6. The regulatory authority in the exporting country sends a copy of the export certificate to the regulatory authority in the importing country.
7. The exporter ships the drugs to the importer, along with the originals of the export certificate and import certificate. It is the responsibility of the exporter to ensure the safe delivery of the drugs.

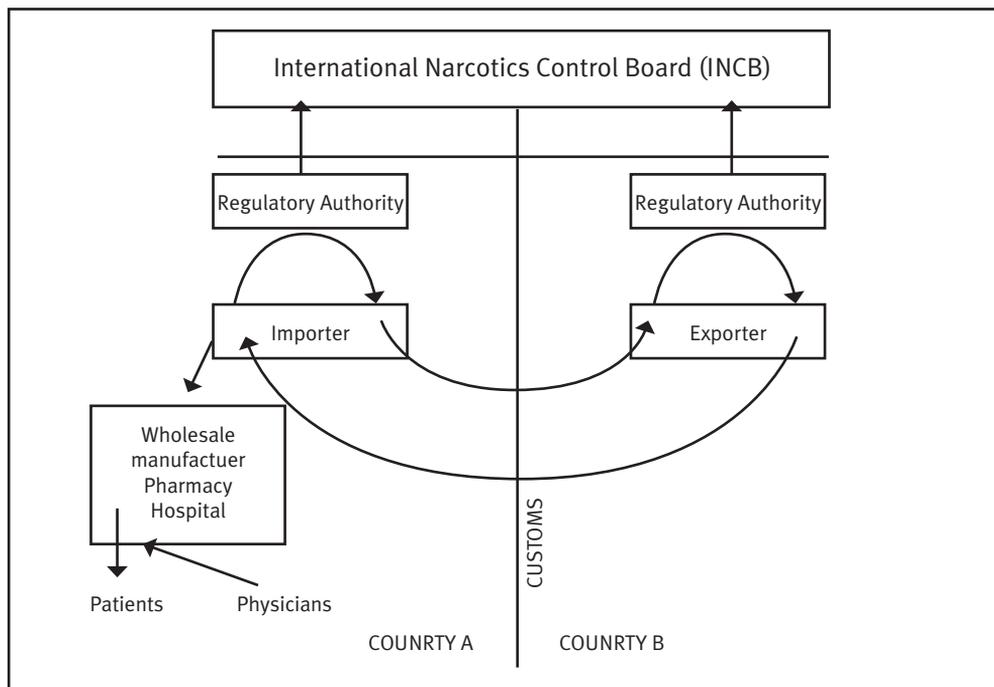


Figure o: Steps in the importation of schedule I/II Medicines



8. The shipment must pass a customs inspection. Officials from customs and the regulatory authority of the importing country verify papers of each consignment at the port of entry before handing over the medicines to the assigned clearing agent.
9. The importer sends both certificates to its regulatory authority as evidence that the order has been consummated. (In some countries a representative of the regulatory authority, an officer from the police anti-narcotics department and a customs officer must be present at the delivery of the controlled substances).
10. Article 34(b) of the Single Convention requires that wholesalers and manufactures keep records of the quantities of controlled drugs received and disposed of. These guidelines recommend recording the quantities received in a Schedule I and II Register (see figure 2) by two people, one of whom one is usually a pharmacist.

DATE	Name and Address of Supplier/ Recipient	Invoice No. / Import License No. / Request No	Batch No.	Expiry Date	Received / Supplied by	Checked by	Quantity Received	Quantity Supplied	Sign. of person collecting	Total in Stock
27/10/09	Balance Brought Forward									1000g
29/10/09	MacFalan Smith Ltd, Edinburgh, UK	Import Licence No. 0001	HD 001	12/12	Ddungu	M. Kaye	2,000g	N/A	N/A	3,000g
29/10/09	Quality Control Lab	Request No. QC004	HD 001	12/12	Ddungu	M. Kaye	N/A	1g	DKidde	2,999g
30/10/09	Manufacturing Unit	Request No. 003	For 05	12/12	Ddungu	M. Kaye	N/A	40g	PBatanda	2,959g

Figure 2: Record Book for Schedule I/II medicines for Wholesalers/Manufacturers – Morphine Sulphate Powder

## Manufacturing

‘Manufacturing’ refers to all the processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of Schedule I/II substances into other formulations, e.g. morphine sulphate powder into elixir (syrup). Regulations of the manufacture of opioid products include licensing, requirements for record keeping and reporting, and quality control.

### Licensing

Article 29 (1) of the Single Convention states that the parties shall ensure that the manufacture of drugs be under licence except where such manufacture is carried out by a state enterprise, e.g. National Medical Stores, etc.

Manufacturers should apply for a licence to manufacture Schedules I/II medicines – e.g. morphine elixir, tablets or any other preparation containing Schedule I/II substances.

The Regulatory Authority inspects the manufacturing premises and issues a licence for each product as appropriate.

Standard procedures, batch sheets and specifications for quality control need to be in place, as laid out in the general manufacturing licences. All records and batch sheets should be kept in accordance with national laws or regulations.

### Record keeping

To fulfill the Single Convention requirements under Article 34 for record keeping, these guidelines recommend that the following documents are filled out and retained for a minimum of two years:

- Importation permit, order and invoice notes for Schedule I and II medicines
- Schedule I/II record books: one in the Schedule I and II medicines store area and another in the manufacturing unit. (See figure 3)
- A separate book for each medicine, e.g. one for morphine and another for codeine, etc. Each book should have a section for each drug form, e.g. a section for morphine solution 5mg/5mls and another section for 50mg/5mls and another for 100mg/5mls, etc. (See Table 2)
- A book for recording (regularly) quantity checks of the finished product.

### Storage

The Single Convention does not have specific storage requirements for Schedule I and II drugs. Each country has the discretion to implement national laws and regulations to meet the fundamental requirements of the Single Convention to ensure access and control diversion of Schedule I and II drugs. These guidelines



recommend the following with regard to storage of Schedule I and II medicines (however, each country has the latitude to establish requirements that are suited to its prevailing conditions):

- Both the finished products and the raw material (e.g. morphine powder) should be stored as required by the national regulations in an immovable separate, double-locked cupboard, away from public access under secure lock-and-key;
- The Key to Schedule I/II medicines should be held by, and be the responsibility of, a designated person of integrity, e.g. the pharmacist-in-charge or an equivalent.
- Both the finished products and the raw material (e.g. morphine powder) should be stored as required by the national regulations (this is usually in an immovable, double-locked cupboard, away from public access under secure lock-and-key.

DATE	Name and Address of Supplier/ Recipient	Invoice No. / Import License No. / Request No	Batch No.	Expiry Date	Re-ceived /Sup-plied by	Check- ed by	Quan- tity Re- ceived	Quan- tity Sup- plied	Quan- tity De- stroyed	Sign. of person collecting	Total in Stock
01/11/09	Balance Brought Forward										10x105 mL 4x250 mL
02/11/09	University Teaching Hospital	Invoice Number 1234	HD 031	12/12	Ddungu	M. Kaye	N/A	3x150 mL	N/A	ABaguma	7x105 mL 2x250 mL
12/11/09	Manufac- turing Unit	Request No. MU014	HD 032	12/13	Ddungu	M. Kaye	99x105 mL 99x250 mL	N/A	N/A	DKidde	106x105 mL 101x250 mL
30/12/09	Destroyed as Expired	N/A3	HDo 30	11/09	Ddungu	Muso- nda	N/A	N/A	2x250 mL	PBatanda	2,959g

Figure 3: Main Store Record Book for Schedule I/II Medicines for Manufacturers – Morphine Elixir 5mg/5mL

The keys to Schedule I/II medicines should be held by, and be the responsibility of, a designated person of integrity, e.g. the pharmacist-in-charge, or an equivalent, who is readily available in case a patient needs the pain medicines.

## Packaging and Labeling

Article 30 (3-5) of the Convention only requires for Schedule I drugs, that ‘... labels under which drugs are offered for sale indicate the international non-proprietary name communicated by the WHO...[and] the exact drug content by weight or percentage’.

These guidelines recommend that labels on the finished products should endeavour to include the following details (see Fig 4)

- Generic name of the medicine (as opposed to proprietary name)
- Formulation – e.g. solution, tablets, etc.
- Strength – e.g. 50mg/5ml

- Quantity
- Manufacture and expiry date
- Batch number
- Name and address of manufacturer
- List of active ingredients
- Storage precautions
- Product licence number.

Morphine elixir should be packaged in an appropriate container – preferably a translucent, hard-to-break bottle;

Other formulations should also be properly labelled in accordance with internationally accepted standards.



Figure 4: Examples of a Schedule I/II Medicine Labels – 5mg/5mL (A) and 50mg/5mL (B)



## Wholesale supply

### Licences

Article 30 (a) of the Single Convention stipulates that parties shall require that the trade in and distribution of drugs be under licence, except where such trade or distribution is carried out by a state enterprise. However, each country has discretion in how to meet this requirement. These guidelines recommend the following with regard to licensing wholesalers:

- A wholesaler applies for a licence to handle Schedule I/II medicines from the national regulatory authority
- The national regulatory authority inspects the wholesaler's premises and procedures before issuing a licence as appropriate
- National laws or regulations may require a formal annual inspection of the premises and procedures or may require an inspection at the discretion of the regulatory authority.

### Records

Article 34(b) of the Single Convention requires that wholesalers and manufacturers keep records of the quantities of controlled drugs manufactured and of each individual acquisition and disposal of drugs. Such records shall respectively be preserved for a period of not less than two years.

These guidelines recommend the following as one approach to meeting the Single Convention requirements (however, it is up to the discretion of each country to decide how to keep such records):

- The DRA should issue a form for each quarter to any wholesaler licensed to sell Schedule I and II drugs. This will enable details of all supplies and any returns of Schedule I and II to be made (see figures 4 and 5)
- The wholesaler completes the forms as supplies are made and returns them at the end of each quarter to the DRA or competent authority
- The wholesaler records details of all Schedule I/II medicines received and issued in a Schedule I/II medicines register
- Standard record books, as stipulated by national laws and regulations, should be obtained from the relevant body.
- Record books should be kept in a locked cupboard for two years from the date of the first entry and must be available for inspection.

### ***On receipt of an order***

These guidelines offer the following recommendations with regard to procedures upon receipt of an order:

- The wholesaler checks that each order is from a genuine source.
- The wholesaler checks records of previous issues to ensure that excessive medicines are not being requested. In situations of doubt the DRA should be notified.
- The order is then recorded in the Schedule I/II medicines book and an invoice issued. The order and copy of the invoice should be securely kept.
- Any Schedule I/II medicines in the form of tablets, solutions or injections issued should be in their original packaging and/or sealed to ensure that they are not tampered with.

Opioid Supplies					
Wholesaler's Name and Address: .....					
Quarter and Year: 1st January – 30th April 2009					
	Supplies and Returns				
	Date	Name & Address of Recipient	Drug Form and Strength	Quantity supplied	Quantity Returned
Recorded by: _____ Checked by: _____					
Drugs Expired or Rejected					
	Date	Drug, Form & Strength	Batch No	Expiry	Method of destruction
Recorded by: _____ Checked by: _____					
Manufactured					
	Quantity Manufactured			Total Quantity of Morphine Powder in Stock	
	Morphine Solution 5mg/5mL	Morphine Solution 50mg/5mL	Morphine Tablets 5mg		
Recorded by: _____ Checked by: _____					

Figure 4: Quarterly forms to be returned to the regulatory authority



Opioid Supplies			
Manufacturer's or Wholesaler's Name and Address: .....			
.....			
Stock at Beginning and End of Quarter: 1st Jan – 30th April 2009			
	Drug, Formulation and Strength	Quantity in Stock at Beginning of Month Date: .....	Quantity in Stock at End of Month: Date: .....
	Morphine Solution 5mg/5mL		
	Morphine Solution 50mg/5mL		
	Morphine Tablets 5mg		
	Morphine Sulphate Powder		
	Morphine Injection 10mg		
	Pethidine Injection 100mg in 2mL		
	Pethidine Injection 50mg in 1mL		
	Recorded by: .....		
	Checked by: .....		

Figure 5: Quarterly forms to be returned to regulatory authority

## Distribution of Schedule I/II medicines:

### Regulations with regard to transportation

Article 30 (1) of the Convention requires that all enterprises and persons in the distribution system should be appropriately licenced or authorised. With regard to transporting medicines, these guidelines make the following recommendations to meet the requirements of the Convention:

1. The Drug Regulatory Authority issues the relevant drivers with a special licence to allow the carriage of narcotic medicines.
2. The wholesaler, importer or manufacturer checks the driver's identification.
3. The driver checks the medicines and records his/her name, signature and date on the original and copy of the invoice. A copy of the signed invoice should be kept by the wholesaler, importer or manufacturer, and the original (signed) invoice taken by the driver
4. The driver signs the Schedule I and II medicines register.
5. Drivers carrying these medicines are not allowed to carry any passengers other than staff approved by the company.
6. The vehicle needs to be kept locked at all times except when loading and unloading, and the key held by the same driver.
7. It is the responsibility of the driver to report to the nearest police station (within 24 hours) any loss of medicines from the vehicle.
8. On arrival where the drugs need to be delivered, the driver hands over the medicines to the person in charge, who checks the medicines and the invoice in presence of the driver. The invoice is kept in the pharmacy in a secure place for a period, as per government regulations.

### Possession of Schedule I/II medicines

Article 33 of the Single Convention stipulates that parties shall not permit the possession of Schedule I/II drugs except under legal authority. Each country (government) has regulations in place describing who is allowed to possess opioids. The medical prescription is evidence of the patient's lawful possession of controlled drugs.



## Who can prescribe Schedule I/II medicines?

Article 30 (b)(i) of the Convention does not specify who may or may not prescribe controlled medicines, other than to say that a ‘*medical prescription*’ is required for the supply and dispensation of drugs to individuals. Those permitted to prescribe narcotic/opioids medicines are defined in the national laws or regulations governing medicines in each respective country. Usually the following cadres are allowed to prescribe opioids:

1. Registered medical and dental practitioners – doctors /dentists
2. Registered veterinary surgeon/doctor
3. In countries where the doctor to population ratio is poor, the need for pain relief overwhelming due to burden of disease, and where palliative care needs to reach out to the remotest village, there is a case for widening the prescriber area. Specially trained Clinical Palliative Care Nurses and Clinical Officers can be given special authorisation to prescribe e.g. as in Uganda since 2004. This would mean that such cadres of health workers would be allowed to prescribe opioids.

## The Prescription Details:

Article 30 (b)(i) of the Convention requires medical prescriptions for the supply, or dispensing of Schedule I/ II medicines to individual patients.

Some governments require that prescriptions for Schedule I and II medicines be made in duplicate; the Single Convention mentions counterfoil prescriptions but does NOT require them (check national laws or regulations and follow accordingly).

The Convention does not specify any limits on the amount or duration of prescriptions. These guidelines therefore recommend that prescriptions be written in amounts and for a period long enough to allow patients who need to travel long distances ample time to make the necessary arrangements or long enough to last the patient through until the next appointment.

*(Some countries have prescription provisions that are overly restrictive so that patients cannot access the opioids: this practice is discouraged, as it would be considered unbalanced.)*

The Convention does not contain any requirements regarding the information on a prescription. These guidelines recommend that, in general, prescriptions for Schedule I/II medicines should contain at least the following details (figure 6):

- Name and address of patient
- Date of issue
- Medicine name, dosage strength and form
- Directions for use (e.g. take 5 (five) mL every after 4 hours and 10 (ten) mL at bed time)
- The total quantity of medicine to be dispensed written in both figures and words
- The duration e.g. one week, one month etc.
- Prescriber’s name and business address
- Prescriber’s signature

### ***Inpatients prescription***

The following are recommendations of these guidelines:

- The legitimate prescriber should write the details of the medicine – form, strength, dosage and directions as required in the patient’s clinical notes and on either the in-patient treatment card or on a separate prescription
- Whoever administers the medicine should indicate on the inpatient treatment card each time the medicine is given or taken by the patient, specifying the dose taken. This should be in addition to the entry in the ward Schedule I/II Register.

Ministry of Health Medical Prescription Form				
Date 31/10/09	Name: Mr. Kauka Oale Mugabo	Sex: Male	Age: 34	Patient No. 0000123
<p>Rx</p> <p>1. Morphine Solution 5mg/5mL.</p> <p>To take 5 (five) mL 4 hourly during the day and 10 (ten) mL at bed time. Please supply 250 (two hundred and fifty) mL only.</p> <p>2. Senna Tablets from 2-4 tablets PO at night (to prevent constipation). Please supply 40 tablets</p> <p>hmathingé Dr. Henry Mathinge 0772123456</p>				

Figure 6: An Example of a prescription for opioids



- On discharge, if necessary, a prescription should be written (in duplicate – one copy goes to the pharmacy and the other remains with the patient) and then dispensed from the pharmacy

## Dispensing of Schedule I/II medicines

### *Who is allowed to dispense?*

The following are recommendations of these guidelines with regard to dispensing Schedule I/II medicines:

Whenever possible schedule I/II medicines should be dispensed under the supervision of a registered pharmacist.

It should be the responsibility of the chief pharmacist to ensure a continuous supply of controlled medicines so that shortages that could lead to interruptions of pain relief for patients do not occur

These guidelines propose that pharmacy dispensers, senior nurses, clinical officers (or equivalent) and palliative care nurses trained in the proper use of Schedule I/II medicines be allowed to dispense oral opioids (e.g. morphine) and other specified medicines used in palliative care.

Where possible, any dispensing should be checked by another member of the pharmacy staff, registered nurse, clinical officer or doctor.

The dispenser should carefully check the details of the prescription:

1. The prescriber's names and signature.
2. The date – in some countries the prescription must be honoured within a specified number of days of being prescribed – e.g. two weeks.
3. The age of the patient, and/ or weight (for children).
4. The form of the medicine e.g. solution, tablets.
5. The prescribed dose.
6. The directions (usually oral morphine is given four-hourly during the day and a double dose at bedtime).
7. Any possible drug interactions.
8. The total quantity requested (written in both figures and words).

If any of the above details are missing or unclear the dispenser should try to contact the prescriber of the medicine for clarification.

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The prescriptions (including the patient’s records, if appropriate) should be endorsed with:

1. The quantity and strength of the medicine dispensed.
2. The dispenser’s name and signature.
3. The date.
4. If possible, a checker’s signature.

The patient, relative or member of staff who receives the medicine should sign in the register/record book.

Prescriptions for these medicines should be kept in the pharmacy for at least two years from the date of dispensing for inspection in future.

An entry should also be made in the Schedule I /II medicines register (figure 7).

Date	Name & Address or No/Ward received from / supplied to or reason for destruction	Invoice No / Ward request No / Prescriber's name:	Received / Supplied / Destroyed by:	Checked by	Quantity Received	Quantity supplied / Destroyed	Sign of Patient / Relative / Person collecting medicine	Total in stock
23.01.10	Balance Brought Forward							10 x 105mL 4 x 210 mL
24.01.10	Ken Tayler	Dr. H. Ddungu	Pius Mikajjo	Kiyange	N/A	1 x 105 mLs	Gombwa	9x105mL 4x210mL
24.01.10	Wholesale supplies, Nairobi	Inv. No 4567	Kiruri W.	Adams	10x105mL 5x210mL	N/A	N/A	19x105mL 9x210mL
26.01.10	Ward 4B	Req. No. 0123	Kamau D	Simon Were	N/A	3x105 mLs	Mirimo	16x105mL 9x210mL
27.01.10	Onyango J	Dr. Ndungu	Njoroge Kenneth	Simon Were	N/A	1 x 105 mL	Njeri	15x105 mL 9x210 mL
27.01.10	Home care Bag 3	Njoroge	Kenneth	Simon Were	N/A	1 x 210 mLs	Kiprop Peter	15x105 mL 8x210 mL
28.01.10	Returned from HC Bag 3	Njoroge	Kenneth	Adams	1 x 105 mLs	N/A	N/A	16x105 mL 8x210 mL

Figure 7: Pharmacy Schedule I/II Medicines Register – (Morphine Solution 5mg/5mL)



### Stock checks

- i. Check stock everyday to ensure that the physical amount of each medicine (Schedule I and II) agrees with quantity in the book.
- ii. Another member of staff should also cross-check to verify the quantities.
- iii. Both members of staff then look at the total balance in each record book to indicate the quantity is correct.
- iv. Any discrepancies should be investigated by the pharmacist-in-charge and appropriate step taken.
- v. Stock checks should identify potential shortages and correct the situation.

### Ward supplies of Schedule I/II Medicines

In large hospitals/health centres it might be appropriate to keep a stock of narcotic medicines on the ward for administration to in-patients. These are the guidelines for this situation:

- The pharmacist-in-charge and nurse-in-charge should agree on the appropriate minimum and maximum stock levels for each form and strength of medicine to be kept in the ward.
- The pharmacist must keep a record of the medicines a ward is allowed to stock, the quantities, and names and signatures of personnel allowed to order these medicines.

WARD: _____.		NO. 00123		
DRUG	FORM	STRENGTH	QUANTITY REQUESTED	QUANTITY SUPPLIED
MORPHINE	SOLUTION	5MG IN 5 ML	3 X 150 ML	3 X150 ML
Requested by: .....		date: .....		
Supplied by: .....		date: .....		
Checked by: .....		date: .....		
Collected by: .....		date: .....		
Received on ward by: .....		date: .....		

Figure 8: Sample of a Ward Opioid Order Book

- Stock should be ordered from the pharmacy using the ward narcotic ordering book.
- The ward-ordering book should be kept on the ward. New ward opioid ordering Books should be obtained from the pharmacy.
- Each form and strength of medicine is ordered on a separate page.
- The pharmacy dispenser should check the details of the order submitted and signature of the person ordering.
- The dispenser records the quantity supplied and signs and dates the form.
- The details should also be recorded in the Pharmacy Medicines Register.
- The staff that can collect these scheduled medicines should be specified and agreed by the Pharmacy-in-charge, Senior Nurse and Medical Director.
- The person collecting these medicines should sign the Ward Ordering Book and the pharmacy Schedule I and II medicines register.
- The ward-in-charge who receives these medicines should check the medicines and then sign the Ordering Book to indicate that they were received.

## **Guide for Hospital Ward Staff**

Trained hospital staff should be familiar with the handling of controlled medicines. However, with the introduction of palliative care into the regular health care system, some areas need to be emphasised. Many palliative care patients leave hospitals and move to their homes for continued care. Strong opioids like morphine in tablets and liquid forms are often used and health staff or patients/families need to carry these opioids into patients' homes for continued pain control.

Palliative care teams will visit patients carrying these opioids and administer them (opioids) and even leave a supply to use at home on their own or with their care providers. Therefore, this section provides guidance about how health staff on wards can meet the basic requirements of the 1961 Single Convention on Narcotics.

### **Ward supplies of scheduled medicines**

#### ***Records to be kept***

Article 34(b) of the Single Convention requires that hospitals keep records of the quantities of controlled drugs manufactured and of each individual acquisition and disposal of drugs. Such records shall respectively be preserved for a period of not less than two years.



Therefore, these guidelines recommend that the following should be available on the hospital ward to meeting the Single Convention requirements for record keeping and to account for their use; however, it is up to the discretion of each country to decide how to keep such records:

- a) Ward Scheduled Medicines Register
- b) Ward Ordering Book (figure 8).

All records should be kept in an immovable locked cupboard for two years from the date of last entry.

There should be one book for each type of opioid e.g. one for morphine and another book for pethidine.

Within each book there should be separate sections for various forms of the medicine e.g. morphine 5mg/ml, 10mg/ml, injectable 10 mg/ml.

New record books should be available from the pharmacy.

### ***Storage of scheduled medicines***

The Single Convention does not have specific storage requirements for Schedule I and II drugs. Each country has the discretion to implement national laws and regulations to meet the fundamental requirements of the Single Convention

to ensure access and control diversion of Schedule I and II drugs. These guidelines recommend the following with regard to storage of Schedule I and II medicines in hospital wards (however, each country has the latitude to establish requirements that are suited to its prevailing conditions):

- Schedule I/II medicines should be stored in a specified locked cupboard
- The keys for the cupboard should be kept by the pharmacist-in-charge (if there is a pharmacy on the ward) or the ward-in-charge.
- Procedures should be in place to allow for 24-hour access in case of emergencies, e.g. accidental spillage that could lead to interrupted supply to patients

### ***Ward ordering of Schedule I/II medicines from the pharmacy***

These guidelines offer the following recommendations for ward ordering of medicines from the pharmacy:

1. Persons to order these medicines should be defined and approved by the Medical Director e.g. senior nurses.
2. Authorised staff must submit their names and sample signatures to the pharmacy.



3. When the stock level falls to a minimum new stock should be ordered from the pharmacy using the ward ordering book (figure 5).
4. Ward ordering books should be kept on the ward. New ward ordering books should be obtained from the pharmacy.
5. Fill out in the order book the medicine and its form, strength and quantity, and submit to the pharmacy.
6. Each form and strength of the medicine is ordered on a separate page.
7. The person making the order of medicines should sign and date the order.
8. Staff authorised to collect these medicines should be specified and agreed by the pharmacist-in-charge, senior nurse and medical director.
9. The person collecting the medicines should sign the Ward Ordering Book and the pharmacy medicines register.
10. The receiving ward nurse-in-charge should check the medicines and then sign the ordering book to indicate that the medicines were received.

### ***Administering Schedule I/II medicines on the ward***

These guidelines offer the following recommendations with regard to administering Schedule I/ II medicines on the ward:

1. These medicines are only administered following the directions of a prescription.
2. Prescriptions are usually written in duplicate – one copy to remain in the pharmacy and another in the patient’s ward file. A prescription may also be written in the patient’s notes.
3. If these medicines are not kept on the ward the nurse should take the prescription or treatment card/sheet to the pharmacy and obtain them.
4. If the ward stocks the required medicines, the nurse should carefully check the details of the prescription:
  - The medicine and form e.g. solution, tablets, injection
  - The dose
  - The prescriber’s name and signature
  - The date and times of administration
  - The patient’s age
  - Any allergies and drug interactions the patient may have.



5. If any of the above details are missing or unclear, the nurse should attempt to contact the prescriber or another doctor.
  6. In all cases, the nurse should record giving the medicine including:
    7. The form and strength
    8. The quantity
    9. The Nurse's name and signature,
    10. The date and, if appropriate, the time of administration
    11. An entry must be made in the medicine register.
    12. The patient or relative could be asked to sign for receiving the medicine in the medicines record book.
  13. When patients keep tablets and solutions by their bedside:
    - c) The nurse should check the total quantity requested and should give the nearest-sized original container. Another member of staff should check the medicine and amount given.
    - d) The nurse should add the patient's name, number and ward on the label and all directions.
    - e) Each day the nurse must check that the patient has taken the medicine as prescribed. The doctor should be informed, a record made in the patient's notes and/or the patient counselled if the medicine was taken inappropriately.
  14. When the medicines are kept centrally or in the case of injections:
    - If it is possible, another nurse should check the medicine, form and quantity, before it is given.
    - The time of administration should be recorded.
    - If the patient does not take the medicine, the reason should be recorded in the patient's notes or on the treatment sheet or card.
    - On discharge, the nurse should advise the prescriber of any medicines the patient still has.
-

## A Guide for Home Care Teams

Home care teams need to be able to carry legally Schedule I/II medicines (opioids) for patients in moderate to severe pain who are at home. The teams need to adhere to national laws and regulations pertaining to handling of Schedule I and II medicines. The following section therefore, provides guidance for home care teams.

### Patient Records

Article 34(b) of the Single Convention requires that hospitals keep records of the quantities of controlled drugs manufactured and of each individual acquisition and disposal of drugs. Such records shall respectively be preserved for a period of not less than two years.

Therefore, these guidelines recommend the following for home care teams as well to account for the use of Schedule I/II medicines (however, it is up to the discretion of each country to decide how to keep such records):

1. Home care teams should keep separate records for each patient. These should include a section for medication, which can also act as a prescription.
2. In order for this record to be a valid prescription, details of each medicine given should be recorded each time it is given to the patient.
3. The total quantity to be dispensed should be written in words and figures to prevent any discrepancies.
4. The records should be securely kept under lock and key and a person responsible for the key nominated.
5. Patient records must be kept for at least two years after the patient leaves the programme.

### Prescribers of Schedule I and II medicines

Article 30 (b)(i) of the Convention does not specify who may or may not prescribe, other than to say that a 'medical prescription' is required for the supply and dispensation of drugs to individuals. These guidelines offer the following recommendations with regard to prescribing:

1. Check national laws and regulations and follow accordingly; however, registered doctors, dental surgeons and veterinary doctors are typically allowed to prescribe.
2. Widening the prescribers area for palliative care is a new proposal where specially trained nurses and clinical officers, etc. should be allowed to prescribe (see earlier comments).
3. Earlier comments still do apply to any authorised prescriber's /name and signature to be given to the pharmacy. Identification should



be checked by the pharmacy. Any new health worker should ensure that his/her name and signature are submitted to the pharmacy.

## Who can dispense Schedule I and II medicines

- Look up the section on dispensing in the national laws and regulations about who can dispense these medicines. However, it could be a pharmacist, a pharmacy technician, a clinical palliative officer, a palliative care nurse, etc.
- Wherever possible, any dispensing should be checked by another member of the home care staff, trained nurse, clinical officer or doctor.

## How these medicines should be stored:

All medicines should be kept in a secure locked cupboard at all times, except during the home visits when they are carried in the health worker's medicine bag.

## Medicine Bags

- a) Need to have a list of medicines and appliances to be taken out by each team.
- b) The quantities of each medicine should be specified, depending on the number and type of patients. This could include a small amount of oral morphine.
- c) The dispenser should ensure that each bag has the required quantities of each medicine and appliances specified before each home visit.
- d) There should be an 'extra medicines bag' to have medicines that are not designated to particular patients but might be required in case of need.
- e) Details of oral morphine and other Scheduled I and II medicines added to the extra bag should be entered in the pharmacy register.

## On the first home visit

- The team should take a full pain history including medications used in the past and any responses or reactions.
  - Ask to see any medicines (including traditional medicines) that the patient is currently taking.
  - The health worker should fill out the medication details as he/she gives the medicines to the patient.
  - The health worker should explain carefully to the patient and the care provider what each medicine is for and how it should be taken.
-

Expected undesired side effects (e.g. constipation) should also be explained, as well as how they can be prevented.

- The patient or care provider should be asked to sign for receipt of the medicines.
- It is recommended that the patient and care provider be given a chart (medicines chart) detailing the medicines and how they should be taken (see fig 9). This should include medicines they were previously taking which the team would recommend they continue.
- The date of the next planned visit should be filled in.

### **Following visits**

1. Prescriptions for the patients to be visited should be given to the facility pharmacy the day before a planned home visit, for dispensing.
2. Details of the prescription should be checked before dispensing, as described earlier.
3. The quantity dispensed should be enough to last until the next planned visit, minus any remaining from the previous visit. The total amount supplied should be in accordance with the regulations. (Refer to national laws and regulations.)

4. The pharmacy should record details of Schedule I/II medicines dispensed in the Scheduled I and II drug book, (see dispenser's guide).
  5. Any Schedule I/II medicines dispensed (including those for the extra bags) should be kept securely overnight.
  6. The team member collecting the drugs from the pharmacy should sign the pharmacy Schedule I/II medicines register.
  7. Any medicines which are no longer required should be recorded during the visit at which they are stopped, and the reason specified.
  8. Any new medicines required during the visit should be dispensed from the extra bag.
  9. If the dose has increased, extra supply should be given from the extra bag.
  10. All changes should be explained to the patient and their care providers.
  11. Any medicines the patient already has should be checked.
- If the patient has excess medicines from the previous visit, they should be left with the patient, amending any directions if necessary, and the quantity noted on the medication chart.



- If any medicines are no longer required they should be returned to the pharmacy.
- 12. The patient's medication chart should be checked and amended as necessary.
- 13. The patient or a relative should sign the records book to confirm receipt of the medicines.
- 14. If a patient was not seen when anticipated and thus no drugs given, this should be indicated on the chart.
- 15. Details of any Schedule I/II medicines returned, unused or any additional patients given Schedule I/II medicines should be made in the pharmacy record book.
- 16. The nurse/doctor who gave or returned the Schedule I/II medicines should sign the appropriate medicines register.
- 17. All non-issued Scheduled I/II medicines can be returned to the pharmacy stock.

The patient records should be kept in a secure place, available for inspection, for at least two years from when the patient leaves the programme.

Patient Name: _____ . Patient No. _____									
Date prescribed	Date stopped	Medicine, form and strength	Dose & Directions	Quantity left	Quantity supplied	Reason prescribed / stopped / dose change	Person who prescribed	Sign of pre-scriber	Sign of patient/ relative
12/02/10		Morphine solution 5mg/5mL	5mg q4h and 10mg at night	New	105ml x 5mg in 5mL (also in words)	For Pain	Dr. H. Ddugnu	hddugnu	mukasa
12/02/10		Senna Tabs 7.5mg	2 at night	New	18 tabs	To prevent constipation	Dr. H. Ddugnu	hddugnu	mukasa
12/02/10		Amitriptyline tabs 25 mg	1 at night	New	14 tabs	Nerve pain	Dr. H. Ddugnu	hddugnu	mukasa
12/02/10		Ibuprofen 200mg tabs	2 tabs q8h	New	32 tabs	Bone pain	Dr. H. Ddugnu	hddugnu	mukasa

Figure 9: Medication Record for Home Care Teams (Adapted from the Uganda Ministry of Health Guidelines for Handling Class A drugs, 2001)

## Appendix I:

### List of Drugs included in Schedule I of the Single Convention on Narcotic Drugs, 1961

**Acetorphine** (3-O-acetyltetrahydro-7-alpha-(1-hydroxy-1-methylbutyl)-6,14-endoetheno-orphavine)

**Acetyl-alphamethylfentanyl** (N-[1-(alpha-methylphenethyl)-4-piperidyl]acetanilide)

**Acetylmethadol** (3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

**Alfentanil** (N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidinyl]-N-phenylpropanamide)

**Allylprodine** (3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine)

**Alphacetylmethadol** alpha-3-acetoxy-6-dimethylamino-4,4-diphenylheptane

**Alphameprodine** alpha-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine

**Alphamethadol** alpha-6-dimethylamino-4,4-diphenyl-3-heptanol

**Alpha-methylfentanyl**  
N-[1(alpha-methylphenethyl)-4-piperidyl]propionanilide

**Alpha-methylthiofentanyl** N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]propionanilide

**Alphaprodine** alpha-1,3-dimethyl-4-phenyl-4-propionoxypiperidine

**Anileridine** 1-para-aminophenethyl-4-phenylpiperidine-4-carboxylic acid ethyl ester

**Benzethidine** 1-(2-benzyloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester

**Benzylmorphine** (3-O-benzylmorphine)

**Betacetylmethadol** (beta-3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

**Beta-hydroxyfentanyl** (N-[1-(beta-hydroxyphenethyl)-4-piperidyl]propionanilide)

**Beta-hydroxy-3-methylfentanyl** (N-[1-(beta-hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide)

**Betameprodine** (beta-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine)

**Betamethadol** (beta-6-dimethylamino-4,4-diphenyl-3-heptanol)

**Betaprodine** (beta-1,3-dimethyl-4-phenyl-4-propionoxypiperidine)

**Bezitramide** (1-(3-cyano-3,3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolyl)-piperidine)

**Cannabis and Cannabis resin** and EXTRACTS and TICTURES OF CANNABIS

**Clonitazene** (2-para-chlorobenzyl-1-diethylaminoethyl-5-nitrobenzimidazole)

**Coca leaf**

**Cocaine** (methyl ester of benzoylecgonine)



**Codoxime** (dihydrocodeinone-6-carboxymethylxime)

**Concentrate of poppy straw** – the material arising when poppy straw has entered into a process for the concentration of its alkaloids when such material is made available in trade

**Desomorphine** (dihydrodeoxymorphine)

**Dextromoramide** (+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl]-morpholine

**Diampromide** N-[2-(methylphenethylamino)-propyl]propionanilide

**Diethylthiambutene** (3-diethylamino-1,1-di-(2«-thienyl)-1-butene)

**Difenoxin** 1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipetric acid

**Dihydromorphine**

**Dimenoxadol** (2-dimethylaminoethyl-1-ethoxy-1,1-diphenylacetate)

**Dimepheptanol** (6-dimethylamino-4,4-diphenyl-3-heptanol)

**Dimethylthiambutene** (3-dimethylamino-1,1-di-(2'-thienyl)-1-butene)

**Dioxaphetyl** butyrate ethyl-4-morpholino-2,2-diphenylbutyrate

**Diphenoxylate** 1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester

**Dipipanone** 4,4-diphenyl-6-piperidine-3-heptanone

**Drotebanol** 3,4-dimethoxy-17-methylmorphinan-6-beta,14-diol

**Ecgonine** (its esters and derivatives which are convertible to ecgonine and cocaine)

**Ethylmethylthiambutene**

(3-ethylmethylamino-1,1-di-(2«-thienyl)-1-butene)

**Etonitazene** (1-diethylaminoethyl-2-para-ethoxybenzyl-5-nitrobenzimidazole)

**Etorphine** (tetrahydro-7-alpha-(1-hydroxy-1-methylbutyl)-6,14-endoetheno-orphavine)

**Etoxidine** 1-[2-(2-hydroxyethoxy)-ethyl]-4-phenylpiperidine-4-carboxylic acid ethyl ester

**Fentanyl** (1-phenethyl-4-N-propionylanilinopiperidine)

**Furethidine**

1-(2-tetrahydrofurfuryloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester

**Heroin** diacetylmorphine

**Hydrocodone** dihydrocodeinone

**Hydromorphinol**

14-hydroxydihydromorphine

**Hydromorphone** dihydromorphinone

**Hydroxypethidine** 4-meta-hydroxyphenyl-1-methylpiperidine-4-carboxylic acid ethyl ester

**Isomethadone** 6-dimethylamino-3-methyl-4,4-diphenyl-3-hexanone

**Ketobemidone** 4-meta-hydroxyphenyl-1-methyl-4-propionylpiperidine

**Levomethorphan** 6\* (-)-3-methoxy-N-methylmorphinan

**Levomoramide** (-)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidiny)-butyl]morpholine

**Levophenacymorphan** (1)-3-hydroxy-N-phenacymorphinan

**Levorphanol** (-)-3-hydroxy-N-methylmorphinan

**Metazocine** 2'-hydroxy-2,5,9-trimethyl-6,7-benzomorphan

**Methadone** 6-dimethylamino-4,4-diphenyl-3-heptanone

**Methadone** intermediate 4-cyano-2-dimethylamino-4,4-diphenylbutane

**Methyldesorphine** 6-methyl-delta-6-deoxymorphine

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\* Dextromethorphan ((+)-3-methoxy-N-methylmorphinan) and dextrorphan ((+)-3-hydroxy-N-methylmorphinan) are specifically excluded from this Schedule.

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**Methyldihydromorphine**  
6-methyldihydromorphine

**3-methylfentanyl** N-(3-methyl-1-phenethyl-4-piperidyl)propionanilide

**3-methylthiofentanyl** N-[3-methyl-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide

**Metopon** 5-methyldihydromorphinone

**Moramide** intermediate  
2-methyl-3-morpholino-1,1-diphenylpropane carboxylic acid

**Morpheridine** 1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester

## **Morphine**

**Morphine** methobromide and other pentavalent nitrogen morphine derivatives, including in particular the

**morphine-N-oxide** derivatives, one of which is codeine-N-oxide

## **Morphine-N-oxide**

**MPPP** 1-methyl-4-phenyl-4-piperidinol propionate (ester)

**Myrophine** myristylbenzylmorphine

**Nicomorphine** 3,6-dinicotinylmorphine

**Noracymethadol** (±)-alpha-3-acetoxy-6-methylamino-4,4-diphenylheptane

**Norlevorphanol** (-)-3-hydroxymorphinan

**Normethadone** 6-dimethylamino-4,4-diphenyl-3-hexanone



**Normorphine** demethylmorphine  
or N-demethylated morphine

**Norpipanone** 4,4-diphenyl-6-  
piperidino-3-hexanone

### Opium

**Oxycodone** 14-hydroxydihydrocodeinone

**Oxymorphone**  
14-hydroxydihydromorphinone

**Para-fluorofentanyl** 4'-fluoro-N-(1-  
phenethyl-4-piperidyl)propionanilide

**PEPAP** 1-phenethyl-4-phenyl-4-  
piperidinol acetate (ester)

**Pethidine** 1-methyl-4-phenylpiperidine-  
4-carboxylic acid ethyl ester

**Pethidine intermediate A** 4-cyano-  
1-methyl-4-phenylpiperidine

**Pethidine intermediate  
B** 4-phenylpiperidine-4-  
carboxylic acid ethyl ester

**Pethidine intermediate C**  
1-methyl-4-phenylpiperidine

**Phenadoxone** 6-morpholino-  
4,4-diphenyl-3-heptanone

**Phenampromide** N-(1-methyl-2-  
piperidinoethyl)-propionanilide

**Phenazocine** 2'-hydroxy-5,9-dimethyl-  
2-phenethyl-6,7-benzomorphan

**Phenomorphan** 3-hydroxy-N-  
phenethylmorphinan

**Phenoperidine** 1-(3-hydroxy-3-  
phenylpropyl)-4-phenylpiperidine-  
4-carboxylic acid ethyl ester

**Piminodine** 4-phenyl-1-(3-  
phenylaminopropyl)-piperidine-  
4-carboxylic acid ethyl ester

**Piritramide** 1-(3-cyano-3,3-  
diphenylpropyl)-4-(1-piperidino)-  
piperidine-4-carboxylic acid amide

**Proheptazine** 1,3-dimethyl-4-phenyl-  
4-propionoxyazacycloheptane

**Properidine** 1-methyl-4-phenylpiperidine-  
4-carboxylic acid isopropyl ester

**Racemethorphan** (±)-3-methoxy-  
N-methylmorphinan

**Racemoramide** (±)-4-[2-methyl-  
4-oxo-3,3-diphenyl-4-(1-  
pyrrolidinyl)-butyl]-morpholine

**Racemorphan** (±)-3-hydroxy-  
N-methylmorphinan

**Sufentanil** N-[4-(methoxymethyl)-1-[2-(2-  
thienyl)-ethyl]-4-piperidyl]propionanilide

**Thebacon** acetyldihydrocodeinone

### Thebaine

**Thiofentanyl** N-[1-[2-(2-thienyl)  
ethyl]-4-piperidyl]propionanilide

**Tilidine** (±)-ethyl-trans-2-(dimethylamino)-  
1-phenyl-3-cyclohexene-1-carboxylate

**Trimeperidine** 1,2,5-trimethyl-4-  
phenyl-4-propionoxypiperidine; and

## **List of drugs included in Schedule II of the Single Convention on Narcotic Drugs, 1961**

### **Acetyldihydrocodeine**

**Codeine** (3-O-methylmorphine)

**Dextropropoxyphene** (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanol propionate)

### **Dihydrocodeine**

**Ethylmorphine** (3-O-ethylmorphine)

**Nicocodine** (6-nicotinylcodeine)

**Nicodicodine** (6-nicotinyldihydrocodeine)

**Norcodeine** (N-demethylcodeine)

**Pholcodine** (morpholinylethylmorphine)

**Propiram** (N-(1-methyl-2-piperidinoethyl)-N-2-pyridylpropionamide)



## Appendix II

### Guidelines for National Competent Authorities<sup>7</sup>

These brief guidelines should facilitate the national competent authorities in the preparation of information, which they are required to submit to INCB in accordance with the provisions of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (referred to in further text as ‘Single Convention’). The guidelines have the form of responses to frequently asked questions:

#### **Question 1: Which forms/information have to be furnished to INCB?**

All national competent authorities have to submit to INCB the following forms with the information governments are required to furnish to the INCB pursuant to the provisions of the Single Convention:

- Form A (Quarterly Statistics of Imports and Exports of Narcotic Drugs; to be submitted four times a year);
- Form B (Annual Estimates of Requirements of Narcotic Drugs, Manufacture of Synthetic Drugs, Opium Production and Cultivation of the Opium Poppy for Purposes other than Opium Production); and
- Form C (Annual Statistics of Production, Manufacture, Consumption, Stocks and Seizures of Narcotic Drugs).

If any government has to modify its estimates, which were furnished to INCB in Form B, the national competent authority shall send to INCB the form entitled **Supplement to Form B** (Supplement to the Annual Estimates of Requirements of Narcotic Drugs).

#### **Question 2: Where can I find the forms?**

All forms can be downloaded from the INCB website – [http://www.incb.org/incb/en/yellow\\_list.html#Forms](http://www.incb.org/incb/en/yellow_list.html#Forms) (Form A, Form B, Supplement to Form B, Form C). In addition, INCB sends letters to national competent authorities requesting them to submit the forms. A few copies of the forms are always attached to the letter. You can send a request to INCB ([secretariat@incb.org](mailto:secretariat@incb.org)) for additional hard copies if you need them.

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<sup>7</sup> <http://www.incb.org/pdf/e/CA/Guidelines%20for%20national%20competent%20authoritiesfinal.doc>

### **Question 3: When do I have to submit the forms?**

- Form A must be submitted to INCB four times a year, not later than one month after the end of the quarter to which it relates, i.e. by 30 April (for the first quarter), 31 July (for the second quarter), by 31 October (for the third quarter) and by 31 January of the next year (for the fourth quarter).
- Form B must be submitted by 30 June of the present year for the next year (for example, in 2006, Form B must be submitted by 30 June 2006 with estimates for the year 2007).
- Supplement to Form B may be submitted at any time before the end of the year to which it relates.
- Form C must be submitted by 30 June of the present year for the previous year (for example, in 2006, Form C must be submitted by 30 June 2006 for the year 2005)

### **Question 4: Where can I find advice on how to fill in the forms?**

The INCB training material for national competent authorities is available on [http://www.incb.org/incb/en/narcotic\\_drugs.html](http://www.incb.org/incb/en/narcotic_drugs.html). It contains detailed guidelines for the preparation of Form A (Part 3, paragraphs 24 to 48 of the training material), Form B (Part 2, paragraphs 45 to 83 of the training material), Supplement to Form B (Part 2), paragraphs 88 to 90 of the training material) and Form C (Part 3, paragraphs 49 to 90 of the training material). These guidelines contain practical examples on how to fill in the forms.

Instructions on how to fill in the forms can also be found on each form. In addition, you will find useful information for the preparation of reports to INCB in the List of Narcotic Drugs under International Control (“[Yellow List](#)”) which is available on this website. Look on page 2 of the Yellow List to see which information it contains.

At any time, you may wish to send a request for clarification concerning reporting on narcotic drugs (estimates, statistics) to the INCB secretariat ([secretariat@incb.org](mailto:secretariat@incb.org)). They will endeavour to respond to you as soon as possible.



### **Question 5: Will there be always something I have to report?**

There will always be information to be reported to INCB, in each country or territory.

- Narcotic drugs must be available for legitimate medical purposes in all countries and territories. Therefore, estimates of requirements for consumption of narcotic drugs shall be reported by all national competent authorities in Form B. If wholesalers (public and/or private) are part of the national distribution chain for narcotic drugs, countries/territories have to report in Form B estimates on stocks of drugs to be held as at 31 December of the year to which the estimates relate.
  - Statistical information on actual consumption of narcotic drugs, shall be reported by all national competent authorities in Form C. If wholesalers (public and/or private) are part of the national distribution chain for narcotic drugs, countries/territories have to report in Form C on actual stocks of narcotic drugs held as at 31 December of the year for which the statistics are furnished.
  - Most national competent authorities will also have also other information to report to INCB, such as estimates (Form B) and statistics (Form C) on utilisation of narcotic drugs for the manufacture of other drugs, of preparations included in Schedule III, and of substances not covered by the Single Convention, statistics on seizures of narcotic drugs and their disposal, etc.
  - All imports and exports of narcotic drugs shall be reported to INCB in **Form A**. It may happen that no narcotic drugs were imported/exported during the quarter to which the respective Form A relates. The form should anyway be furnished to INCB indicating that no imports and exports took place during the respective quarter.
  - If you cannot provide all information required, because it is not available to you, furnish the information at your disposal and indicate in the cover page of the form in the section for 'Remarks' which information is missing, why and when it can be submitted.
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### **Question 6: What should I be particularly aware of when preparing the reports?**

- Some terms used in the Single Convention have a special meaning, which is different from their usual understanding in normal language use. You have to be aware of the proper meaning of these terms/concepts as defined by the Single Convention (Article 1, Definitions) to be able to prepare correctly the reports to INCB. The basic terms you have to understand include 'consumption' and 'stocks' (see appendix III below)
- Some preparations containing narcotic drugs are included in Schedule III of the Single Convention. Control requirements for these preparations, including those regarding information to be furnished to INCB in Forms A, B and C, are different from requirements for other preparations containing narcotic drugs.
- Quantities of narcotic drugs reported to INCB should be expressed in terms of the pure anhydrous content of the drugs.

### **Question 7: Which information is most frequently omitted from the reports?**

Any omission to submit mandatory information to INCB creates a problem and requires additional correspondence between INCB and the national competent authority to clarify the matter.

The list of the most frequent omissions is as follows:

- **Form A** – Some authorities fail to provide details on the countries of origin of their imports or the countries of destination of their exports.
- **Form B** – Some authorities fail to provide estimates for stocks.
- **Supplement to Form B** – Some authorities fail to provide detailed supporting explanations for supplementary estimates.
- **Form C** – Some authorities fail to provide statistics on stocks.



- **Form C** – Some authorities fail to provide information on seizures of narcotic drugs and their disposal.

### **Question 8: Which are the most frequent mistakes in reports furnished to INCB?**

The most frequent mistakes are those related to incorrect understanding of the meaning of the basic terms, such as ‘consumption’ and ‘stocks, incorrect understanding of reporting requirements for preparations included in Schedule III of the Single Convention, and incorrect indication in the forms of quantities of narcotic drugs (see also the answer to Question 6).

The mistakes happen most frequently in the following cases:

- **Form A** - Import/export statistics should not include information on imports/exports of preparations included in Schedule III of the Single Convention. If the national competent authority includes this information in Form A, this should be clearly stated in the form, using the blank space under the label ‘Remarks’ on the cover page.
  - **Form A** – A narcotic drug shall be reported as imported only when it has actually arrived to the importing country/territory (physical transfer). The issuance of an import certificate is not enough for drugs to be included in the import statistics. Similarly, the issuance of the export authorisation is not enough for drugs to be included in the export statistics.
  - **Form B** - Estimates for consumption should cover only domestic medical and scientific requirements, and not requirements for exports.
  - **Form B** - Estimates for consumption should not include consumption of preparations included in Schedule III of the Single Convention.
  - **Form B** - Estimates for stocks should not include stocks of preparations included in Schedule III of the Single Convention.
  - **Form C** - Statistics on manufacture should not include information on transformation of drugs into salts or preparations of the same drug.
  - **Form C** - Statistics on consumption should not include consumption of
-

preparations included in Schedule III of the Single Convention.

- **Form C** - Statistics on stocks should not include stocks of preparations included in Schedule III of the Single Convention.

Quantities of narcotic drugs indicated in all forms should not be expressed in terms of esters, ethers or salts but in terms of their pure anhydrous drug content.

### **Question 9: Why is the high quality of my reports so important?**

- Timely and complete submission of all mandatory reports to INCB by national competent authorities is very important for the proper functioning of the international drug control system as a whole, and the control of narcotic drugs in each reporting country/territory.
- Estimates of requirements for narcotic drugs confirmed and published by INCB are used to determine the limits of the quantities of narcotic drugs which individual countries and territories may acquire through import and/or manufacture. The Parties shall not permit the export of drugs to any country or territory except within the limits of the total of the estimates for that country or territory. Appropriate estimates are therefore very important to ensure adequate availability of narcotic drugs for legitimate uses.
- Failure by a national competent authority to provide mandatory reports to INCB, or frequent mistakes and inconsistencies in reporting, may indicate problems in the implementation of the provisions of the Single Convention in the respective country. In accordance with its treaty mandate, INCB has to bring such situation to the attention of the government concerned in order to ensure proper implementation of the respective treaty provisions. Failure by a national competent authority to furnish mandatory reports is also reflected in INCB publications (see answer to Question 10).
- INCB uses information received from national competent authorities for various studies and analyses. The quality of these studies/analyses depends to a large extent on the data available. For example, by analysing reports on international trade received from governments, INCB may identify attempts at diversion of narcotic drugs from licit trade into the illicit traffic. Failure by any national competent authority to provide complete reports on international trade in narcotic



drugs (Forms A) makes the identification and prevention of diversion attempts more difficult. Similarly, INCB analyses the balance between the supply of and demand for opiates for medical and scientific purposes in order to support the balance between the two. Failure by any national competent authority to provide complete reports (estimates and statistics) makes such an analysis more difficult.

### **Question 10: Are my reports reflected in any publications?**

- The status of receipt by INCB of estimates and statistics (Forms A, B, and C) from all countries and territories is reflected in part two of the annual INCB technical publication on narcotic drugs (Narcotic Drugs: Estimated World Requirements for ...; Statistics for ...). A copy of this publication is available at the website.
  - Estimates and statistics received from national competent authorities are reflected in parts three, four and five of the above-mentioned INCB technical publication on narcotic drugs. You may wish to check whether the data reported by you were correctly included in the respective tables of this publication and inform the INCB secretariat of any difference between your reports and the data published.
  - The updates of the estimates for narcotic drugs of all countries and territories are published every month at this website in the section 'Status of estimates'.
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## Appendix III:

### **Form B: Annual Estimates of Requirements of Narcotic Drugs, Manufacture of Synthetic drugs, Opium Production and Cultivation of the Poppy for Purposes other than Opium Production**

Single Convention on Narcotic Drugs, 1961: Articles 1, 12 and 19. Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs, 1961: Articles 5 and 9.

COUNTRY OR TERRITORY: \_\_\_\_\_

DATE: \_\_\_\_\_

COMPETENT OFFICE: \_\_\_\_\_

RESPONSIBLE OFFICER'S NAME: \_\_\_\_\_

TITLE OR FUNCTION: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

These estimates relate to the calendar year

REMARKS

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These estimates, in a single copy, should be sent to the  
INTERNATIONAL NARCOTICS CONTROL BOARD  
Vienna International Centre  
P.O. Box 500, A-1400 Vienna, Austria  
Telephone: (+43-1) 26060-4277 Facsimile (+43-1) 26060-5867/5868  
Telegraphic address: UNATIONS VIENNA Telex: 135612 uno a  
E-mail: secretariat@incb.org Internet address: <http://www.incb.org/>



## INSTRUCTIONS

### **General:**

1. This form is divided into five parts:
    - Part I: Background information and statement of the method
    - Part II: Annual estimates of requirements of narcotic drugs
    - Part III: Annual estimates of the manufacture of synthetic drugs
  2. In order to ensure the accurate completion of this form, the definitions given below, in accordance with the provisions of article 1 of the Single Convention on Narcotic Drugs, 1961, should be borne in mind.
    - a. **Consumption** is the action of supplying a narcotic drug to any person or enterprise for retail distribution, medical use or scientific research.
    - b. **Drug** designates any substance included in Schedules I and II of the Convention, whether natural or synthetic, and subject to specific control measures under the Convention.
    - c. **Manufacture** is any process, other than production (see definition below) by which drugs may be obtained, including the refining and transformation of one drug into another drug.
    - d. **Preparation** is a mixture solid, or liquid, containing a drug and subject to the same control measures as the drug it contains. It should be noted, however, that preparations listed in Schedule III of the Single Convention are exempted from some control measures.
    - e. **Production** is the separation of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained.
    - f. **Stocks** are the amounts of drugs held in a country or territory for domestic consumption, manufacture of other drugs or exports.
    - g. **Special stocks** are the amounts of drugs held by the government of a country or territory, for special government purposes and to meet exceptional circumstances.
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3. All drugs are listed in the *List of Narcotic Drugs under International Control* (Yellow List), a supplement to the statistical forms on narcotic drugs, distributed to governments on a yearly basis.
4. Figures included in this form should be expressed in terms of the **pure anhydrous** drug content contained in crude drugs, salts and preparations. Tables showing the pure drug content of bases and salts, as well as their equivalents, in terms of the pure drug, of certain extracts and tinctures are given in the *List of Narcotic Drugs under International Control* (Yellow List).
5. The estimated quantities should be expressed in kilograms and grams without decimal points or commas.

**Part I: This part is to be filled in by all governments.**

6. Governments are required to provide information on some health-related parameters and on the method used to determine the estimates furnished in the Form B.

**Part II: This part is to be filled in by all governments.**

7. **Column 1:** The term ‘quantity to be consumed’ refers to the quantity to be supplied for retail distribution, use in medical treatment or scientific research, to any person, enterprise or institute (retail pharmacists, other authorised retail distributors, institutions or qualified persons duly authorised to exercise therapeutic or scientific functions such as doctors, dentists, veterinarians, hospitals, dispensaries and similar health institutions, scientific institutes, both public and private). Only the amounts needed for *domestic* purposes and not those required for *export* should be taken into account.
8. **Column 2:** Not only the requirements for *domestic* purposes, but also those for *export* should be taken into account.



9. **Column 2 (a):** The estimated quantities should include the quantities of the **drug to be transformed by a chemical process into another drug, but not the amounts of the drug to be transformed into the salts thereof**. For example, the quantities of morphine base to be converted into codeine base, but not the quantities of morphine base to be transformed into morphine hydrochloride or morphine sulphate.
  10. **Column 2 (b):** The estimated quantities in this column should include the quantities of drugs needed for the manufacture of **preparations for the export of which export authorisations are not required (Schedule III preparations)** whether such preparations are intended for domestic consumption or for export. For example, quantities of codeine base to manufacture preparations containing codeine phosphate with a concentration of not more than 2.5 per cent (e.g. 3 mg/15 ml).
  11. **Column 2 (c):** The estimated quantities to be inserted in this column should include the quantities of drugs needed for the manufacture of **substances not covered by the 1961 Convention**, for example quantities of thebaine to manufacture naloxone.
  12. **Column 3:** The term **'special stocks'** is defined in Article 1, paragraph 1 (w), of the 1961 Convention as 'the amounts of drugs held in a country or territory by the government of such country or territory for special government purposes and to meet exceptional circumstances.' Quantities held for *'special Government purposes'* include in particular requirements for the armed forces. *'Exceptional circumstances'* refer to catastrophic events such as large-scale epidemics and major earthquakes. The quantities to be added to the stocks held by the government for the normal needs of the civilian population are not to be taken into account in computing the estimated quantities to be inserted in this column. The quantities to be held by the government for such purposes should be included in the estimates to be inserted in Column 4.
  13. **Column 4:** Governments are required to furnish an estimate of the stocks they expect to hold at the end of the year. The quantities should
-

cover the actual stocks held at 31 December of the year to which the estimates relate. The estimate should include the quantities to be held in stock for domestic consumption, manufacture of other drugs or preparations and exports. The term **'stocks'** in accordance with Article 1, paragraph 1 (x), of the 1961 Convention refers to the amounts of drugs held in a country or territory except:

- (a) The quantities held by retail pharmacists or other authorised retail distributors and by institutions or qualified persons in the duly authorised exercise of therapeutic or scientific functions (see 7 above);  
and
- (b) 'Special stocks' held by the government. Stocks held by the government for the normal needs of the civilian population should be included in Column 4 (see 12 above).

**Part III: This part concerns only countries where the manufacture of synthetic drugs is authorized.**

- 15. For the purposes of preparing the estimates and ensuring uniform interpretation of the term 'synthetic drugs', the definition proposed in the Commentary on the 1972 Protocol prepared by the Secretary-General of the United Nations should be followed. The definition is as follows: "Synthetic drugs' are all drugs appearing in Schedules I and II of the 1961 Convention, except those at present normally obtained from the opium poppy (its opium or straw), the coca bush or the cannabis plant."
- 16. The 'synthetic drugs' according to this definition are listed in the corresponding part of this Form B.
- 17. **Industrial establishments** which simply manufacture salts or preparations of 'synthetic drugs' from 'synthetic drugs' manufactured in other industrial establishments in the country or abroad should not be included in the estimate. In fact, only the quantities of synthetic drugs to be manufactured should be included in the estimates, i.e. not any quantities of **preparations** of synthetic drugs to be manufactured.











## Part II

### Annual Estimates of Requirements of Narcotic Drugs (FOR ALL COUNTRIES AND TERRITORIES)

Narcotic drug		1		2						3		4	
		Quantity to be consumed for domestic medical and scientific purposes		Quantity to be utilised for the manufacture of:						Quantity to be added to special stocks		Quantity to be held in stocks at 31 December of the year to which the estimates relate	
				(a) Other drugs	(b) Preparations included in Schedule III of the 1961 Convention		(c) Substances not covered by the 1961 Convention						
					Whether these other drugs, preparations or substances are intended for domestic consumption or for export								
		kg	g	kg	g	kg	g	kg	g	kg	g	kg	g
Concentrate of poppy straw (M)	**	*		*				*		*		*	
AMA (%)	**	*		*				*		*		*	
ACA (%)	**	*		*				*		*		*	
ATA (%)	**	*		*				*		*		*	
Concentrate of poppy straw (T)													
ATA (%)	**	*		*				*		*		*	
AMA (%)	**	*		*				*		*		*	
ACA (%)	**	*		*				*		*		*	
Concentrate of poppy straw (O)													
AOA (%)	**	*		*				*		*		*	
AMA (%)	**	*		*				*		*		*	

\* Quantities to be expressed in gross weight.

\*\*Average anhydrous alkaloid content of the concentrate of poppy straw.

## Appendix IV:

### Further Reading:

1. 1961 Single Convention on Narcotic Drugs Part 1+2  
The Estimates System for Narcotic Drugs E/INCD/2005/NAR-2.
2. Achieving Balance in National Opioids Control Policy. Guidelines for Assessment.  
WHO/EDM/QSM/2000.4
3. Guidelines for Handling of Class A Drugs, Ministry of Health, Republic of Uganda,  
March 2007.
4. Statutory Instruments supplement No.13. 23rd April 2004. Refer to the Uganda  
Gazette No.18 vol. xcvi, 23 April /2004, printed by UPPC, Entebbe.





**African Palliative Care Association**  
PO Box 72518  
Plot 850 Dr Gibbons Road  
Kampala, Uganda

**Tel: +256 414 266251**  
**Fax: +256 414 266217**  
**Email: [info@africanpalliativecare.org](mailto:info@africanpalliativecare.org)**  
**Website: [www.africanpalliativecare.org](http://www.africanpalliativecare.org)**

NGO Registration Number 4231



The True Colours Trust

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