National Medicine Policy For Narcotic and Controlled Medicines
PREFACE

This is the overall policy document for Narcotic and Controlled Medicines of Afghanistan pharmaceutical sector. This policy constitutes part of continuous efforts by the Ministry of Public Health (MoPH) and the stakeholders to ensure accessibility to and prevention of abuse of narcotic and controlled medicines. It aims to make narcotic and controlled medicines available to all patients when needed at the treatment site but also provide proper control to prevent misuse and abuse.

This comprehensive Afghanistan medicine policy covers narcotic and controlled medicines through their procurement, sampling, screening and analysis, storage and distribution, registration, importation, and in-country manufacturing. In addition, the policy provides mechanisms to secure sustainable financing and build local human capacity for services. Strategies for international cooperation and systems for monitoring and evaluating implementation have also been included.

The Afghanistan medicine policy for narcotic and controlled medicines was developed through a systematic and internationally accepted process by using a National Controlled Medicines Sub-Policy (NCMP) Task Force of key technical stakeholders established under the direct supervision and leadership of the MoPH. The NCMP reviewed the current narcotic and control medicine situation in Afghanistan. An initial draft Afghanistan medicine policy for narcotic and controlled medicines document was developed and subjected to widespread consultation with stakeholders. The final draft document was compiled and presented to the MoPH, which took the final decision on all aspects of the policy and duly approved it for implementation.

This policy document will be followed by an implementation plan, which will set out strategies, objectives, activities and expected outcomes/outputs to implement all agreed components of this policy.

I am very optimistic that all stakeholders involved in developing this policy will remain committed to it, and support government efforts to fully implement it. It is also my hope that our development partners will find the policy a useful guide in providing technical and financial assistance in the Narcotic and Controlled Medicines Affairs. Hopefully, in the next few years when we have implemented this policy, we can together rejoice over positive results of our combined efforts.

I wish to sincerely commend the Strengthening Pharmaceutical Systems (SPS) Project funded by the US Agency for International Development (USIAD) and implemented by Management Sciences for Health (MSH) for the tremendous technical support, I also thank the NCMP members and all those who contributed to developing this policy document.

Dr. Ferozuddin Feroz
Minister of Public Health
Acknowledgments

The National Medicine Policy For Narcotic and Controlled Medicines was developed based on the outline provided in the Afghanistan’s National Medicine Policy. This policy closely follows all the World Health Organization’s recommendation for narcotic and controlled medicines and is in accordance with the realities of the criteria and needs of narcotic and controlled medicines in Afghanistan and it has been drafted through a systematic process.

The development of this policy has involved many staff members of the MoPH, Many stakeholders, and technical consultants have contributed to the policy’s development and played a key role in its final formulation. We extend our sincere thanks to all.

- Pharmacist Nazir Ahmad Ahmad Zad, Head of Planning Department/ GDPA
- Pharmacist Azizullah Bahrami, Head of Narcotic & Controlled Medicines Department/ GDPA
- Pharmacist Zakeria Fatehzada, Head of Inspection Department/ GDPA
- Pharmacist Mohammad Omar Mansory, Head of Registration Department/ GDPA
- Pharmacist Mohammad Nazir Heidarzad, GDPA
- Pharmacist Nematullah Nawrozian, NMFB Advisor
- Pharmacist Shakila Amerkhail, GDPA

Colleagues who cooperated in development of this policy as technical consultants:

- Pharmacist Sayed Murtaza Sadaat, Technical Officer/ SPS
- Pharmacist Mohammad Basir, Regulatory Systems Technical Advisor/ SPS
- Pharmacist Mohammad Zafar Omari, SPS/Afghanistan Chief of Party
- Pharmacist Jamshed Noori, Technical Adviser/SPS
- Andy Barraclough, consultant, SPS/Thailand

Furthermore, I would like to express sincere thanks for contributions of Medicine Committee; National Medicine and Food Board (NMFB) members.

The General Directorate of Pharmaceutical Affairs further expresses its gratitude to the Strengthening Pharmaceutical Systems (SPS) Project for the technical support, with the financial assistance of US Agency for International Development (USAID). Contributors who played oversight and consultancy roles in drafting of this policy
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<td>active pharmaceutical ingredient</td>
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<td>AMR</td>
<td>Anti Microbial Resistance</td>
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<td>Controlled Medicines</td>
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<td>Essential Medicines List</td>
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<td>FPP</td>
<td>finished pharmaceutical products</td>
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<td>GDP</td>
<td>Good Dispensing Practice</td>
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<td>Good Manufacturing Practice</td>
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<td>HRD</td>
<td>Human Resources Development</td>
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<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for</td>
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<td></td>
<td>Pharmaceuticals for Human Use</td>
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<td>INCB</td>
<td>International Narcotics Control Board</td>
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<td>INN</td>
<td>international nonproprietary name</td>
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<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<td>MOPH</td>
<td>Ministry of Public Health</td>
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<td>NPNCM</td>
<td>National Policy for Narcotics and Controlled Medicines</td>
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<td>NGO</td>
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<td>National Medicine Regulatory Authority</td>
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<td>NQAPP</td>
<td>National Quality Assurance Policy for Pharmaceuticals</td>
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<td>QA</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>SOP</td>
<td>standard operating procedure</td>
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<td>STG</td>
<td>standard treatment guideline</td>
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<td>USD</td>
<td>United States dollar</td>
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## National Medicine Policy For Narcotic and Controlled Medicines

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1. **INTRODUCTION**

1.1. **Introduction to Controlled Medicines**

In Afghanistan, the basic requirements for the prescribing and supply of prescription medicines are described within the medicine law—Section 6, articles thirty and thirty one, Medicine law 963. However, there are a small number of medicines, which although are deemed essential to the practice of modern medicine, have the potential, to be abused by individuals and lead to addiction if not used responsibly. These medicines encompass a number of pharmaceutical and therapeutic classifications and are therefore referred to collectively as “narcotic and controlled medicines.” For these medicines, in addition to normal pharmaceutical policies and procedures, additional levels of control and accountability apply. The majority of narcotic and controlled medicines, notably narcotic drugs and psychotropic substances, have a variety of medical uses. Opioid analgesics, such as codeine and morphine, and anti-epileptics, such as phenobarbital, are considered essential medicines by the World Health Organization (WHO). There is broad consensus that opioid analgesics are indispensable for the treatment of moderate to severe pain and some, like methadone, buprenorphine, and tincture of opium, are increasingly used for the treatment of drug dependence. The widespread recognition of the therapeutic value of these medicines has led in recent years to a substantial increase in their consumption. While it is essential that patients in the Afghanistan Health Sector have access to controlled medicines for the management of acute and chronic disease in accordance with modern medical practice, it is also necessary that these medicines be adequately controlled to prevent addiction and minimize the potential for abuse. The management of this medicines requires the particular knowledge and expertise of pharmaceutical management so all management and control of these medicines must be handled through the National Medicine Regulatory Authority (NMRA).

International conventions guide the control of these medicines—Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971, and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
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of 1988. Afghanistan is a signatory to these conventions and supports the International Convention for the Control of Narcotics and Psychotropics. Additionally, Afghanistan legislative documents stipulates under what circumstances narcotic and controlled medicines are to be used, and what the penalties are for breaking these laws.

In the past, a range of policies were developed to minimize the risk of these medicines being diverted and abused, but these policies have not always been seamless, and there has been less clear direction in ensuring their availability and appropriate. This policy seeks to draw together all pharmaceutical aspects of narcotic and controlled medicines and to strike the balance between ensuring their availability and adequately controlling use to minimize potential for addiction and misuse. The key feature of this policy is that of the public health imperative—narcotic and controlled medicines control should not be approached as an objective in itself, but as a tool to optimize public health. One focus should be the prevention of abuse and dependence; the other to avoid collateral harm. The outcomes should be judged both by the harms from abuse it prevents and the harm it causes through, for example, lack of access.

1.2. Defining controlled medicines

- Controlled medicines are defined by the international treaties which the Government of Afghanistan has signed, supports, and upholds:
  - Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol,
  - Convention on Psychotropic Substances of 1971
  - United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988
  - Endorsed laws
  - Endorsed regulations
  - International convention

The actual drugs covered by these conventions are listed in two sources.

- List of narcotic drugs under international control (annex A).
  - International Narcotics Control Board
  - Vienna International Centre
P.O. Box 500, A-1400 Vienna, Austria
Internet address: http://www.incb.org/
(Of ten referred to as the ‘Yellow List.”)

- List of psychotropic substances under control as of the 1971 convention (annex B).


**Endorsed and regulation laws—Afghanistan Medicine laws and regulations regarding import and export medicines and national lists.**

1.2.1. **Afghanistan National Health Framework**
According to the National Health Policy and Strategy, Afghanistan is a developing country of low income level. The national health policy was developed based upon the core values of the Ministry of Public Health (MoPH). To safeguard the public and, in particular, to ensure quality of clinical services, the MoPH has been focusing on reviewing, developing, and enforcing relevant legal and regulatory instruments and policies that govern health and health-related work. This Narcotic and Controlled Medicines Policy document is expected to form a complementary policy of the National Medicines Policy and will be both influenced by, and contribute to the work the MoPH is currently doing to develop regulatory instruments for health-related activities.

1.2.2. **General Directorate of Pharmaceutical Affairs Vision**
The vision of the General Directorate of Pharmaceutical Affairs (GDPA) is that all the country needs in terms of pharmaceutical and health products and also standard pharmaceutical services are met.

1.2.3. **Afghanistan Pharmaceutical Market**
This policy has application to all aspects of narcotic and controlled medicines operations and includes detailed requirements for the import, storage, and
distribution of narcotic and controlled medicines as well as for their correct compounding and dispensing by pharmacists in both the public and private sectors. It applies to all parties involved in the handling of narcotic and controlled medicines.

1.2.4. Afghanistan’s National Medicine Policy
Afghanistan’s National Medicine Policy (NMP) was developed through a systematic process of consultation with all major stakeholders in both the public and private pharmaceutical sectors. The stakeholders defined and agreed upon the goal and objectives, set priorities, developed strategies, and made commitments based on available and anticipated resources.

The revised NMP provides:
- A formal record of values, aspirations, aims, decisions, and government commitments.
- Clearly defined national goals, objectives, and priorities for the pharmaceutical sector
- Creation of a forum to discuss these national issues.
- The strategies needed to meet those objectives and actors responsible for implementing the main components of the policy

This draft National Controlled Medicines Policy document seeks to incorporate all the relevant elements from the NMP and build on that structure to provide more detail for the medicines policy together with an outline for the implementation of narcotic and controlled medicines activities. The document will also create a forum for national discussions on these issues.

1.3. Emergency Situations
In accordance with the WHO model guidelines for the international provision of controlled medicines for emergency medical care, the INCB recommendation of 1994, and the principle endorsed at the UN Commission on Narcotic Drugs and the World Health Assembly, a simplified procedure for importation and exportation of controlled medicines into a country where disaster disrupted the functioning of the drug control authorities may be applied. These may be both natural and/or man-made disasters which may cause an increased demand for controlled medicines.
The model WHO guidelines for narcotic and controlled medicines provision during disasters assists national authorities with simplified regulatory procedures. In cases where there is doubt in relation to their applicability, it is recommended that the International Narcotics Control Board is consulted. It will be the responsibility of the Minister of Health (or his/her appointed delegate) to declare a disaster situation for the use of the emergency procedures for the provision of controlled medicines. After that declaration has been made, emergency procedures as described in this policy can be activated.

1.4. Terminology
The declared policy is to use clear, unambiguous terminology and avoid the use of stigmatizing terms throughout this policy and to encourage such use in all policies, legislation, regulations and procedures involving narcotic and controlled medicine issues. Patients are always to be referred to in a respectful way and the terms “addict” and “dangerous drugs” are to be avoided. Wherever possible, standard WHO terminology and definitions are to be used.

A definition of all technical terms used in this policy is contained in the glossary at the end of this document. Throughout this policy the terms narcotic medicines and psychotropic medicines have clearly defined meanings and complete listings of the exact classifications; they are not to be interpreted in a generalized sense.
2. GOALS AND OBJECTIVES

2.1. Goals
The goals of this Narcotic and Controlled Medicines Policy for Pharmaceuticals are to contribute to the overall goals of essential medicines to meet the health care requirements of all people living in Afghanistan, through the prevention, diagnosis, and treatment of all diseases; and particularly by ensuring that narcotic and controlled medicines are both available at treatment sites and adequately controlled to prevent misuse and abuse.

In all respects, this policy will be in line with the MoPH’s current strategic planning and should be interpreted in keeping with the endorsed laws and regulations in Afghanistan.

2.2. Objectives
The objective of this policy is to provide the environment, mechanisms, and systems to ensure the availability, accessibility, affordability, control of medicines made from substances that are controlled under the international drug control conventions and Afghan national law and regulation.

These policies will apply to:

- All importers, wholesalers, stockholders, stores, and retail pharmacies handling controlled medicines
- All pharmacists, physicians, dentists, nurses and other recognized health professionals prescribing, dispensing, or providing controlled medicines
- Academics handling narcotic and controlled medicines
- Health care professionals organizations
- Individuals in possession of narcotic and controlled medicines (including patients and their families)
- Organizations whose area of work or interest is medicine control or public health.

2.3. Scope of Policy
The scope of this policy is all narcotic and controlled medicines. These are medicines made from substances controlled internationally under the Single Convention on Narcotic Drugs (hereafter referred to as “Single Convention”) and under the Convention on Psychotropic Substances and under endorsed drug laws and regulations of Afghanistan.
3. APPLICABILITY OF THIS POLICY

3.1. Pharmaceutical Products

This policy applies to:

- **Controlled medicines as finished pharmaceutical products (FPP)**
  All narcotic and controlled medicines, as a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labeling. A medicine is defined as any substance or mixture of substances prepared, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of disease, disorder or abnormal physical state, or symptoms thereof, or restoring, correcting, or modifying organic functions in humans.

- **Narcotic and controlled medicines as active pharmaceutical ingredient (API)**
  Any narcotic and controlled medicine, as any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the human body.

- **Prepared/compounded narcotic and controlled medicines**
  Any narcotic and controlled medicine—as any substance included in any publication mentioned in the Food and Drugs Laws, or any substance or mixture of substances prepared, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of disease, disorder, or abnormal physical state, or symptoms thereof, or restoring, correcting or modifying organic functions in man—which is prepared by compounding, mixing, admixing, modifying, or adjusting an API or FPP (usually within a pharmacy setting) that contains any controlled substance.

This policy does not apply to traditional/herbal medicines as defined within the endorsed health laws and regulation of Afghanistan.
3.2. **Organizations and Bodies**
This policy will apply to all bodies, organizations, structures, pharmaceutical manufacturers, pharmaceutical retailers, and dispensing operations that are involved in specifying, manufacturing, compounding, selling, procuring, storing, transporting, distributing, sampling, testing, analyzing, prescribing, dispensing, administering, and receiving narcotic and controlled medicines for human use in Afghanistan.

3.3. **Persons, officers, and operatives**
This policy will apply to all persons who are in possession of, or involved in specifying, manufacturing, compounding, selling, procuring, storing, transporting, distributing, sampling, testing, analyzing, prescribing, dispensing, and administering narcotic and controlled medicines for human use in Afghanistan.
4. **KEY PRINCIPLES**

4.1. **Recognition of need for narcotic and controlled medicines**

This policy recognizes the necessity for narcotic and controlled medicines in the practice of modern medicine, and especially that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering, and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. The policy also recognizes that the use of psychotropic substances for medical and scientific purposes is indispensable; and that the availability of both categories of medicines for such purposes should not be unduly restricted.

4.2. **Recognition of need to comply with international treaties and legal obligations to ensure adequate availability and accessibility of narcotic and controlled medicines for all medical and scientific purposes**

This policy recognizes the need to comply with the international treaties and legal obligations to ensure adequate availability and accessibility to narcotic and controlled medicines for medical and scientific use. In particular, it recognizes that Afghanistan is a signatory to the

- Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol
- The Convention on Psychotropic Substances of 1971
- The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

To ensure available and accessible narcotic and controlled medicines, policies, procedures, and regulations should be formulated, developed and implemented. The key requirement of an obligation to prevent and treat substance abuse is recognized.

4.3. **Recognition of the need for balance in controlled medicines policies and regulations**

This policy recognizes the central principle of achieving balance in all narcotic and controlled medicines issues. Balance represents a dual obligation to establish a system of control that ensures the adequate availability of
narcotic and controlled medicines for medical and scientific purposes, while simultaneously preventing abuse, diversion, and trafficking. It is recognized that many narcotic and controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness, and the prevention of premature death. To ensure the rational use of these medicines, it is necessary to enable and empower health care professionals to prescribe, dispense, and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meet those needs. While misuse of narcotic and controlled medicines poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care.

The overall approach of this Policy on Narcotic and Controlled Medicines is to be an aid to optimize public health when it is used as a guideline in practice.

4.4. **Designation of a national body to ensure adequate availability and accessibility of controlled medicines in health care**

The administration of narcotic and controlled medicines is complex and requires numerous bodies and organizations. The proposed organizational structure is described in detail in Section 5 of this policy. Different bodies are proposed for different functions—policy, implementation, review, coordination etc. However, in relation to ensuring adequate availability and accessibility in practical terms of physical medicines, the designated body is the National Medicines Regulatory Authority (NMRA) Controlled Medicines Department (CMD). Details of their functions and operations is described in Section 5 of this policy.

4.5. **Affordability of narcotic and controlled medicines**

In determining, developing, and implementing all policy, legislative, regulatory, licensing, importation, storage, distribution, dispensing, and procedural requirements for narcotic and controlled medicines, all parties are to be fully aware of the cost implications of such requirements and seek to minimize the cost impact of the control requirement.
The guidance principle in setting fee/charge levels for all required services, import permits, registration, licensing, etc., for controlled medicines should be to achieve no more than cost recovery. No such fees/charges relating to Controlled medicines should be used for income generation. As a general guide, the cost of all regulatory and control procedures should not increase the cost of medicine at point of dispensing by more than 10% over the medicine acquisition price.

4.6. **Openness and transparency**
The principles of honesty, respect, openness, and transparency are ensured in all narcotic and controlled medicine operations and procedures, while recognizing the security concerns that are an integral part of handling all such medicines, and the need to protect staff, officers, and operatives from security threats.

4.6.1. **Openness**
Wherever possible; minutes of narcotic and controlled medicine meetings will be open and available to the public (provided there is no legal or regulatory impediment).
- But details of specific quantities, importers/wholesalers, locations, and transportation and storage sites will not (normally) be released.
- Product specifications will be clearly stated and based on published information.
- Enforcement actions will be publically announced (provided there is no legal or regulatory impediment).

For security reasons, announcements of actions relating to narcotic and psychotropic products may need to be delayed or withheld completely so as not to compromise the security of location of such materials. Also, locations of stores/warehouses holding narcotic and controlled medicines And names of persons/officers involved in handling narcotic and controlled medicines should not be released. For legal and regulatory reasons, announcements relating to cases that are intended for, or undergoing legal action, may need to be delayed until the conclusion of the legal/regulatory procedures.
4.6.2. **Avoidance of conflict of interest**

Because of the diversity of interests and perspectives represented by those key players and stakeholders who will implement narcotic and controlled medicine procedures for pharmaceuticals in Afghanistan, it is particularly important that all operations are undertaken in an ethical, collaborative, and, in as far as is permitted by security concerns, transparent and open manner. This policy shall be interpreted so as to be consistent with the endorsed laws and regulations in Afghanistan. It shall apply to all persons and officers undertaking narcotic and controlled medicines pharmaceuticals functions in Afghanistan.

The basis for the avoidance of conflict of interest policy is the duty to disclose a potential or actual conflict of interest. All officers involved in narcotic and controlled medicine pharmaceutical activities are required to complete and sign a no conflict of interest declaration, and to make a declaration of a potential conflict of interest if a situation arises in which such a potential conflict may occur. A conflict of interest shall be as defined under the applicable regulations of Afghanistan pertaining to the organization of the implementing officer (e.g., for government staff, Civil Service code of conduct), but generally results from either a financial or perceived potential financial involvement or (potential) benefit arising either directly or through a connected party to the implementing officer.

In the event that an implementing officer declares a potential or real conflict of interest, a replacement implementing officer must be appointed for that specific task.
5. OFFICIAL DEFINITION, LISTING, AND CATEGORIZATION OF NARCOTIC AND CONTROLLED MEDICINES

5.1. Official Definition and Listing of Narcotic and Controlled Medicines

For the purposes of this policy, and all subsequent regulation and requirements relating to this policy, Narcotic and Controlled Medicines in Afghanistan will be defined by the Official List of Narcotic and Controlled Medicines to be produced by the National Medicines Regulatory Authority (NMRA) Controlled Medicines Department (CMD).

The NMRA-CMD will develop the narcotic and controlled medicine list according to the following international lists:

- List of narcotic drugs under international control (annex A).
  International Narcotics Control Board
  Vienna International Centre
  P.O. Box 500, A-1400 Vienna, Austria
  Internet address: http://www.incb.org/
  (Often referred to as the ‘Yellow List.’)

- List of psychotropic substances under control as of the 1971 convention (annex B).

In compiling the official listing of controlled medicines, the National Medicine and Food Board (NMFB) Controlled Medicines Group (CMG) will take full cognizance of the International Treaties and Agreements to which Afghanistan is a signatory, and especially the listing of medicines contained in those agreements. The NMFB CMG will also:

- Consult and liaise with the Ministry of Counter Narcotics
- Consult and liaise with the Ministry of Justice
- Consult and liaise with medical and pharmaceutical bodies
- Consult and liaise with the pharmaceutical industry in Afghanistan (largely through organizational representation and including importers, wholesalers/distributors, and retail outlets)
- Consult and liaise with Essential Medicines List committee

NMRA-CMD may request specialist advice and assistance in its task, notably from WHO and the INCB and other such sources as it may deem appropriate. In the event that NMRA-CMD cannot reach consensus agreement among the
active players on inclusion of an item(s) in the Official Listing of Narcotic and Controlled Medicines, it may refer the matter to NMFB-CMG. The decision of the NMFB-CMG will be final in all such matters.

NMRA-CMD will review and revise the Official Listing of Controlled Medicines at least annually. NMRA-CMD will publish and ensure ease of access to the Official Listing of Controlled Medicines through hard copy and electronic and on-line media.

Key features of the official listing of narcotic and controlled medicines
- Not every item included in the Official Listing of Narcotic and Controlled Medicines needs to be permitted for use in Afghanistan.
- The Official Listing of Narcotic and Controlled Medicines serves as a clear definition of an item as a narcotic and controlled medicine, not an automatic approval for its use.
- In general, items permitted for use in Afghanistan will be controlled through the use of the existing mechanisms of the:
  - Essential Medicines List (EML)
  - Licensed Medicines List
  - Importation Permissions
  - Registration permits
  - Importation certificate

5.2. Categorization of narcotic and controlled medicines
To better administer the many different classes of narcotic and controlled medicines, and ensure improved accessibility to narcotic and controlled medicines for medical use, NMRA-CMD will classify controlled medicines into different categories, and different regulations will apply to each classification of narcotic and controlled medicines.

5.2.1. Categories of controlled medicines
Category 1 (controlled drug by special license only) has no generally accepted/recognized medicinal use. It includes products such cannabis, coca leaf, lysergic acid diethylamide (LSD), and mescaline. Production, possession, and supply of these drugs are limited to medical and scientific researches.
Medical practitioners (doctors) and pharmacists may not lawfully possess Category 1 drugs except under a special license issued for a specific research activity. Such special licensing can be issued only by the National Medicine
and Food Board and the certificate will be issued by NMRA-CMD.

**Category 2 (narcotic and controlled medicines)** includes products generally accepted/recognized for medicinal use. It encompasses most narcotics and psychotropic medicines such as diamorphine, morphine, remifentanil, pethidine, secobarbital, glutethimide, amphetamines, and cocaine. A license is required to import or export drugs in Category 2, which is to be issued by NMRA-CMD. These medicines are subject to safe custody requirements—they must be stored in a locked receptacle which can only be opened an authorized person.

The medicines may be prescribed by an authorized person (doctor, dentist, etc., as described in later sections of this policy) and dispensed by any qualified pharmacist. The medicine may be administered to a patient by an authorized person (doctor or dentist), or by any person acting in accordance with the directions of an authorized person.

A register must be kept by all parties handling Category 2 Narcotic and Controlled Medicines; this register must comply with the relevant regulations. The destruction of Category 2 Narcotic and Controlled Medicines must be appropriately authorized by NMRA-CMD and the persons witnessing the destruction must be authorized by NMRA-CMD to do so.

**Category 3 (narcotic and controlled medicines)** includes a small number of minor stimulant drugs and other drugs which are less likely to be misused than the drugs in Category 2, and hence do not require such strict levels of control.

Category 3 medicines include most barbiturates (except secobarbital, Category 2), buprenorphine, diethylpropion, mazindol, meprobamate, midazolam, pentazocine, phentermine, and temazepam).

These medicines are subject to the same control as Category 2 **except:**

- There is no requirement to record transactions in a register.
- They are exempt from safe custody requirements and can be stored on the open dispensary shelf.
- The requirements relating to destruction do not apply.

**Category 4** consists of medicines that are not included in these categories nor legally used in the country (androgenic and anabolic steroids, clenbuterol, human chorionic gonadotrophin, non-human chorionic gonadotrophin, somatotropin, somatrem, and somatropin).
Category 5 (narcotic and controlled medicines—compounded medicines low strengths) are pharmaceutical preparations which contain controlled medicines as defined by the narcotic and controlled medicines list, but in which the narcotic and controlled medicines is present in such low strengths that extra controls are not necessary. This category includes preparations of certain controlled drugs (e.g., codeine, pholcodine) which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced. There are no extra restrictions on the import, export, possession, administration or destruction of these preparations and safe custody regulations; only normal pharmaceutical/medicines regulation apply. Practically, they are exempt from virtually all narcotic and controlled medicines requirements.

5.2.2. Lists of Categories of Controlled Medicines
NMRA-CMD will be responsible for producing the Official Listing of the Categories of Narcotic and Controlled Medicines. In the event that NMRA-CMD cannot reach consensus agreement among the active players on including or not including an item(s) in the Official Listing, it may refer the matter to the NMFB-CMG which will make the final decision. NMRA-CMD will review and revise the Official Listing of Narcotic and Controlled Medicines at least annually. It will publish and ensure easy access to the Official Listing of Categories through hard copy and electronic and on-line media.

Main features of the Official Listing of the Categories of Narcotic and Controlled Medicines include:

- Not every item included in the Official Listing of Narcotic and Controlled Medicines needs to be included in the Official Listing of Categories of Narcotic and Controlled Medicines.
- Not every item included in the Official Listing of Categories of Narcotic and Controlled Medicines needs to be approved for use in Afghanistan. The Official Listing of Categories of Narcotic and Controlled Medicines serves as a clear definition of the category of an item defined as a Narcotic and Controlled Medicine; it is not an automatic approval for its use. Every narcotic and controlled medicine approved for use in Afghanistan does need to be included in the Official Listing of Categories of Narcotic and Controlled Medicines.
6. ORGANIZATION AND RESPONSIBILITIES OF KEY PLAYERS

6.1. Background and Guiding Principles for Formulating Management Structures for Narcotic and Controlled Medicine Functions

For largely historical reasons of development in a post/on-going conflict situation, the current narcotic and controlled medicines supply mechanisms in Afghanistan are characterized by multiple funding sources, and a large number of active players. This gives rise to a fragmented and currently largely uncoordinated service of multiple vertical supply streams of varying efficiency. This is not to say that the narcotic and controlled medicines supply service has been unsuccessful; through the Basic Package for Health Services and Essential Package of Hospital Services schemes, medicines are clearly reaching patients, which is a major achievement in a complex and fragile operating environment.

As noted, the service is functional—medicines are reaching patients—but it is essential to realize that the operational environment is fragile.

The guiding principle for introducing new systems and procedures must be to ensure that any changes and developments do not threaten to disrupt existing operations and the security of narcotic and controlled medicines provision to patients. In addition, change must be designed and implemented in ways that maintain continuity of supply.

6.1.1. Structures past, present, and future—need for functional unit descriptions

At the current time, the overarching bodies and mechanisms that are responsible for national essential medicine services in Afghanistan are debating and discussing what future structures are needed, and are reviewing medicines legislation with a view to major reform.

To formulate a Narcotic and Controlled Medicines Policy for pharmaceuticals and refer to the responsibilities of essential personnel in such a situation, it has been necessary to refer to the function, rather than to a specific body. As an example, reference will be made to the NMRA. This body does not currently exist, and it is not the purpose of this policy to decide on such a matter. Rather this policy refers to whichever organization is appointed to fulfill that function; currently, these are departments within GDPA. All titles of responsible bodies in this policy should therefore be interpreted as functional titles, and should
not be viewed as recommendations to establish such units or new bodies.

6.1.2. **Reality of current situation**
At the present time there is a highly fragmented system for narcotic and controlled medicines, involving multiple supply streams and players. This places a huge burden on the regulatory authorities to process numerous small orders for narcotic and controlled medicines and greatly complicates the overall coordination and measurement of narcotic and controlled medicine use.

In the short term, it is recognized that the current players will be required to continue to implement individual narcotic and controlled medicine supply, but that over the longer term (a target of three to five years), there will be a phased-in move to an overall national narcotic and controlled medicines pharmaceuticals supply system in Afghanistan, as described below:

6.2. **Proposed Structure**

6.2.1. **Narcotic and controlled medicines pharmaceutical issues—national policy body**
Narcotic and controlled medicines is a wide-ranging concept which covers all matters that individually or collectively influence the availability and use of such medicines. It therefore involves a wide range of participants who need to interact and address cross-cutting issues across organizational departments, governmental ministries, private sector bodies, professions, technologies, and disciplines.

In recognition of these issues, a new body is proposed. It is not intended to be a stand-alone body, but will form part of the overall essential medicines structure and will need to be located within new structure as it is being developed. Initially, it should be a specialist grouping (sub-committee) that will act as an appointed advisory committee to the NMFB. It will have an overarching brief to address all narcotic and controlled medicines policy issues. This body will not undertake implementation. Its role is solely to address policy issues by advising the NMFB. It will have the ability to consult widely and take advice and opinion from a broad range of players.

For the purposes of this policy, the subcommittee will be referred to as National Controlled Medicines Policy Panel (NCMPP).
Membership should be by appointment of the NMFB, and be wide ranging, including representatives from the pharmaceutical industry, academia, government health care, international organizations (WHO/UN agencies), pharmacy profession, and the private sector.

It will have three main roles:

- To be the prime body for developing, maintaining, and updating policies for narcotic and controlled medicines and in setting the detailed guidance for policy implementation.
- To ensure that Narcotic and controlled medicines issues are correctly incorporated into all MoPH policies, including:
  - All pharmaceutical related policies: National Medicines Policy and the National Quality Assurance Policy for Pharmaceuticals
  - All program specific policies: including, HIV and AIDS, cancer treatments, terminal diseases, mental health, substance abuse therapy, maternal health
  - All general health policies, including pain relief
- To advise the NMFB on all narcotic and controlled medicines policy issues
Table 1. Policy planning for availability and accessibility, WHO guidelines

<table>
<thead>
<tr>
<th>DISEASE PROGRAM</th>
<th>ITEMS TO INCLUDE IN THE PROGRAM</th>
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<tbody>
<tr>
<td>Cancer control</td>
<td>• Access to and availability of strong opioid analgesics (70)(^a)</td>
</tr>
<tr>
<td></td>
<td>• Integrated hospice and palliative care services (71)</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>• Access to and availability of strong opioid analgesics (70)</td>
</tr>
<tr>
<td></td>
<td>• Integrated hospice and palliative care services (71)</td>
</tr>
<tr>
<td></td>
<td>• Prevention of HIV transmission through availability and accessibility of opioid agonist therapy (72, 73)</td>
</tr>
<tr>
<td>Mental health (substance abuse and dependence syndrome)</td>
<td>• Prevention of substance abuse and dependence syndrome (74)</td>
</tr>
<tr>
<td></td>
<td>• Treatment of dependence syndrome through availability and accessibility of opioid agonist therapy (24)</td>
</tr>
<tr>
<td>Mental health (other psychiatric and neurological disorders)</td>
<td>• Availability and accessibility of anxiolytics, hypnotics and antiepileptic</td>
</tr>
<tr>
<td>Maternal health</td>
<td>• Availability and accessibility of oxytocin (not-controlled) and/or ergometrine and of ephedrine for emergency obstetric care (75-77)(^b)</td>
</tr>
</tbody>
</table>

\(^a\) indicates paragraphs pertaining to disease program

\(^b\) Table information from [http://www.who.int/medicines/areas/quality_safety/guide_nocp_sanend/en/](http://www.who.int/medicines/areas/quality_safety/guide_nocp_sanend/en/)

In the past, the focus has been on the control element of narcotic and controlled medicines.

The NCMPP is expected to have a major role in advising on all MoPH policies to ensure issues relating to the accessibility and availability of narcotic and controlled medicines as well as appropriate control mechanisms to ensure correct use and minimize potential for abuse are fully incorporated into all policies. The primary function of the NCMPP will be to ensure the balance between control and assured access/availability is achieved for narcotic and controlled medicines in all MoPH policies. In this regard the NCMPP will provide representatives to all relevant policy development/review committees (especially NMP, quality assurance (QA) and disease specific programs such as HIV and AIDS, cancer, substance abuse therapy) to ensure that narcotic and controlled medicines issues are adequately addressed in policy developments. The NCMPP should meet at least three times per year and report to the NMFB.
6.2.2. **Controlled medicines—medicines regulatory body**

It is neither necessary or desirable to have a stand-alone regulatory body just for narcotic and controlled medicines issues. These regulatory issues should be part of the functions of the NMRA—currently departments within GDPA—and be a specialist grouping. The body should have the power to enact and enforce regulation relating to narcotic and controlled medicines. It should have the power to seize and impound narcotic and controlled medicines or purported medicines suspected of containing controlled substances and to subsequently destroy such medicines if they are found to be in breach of regulation.

In addition to the normal control functions for all medicines and the specialist requirements detailed elsewhere in this policy, the NMRA-CMD must also:

- Control advertising of narcotic and controlled medicines
- Provide information on narcotic and controlled medicines
- Provide information on the government policy for therapy for opioid addiction
- Educate workers involved in drug control, including customs officials and police, on government policy for narcotic and controlled medicines and opioid addiction therapy

The NMRA-CMD must have adequate specialist staffing and resources to establish and handle such tasks as

- **Advertising**
  - Clear links with the media and advertising operations to ensure their professional bodies and organizations are fully aware of the restrictions on advertising involving narcotic and controlled medicines.
  - A method of including information on advertising restrictions in media training courses (universities/vocational/higher learning organizations that provide professional media training).
  - A mechanism for monitoring advertising of narcotic and controlled medicines within the media.

- **Web and library**
  - An easily accessible web-based information portal on narcotic and
controlled medicines for public access.

- A restricted access (health care professionals only) web-based information outlet for narcotic and controlled medicines providing more detailed clinical information.

- A restricted access (pharmaceutical industry only) web-based information outlet for narcotic and controlled medicines providing more detail on current availability, importation, storage distribution, dispensing requirements, and re-distribution of remaining short shelf-life products.

- In conjunction with the Ministries of Counter Narcotics and Justice, a restricted access (enforcement offices only) web-based information outlet regulatory and enforcement actions relating to narcotic and controlled medicines.

- A library with different levels of access (hard copy and/or electronic information) for information on narcotic and controlled medicines.

- An information unit which can provide information on narcotic and controlled medicines and responds to requests for such information, and provide speakers to public, professional bodies, and academia on Narcotic and controlled medicines issues.

- In conjunction with MoPH, a web-based information outlet which can provide information on the Government policy for the therapies available for opioid addiction.

- MoPH training
  
  - Setting up clear links with all universities, colleges, and training centers for all health care professionals, to ensure that information on narcotic and controlled medicines is included in all academic curriculum, pre-service training and post-qualification refreshers, upgrading and specialist development courses. NMRA-CMD should consider providing a specialist tutors who could provide the needed information to all such institutions.

  - Develop and provide a specialist training courses for:
    - All workers involved in drug control activities, including customs officers, police, judiciary, enforcement officers.
National Medicine Policy For Narcotic and Controlled Medicines

- Government policy on narcotic and controlled medicines and therapies available for opioid addiction.

**Narcotic and Controlled Medicines Regulatory Review Body**

Following is the background for the establishment of the Regulatory Review Body for Narcotic and Controlled Medicines.

Regrettably, the history of narcotic and controlled medicines in many countries has been that in the zeal to control opioid medicines, legitimate access and therapeutic need for narcotic and controlled medicines has been greatly impeded. This has been partly because law enforcement bodies have not been adequately educated and trained in the practical effects and operations of therapy for opioid addiction; and also because too much emphasis has been placed on achieving control without the necessary degree of consideration of the therapeutic need for narcotic and controlled medicines. Subsequently, it is a WHO recommendation (WHO guideline No. 6) that all regulatory operations be regularly reviewed and all national legislation and regulation be regularly reviewed (WHO guideline No. 9) to ensure that an adequate balance between control and access is being provided.

Non-discrimination is a fundamental principle that runs throughout the entire body of international human rights law. Subsequently it is necessary to ensure that all population groups have access to a forum to provide their views and inputs on narcotic and controlled medicines. It is a WHO recommendation (guideline No. 8) that “Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rational medical use and the prevention of diversion, abuse, and dependence syndrome.” The NMFB-CMG can serve as the forum for all population groups to present their views.

**The NMFB-CMG Review Body**

It is neither necessary or desirable to have a standalone regulatory review body just for narcotic and controlled medicines issues. So, the narcotic and controlled medicines regulatory review activities group should form a specialist grouping/committee within the NMFB—this is the CMG. The main features of the NMFB-CMG regulatory review body will include:
• In addition to the normal NMFB Membership, it should include representatives from the law enforcement agencies, such as customs agents, police, and those authorities implementing opioid addiction therapies.
• It should act as a forum for all population groups to present their views on narcotic and controlled medicines.

Role of NMFB-CMG Review Body
The prime roles of the narcotic and controlled medicines regulatory review body are to:
• Review all national legislation and regulation which relates to narcotic and controlled medicines (not just health legislation).
• Review the activities of the NMRA-CMD and ensure implementation of policies, regulations, guidelines and all activities relating to narcotic and controlled medicines are not impeding health policies and legitimate access to treatment with narcotic and controlled medicines.
• Provide a forum to accept representation from all population groups on controlled medicines issues and make appropriate recommendation to the Narcotic and Controlled Medicines policy Development Unit NCMPP, NMRA-CMD and NMFB on Controlled Medicines issues.

The body (NMFB-CMG) should form a joint legislation review group with Ministry of Justice and Ministry of Counter Narcotics, which should meet at least three times per year to review national legislation.
The body (NMFB-CMG) should independently meet at least four times per year to review NMRA-CMD implementation and deliver a report to the Food and Medicines Board on their findings.
The NFMB-CMG should hold at least two open forum per year to receive representation from any population groups desirous of commenting on narcotic and controlled medicines issues and forward recommendation to NCMPP and NMRA-CMD for implementation.
7. NARCOTIC AND CONTROLLED MEDICINES PRODUCT QUALITY ASSURANCE

7.1. Narcotic and Controlled Medicines Product Specification—Principles of Acquisition

For every act of narcotic and controlled medicines acquisition (ordering, resupply, procurement, purchase, donation, shipping, delivery, etc.), a clear product specification should be stated. All deliveries/receipts of pharmaceutical products should be compared against the stated specification. All acquisition documentation should clearly state the pharmaceutical product specification. Any testing/analysis of pharmaceutical product should be undertaken against its stated specification. All pharmaceutical products must be clearly labeled with the product specification. (It is not necessary to state the full specification; international recognized acronyms are acceptable, e.g., IP [International Pharmacopeia], BP [British Pharmacopeia], EP [European Pharmacopeia], USP [United States Pharmacopeia]).

7.2. Narcotic and Controlled Medicines Product Specification—Pharmacopeial Standard’s Main Principles

The main principle of pharmaceutical product specification will be that wherever possible, use a recognized, published pharmacopeial standard. In those cases where no acceptable pharmacopeia standards are available (new products), a WHO pharmaceutical monograph should be specified. When no published pharmacopeia standard and no WHO monograph are available, a Quality Assurance of Pharmaceuticals Regulatory Body of NMRA is to be established as an advisory group. Also refer to US Food and Drug Administration, and the UK and EC regulatory authorities, and the National Medicines Regulatory Body (currently departments within GDPA) as to whether a manufacturer-derived specification can be used.

7.3. Product Specification—Documentation Requirements

The same requirements and regulations for quality assurance of all pharmaceuticals will similarly apply to all narcotic and controlled medicines. For every act of pharmaceutical product acquisition (ordering, resupply, procurement, purchase, donation, etc.), the following product documentation
will be required:

- Certificate of Analysis (conforming to the WHO Model Certificate of Analysis format)

- Certificate of International Movement of Pharmaceutical Product (conforming to the WHO format for Pharmaceutical Products in International Commerce)
  - Use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. EDM Research Series No. 016, 1995

- Certificate of product registration with NMRA (or waiver by NMRA)
8. PRESCRIBING AND DISPENSING OF NARCOTIC AND CONTROLLED MEDICINES

8.1. Prescribing Narcotic and Controlled Medicines

8.1.1. Permitted prescribers
For Category 1 Narcotic and Controlled Substances, only duly qualified and authorized medical practitioners who have been specifically and personally authorized by the NFMB may possess, prescribe, and administer such medicines.
For Categories 2 to 5 Narcotic and Controlled Medicines: all duly qualified and registered medical practitioners (doctors) recognized by the Medical Council of Afghanistan may prescribe Categories 2 to 5 of Narcotic and Controlled Medicines for normal medical therapy.
Certain paramedical groups may be authorized by the MoPH to prescribe individual categories of narcotic and controlled medicines in limited quantities (these may include for example: military paramedics operating in civilian environments, police paramedics, specialist ambulance crew/paramedics). A list of such authorized groups will be published by the MoPH at least annually.

8.1.2. Prescription Requirements
A prescription for a Category 1 Narcotic and Controlled Medicine must be made on a pre-numbered (sequentially numbered) and duplicate/counter foiled prescription form, written in ink or indelible pencil or typewritten/computer printed and must be manually signed by the prescribing officer who has been specifically and personally authorized by the NFMB to prescribe such items. The NFMB authority reference number should be included next to the prescriber’s signature. The practitioner is responsible for ensuring that the prescription conforms in all essential respects to the law and regulation.
A prescription for Categories 2 to 4 Narcotic and Controlled Medicines for normal medical therapy must be written in ink or indelible pencil or typewritten/computer printed and must be manually signed by the prescribing officer. An individual may be designated by the prescribing officer to prepare the prescriptions for his/her signature but the practitioner is responsible by law and regulation for ensuring that the prescription conforms in all essential
respects to the law and regulation. It is preferable that the official prescription form in the process of being designed and issued by NMRA-CMD for narcotic and controlled medicine is used.

The prescription must contain:

- Date of issue
- Patient’s full name and address
- Practitioner’s name, address, and professional registration number
- A notation that this is a controlled medicine (stamp, watermarked pad, or similar)
- Drug name
- Drug strength
- Dosage form
- Quantity prescribed in words and figures
- Directions for use
- Hand-written signature of prescriber
- Signature box for the patient to complete when receiving the medicine

The prescription is valid for a maximum of 14 days from the time it is written. Prescriptions for Category 5 narcotic and controlled medicines should follow normal prescribing practice for all medicines (no special prescription requirements).

8.1.3. Prescription forms and format requirements

NMRA-CMD will issues official prescriptions pads for use with Category 1 Narcotic and Controlled Medicines which will include counterfoils/duplicate pads. Use of the NMRA-CMD prescription forms is compulsory for Category 1 Narcotic and Controlled Medicines. Use of the NMRA-CMD prescription forms is strongly advised for Categories 2 to 4 Controlled Medicines but is not compulsory. NMRA-CMD will issue official designs of prescriptions pads for use with Categories 2 to 4 narcotic and controlled medicine.

No special prescription form is necessary for Category 5 Narcotic and Controlled Medicines, but use of the standard general medicines forms are strongly encouraged.
8.2. Dispensing Narcotic and Controlled Medicines

8.2.1. Permitted Dispensers
For Category 1 Narcotic and Controlled Medicines, only duly qualified and registered pharmacists who have been specifically and personally authorized by the NFMB may possess and dispense such medicines. All duly qualified pharmacists recognized by the Regulations of Afghanistan may dispense Categories 2 to 5 Narcotic and Controlled Medicines (including diamorphine, dipipanone, and cocaine for substance abuse therapy to substance misusers) in accordance with the regulations and requirements for prescription medicines, and narcotic and controlled medicines.
All duly qualified and registered medical physicians recognized by the Medical Council of Afghanistan may, when no pharmacist is available, also dispense Categories 2 to 5 Narcotic and Controlled Medicines for normal medical therapy.
In view of the shortage of pharmaceutical services in some areas of the country, and as a temporary measure until an adequate number of dispensing outlets are available, certain paramedical groups may be authorized by the MoPH to dispense certain Categories of Narcotic and Controlled Medicines in limited quantities. These may include midwives, nurse anesthetists, intensive care unit nurses, junior pharmacists (not yet qualified), paramedics, police paramedics, prison paramedics, and specialist ambulance crew/paramedics. A list of such authorized groups will be published by the MoPH at least annually.

8.2.2. Permitted corrections of prescription for narcotic and controlled medicines
No changes/corrections to prescriptions for Category 1 Narcotic and Controlled Medicines are permitted. No changes/corrections to prescriptions for diamorphine, dipipanone, and cocaine for substance abuse therapy to substance misusers are permitted.
Only qualified pharmacists may make changes to prescriptions for Categories 2 to 5 Narcotic and Controlled Medicines. Other officers undertaking dispensing duties are not permitted to make any changes, and in the case of a detected error or omission on the prescription, it must be returned to the patient or prescribing officer.
Pharmacists may, at their professional discretion, make certain corrections, as
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detailed below, to Prescriptions for Categories 2 to 5 Narcotic and Controlled Medicines for normal therapy. All such corrections must be received by the prescribing physician within 48 hours of dispensing, be recorded and initialed by the dispensing pharmacists, and recorded in the appropriate narcotic and controlled medicines ledgers/logs and reporting forms. The prescription must be amended in ink or otherwise indelibly, and the pharmacist must mark the prescription so that the amendment is attributable to him or her, by signing the amendment. If there is more than one amendment on the same prescription, each amendment must be marked.

Permitted corrections include:

- Correct minor spelling mistakes, provided the intent of the prescribing officer is clear.
- Correct minor writing/typographical mistakes (this may include, for example, a number being substituted for a letter or two letters being inverted but where the prescriber’s intention is still clear).
- The dispensing pharmacist may fill in/complete a missing patient address on the prescription form if the patient can provide proof of address.
- The pharmacist may substitute a generic form of the medicine if a brand name/trade name has been written on the prescription.
- The pharmacist may reduce the total amount of medicine to be dispensed if it exceeds the (quantity) prescription limit of the prescribing.
- Dispensing pharmacists may reduce the amount of medicines to be dispensed at one time, i.e., phased/timed dispensing of partial quantities over a period of time, but in no case should the time period to complete dispensing exceed one month.
- No other changes are permitted without written consultation with the prescribing officer. No changes are permitted based solely on spoken exchanges (telephone), SMS, or similar text messaging with the prescribing officer.
8.2.3. **Dispensing narcotic and controlled medicines in exceptional situations**
Dispensing without a valid prescription is not permitted for Category 1 medicines. Dispensing without a valid prescription is not permitted for alternative drugs used for substance abuse therapy (methadone, bepronorpine) for substance misusers.
Pharmacists may, at their professional discretion, consider a situation to be exceptional and of such an urgent nature that they may dispense Categories 2 to 5 Narcotic and Controlled Medicines without a prescription for use for medical purposes by named individuals. Such dispensing must not exceed two days’ supply of medicine, and must be reported to the supervising physician of that patient within 48 hours of the dispensing occurring. (e.g., phenobarbital for the treatment of epilepsy).

8.2.4. **Dispensing of narcotic and controlled medicines in emergency situations**
In the event of a natural or man-made disaster (earthquake, mud-slide, explosion) resulting in serious injury to multiple people, supplies of narcotic and controlled medicines may be provided directly to all health care professionals/paramedics and suitably qualified disaster relief workers providing support to injured persons in that disaster.
Pharmacists providing supplies in such situations should endeavor to obtain written acceptance of the narcotic and controlled medicines from the most senior health care office present at the disaster site or, if no such officer is present, the most senior police, armed forces personnel, or disaster relief officer present.

8.3. **Compounding (extemporaneous dispensing) of narcotic and controlled medicines**
Compounding (extemporaneous dispensing) is defined as providing a customized therapeutic solution to improve patient care without duplicating a commercially available, approved product. It is not included in the manufacturing regulation for narcotic and controlled medicines. In practice, such compounding relates to the mixing of two or more drugs of which one is a narcotic and controlled medicine, usually, for such instances as palliative care. Only pharmacists have authority to compound any drugs in
categories 2-5 in accordance with the terms of a clinical management plan prior to administration to a patient. Compounding should normally take place according to a prescription from a doctor or authorized practitioner. The compounded medicine may be administered by a nurse acting under the instructions of a doctor or authorized practitioner within the terms of a clinical management plan.
9. REGISTRATION OF NARCOTIC AND CONTROLLED MEDICINES

9.1. Registration

9.1.1. Narcotic and controlled medicines must follow the same general medicines registration process as all other medicines/pharmaceuticals, except that there will be additional requirements for the status of the organization (company) undertaking registration of the medicine.

9.1.2. Only narcotic and controlled medicines that are registered in Afghanistan can be supplied to the pharmaceutical markets in the country, unless otherwise approved by the Minister of Public Health in consultation with the NMRD-CMD.

9.1.3. The criteria for the registration of narcotic and controlled medicines will be exactly the same as for all other medicines and be based on the scientific evaluation of quality, efficacy, safety, therapeutic advantage, laboratory testing results, and evidence of Good Manufacturing Practices (GMP).

9.1.4. Registration and marketing authorization of narcotic and controlled medicines and other can only be carried out if the procedures, standards, and facilities for manufacturing of such medicines and other pharmaceuticals have been evaluated and have received prior approval from the NMRA.

9.1.5. A fast-track registration procedure for narcotic and controlled medicines will be established, and will essentially follow the same fast track procedure for essential medicines.

9.1.6. Registration status for narcotic and controlled medicines will be granted for the same period as all other essential medicine—currently a period of five years—subject to review and renewal as determined by the NMRA-CMD.

9.1.7. Accordingly, county registration guideline and internationally acceptable standards will be adopted for the registration of narcotic and controlled medicines in Afghanistan.
9.1.8. The manufacture, exportation, importation, and distribution of unregistered, counterfeit, substandard, or expired narcotic and controlled medicines and raw materials for the production of narcotic and controlled medicines will not be permitted and will be punishable by law.

9.1.9. NMRA-CMD will issue detailed procedures and requirements for registration of controlled medicines conforming to these requirements.
10. REGISTRATION/LICENSING OF IMPORTERS, WHOLESALERS/DISTRIBUTORS, AND RETAILERS OF NARCOTIC AND CONTROLLED MEDICINES

10.1. It is a requirement that all companies undertaking the manufacture, pharmaceutical compounding, importation, export, wholesale, bulk storage, or distribution of narcotic and controlled medicines or their precursor chemicals be licensed.

10.1.1. All companies, organizations, bodies, and other entities involved in the trade, manufacture, pharmaceutical compounding, importation, export, wholesale, bulk storage, or distribution of Narcotic and Controlled Medicines or their precursor chemicals must be correctly registered and licensed for their specific activities by the NMRA-CMD. Failure to hold a valid and current license can result in prosecution and severe penalties.

10.1.2. The NMRA-CMD will be responsible for licensing of companies, organizations, bodies and other entities involved in the trade in narcotic and controlled medicines.

10.1.3. NMRA-CMD will issue detailed registration and licensing requirements.

10.1.4. For recognized nongovernmental organizations (NGOs), charities, and other institutions approved by the Government of Islamic Republic of Afghanistan that undertake only the importation, storage and distribution of Narcotic and Controlled Medicines to Government approved hospitals and clinics, administrative facilities will be provide by government.

10.1.5. Only registered and licensed companies will be allowed to register Narcotic and Controlled Medicines for use in Afghanistan.

10.1.6. To be registered/licensed companies, organizations and other entities must fulfill the following general conditions and further conditions will apply for each specific function.

- All members of senior management and all staff involved in handling Narcotic and Controlled Medicines are to be subject to a Criminal Records check and are required to produce a police/judicial certificate
of “no know criminal record.”

- Companies, organizations, bodies and other entities must be fully registered as trading enterprises within the laws and regulations of Afghanistan and must provide a copy of the relevant certificate of registration. Registration and licenses for narcotic and controlled medicines will only be issued in the officially registered trading name of the company (entity). If the entity is a charity or NGO or similar organization, then registration in that capacity is required.

- Registration and licensing is site specific. If a company has multiple sites, each site handling narcotic and controlled medicines will require a license. Sites must be clearly identified by a physical address, preferably linked with a GPS or similar coordinates. Virtual sites or post office boxes or offices are not permitted.

- Applicants for narcotic and controlled medicines registration licensing must state the categories of narcotic and controlled medicines for which they require a license.

- The premises in which the trading activities take place must meet certain security standards/expectations, dependent on the categories of the drugs held and quantities. The physical storage conditions of the medicines must meet various secure storage conditions. These requirements are detailed in later sections.

- Security of premises where narcotic and controlled medicines are stored, handled, or produced is extremely important and all applicants need to be aware of the need to provide adequately levels of security.

- All applicants must have a set of standard operating procedures (SOPs) for the handling of narcotic and controlled medicines which are written down, understood by staff and available for inspection at any time.

- All companies/organization must appoint a ‘responsible person’ who will serve as the prime point of contact with the NMRA-CMD and be responsible for full observation of all laws, regulations and requirements relating to Narcotic and Controlled Medicines.

- All records must be kept in hard copy ink or a permanent, unalterable format.
• The company must nominate appropriately qualified personnel who are authorized to witness destruction of any date expired damaged or sub-standard narcotic and controlled medicines.

10.2. **Requirement for undertaking the manufacture of narcotic and controlled medicines or their pre-cursor chemicals.**

10.2.1. **Definition manufacturing of narcotic and controlled medicines**

Manufacturing of narcotic and controlled medicines refers to those processes that are independent of the directly regulated health care professional-patient relationship or valid pharmacist-client-patient relationship. In this context, “manufacture” means the, processing, making, preparing, or otherwise engaging in any part of the production of a drug by propagating, compounding, converting, or processing, either directly or indirectly by extracting from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes the following:

- Any packaging or repackaging of the drug or labeling or relabeling of its container, the promotion and marketing of the drug, and other activities incident to production;
- The preparation and promotion of commercially available products from bulk compounds for resale by pharmacies with licensed health professionals authorized to prescribe drugs.

In this context, “manufacture” does not include the preparation, compounding, extemporaneous dispensing, packaging, or labeling of a medicine by a pharmacist as an incident to either of the following:

-Dispensing a medicine in the usual course of professional practice
-Providing a licensed health professional authorized to prescribe medicines with a medicine for the purpose of administering to patients or for using the drug in treating patients in the professional’s place of work.

10.2.2. **Manufacturing licenses for narcotic and controlled medicines**

All companies, bodies, or entities undertaking manufacturing of narcotic and controlled medicines or their pre-cursor chemicals must be in possession of a valid operating license issued by the NMRA-CMD.
10.2.3. **Responsible body for manufacturing licenses for narcotic and controlled medicines**
After approval of the research proposal by NFMB, the NMRA will issue manufacturing licenses for Category 1 Narcotic and Controlled Medicines. NMRA-CMD will serve as the responsible body for issuing manufacturing licenses for Categories 2 to 5 Narcotic and Controlled Medicines. NMRA-CMD will issue detailed regulations on the requirements of manufacturing licenses for narcotic and controlled medicines. The licenses will be specific to the premises and the product(s) to be manufactured.

10.2.4. **Manufacturing companies**
All companies, bodies or entities whether commercial or academic or not-for-profit undertaking manufacture of narcotic and controlled medicines must comply with:
- All the requirement of general pharmaceutical manufacturers (including Good Manufacturing Practice)
- All the general requirements for trade in narcotic and controlled medicines
- The specific requirements to be issued by NMRA-CMD for narcotic and controlled medicines manufacturing

The companies must apply for a specific license for the manufacture of narcotic and controlled medicines. The licenses will be specific to the premises and the products to be manufactured.

10.3. **Requirement for undertaking the importation, or export, of narcotic and controlled medicines or their pre-cursor chemicals.**

10.3.1. **International travelers/international transit**
Individual international travelers are not permitted to transport Category 1 Narcotic and Controlled Medicines, except by special permit with the approval of NMFB and a license issued by NMRA.
Bona fide individual international travelers who are in possession of a valid copy prescription in English language and signed by a registered medical practitioner, or a document conforming to the requirements of the international guidelines for national regulations concerning travelers’ under
treatment with internationally controlled drugs as issued by the INCB (annex C) may carry narcotic and controlled drugs Categories 2 to 4 out of or into Afghanistan for their own personal use, providing the quantity does not exceed 30 days’ personal supply.

According to the INCB, “The quantities were calculated on the basis of a 30 day-period of treatment and defined average daily doses used by INCB for statistical purposes. Those doses correspond, in most cases, to the doses recommended by WHO for drug utilization studies. In the case of substances used for the treatment of chronic or severe pain for terminally ill patients and in the case of substances used for maintenance treatment and/or substitution treatment of drug dependence, the quantities indicated were calculated taking into account doses actually used for those categories of patients. This mode of calculation may be used by countries, which, due to local considerations, need to establish maximum quantities for additional types of preparations or introduce modifications to the quantities indicated in the examples.”

No additional specific restrictions apply to Category 5 Controlled Medicines (i.e., no copy of prescription required), but observation of normal medicines transport of not exceeding three months’ personal supply will apply. Travelers who need to transport more than 30 days’ personal supply of a Category 2 to 5 Narcotic and Controlled Medicine must apply to the NMRA CMD for an individual Controlled Medicines permit in the format following the INCB International guidelines for national regulations concerning travelers’ under treatment with internationally controlled drugs. Travelers should be advised that such permits issued in Afghanistan may not be acceptable in other countries.

10.3.2. Commercial import and export of narcotic and controlled medicines

10.3.3. Obtaining a license for the importation of narcotic and controlled medicines is a two-stage process. First the entities undertaking the importation must be licensed to undertake importation; second, license/import permission must be granted for the specific shipment which will specify the exact substances and quantities.
10.3.4. All companies and other entities involved in the commercial importation, and/or export of Narcotic and Controlled Medicines or their precursor chemicals must be correctly registered and licensed for their specific activity(ies) by the NMRA-CMD. Failure to hold a valid and current license can result in prosecution and severe penalties.

10.3.5. Licensing of companies, organizations, bodies, and other entities involved in the trade in narcotic and controlled medicines will be undertaken by NMRA-CMD. NMRA-CMD will issue detailed registration and licensing requirements which as a minimum will include the following requirements:

- To obtain a narcotic and controlled medicines importation license an importer must first be registered as a pharmaceutical importer for a period of not less than three years.
- The applicant must comply with all the conditions detailed in section 10.1.6 especially relating to criminal records checks.
- The applicant must have secure premises of adequate size for the volumes of medicines they intend to import.

10.3.6. The Importer must provide annual statistical returns on the full details of the medicines imported, distributed, exported and currently in stock in keeping with the detail reporting formats and requirements to be issued by NMRA-CMD.

10.3.7. The importer must provide annual estimates of the volumes of narcotic and controlled medicines they wish to import/export during the forthcoming reporting year in keeping with the detailed formats and requirements to be issued by NMRA-CMD.

10.3.8. The importer must immediately report, and in any event within not more than 24 hours of the discovery, to both the judicial authorities (police) and NMRA-CMD any loss or theft of Narcotic and controlled medicines.

10.3.9. The licensed importer must apply for a license permission for every shipment of narcotic and controlled medicines. NMRA-CMD will issue detailed registration and licensing requirements which as a minimum will include the following requirements:
• Names of substances
• Pharmaceutical specification
• Quantities
• Sources of substances
• Importation route (port)

10.3.10. NMRA-CMD will verify that the requested substances for import conform to the annual quota allocations and represents reasonable quantities for the intended use.

10.3.11. Noncommercial import and export of narcotic and controlled medicines definitions

10.3.11.1 Noncommercial import of Narcotic and Controlled Medicines will apply only to FPPs. The noncommercial importation of narcotic and controlled medicines APIs or pre-cursor chemicals is not permitted. Noncommercial import of narcotic and controlled medicines FPP is defined as permitted importation of narcotic and controlled medicines FPP by approved noncommercial bodies/entities, which may include: government hospitals and health units, government stores and warehouse bodies, approved NGOs implementing governmental health programs, approved charities and foundations implementing governmental health programs, approved academic bodies and entities, approved international organizations (e.g., United Nations bodies), and any other bodies as identified by the MoPH; when the medicines are to be used solely in support of governmental health programs or approved activities. Narcotic and controlled medicines imported under the noncommercial methodology may not be sold, and can be provided for private sector use only in exceptional/emergency situations that require the specific authorization of NMRA-CMD.

10.3.11.2 Approved noncommercial bodies
MoPH will be responsible for issuing a list of the types of noncommercial bodies which can be considered for registration for the importation of medicines. NMRA-CMG will be responsible for registering those specific/individual
noncommercial bodies/entities, from the types which have been authorized by the MoPH, to be permitted to import controlled medicines; and will issue detailed regulations which will provide more administrative facilities than registration of the commercial importers of Controlled Medicines.

10.3.11.3 Noncommercial importation policy
The use of noncommercial importation of narcotic and controlled medicines is seen as a short to medium-term (under five years duration) mechanism to permit time for transition to a mechanism whereby all narcotic and controlled medicines supply will be through registered and approved commercial importers (or from local manufacturers).
In essence, all authorized bodies requiring narcotic and controlled medicines should, eventually obtain them in-country, from approved, registered, or licensed suppliers, and the use of noncommercial importation will no longer be necessary.
11. PROCUREMENT AND SOURCES OF MEDICINES

11.1. Acquisition
All acts of acquisition of narcotic and controlled medicines are to conform to sections 5 and 7 of this policy.
In particular:

- Only those medicines registered for use in Afghanistan may be procured internationally and imported.
- A clear specification of the medicine must be stated including the pharmaceutical standard.
- The source of all medicines must be a GMP certified manufacturer who has national licenses to conduct international supply in accordance with international regulations for the movements of narcotic and controlled medicines.
- Full documentation of both quality assurance and movement of narcotic and controlled medicines must be provided as specified in sections 5 and 7 of this policy.

11.2. Donations
All international donations of narcotic and controlled medicines are to comply with all national laws and regulation of Afghanistan relating to narcotic and controlled medicines and the WHO revised guidelines for medicine donations (see references).
In particular, paragraph 3.1.4 of the WHO Medicine Donation Guidelines is a central concept:
“All donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.”
- Donated medicines must go through the same approach to product specification and documentation as all other medicines entering Afghanistan.
• Donated medicines must go through the same approach and rates of sampling and testing for quality assurance as all other medicines entering Afghanistan.

• Medicine donors are to be requested to contribute 5% of the cost of the medicine to enable narcotic and controlled medicines documentation and quality assurance activities to be undertaken.
12. STORAGE AND DISTRIBUTION OF NARCOTIC AND CONTROLLED MEDICINES

12.1. Registered premises
Only duly registered premises may be used by local manufacturers, importers, exporters, and distributors of narcotic and controlled medicines to store narcotic and controlled medicines. As part of the premises licensing conditions, NMRA-CMG will state the maximum quantity of controlled medicines which can be held in those premises.

12.2. Conditions and requirements for premises
NMRA-CMD will issue detailed regulations for the granting of licenses for registered premises for narcotic and controlled medicines and, in general, the detailed requirements will be informed by the following guidelines:

- The operator of the licensed premises must have clear, written SOPs that govern the manner which all narcotic and controlled medicines are stored and handled on site, subjected to periodic stock checks
- compliance with Good Storage Practices of Pharmaceutical products as contained in the WHO guidelines.
- This document should be regularly reviewed and updated and all employees should be familiar with these SOPs and a hard copy must be available for reference.

Guideline on good storage practice
Premises for the storage of small quantities of narcotic and controlled medicines as used by a hospital or clinic are covered in Section 12.5. Premises for the bulk storage of narcotic and controlled medicines (importers, wholesalers, distributors, warehouses, etc.) generally considered to be holding more than 5% of the total national annual supply volume of controlled medicines of Afghanistan or a value of controlled medicines in excess of USD 100,000.

External requirements
- A perimeter fence and lockable/access control gates:
  - An access control system with a clear audit trail of entry and exit of all staff and visitors.
• An automated alarm system is strongly encouraged.
• Links to security response system is strongly encouraged.

**Structural requirements for premises and rooms used for keeping bulk controlled medicines:**

**Rooms**

• Each wall shall be securely attached to the floor, ceiling, and adjacent walls, and shall be constructed of
  o Bricks laid in cement mortar to at least 229 millimeters (9 inches) in thickness or, if the joints are reinforced with metal reinforcing ties, to at least 115 millimeters (4 inches) thickness; or
  o Concrete (being solid concrete, reinforced concrete, or dense concrete blocks laid in cement mortar) of at least 152 millimeters (6 inches) in thickness, the joints being reinforced with metal reinforcing ties where concrete blocks are used; or
  o Steel mesh fixed externally by welding upon angle-iron frames of at least 50 millimeters (2 inches) by 50 millimeters (2 inches) section and 6 millimeters (0.25 inch) in thickness, having vertical members not more than 610 millimeters (2 feet) apart and horizontal members not more than 1,220 millimeters (4 feet) apart; or
  o Sheet steel of not less than 16 gauge fixed externally by welding, or bolting with steel bolts of not less than 12 millimeters (0.5 inch) diameter and at intervals of not more than 305 millimeters (1 foot), upon either angle-iron frames as specified in 3 above or timber frames of at least 50 millimeters (2 inches) by 100 millimeters (4 inches) section, having vertical and horizontal members spaced as specified in steel mesh above.

• If a party wall (joined to another building) or, in the case of a room of in which the floor level is less than 2,440 millimeters (8 feet) above the external ground level, an external wall is used to form one of the walls of the room, that wall shall be reinforced internally by means of an additional wall which is constructed in accordance with and meets the requirements of the paragraphs above.
Floors

- The floors should be constructed of solid concrete or reinforced concrete; or
- Covered internally with sheet steel or steel-welded at all joints; or
- Otherwise constructed so that it cannot be readily penetrated from below.

Ceilings

- Ceilings shall be constructed of solid concrete or reinforced concrete as specified above; or
- Steel mesh fixed internally by welding up on angle-iron frames as specified in sub-paragraph above, the members of which shall not be more than 610 millimeters (2 feet) apart in one direction or more than 1,220 millimeters (4 feet) in the other; or
- Sheet steel of not less than 16 gauge fixed externally by welding upon angle-iron frames as specified in sub-paragraph above, the members being spaced as specified in (b) above.

Doors

- Each door or, in the case of a stable-type door, each half-door shall be constructed of steel mesh fixed externally by welding upon angle-iron frames as specified in sub-paragraph above; or
- Sheet steel fixed externally by welding upon angle-iron frames as specified in paragraph above, the members being spaced as specified above; or
- Sheet steel of not less than 16 gauge fixed externally upon a hardwood frame of at least 50 millimeters (2 inches) by 75 millimeters (3 inches) to stiles, rails, and braces; or muntins by means of coach bolts at intervals of not more than 305 millimeters (1 foot) (the nuts being on the inside of the door) and with non-withdrawable screws between the bolts at intervals not exceeding 102 millimeters (4 inches), the members of the frame being spaced as specified in sub-paragraph above; or
- Sheet steel fixed externally upon a solid timber core of at least 50
millimeters (2 inches) in thickness.

- Each door or, in the case of a stable-type door, each half-door shall be fitted with an effective lock, being a single-aided dead lock having a resistance to manipulation and forcing. If the room is fitted with a two-leaf door the second opening leaf shall be secured top and bottom by means of
  - An espagnolette bolt, opened only from within the room, with vertical fastening rods of mild steel of a least 16 millimeters (0.6 inch) by 16 millimeters (0.6 inch) section or 16 millimeters (0.6 inch) diameter; or
  - At least two internal tower bolts of mild steel of at least 16 millimeters (0.6 inch) diameter, designed to swivel into a secure holding recess when in the thrown position,
  - And, for either case, the bolts shall have a total throw at least 25 millimeters (1 inch) greater than the clearance between the door and the floor or lintel with the lower shooting hole being kept at all times free from obstruction.

- The closing frame of each doorway shall be constructed of
  - An angle-iron frame as specified in sub-paragraphs above; or
  - Hardwood of at least 50 millimeters (2 inches) by 100 millimeters (4 inches) section, covered by sheet steel of not less than 16 gauge bolted through the timber at intervals not exceeding 457 millimeters (18 inches) by means of coach bolts (the nuts whereof not accessible from outside the room); or
  - Pressed steel not lighter than 10 gauge welded at all joints.

- Each section of the closing frame of each doorway shall be fixed to the adjoining wall at intervals not exceeding 457 millimeters (18 inches) by means of
  - Where the wall is constructed of bricks, bent and tonged straps of wrought iron, screwed or bolted to the frame and built into the brick work;
  - Where the wall is constructed of concrete; rag-bolts; or
  - Where the wall is constructed of steel mesh or sheet steel, steel
bolts, or dowels of at least 12 millimeters (0.5 inch) diameter or welded to the frame-work or cladding of the room.

Windows

- Each glass window shall either be constructed of glass blocks not larger than 190 millimeters (7.5 inches) by 190 millimeters (7.5 inches) and of at least 80 millimeters (3 inches) in thickness, set in a reinforced concrete frame having a reinforcing bar between every block, or be guarded by a grille consisting of panels of steel mesh fixed on angle-iron frames as specified above. The windows should be fixed
  - Where the surrounding wall or ceiling is constructed of sheet steel on angle-iron frames by welding to the sheet steel or framework at intervals not exceeding 305 millimeters (12 inches); or
  - Where the surrounding wall is constructed of sheet steel on timber frames, by means of steel bolts of at least 12 millimeters (0.5 inch) diameter, bolted through the timber at intervals not exceeding 457 millimeters (18 inches); or
  - Where the surrounding wall is constructed of bricks, by means of bent and tonged straps of wrought iron screwed or bolted to the frame and built in to the brickwork at intervals not exceeding 457 millimeters (18 inches); or
  - Where the surrounding wall or ceiling is constructed of concrete, by means of rag-bolts at intervals not exceeding 457 millimeters (18 inches); or
  - Vertical bars of solid mild steel of at least 25 millimeters (1 inch) by 25 millimeters (1 inch) square section, having one of their diagonal axes in a plane parallel to that of the window aperture, spaced not more than 127, millimeters (5 inches) apart center to center with the outer bars not more than 76 millimeters (3 inches) from the reveals of the window, and running through and welded to flat mild steel horizontal guard-bars which
    - Are of at least 62 millimeters (2.5 inches) in width and 9 millimeters (0.5 inch) thickness;
- Are spaced not more than 762 millimeters (2.5 feet) apart, the upper and lower guard-bars being at a distance not exceeding 102 millimeters (4 inches) from the ends of the vertical bars and not exceeding 76 millimeters (3 inches) from the head and sill of the window;
- Are welded at each end to steel brackets of at least 152 millimeters (6 inches) in length, 62 millimeters (2.5 inches) in width and 12 millimeters (0.5 inch) in thickness fixed to the surrounding wall or ceiling, as the case may be, in the manner required by (a) above at a distance of at least 152 millimeters (6 inches) from the reveals of the window;
- If more than 1,830 millimeters (6 feet) in length, have the uppermost and lowermost of them fixed to the head and sill of the window at intervals not exceeding 1830 millimeter (6 feet), by means of angle-iron fixings of at least 50 millimeters (2 inches) by 50 millimeters (2 inches) section and 6 millimeters (0.25 inch) thickness welded to the guard-bars and fixed to the surrounding wall or ceiling, as the case may be, in the manner required by (a) above.

- Service hatches, if present, shall be guarded by a grille consisting of
  - Panels of steel mesh or sheet steel on angle-iron frames as specified in sub-paragraphs above; or
  - Vertical bars of solid mild steel as specified in sub-paragraph above, and the grille shall be secured at all times when the hatch is not in use in such a way as to be secure against removal from outside the room.
- Each aperture other than a window or service hatch shall be guarded by a grille which satisfies the requirements of sub-paragraphs above.
- Each shelf in a room shall be so situated as to prevent controlled medicines placed upon it from being extracted from outside through any aperture.
- Nothing shall be displayed outside a room to indicate that controlled medicines are kept in the room.
12.3. **Access to bulk storage of controlled medicines on premises**

To minimize the possibility of internal diversion, the licensee of the premises shall limit access to the storage areas for controlled substances to a minimum number of employees with a security pass system. Where it is necessary for employee maintenance or nonemployee maintenance personnel, business guests, or other visitors to have access to or pass through the controlled medicines storage area, the licensee shall authorize in writing an employee to provide adequate observation during the time these otherwise unauthorized persons are in the storage area.

12.4. **Storage premises inspections and control**

NMRA-CMD will undertake inspection of premises used for the bulk storage and distribution of Controlled Medicines to verify compliance with the licensing conditions. As a guiding principle it is expected that storage premises are to be inspected at least every three years.

12.5. **Storage cabinets and safes**

Smaller quantities of medicines for use at hospitals and clinics are to be stored in cabinets which comply with the following requirements:

- A safe or cabinet shall be constructed of pressed and welded sheet steel; or
  - Pressed arid welded steel mesh; or
  - Sheet steel or steel mesh welded upon an angle-iron frame of at least 25 millimeters (1 inch) by 25 millimeters (1 inch) section and of at least 5 millimeters (0.2 inch) in thickness.
- The clearance between the door and jamb or, in the case of a two-leaf door, between the two leaves or each leaf and a central pillar shall not be greater than 3 millimeters (0.13 inch).
- Each door shall be fitted with an effective lock
  - Having at least 5 differing levers or, in the case of a pin and tumbler mechanism, at least 6 pins;
  - Designed to permit at least 1,000 effective key-differs independent of wards or any other fixed obstruction to the movement of the
key; and
  - Provided with a dead-bolt which is either of mild steel of at least 19 millimeters (0.75 inch) by 8 millimeters (0.31 inch) section or incorporates a suitable anti-cutting device and which has a total throw of at least 12 millimeters (0.5 inch).

- If the length of the vertical closing edge of a door exceeds 914 millimeters (3 feet) and the length of the horizontal edge exceeds 457 millimeters (18 inches) the door shall be fitted with two such locks as are specified above, one situated at not more than one third of the length of the vertical closing edge from the top and the other at not more than one-third from the bottom. Otherwise the lock required above shall be situated in the center of the vertical closing edge.

- If a safe or cabinet is fitted with a two-leaf door, either:
  - The lock or locks required as above shall be fitted with an integral espagnolette bolt which is of at least 19 millimeters (0.75 inch) by 8 millimeters (0.31 inch) section and which has a total throw, at both the top and bottom, of at least 12 millimeters (0.5 inch); or
  - The second opening leaf shall be secured at the top and bottom by means of internal bolts of mild steel of at least 6 millimeters (0.25 inch) by 6 millimeters (0.25 inch) section or 6 millimeters (0.25 inch) diameter, each of which has a total throw of at least 12 millimeters (0.5 inch), the bolt handles returnable into a holding recess.

A safe or cabinet shall be rigidly and securely fixed to a wall or floor by means of at least two rag-bolts each passing through an internal anchor plate of mild steel which is of at least 3 millimeters (0.13 inch) in thickness and which has a surface area of at least 19,355 square millimeters (30 square inches). Nothing shall be displayed outside a safe or cabinet to indicate that controlled medicines are kept inside it.

### 12.6. Quality of Narcotic and Controlled Medicines in Storage

Quality assurance procedures for narcotic and controlled medicines will follow the same procedures as detailed in the national pharmaceutical quality assurance policy (4,1,1) with the exceptions that sampling of narcotic and
controlled medicines will NOT be open to the public. Any witnesses requested to view the sampling must be registered pharmacists or clinicians).

12.6.1. **Openness**

Wherever possible:

- Quality Assurance meetings will be open to the public and the meeting minutes will be available.
- Product specifications will be clearly stated and based on published information.
- Sampling procedures will be open and available to the public.
- Independent parties/bodies are encouraged to attend to witness sampling.
- Testing and verification of products will be based on published methodologies.
- Results of testing will be made public (provided that there is no legal or regulatory impediment).
- Enforcement actions will be publically announced (provided there is no legal or regulatory impediment).

For security reasons, announcements of actions relating to narcotic and psychotropic products may need to be delayed so as not to compromise the security of location of such materials.

- The sampling officers must be registered pharmacists, approved by NMRA to undertake sampling functions, and then further approved by NMRA-CMD to undertake sampling of controlled medicines. (Information note: Current QA policy does not require sampling officers (of general medicines) to be registered pharmacists, but does require that they be certified/approved by NMRA.)
- At least two sampling officers must be present when sampling of controlled medicines take place.
- NMRA-CMD will review the rate and quantity of sampling to ensure that it is reasonable.
- NMRA will issue special forms to document the sampling of narcotic and controlled medicines which has taken place so that inventory levels of narcotic and controlled medicines can be adjusted for the samples
taken. These forms must be signed by at least two sampling officers. Deteriorated, obsolete, expired, damaged, banned, and unwholesome medicines must be properly documented and separated from the main medicines in all warehouses and storage sites. They should then disposed of in accordance with national disposal guidelines, under the supervision of the NMRA-CMD, and in such a way which precludes their use by any person, and with minimal environmental impact.

NMRA will issue detailed instructions and forms for the disposal of expired or damaged narcotic and controlled medicines. In general, all such medicines will be physically sent to NMRA-CMD for them to ensure full documentation and correct disposal; however if large volumes are present, NMRA-CMD can elect to visit the holding/storage site and witness disposal if a minimum of two accredited officers are present.

12.7. Transporting narcotic and controlled medicines
All licensees should have an agreed set of SOPs for transport of narcotic and controlled medicines, which all staff are aware of and follow. These SOPs should include procedures to cover the following:

- Responsibility—where it rests, how far it extends, whether and to whom it can be delegated
- Record keeping—what is to be recorded, when and in what form it is to be recorded; who is to record it, where and for how long are records to be kept
- Reconciliation—what is to be checked, who is to check it, when are the checks to be made, who is to investigate discrepancies, what enquiries investigators are to make
- Reporting—when should thefts/losses be reported, who reports thefts/losses to the NMRA-CMD and the police.

NMRA-CMD will review and approve the licensees’ SOPs as part of the licensing process.

As a guiding principle, narcotic and controlled medicines being transported between licensees remain the responsibility of the original licensee until ownership is transferred to the recipient (e.g., a customer or patient). As a
result, while narcotic and controlled medicines are in transit, responsibility for their security remains with the owner (normally the supplier) and does not transfer to either the courier or the customer until the medicines arrive at their destination and are signed for.

To enhance security, it is good practice that details of particular deliveries/shipments (contents, times, routes, etc.) are restricted to those who need to know them. Transfers of narcotic and controlled medicines by “cross docking” or otherwise transferring narcotic and controlled medicines stocks directly between vehicles is not permitted.

**Vehicles**

- All road vehicles carrying narcotic and controlled medicines should be in good repair and maintained in accordance with the manufacturer’s recommendations. The vehicles should have adequate locking systems and be fitted with anti-theft devices (alarms, immobilizers).
- Vehicles must be full enclosed. The use of curtain-sided vehicles is not permitted.
- Drivers should have comprehensive and readily understandable instructions covering both routine and emergency (delays, attempted theft, etc.) situations. Carrying unauthorized passengers and making visits to their homes or unauthorized locations is not permitted.
- Route and times of delivery vehicles should be varied where this is a practicable option.
- Where vehicles make multiple deliveries, the driver should only leave the vehicle unattended for the minimum period necessary. Whenever practical (and lawful), the vehicle should be parked during these absences in a location where any attempt to break into the vehicle is likely to be observed (i.e., a busy location).
  - Vehicles should be secured at all times when they are left unattended, even if for a very short time. Strict key security should prevail to minimize the risk of unauthorized access to the medicines, whether by drivers or others. Where a vehicle contains a separate narcotic and controlled medicines cabinet equivalent to a narcotic and controlled medicines cabinet on the licensee’s
premises, the key should not be left unattended in the vehicle during deliveries but should remain on the driver’s person. The cabinet should be bolted to the main chassis of the vehicle in a way which makes it very difficult/impossible to remove quickly.

- Tamper-evident containers or packages should be used for all consignments.
- Where a vehicle undertakes a delivery lasting more than one day, particular care should be given to the overnight security of the vehicle, even when it is standard practice for a member of the vehicle’s crew to sleep in the vehicle. The preferred option would be to transfer the load to a store at premises with the appropriate level of physical security.

Thefts and losses

- Any thefts or losses occurring during transportation must be reported immediately to the NMRA-CMD and the local police force.
- When thefts/losses occur, the suppliers are must submit a theft and losses report form to the NMRA-CMD as soon as possible. Once the incident has been investigated and new procedures have been put in place to prevent a similar incident from happening again, suppliers are expected to submit a full incident report to the NMRA-CMD. Failure to do so may have a negative impact on future license applications and is likely to result in a contravention being issued against the licensee.

Emergency procedures during transport

- All suppliers’ SOPs should contain procedures for emergency situations or unscheduled interruptions during transit such as vehicle breakdown. These should be communicated to the drivers and recognize the possibility that an accident or other incident could be perpetrated with the intention of attacking a vehicle transporting narcotic and controlled medicines.
- Whenever an accident occurs which requires the attendance of the emergency services, the police should be made aware of the incident and the vehicle’s contents as soon as possible.
- For deliveries of large amounts of narcotic and controlled medicines,
suppliers should consider warning emergency services in advance so that if an accident occurs, their response takes the contents of the consignment into account.

- For particularly high-risk consignments, suppliers should consider a system whereby a staff member is “on call” to go and collect a particular consignment in the event of a vehicle breakdown. In this situation, ideally the relief vehicle will have the same security set up as the original one. However, this may not always be possible and where it is not, priority should be given to getting the narcotic and controlled medicines to a secure location as quickly as possible.
- Should there be any threats to delivery staff from people trying to steal the controlled medicines en route, staff should not risk their safety to prevent the theft. Instead, the staff should call the police as soon as possible to inform the authorities.
13. FINANCING OF NARCOTIC AND CONTROLLED MEDICINES

13.1. Guiding principle for financing narcotic and controlled medicines
Narcotic and controlled medicines should be financed in exactly the same way as all other medicines required for Afghanistan as described in the National Medicines policy Section 11.

13.2. Guiding principle for financing of regulatory procedures (licensing) of narcotic and controlled medicines
The guiding principle for the financing of operating costs for narcotic and controlled medicines functions is that the regulatory activities should be largely self-financing with income collected from licenses, charges, and fees for medicine activities.
It is recognized that in the short to medium term (five years) collected income is unlikely to be able to meet the anticipated large cost requirements for establishing enhanced narcotic and controlled medicines functions, especially for inspection and enforcement services, and also the human resources development costs for extensive staff training. Nevertheless, the key principle of eventual complete self-financing of regulatory functions should be established.

13.3. License fees and regulatory charges
The NMRA-CMD should meet at least yearly to set the overall guidance target (budget) cost level of narcotic and controlled medicines regulatory activities, expected to be generally less than 1% of the FOB (Free on Board) cost of the total narcotic and controlled medicines annual importation.
This established target guidance (budget) level should set the charge for the licenses, import permits for importation of medicines, and other regulatory functions concerning narcotic and controlled medicines. For example, if NMRA-CMG establish a budget for Controlled Medicines regulatory functions which equates to X% of the estimates total Controlled Medicines value, then a charge equivalent to X% of the medicine cost should be made for all import permissions/licenses.
13.4. Donations of Narcotic and Controlled Medicines
In general, because of the complex regulatory requirements, specific donations of narcotic and controlled medicines will not be solicited, except in emergency situations as described in Section 1.3 of this document (also refer to Paragraph 11.2).
When donations of narcotic and controlled medicines do occur:

- All donors of narcotic and controlled medicines will be requested to contribute the same import license fee value as all other sources of supply to enable narcotic and controlled medicines regulatory activities to be undertaken. (i.e., no exemption of license fees for donor financed products).
- All donations will be subject to the same controlled medicines regulations as all other controlled medicines, i.e., the requirements of this policy will apply to donations as well.
14. LOCAL MANUFACTURE

14.1. Basic principles
The same basic principles for local manufacturer of narcotic and controlled medicines as expressed in the NMP and QA Policy for all medicines shall apply.

14.2. Manufacturer responsibility
The manufacturer is responsible for the quality of the medicine that it has produced/marketed and must take all precaution to ensure the safety and quality of the products produced.

14.2.1. Promotion of local manufacture of narcotic and controlled medicines
The standard conditions for promotion of local pharmaceutical manufacturers as expressed in the NMP and QA policies shall apply to the promotion of the local manufacture of narcotic and controlled medicines with the added conditions that:

- Extra consideration shall be given to the security conditions and site before promotion of narcotic and controlled medicines manufacturing takes place.
- Security issues will be discussed with the security agencies and narcotics control (abuse/misuse) authorities and a consensus agreement achieved before any promotion of local manufacture of controlled medicines takes place.

In accordance with the National Medicines Policy of Afghanistan, the Government of Afghanistan encourages the local pharmaceutical industry to continuously work toward meeting high quality manufacturing standards essential and complementary medicines needed in Afghanistan and for export.

- The Government will actively encourage local manufacturing companies to produce licensed medicines that are of the same standard of quality and reasonably comparable in terms of cost to the corresponding items from foreign suppliers.
- Such support may involve a degree of preference in procurement, provision of training, export incentives or tax relief, or other measures that are acceptable in normal commercial practice, regulation, law, and international agreements. The Government may also promote
collaboration with other countries to develop local production, where appropriate, of raw materials or finished products.
- Priority will be accorded to the local production of items.
- The government will support the establishment of industrial parks for local pharmaceutical manufacturing companies.
- It should be clearly recognized that neither other statements within this document or any of the activities undertaken to promote manufacturing of medicines within Afghanistan will in any way exempt or relieve the manufacturer from full compliance with all quality requirement, quality control, and assurance activities, as specified in both Good Manufacturing Practice for pharmaceutical and this policy.

14.2.2. Local Manufacturing Plant/Factories for Narcotic and Controlled Medicines

The standard conditions for the operation of local pharmaceutical manufacturers as expressed in the NMP and QA policies and the need for them to observe GMP will also apply to the local manufacture of narcotic and controlled medicines. Additional conditions, specifically those for controlled medicines as specified in Section 14.2 of this policy will also be applicable.

14.3. Specific conditions for local manufacturers of narcotic and controlled medicines

14.3.1. Registration and licensing of local manufacturers of narcotic and controlled medicines

All manufacturers and all manufacturing sites undertaking the manufacture of narcotic and controlled medicines—as defined in Section 10 of this policy—must be registered and licensed. NMRA-CMD will be the responsible agency for this licensing.

For conditions of licensing and registration of manufacturers of narcotic and controlled medicines, refer to Section 10.1.5 and 10.2 and the following checks and requirements for on all holding positions of authority with the manufacturer of narcotic and controlled medicines:
- Except as hereinafter provided, no person shall obtain a class 1 or 2
license for controlled substances unless he or she employs a full-time pharmacist. and, except as hereinafter provided, no licensed activity shall be conducted by a holder of a class 1 or 2 license unless such activity is under the personal supervision of a pharmacist.

- The responsible officer for the license must be a citizen of Afghanistan or lawfully admitted for permanent residence in the Afghanistan;
- Be age 21 or over;
- Be of good moral character as attested to by affidavits signed by either a responsible government office of the Province of residence, local police officials, or other such persons acceptable to NDRA;
- Not have been convicted of a misdemeanor or felony by any court in Afghanistan;
- Not be, and never have been, a habitual user of narcotics or any other habit-forming drugs.

14.4. **Specific Conditions for Local Manufacturing Factories and Sites**

The conditions for local manufacture of narcotic and controlled medicines are specified in this section and sections 10.2 and 14.3 of this policy. All manufacturers must comply with principles of GMP which include the conditions for the factory and location sites.

When reviewing the license application, NMRA-CMG will pay particular attention to the manufacturing site location and consult with security and law enforcement agencies as to its suitability. As a minimum, the site must have:

- A perimeter fence and lockable/ access control gates
- Perimeter surveillance, e.g., CCTV which is recorded
- External doors (including fire escape doors) manufactured to high security standards
- An access control system with a clear audit trail
- Alarms and alert system for intruder entry

See also **12.2 Conditions and requirements for premises.** The licenses applications must contain details of the proposed security of premises where the controlled medicines are to be manufactured.
15. NARCOTIC AND CONTROLLED MEDICINES PRODUCT RECALLS

15.1. General conditions for controlled medicines product recalls

In general, pharmaceutical product recalls will follow the same conditions and regulation as specified in the National Quality Assurance of Medicines Policy (Section 11) but with additional conditions specified in 15.2 below:

- NMRA will serve as the regulatory body to issue a national pharmaceutical product recall notice.
- NMRA will prepare detailed SOPs for actions to be taken when a recall notice is issued.
- NMRA will determine the class of recall as detailed in Section 12.3 of the National Pharmaceutical Quality Assurance Policy for Pharmaceuticals.
- Medicine manufacturers, exporters, importers and wholesalers shall physically remove all medicines subject to a statutory recall notice from the marketplace and no longer make these medicines available to the public; and ensure that the recalled medicines are segregated and quarantined in secure premises, awaiting further instructions from NMRA as to their eventual disposition.
- Medicine manufacturers, exporters, importers, import and wholesalers shall upon receiving recall notices from NMRA:
  - Notify all medicines wholesalers and retailers and localities where medicines are circulated about the recall;
  - Promptly recall all violating goods items or medicine lots from these units;
  - Make medicine recall dossiers. A standardized medicine recall dossier according to a set form, will show all evidence of the supply of medicines to and recall of medicines from wholesalers, retailers, and users that have purchased medicines;
  - Send reports, that were produced according to NMRA procedures, on the process and results of recall and handling of recalled medicine lots to NMRA and relevant functional agencies within 72 hours for level-1 recalls; and 30 days for level-2 and level-3 recalls.
• All health units, stores, warehouses, and other premises handling controlled medicines shall physically remove all medicines subject to a statutory recall notice from their supply, and ensure that the medicines are separated and quarantined in secure premises, until the health units and other premises receive further instructions from NMRA on the medicines disposal.

15.2. **Specific (additional) conditions for controlled medicines product recalls**

All narcotic and controlled medicines subject to recall procedures (following a statutory notice from NMRA) are to be returned to a central location to be specified by NMRA (usually Central Medical Stores, Kabul) at the manufacturers/distributors expense. Physical destruction of the medicines is to follow standard Write of Disposal Authority procedures with the additional condition that:

• At least two fully qualified pharmacists appointed by NMRA must witness the entire physical destruction procedures.

• Members of the law enforcement agencies (police, counter narcotics) should be invited to witness the physical destruction.

• All of the wrapping, packaging, boxes, labels, and external containers must be destroyed so not to be reused The method of destruction must be such that all and every part of the medicine is physically destroyed and unable to provide any remaining controlled substance (usually by fire).
16. MONITORING AND REPORTING

16.1. Overall responsibility and coordination of data for narcotic and controlled medicines

NMRA will have prime responsibility for overall monitoring and reporting of narcotic and controlled medicines at national level. In particular, the authority will:

- Determine the key indicators to be used for monitoring of narcotic and controlled medicines
- Set the reporting frequency and data formats for reporting from all levels and users of narcotic and controlled medicines
- Collect, collate, and review the information on narcotic and controlled medicines
- Analyze and seek to reconcile the reports of narcotic and controlled medicines manufactured, imported, in stock and used, and produce an overall status report.
- Prepare the estimates of national narcotic and controlled medicine requirements
- Prepare the reports to the International Narcotics Control Board reporting and quantity estimations.

16.2. Key monitoring indicators

In determining the key indicators, NMRA will take into account the WHO Guidelines for Narcotic and Controlled Medicines and seek to monitor:

- Access/availability of narcotic and controlled medicines
- Measures for abuse and misuse prevention
- Rational use of narcotic and controlled medicines

And wherever possible and practical, these indicators should be integrated into the MoPH’s overall medicines monitoring activities. That is, that no separate/unique indicators should be developed for narcotic and controlled medicines monitoring for access/availability and rational medicine use, but rather that this task should be undertaken by including some narcotic and controlled medicines into the tracer medicines lists that are already used for regular pharmaceutical monitoring for access/availability and rational use of
Monitoring for effectiveness of control measures for prevention of abuse and misuse of narcotic and controlled medicines will need to be undertaken in addition to other pharmaceutical activities. Such indicators are complex to develop and implement, and will need to be developed in conjunction with a multidisciplinary team of experts from agencies and stakeholders. Initially, only very basic narcotic and controlled medicines prescription screening is likely to be practical, however, this will eventually develop into a Prescription Drug Monitoring Program.
17. **NARCOTIC AND CONTROLLED MEDICINES POLICY IMPLEMENTATION**

17.1. **Narcotic and controlled medicines sub-policy review**
It is recognized that the implementation of the NCMP will involve many players and will require a high degree of coordination and networking among many bodies, agencies, and private sector operators. To ensure the relevance and applicability of the sub-policy, the NCMPP (Section 6.2.1) will review the policy annually and effect such changes as may be required for better efficiency and coordination among the involved parties.

17.2. **Controlled Medicines Implementation Plan**
The NCMPP will set out priority areas for the narcotic and controlled medicines implementation plan. A National Narcotic and Controlled Medicines Implementation Plan will be developed and adopted by NMRA to facilitate the implementing this policy. NMRA will outline short, medium, and long-term action plans with defined activities, budgets, time frames, responsibilities, and expected outcomes and outputs, as appropriate. The implementation plan will include measures to ensure an adequate national supply of narcotic and controlled medicines including stock holding mechanisms for emergency and disaster situations, as well as establishment of a task force to implement and enforce narcotic and controlled medicines control measures.

17.3. **Controlled medicines control enforcement**
The main feature of the enforcement activities is that, wherever possible and practical, they should not be undertaken as stand-alone/vertical activities, but rather should be integrated into all pharmaceutical enforcement activities. Therefore, inspections of pharmaceutical retail outlet for compliance with narcotic and controlled medicines regulation should be undertaken by the general pharmaceutical retail outlet inspection/enforcement teams—no separate/unique inspections teams are envisioned. A similar approach applies to all levels of narcotic and controlled medicines activity from active pharmaceutical ingredient (API) manufacturers through importers wholesalers to dispensing pharmacies.
17.4. **Narcotic and controlled medicines human resource development**

The MoPH will be the prime body for supporting human resource development for the Controlled Medicines Sub-Policy. The NCMPP will advise the MoPH on the likely human resource requirements for effective implementation and to undertake necessary oversight of controlled medicines in Afghanistan. The NCMPP will seek to engage with academic bodies, training institutions, and professional organizations to raise the profile and awareness of narcotic and controlled medicine matters and include adequate training on professional health care topics and qualification programs.

These programs will include:

- Encouraging wide awareness among the institutions and organization of this policy and its contents and requirements
- Increased understanding among doctors and pharmacists of pain management and the WHO pain ladder approach
- Increase understanding among doctors and pharmacists about safe storage of narcotic and controlled medicines and proper disposal of unused medications, such as through return programs for unused medicines
- Understanding of prescription monitoring programs to identify problem prescribers

17.5. **Narcotic and controlled medicines public awareness development**

One of the most effectiveness ways to reduce misuse of narcotic and controlled medicines is through patient education.

NMRA will be responsible for integrating information and messages on narcotic and controlled medicines into its existing patient education activities.

These are to include:

- Educating the public to understand the risks of controlled medicines use to avoid misuse in the first place
- Increasing patient counseling to help patients understand about safe storage of controlled medicines at home and proper disposal of unused medications, such as through return to pharmacy programs (for unused medicines)
18. SPECIFIC ROLES AND RESPONSIBILITIES FOR CONTROLLED MEDICINES POLICY IMPLEMENTATION

18.1. Active pharmaceutical ingredient manufacturers of controlled medicines based in Afghanistan

In addition to all the regulatory and control requirements specified in this policy, and to be issued as detailed requirements by NMRA, API manufacturers of narcotic and controlled medicines are required to maintain detailed records and ensure that sales of API narcotic and controlled medicines are only made to genuine, authorized pharmaceutical manufacturers.

API manufacturers should provide their products within Afghanistan only to licensed narcotic and controlled medicines pharmaceutical manufacturers or to bodies duly authorized by the NMRA to receive such materials. For exporting narcotic and controlled medicines products outside Afghanistan, API manufacturers should comply with all WHO principles for exports of pharmaceutical products and international conventions for trade in narcotic and controlled medicines and obtain all necessary licenses from NMRA. API manufacturers are responsible to undertake and bear all associated costs for the environmentally safe destruction of all date expired, damaged, or substandard products, and all such destructions must be witnessed by NMRA.

18.2. FPP Manufacturers of Controlled Medicines based in Afghanistan

FPP manufacturers of narcotic and controlled medicines in Afghanistan have the prime responsibility for ensuring the security of the medicine they produce until it is sold on to authorized bodies.

FPP manufacturers of narcotic and controlled medicines should provide their products within Afghanistan only to licensed pharmaceutical distributors, retailers, or any health facilities duly authorized by the NMRA to receive Narcotic and Controlled Medicines. For export of narcotic and controlled medicines products outside Afghanistan, the FPP manufacturer should comply with the WHO principles for exports of pharmaceutical products and the international convention for trade in narcotic and controlled medicines. FPP manufacturers are responsible for undertaking and bearing all associated
costs for the environmentally safe destruction of all date-expired, damaged, or substandard controlled medicines product that has not been already been supplied to distributors/wholesalers or health bodies, and all such destruction must be witnessed by NMRA.

18.3. **API importers of narcotic and controlled medicines**

Only licensed narcotic and controlled medicines pharmaceutical manufacturers or other bodies specifically authorized by the NMRA may apply for permission to import narcotic and controlled medicines API products. All requests for narcotic and controlled medicine API importation must follow, and comply with all the procedures to be specified by the NMRA. Wherever possible, the API should be manufactured to a clearly stated international recognized pharmacopeia standard. In cases where such standard may not be available (new products/formulations), the relevant WHO monograph may be used. If neither is available, the import requestor should register an agreed manufacturing standard with the NMRA.

The standard operations should be that the API importer obtains product directly from the API manufacturer or a WHO/United Nations API approved supply scheme. Only in very special cases (very small volume production runs), should the API product be obtained from a supplier or non-manufacturer source.

In all cases, the API narcotic and controlled medicines importer should use internationally recognized and approved sources of narcotic and controlled medicines API products. As a minimum, the API manufacturer must have a GMP certificate from the country of manufacture and comply with the WHO guidelines for the export of pharmaceutical products and be full authorized to conduct international trade in narcotic and controlled medicines. API importers bear the prime responsibility for ensuring the security of the API they import until it is handed over to a manufacturer.

Importers of narcotic and controlled medicines API products may only supply those products in Afghanistan to licensed pharmaceutical manufacturers or other bodies specifically authorized by the NMRA (e.g., university- pharmacy schools, research laboratories). Provision of narcotic and controlled medicines
API products to wholesalers/distributors/retailers is not permitted without specific and individual authorization from the NMRA.

Controlled medicine API importers are responsible to undertake and bear all associated costs for the environmentally safe destruction of all date-expired, damaged, or substandard product that has not been provided to FPP manufacturers or other authorized bodies; all such destruction must be witnessed by NMRA.

18.4. FPP importers of controlled medicines

FPP importers of narcotic and controlled medicines bear prime responsibility for the security of the medicines they import until the medicines are sold or transferred to another authorized party. All imports should be aware of the security requirements outlined in this policy and the detailed regulations issued by NMRA.

Only licensed narcotic and controlled medicines pharmaceutical manufacturers/ importers/ wholesalers/distributors or other bodies specifically authorized by the NMRA may apply for permission to imports FPPs.

All requests for narcotic and controlled medicines FPPs importation must follow, and comply with all the procedures to be specified by the NMRA.

Standard operations should be that the narcotic and controlled medicines FPP importer obtains narcotic and controlled medicine FPP product directly from the FPP manufacturer or a WHO/United Nations approved supply scheme. Only in special cases (very small volume requirements) should the narcotic and controlled medicines FPP product be obtained from a supplier or non-manufacturer source.

In all cases, the FPP importer should use internationally recognized and approved sources of narcotic and controlled medicines FPPs. As a minimum, the narcotic and controlled medicines FPP manufacturer must have a GMP certificate from the country of manufacture and comply with the WHO guidelines for the export of pharmaceutical products and be authorized to undertake international trade in narcotic and controlled medicines. Importers of narcotic and controlled medicines FPP products may only supply those products in Afghanistan to licensed narcotic and controlled medicines
pharmaceutical wholesalers/distributors/retailers or other health bodies specifically authorized by the NMRA.

Narcotic and controlled medicines FPP importers are responsible for undertaking and bearing all associated costs for the environmentally safe destruction of all date-expired, damaged, or sub-standard product that has not been provided to other authorized bodies; all such destructions must be witnessed by NMRA.

18.5. Narcotic and controlled medicines FPP wholesalers

Narcotic and controlled medicines FPP wholesalers are responsible to ensure the security of the product until it is sold or transferred to another authorized body. The wholesalers should be aware of the security and reporting requirements contained in this policy and the detailed requirements issued by NMRA. They also must be licensed in accordance with the NMRA’s prevailing regulations. Only licensed narcotic and controlled medicines pharmaceutical wholesalers may provide FPP narcotic and controlled medicines to retail pharmacies, health facilities, and other duly authorized bodies.

Narcotic and controlled medicines FPP wholesalers should obtain their medicines only from duly authorized Afghan controlled medicines FPP manufacturers, licensed narcotic and controlled medicines FPP importers, other authorized narcotic and controlled medicines FPP wholesalers, or other bodies duly authorized by the NMRA. Any narcotic and controlled medicines FPP wholesaler that is in possession of narcotic and controlled medicines which are not from authorized sources is liable to the full weight of sanctions as detailed in law and regulation, and to having those medicines seized and destroyed with the cost charged to the wholesaler.

Wherever possible, the Narcotic and Controlled Medicines FPP wholesalers should obtain only those medicines which have been manufactured to a clearly stated international recognized pharmacopeia standard. In cases where such standards may not be available (new products/formulations), the relevant WHO monograph may be used. If neither is available, the import wholesaler should register an agreed manufacturing standard with the NMRA.

FPP wholesalers are responsible for undertaking and bearing all associated
costs for the environmentally safe destruction of all date-expired, damaged, or substandard products which have not been provided to other authorized bodies; all such destruction must be witnessed by NMRA.

18.6. Retail pharmacies (shops) handling narcotic and controlled medicines
Retail pharmacies handling narcotic and controlled medicines must be licensed in accordance with the prevailing regulations of the NMRA. Retail pharmacies should obtain their narcotic and controlled medicines only from duly authorized Afghan FPP manufacturers, licensed FPP importers, other authorized FPP wholesalers, or other bodies duly authorized by the NNMRA. Any retail pharmacy that is in possession of narcotic and controlled medicines that are not from authorized sources is liable to the full weight of sanctions as detailed in law and regulation, and to having those medicines seized and destroyed with the cost charged to the retailer. Retail pharmacies should obtain only those narcotic and controlled medicines which are included in the licensed medicine list of Afghanistan and have been manufactured to a clearly stated international recognized pharmacopeia standard. Retail pharmacies are responsible for the security of the narcotic and controlled medicines in their possession and should be aware of the requirements in this policy and the detailed regulations for the medicines storage reporting and accounting. Retail pharmacies are responsible for undertaking and bearing all associated costs for the return of all unused, date expired, damaged, or substandard products that have not been dispensed to patients or provided to other authorized bodies, to the wholesaler that supplied the medicine to arrange for its destruction.

18.7. Public/governmental sector—national central level
The public national central level, as represented by MOPH, and specifically NMRA, has the prime responsibility to coordinate and oversee narcotic and controlled medicine activities in the country. There is a dual responsibility to ensure the availability of narcotic and controlled medicines to meet all legitimate medical needs and to ensure the control of narcotic and controlled
medicines so as to prevent abuse and misuse. The public national central level will ensure that the public sector will obtain medicines only from duly authorized and clearly identified secure source international suppliers or donors, Afghan FPP manufacturers, licensed FPP importers, other authorized FPP wholesalers, or or other bodies duly authorized by the National Medicine Regulatory Authority. In the case of donations, the central level will advise the donor of the need to comply with the national medicines policy for the donation of medicines, and especially the need to observe the same quality assurance requirements as all over imported medicines to Afghanistan. Further, all donors of medicines will be encouraged to donate at least 5% of the commodity cost of the donated medicines (Delivered Duty Paid [DDP] commodity cost basis) to assist the national regulatory authority undertake narcotic and controlled medicines functions.

Wherever possible, the public national central level should obtain only those medicines that have be manufactured to a clearly stated international recognized pharmacopeia standard. In cases where such standard may not be available (new products/formulations), the relevant WHO monograph may be used. If neither is available, the import wholesaler should register an agreed manufacturing standard with the NMRA.

The public national central level is responsible for undertaking and bear all associated costs for the environmentally safe destruction of all date- expired, damaged, or substandard product that has not been provided to other authorized bodies.

Public/governmental sector provincial level
The public provincial level has the prime responsibility to ensure the quality of the medicines it procures and supplies. In conjunction with the NMRA, it will arrange for a quality assurance program to at least Category 1 level as described in section 4.4 of this policy.

The public provincial level should obtain their medicines only from public sector central level duly authorized Afghan FPP manufacturers, licensed FPP importers, other authorized FPP wholesalers, or through donors or other
bodies duly authorized by the NMRA. In the case of donations, the public provincial level will advise the donor of the need to comply with the national medicines policy for the donation of medicines, and especially the need to observe the same quality assurance requirements as all other imported medicines to Afghanistan. Further, all donors of medicines will be encouraged to donate at least 5% of the commodity cost of the donated medicines (DDP commodity cost basis) to assist the national regulatory authority undertake quality assurance activities, on the donated medicines. Wherever possible, the public provincial level should obtain only those medicines which have be manufactured to a clearly stated international recognized pharmacopeia standard. In cases where such standard may not be available (new products/formulations), the relevant WHO monograph may be used. If neither are available, the import wholesaler should register an agreed manufacturing standard with the NMRA.

18.8. Public/Governmental Sector Provincial Level
The role of the provincial level has not yet been clearly defined but is expected to include delegated authority to enforce and monitor all narcotic and controlled medicines activity under the direction of NMRA.

18.9. Dispensing pharmacies in hospitals and clinics, including all public/ governmental, nongovernmental organizations, and private sector
Dispensing pharmacies should obtain their medicines only from duly authorized sources, which may include public sector central and provincial level supplies, Afghan FPP manufacturers, authorized FPP wholesalers, licensed retail pharmacies, other health facilities, or other bodies duly authorized by the NMRA to handle narcotic and controlled medicines. Any dispensing pharmacy that is in possession of controlled medicines which are not from authorized sources is liable to the full weight of sanctions as detailed in law and regulation, and to having those medicines seized and destroyed with the cost charged to the retail pharmacy owner. Dispensing pharmacies should obtain only controlled medicines which are included in the licensed medicine list of Afghanistan and have been
manufactured to a clearly stated international recognized pharmacopeia standard. Dispensing pharmacies are encouraged to develop detailed written SOPs for the handling of narcotic and controlled medicines. Dispensing pharmacies are responsible to undertake and bear all associated costs for the environmentally safe destruction of all date expired, damaged or sub-standard narcotic and controlled medicines, in accordance with the procedures issued by NMRA, which has not been dispensed to patients or provided to other authorized bodies.
GLOSSARY

Abuse is defined by the WHO Expert Committee on Drug Dependence as “persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice” (1) Abuse of a substance is a term in wide use but can vary in meaning. The term abuse is sometimes used disapprovingly to refer to any drug use at all, particularly of illicit drugs. Because of its ambiguity, “abuse” is not used in ICD-10, except in the case of non-dependence-producing substances; harmful use and hazardous use are the equivalent terms in WHO usage, although they usually relate only to effects on health and not to social consequences (2) The international drug conventions use the word “abuse” and not “misuse” or “harmful and hazardous use”; therefore, these guidelines use this word frequently, in particular when in relation to the conventions or their objectives.

Accessibility is the degree to which a medicine is obtainable for those who need it at the moment of need with the least possible regulatory, social or psychological barriers.

Affordability is the degree to which a medicine is obtainable for those who need it at the moment of need at a cost that does not expose them to the risk of serious negative consequences such as not being able to satisfy other basic human needs.

Agonist is a substance that binds to a receptor of a cell and triggers a response by that cell. Agonists often mimic the action of a naturally occurring substance.

Analgesic is a medicine that reduces pain.

Antagonist is a substance that blocks the action of an agonist.

Availability is the degree to which a medicine is present at distribution points in a defined area for the population living in that area at the moment of need.

Consumption statistics have to be reported by governments to the International Narcotics Control Board (INCB) annually and represent the amounts of narcotic medicines that were distributed in the country to the
Controlled medicines are medicines containing controlled substances or medicinal products under control to spice that gets called by the Ministry of public health has been classified among the Spice production, distribution, supply and trading (purchase, sale, import and export) them in the context of the law and regulations and under the supervision of special is possible.

1.2. This definition is all the chemicals with the name of the medicine or the international non-proprietary name (INN) in the current list of the international drug control board, INCB corresponds to seasoning drugs (1961 Convention and the 1972 reformed) and Spice psychotropic (1971 Convention) are on the take.

Controlled substances are the substances listed in the international drug control conventions.

Convention is a formal agreement between States. The generic term “convention” is thus synonymous with the generic term “treaty”. Conventions are normally open for participation by the international community as a whole, or by a large number of States. Usually the instruments negotiated under the auspices of an international organization are entitled conventions.

Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a medicine used on its main indication in adults.

Dependence is defined by the WHO Expert Committee on Drug Dependence as “A cluster of physiological, behavioral and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behavior. Determinants and problematic consequences of drug dependence may be biological, psychological or social, and usually interact.” Dependence is clearly established to be a disorder. WHO’s International classification of diseases, 10th Edition (ICD-10) requires for ependence syndrome that three or more of the following six characteristic features have been experienced or exhibited:

- A strong desire or sense of compulsion to take the substance
- Difficulties in controlling substance-taking behavior in terms of its onset,
termination, or levels of use

- A physiological withdrawal state when substance use has ceased or been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or a closely related) substance with the intention of relieving or avoiding withdrawal symptoms
- Evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses
- Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects;
- Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm

The Expert Committee on Drug Dependence (ECDD) concluded that “there were no substantial inconsistencies between the definitions of dependence by the ECDD and the definition of dependence syndrome by the ICD-10.”

**Diversion** refers to the movement of Narcotic and Controlled Medicines from licit to illicit distribution channels or to illicit use.

**Essential medicines** (for children) are those medicines that are listed on the WHO Model List of Essential Medicines or the WHO Model List of Essential Medicines for Children. Both model lists present a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions.

**Estimates** of the requirements for controlled substances for legitimate purposes have to be submitted to INCB by the national competent authority. For narcotic drugs and for certain precursor chemicals, estimates have to be submitted to INCB annually and for psychotropic substances, simplified estimates (known as assessments) have to be submitted at least every three years.

Law refers to collection of legal rules that are mandatory in accordance with the 94th sentence of article Afghan Constitution and have been adopted during the stages of both the Houses, and the President of Afghanistan has endorsed; or refers to a set of rules on a specific topic enacted by the legislative body at the national, state or local level and having binding legal force.

Legislation refers to all rules having binding legal force at the national, state, or local level.

Maintenance therapy (or opioid substitution therapy) with long-acting opioid agonists for the treatment of opioid dependence involves relatively stable doses of the agonists (usually methadone or buprenorphine) prescribed over prolonged periods of time (usually more than six months), which allows stabilization of brain functions and prevention of craving and withdrawal.

Misuse (of a controlled substance) for the purposes of these guidelines, is defined as the non-medical and non-scientific use of substances controlled under the international drug control treaties or under national law.

Narcotic drugs is a legal term that refers to all those substances listed in the Single Convention.

National authority, in these guidelines, refers to any government institution involved with the issues discussed in this document. The term applies not just to national government institutions but may equally apply to other relevant institutions in the national territory involved with these issues, such as federal, state or provincial institutions.

National competent authority, in these guidelines, refers to any government agency responsible under its national law for the control or regulation of a particular aspect of the country’s controlled substances legislation, in particular to issue certificates and authorizations for the import and export of
narcotic drugs and psychotropic substances.

**Opioid** literally means “opium-like substance.” It can be used in different contexts with different but overlapping meanings:

- **Botanical:** chemical substances belonging to the class of alkaloids produced by the poppy plant (*Papaver somniferum L.*). They can also be called natural opioids. Some of them (e.g. morphine and codeine) have analgesic properties (“pain killers”); others do not.

- **Chemical:** chemical substances having similar structural formulas as morphine, codeine and other natural opioids (the benzylisoquinoline structure). They may be natural or synthetic. An example of a (semi-) synthetic opioid is buprenorphine.

- **Pharmacological:** chemical substances having similar pharmacological activity as morphine and codeine, i.e. analgesic properties. They can stem from the poppy plant, be synthetic or even made by the body itself (endorphins), and they may be structurally related to morphine or not. An example of a synthetic opioid not structurally related to morphine is methadone.

**Overly restrictive law or regulation:** In these guidelines, the term “overly restrictive law or regulation” refers to drug regulatory provisions that either:

- do not materially contribute to the prevention of misuse of the controlled medicines but do create an impediment to their availability and accessibility; or

- have the potential to prevent the misuse of narcotic and controlled medicines but disproportionately impede their availability and accessibility.

**Party or State Party** to a treaty is a country that has ratified or acceded to that particular treaty, and is therefore legally bound by the provisions in the instrument.

**Preamble.** An introductory statement (e.g., to a convention).

**Psychotropic substances.** A legal term that refers to all those substances listed in the Convention on Psychotropic Substances.
Rational (medical) use, for the purposes of these guidelines, is defined as the appropriate use of a medicine by both health professionals and consumers in their respective roles. Rational medical use aims at meeting the clinical needs of the individual patient by prescribing, dispensing, and administering effective medicines for the medical condition of the patient, at the adequate dose, within the required time schedule and for the required amount of time to treat or cure the patient’s medical condition; it should also enable the patient to adhere to such treatment.

Regulation refers to a set of rules on a specific topic with binding legal force at the national, state or local level and enacted by an administrative body to which the authority to issue such rules has been delegated by the national, state or local legislative body.


Tolerance refers to a reduction in the sensitivity to a pharmacological agent following repeated administration, in which increased doses are required to produce the same magnitude of effect.

Withdrawal syndrome is the occurrence of a complex (syndrome) of uncomfortable symptoms or physiological changes caused by an abrupt discontinuation or a dosage decrease after repeated administration of a pharmacological agent. Withdrawal syndrome can also be caused by the administration of an antagonist.

Yellow List. List of narcotics defined by the International Narcotics Control Board as being under international control (annex A).
REFERENCES


INCB. 2013. List Of Narcotic Drugs Under International Control (Yellow List). Vienna, INCB.

INCB. n.d. International guidelines for national regulations concerning travellers under treatment with internationally controlled drugs.


World Health Organization (WHO). 2011. Ensuring balance in national policies


ANNEX A. LIST OF NARCOTIC DRUGS UNDER INTERNATIONAL CONTROL

International Narcotics Control Board
Yellow List
Annex to Forms A, B and C
50th edition, December 2011

List Of Narcotic Drugs Under International Control
Prepared by the
International Narcotics Control Board*
Vienna International Centre
P.O. Box 500
A-1400 Vienna, Austria
Internet address: http://www.incb.org/
in accordance with the
Single Convention on Narcotic Drugs, 1961**

* On 2 March 1968, this organ took over the functions of the Permanent Central Narcotics Board and the Drug Supervisory Body, retaining the same secretariat and offices.
* Subsequently referred to as “1961 Convention.”

Purpose
The Yellow List contains the current list of narcotic drugs under international control and additional relevant information. It has been prepared by the International Narcotics Control Board to assist Governments in completing the annual statistical reports on narcotic drugs (Form C), the quarterly statistics of imports and exports of narcotic drugs (Form A) and the estimates of annual requirements for narcotic drugs (Form B) as well as related questionnaires.
The Yellow List is divided into four parts:

**Part 1** provides a list of narcotic drugs under international control in form of tables and is subdivided into three sections:

(1) the first section includes the narcotic drugs listed in Schedule I of the 1961 Convention and/or Group I of the 1931 Convention;
(2) the second section includes the narcotic drugs listed in Schedule II of the 1961 Convention and/or Group II of the 1931 Convention; and
(3) the third section includes the narcotic drugs listed in Schedule IV of the 1961 Convention and/or Group II of the 1931 Convention.

Each section contains tables with 4 columns:

- In the 1st column, the International Drug System (IDS) Codes are provided for each scheduled narcotic drug.
- These codes are assigned to the controlled drugs in the INCB/UNODC drug control system databases containing all submitted statistical data. Narcotic drugs in Forms A, B, C submitted in XML format are as such encoded and can then be directly uploaded into the international drug control databases.
- In order to facilitate identification of all scheduled narcotic drugs, existing CAS (Chemical Abstracts Service) registry numbers are included in the 2nd column. Please note that the absence of a CAS number does not mean that the narcotic drug concerned is not under international control but that the CAS registry number has not been available, as it is the case in some scheduled plant material.
- The drug names listed in the 3rd column correspond to the ones assigned to the narcotic drugs under international control as scheduled in the 1961 Convention and in the official notifications of the Secretary-General of the United Nations. International non-proprietary names (INN) recommended by the World Health Organization are printed in bold type.
- The chemical names/descriptions listed in the 4th column provide additional information for easier identification of the scheduled narcotic drugs.
Part 2 provides a list of the preparations of narcotic drugs exempted from some provisions and included in Schedule III of the 1961 Convention.

Part 3 provides a list (in alphabetical order) of names and trade names of known preparations of narcotic drugs listed in the Schedules of the 1961 Convention.

Please note: The frequent introduction of new preparations of narcotic drugs and the withdrawal of old ones by the pharmaceutical industry makes the regular updating of the present “Yellow List” necessary for the effectiveness of controls. In pursuit of this objective, the International Narcotics Control Board (INCB) maintains a database containing a list of such preparations. Therefore, Governments are kindly requested to inform INCB of any additions, deletions or amendments that should be made to the present list.

Part 4 contains tables showing the pure anhydrous drug content of esters, ethers and salts of narcotic drugs listed in the Schedules as well as the equivalents of certain extracts and tinctures, in terms of the pure anhydrous drug.

For more specific information on the names used for narcotic drugs under international control and preparations containing these narcotic drugs, as well as on chemical and structural formulae and other technical information, please see the “Multilingual Dictionary of Narcotic Drugs and Psychotropic Substances under International Control” (ST/NAR/1/REV.2) 1. United Nations publication, Sales No. M.06.XI.16., December 2006; the publication can also be accessed via the INCB website http://www.incb.org/incb/yellow_list.html.
# Part 1. Narcotic Drugs Under International Control

## Section 1. Narcotic Drugs Included in Schedule I of the 1961 Convention

<table>
<thead>
<tr>
<th>IDS CODE</th>
<th>CAS NO.</th>
<th>NARCOTIC DRUG</th>
<th>CHEMICAL NAME/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA 001</td>
<td>25333-77-1</td>
<td>ACETORPHINE</td>
<td>3-O-acetyltetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-endo-ethenooripavine</td>
</tr>
<tr>
<td>NA 015</td>
<td>101860-00-8</td>
<td>ACETYL-ALPHA-METHYLFENTANYL</td>
<td>N-[1-(α-methylphenethyl)-4-piperidyl]acetonilide</td>
</tr>
<tr>
<td>NA 004</td>
<td>509-74-0</td>
<td>ACETYL METHADOL</td>
<td>3-acetoxy-6-dimethylamino-4,4-diphenylheptane</td>
</tr>
<tr>
<td>NA 014</td>
<td>71195-58-9</td>
<td>ALFENTANIL</td>
<td>N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidiny]-N-phenylpropanamid</td>
</tr>
</tbody>
</table>
### National Medicine Policy For Narcotic and Controlled Medicines

<table>
<thead>
<tr>
<th>IDS CODE</th>
<th>CAS NO.</th>
<th>NARCOTIC DRUG</th>
<th>CHEMICAL NAME/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NC 007</td>
<td>NC 019-NC043</td>
<td>CONCENTRATE OF POPPY STRAW</td>
<td>concentration of its alkaloids when such material is made available in trade, (“Poppy straw”: all parts (except the seeds) of the opium poppy, after mowing)</td>
</tr>
<tr>
<td>ND 002</td>
<td>427-00-9</td>
<td>DESOMORPHINE</td>
<td>Dihydrodesoxymorphine (derivative of morphine)</td>
</tr>
<tr>
<td>ND 003</td>
<td>357-56-2</td>
<td>DEXTROMORAMIDE</td>
<td>(+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl) butyl] morpholine (Dextro-rotatory isomer of moramide)</td>
</tr>
<tr>
<td>ND 005</td>
<td>552-25-0</td>
<td>DIAMPROMIDE</td>
<td>N-[2-(methylphenethylamino)-propyl]propionanilide</td>
</tr>
<tr>
<td>ND 006</td>
<td>86-14-6</td>
<td>DIETHYLTHIAMBUTENE</td>
<td>3-diethylaminopropyl-1,1-di-[2'-thiényl]-1-butenol</td>
</tr>
<tr>
<td>ND 007</td>
<td>28782-42-5</td>
<td>DIFENOXIN</td>
<td>1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecatic acid</td>
</tr>
<tr>
<td>ND 025</td>
<td>14357-76-7</td>
<td>DIHYDROETORPHINE</td>
<td>7,8-dihydro-7α-[1-(R)-hydroxy-1-methylbutyl]-6,14-endo-tetrahydrooripavine Derivative of etorphine</td>
</tr>
<tr>
<td>ND 009</td>
<td>509-60-4</td>
<td>DIHYDROMORPHINE</td>
<td>(derivative of morphine)</td>
</tr>
<tr>
<td>ND 011</td>
<td>509-78-4</td>
<td>DIMENOXADOL</td>
<td>2-dimethylaminoethyl-1-ethoxy-1,1-diphenylacetate</td>
</tr>
<tr>
<td>ND 012</td>
<td>545-90-4</td>
<td>DIMEPHEPTANOL</td>
<td>6-dimethylaminopropyl-4,4-diphenyl-3-heptanol</td>
</tr>
<tr>
<td>ND 014</td>
<td>524-84-5</td>
<td>DIMETHYLTHIAMBUTENE</td>
<td>3-dimethylaminopropyl-1,1-di-[2'-thiényl]-1-butenol</td>
</tr>
<tr>
<td>ND 015</td>
<td>467-86-7</td>
<td>DIOXAPHETYL BUTYRATE</td>
<td>ethyl-4-morpholino-2,2-diphenylbutyrate</td>
</tr>
<tr>
<td>ND 016</td>
<td>915-30-0</td>
<td>DIPHENOXYLATE</td>
<td>1-(3-cyano-3,3-diphenylpropyl)-4-phenylpipideridine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>ND 017</td>
<td>467-83-4</td>
<td>DIPIPANONE</td>
<td>4,4-diphenyl-6-piperidine-3-heptanone</td>
</tr>
<tr>
<td>ND 018</td>
<td>3176-03-2</td>
<td>DROTEBANOL</td>
<td>3,4-dimethoxy-17-methylmorphinan-6β,14-diol</td>
</tr>
<tr>
<td>NE 001</td>
<td>481-37-8</td>
<td>ECgonine</td>
<td>its esters and derivatives which are convertible to ecgonine and cocaine</td>
</tr>
<tr>
<td>NE 004</td>
<td>441-61-2</td>
<td>ETHYLMETHYLTHIAMBUTENE</td>
<td>3-ethylmethylamino-1,1-di-[2'-thiényl]-1-butenol</td>
</tr>
<tr>
<td>NE 006</td>
<td>911-65-9</td>
<td>ETONITAZENE</td>
<td>1-diethylaminoethyl-2-p-ethoxybenzyl-5-nitrobenzimidazole</td>
</tr>
<tr>
<td>NE 007</td>
<td>14521-96-1</td>
<td>ETORPHINE</td>
<td>tetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-endo-thebainipavine (derivative of thebaine)</td>
</tr>
<tr>
<td>NE 008</td>
<td>469-82-9</td>
<td>ETOXERIDINE</td>
<td>1-[2-(2-hydroxyethoxy)-ethyl]-4-phenylpipideridine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NF 001</td>
<td>437-38-7</td>
<td>FENTANYL</td>
<td>1-phenethyl-4-N-propionylanilinopiperidine</td>
</tr>
<tr>
<td>NF 002</td>
<td>2385-81-1</td>
<td>FURETHIDINE</td>
<td>1-[(2-tetrahydrofurufuryloxyethyl)-4-phenylpipideridine-4-carboxylic acid ethyl ester]</td>
</tr>
<tr>
<td>NH 001</td>
<td>561-27-3</td>
<td>HEROIN</td>
<td>diacetylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NH 002</td>
<td>125-29-1</td>
<td>HYDROCODONE</td>
<td>dihydrocodeinone (derivative of morphine)</td>
</tr>
<tr>
<td>NH 003</td>
<td>2183-56-4</td>
<td>HYDROMORPHINOL</td>
<td>14-hydroxydihydromorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NH 004</td>
<td>466-99-9</td>
<td>HYDROMORPHINE</td>
<td>dihydromorphinone (derivative of morphine)</td>
</tr>
<tr>
<td>NH 005</td>
<td>468-56-4</td>
<td>HYDROXYPHETHIDINE</td>
<td>4-m-hydroxyphenyl-1-methylpipideridine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NI 001</td>
<td>466-40-0</td>
<td>ISOMETHADONE</td>
<td>6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone</td>
</tr>
<tr>
<td>NK 001</td>
<td>469-79-4</td>
<td>KETOBEMIDONE</td>
<td>4-m-hydroxyphenyl-1-methyl-4-propionylpipideride</td>
</tr>
<tr>
<td>NL 004</td>
<td>125-70-2</td>
<td>LEVOMETHORPHAN*</td>
<td>(-)-3-methoxy-N-methylmorphinan</td>
</tr>
<tr>
<td>NL 005</td>
<td>5666-11-5</td>
<td>LEVOMORAMIDE</td>
<td>(-)-4-[2-methyl-4-oxo-3,3-diphenyl-4-[1-pyrrolidinyl] butyl] morpholine</td>
</tr>
<tr>
<td>NL 006</td>
<td>10061-32-2</td>
<td>LEVOPHENACYLMORPHAN</td>
<td>(-)-3-hydroxy-N-phenacylmorphinan</td>
</tr>
<tr>
<td>NL 007</td>
<td>77-07-6</td>
<td>LEVORPHANOL*</td>
<td>(-)-3-hydroxy-N-methylmorphinan</td>
</tr>
</tbody>
</table>

* Dextromethorphan ((+)-3-methoxy-N-methylmorphinan) and dextrorphan ((+)-3-hydroxy-N-methylmorphinan) are isomers specifically excluded from this Schedule (and not under international control).
<table>
<thead>
<tr>
<th>IDS CODE</th>
<th>CAS NO.</th>
<th>NARCOTIC DRUG</th>
<th>CHEMICAL NAME/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NM 001</td>
<td>3734-52-9</td>
<td>METAZOCINE</td>
<td>2’-hydroxy-2,5,9-trimethyl-6,7-benzomorphan</td>
</tr>
<tr>
<td>NM 002</td>
<td>76-99-3</td>
<td>METHADONE</td>
<td>6-dimethylamino-4,4-diphenyl-3-heptanone</td>
</tr>
<tr>
<td>NM 003</td>
<td>125-79-1</td>
<td>METHADONE INTERMEDIATE</td>
<td>4-cyano-2-dimethylamino-4,4-diphenylbutane</td>
</tr>
<tr>
<td>NM 004</td>
<td>16008-36-9</td>
<td>METHYLDESORPHINE</td>
<td>6-methyl-Δ6-deoxymorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NM 005</td>
<td>509-56-8</td>
<td>METHYLDIHYDROMORPHINE</td>
<td>6-methyldihydromorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NM 017</td>
<td>42045-86-3</td>
<td>3-METHYL FENTANYL</td>
<td>N-[3-methyl-1-phenethyl-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NM 024</td>
<td>86052-04-2</td>
<td>3-METHYLTHIOFENTANYL</td>
<td>N-[3-methyl-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NM 006</td>
<td>143-52-2</td>
<td>METOPON</td>
<td>5-methyldihydromorphinone (derivative of morphine)</td>
</tr>
<tr>
<td>NM 007</td>
<td>3626-55-9</td>
<td>MORAMIDE INTERMEDIATE</td>
<td>2-methyl-3-morpholino-1,1-diphenylpropane carboxylic acid</td>
</tr>
<tr>
<td>NM 008</td>
<td>469-81-8</td>
<td>MORPERIDINE</td>
<td>1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NM 009</td>
<td>57-27-2</td>
<td>MORPHINE</td>
<td>the principal alkaloid of opium and of opium poppy</td>
</tr>
<tr>
<td>NM 009METH</td>
<td>125-23-5</td>
<td>MORPHINE METHOBROMIDE</td>
<td>AND OTHER PENTAVALENT NITROGEN MORPHINE DERIVATIVES including in particular the morphine-N-oxide derivatives, one of which is codeine-N-oxide</td>
</tr>
<tr>
<td>NM 012</td>
<td>639-46-3</td>
<td>MORPHINE-N-OXIDE</td>
<td>(derivate of morphine)</td>
</tr>
<tr>
<td>NM 018</td>
<td>13147-09-6</td>
<td>MPPP</td>
<td>1-methyl-4-phenyl-4-piperidinol propionate (ester)</td>
</tr>
<tr>
<td>NM 013</td>
<td>467-18-5</td>
<td>MYROPINE</td>
<td>Myristylbenzylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NN 003</td>
<td>639-48-5</td>
<td>NICOMORPHINE</td>
<td>3,6-dinicotinylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NN 004</td>
<td>1477-39-0</td>
<td>NORACYMETHADOL</td>
<td>(+)-α-3-acetoxy-6-methylamino-4,4-diphenylheptane</td>
</tr>
<tr>
<td>NN 006</td>
<td>1531-12-0</td>
<td>NORLEVORPHANOL</td>
<td>(-)-3-hydroxymorphinan</td>
</tr>
<tr>
<td>NN 007</td>
<td>467-85-6</td>
<td>NORMETHADONE</td>
<td>6-dimethylamino-4,4-diphenyl-3-hexanone</td>
</tr>
<tr>
<td>NN 008</td>
<td>466-97-7</td>
<td>NORMORPHINE</td>
<td>demethylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NN 009</td>
<td>561-48-8</td>
<td>NORPIPANONE</td>
<td>4,4-diphenyl-6-piperidino-3-hexanone</td>
</tr>
<tr>
<td>NO 001</td>
<td>8008-60-4</td>
<td>OPIUM*</td>
<td>the coagulated juice of the opium poppy (plant species <em>Papaver somniferum</em> L.)</td>
</tr>
<tr>
<td>NO 010</td>
<td>467-04-9</td>
<td>ORIPAVINE</td>
<td>3-O-demethylthebaine</td>
</tr>
<tr>
<td>NO 002</td>
<td>76-42-5</td>
<td>OXYCODONE</td>
<td>14-hydroxydihydrocodeine (derivate of morphine)</td>
</tr>
<tr>
<td>NO 003</td>
<td>76-41-5</td>
<td>OXYMORPHINE</td>
<td>14-hydroxydihydromorphinone (derivate of morphine)</td>
</tr>
</tbody>
</table>

* For the calculation of estimates and statistics in accordance with the terms of the 1961 Convention, all preparations made direct from opium are considered to be opium (preparations). If the preparations are not made direct from opium itself but are obtained by a mixture of opium alkaloids (as is the case, for example, with pantopon, omnopon and papaveretum) they should be considered as morphine (preparations).
<table>
<thead>
<tr>
<th>IDS CODE</th>
<th>CAS NO.</th>
<th>NARCOTIC DRUG</th>
<th>CHEMICAL NAME/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NF 003</td>
<td>90736-23-5</td>
<td>PARA-FLUOROFENTANYL</td>
<td>4'-fluoro-N-[1-phenethyl-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NP 026</td>
<td>64-52-8</td>
<td>PEPAP</td>
<td>1-phenethyl-4-phenyl-4-piperidinol acetate (ester)</td>
</tr>
<tr>
<td>NP 001</td>
<td>57-42-1</td>
<td>PETHIDINE</td>
<td>1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NP 002</td>
<td>3627-62-1</td>
<td>PETHIDINE INTERMEDIATE A</td>
<td>4-cyano-1-methyl-4-phenylpiperidine</td>
</tr>
<tr>
<td>NP 003</td>
<td>77-17-8</td>
<td>PETHIDINE INTERMEDIATE B</td>
<td>4-phenylpiperidine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NP 004</td>
<td>3627-48-3</td>
<td>PETHIDINE INTERMEDIATE C</td>
<td>1-methyl-4-phenylpiperidine-4-carboxylic acid</td>
</tr>
<tr>
<td>NP 005</td>
<td>467-84-5</td>
<td>PHENADOXONE</td>
<td>6-morpholino-4,4-diphenyl-3-heptanone</td>
</tr>
<tr>
<td>NP 019</td>
<td>129-83-9</td>
<td>PHENAMPROMIDE</td>
<td>N-(1-methyl-2-piperidinoethyl)propionanilide</td>
</tr>
<tr>
<td>NP 008</td>
<td>127-35-5</td>
<td>PHENAZOCINE</td>
<td>2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphan</td>
</tr>
<tr>
<td>NP 009</td>
<td>468-07-5</td>
<td>PHENOMORPHAN</td>
<td>3-hydroxy-N-phenethylmorphinan</td>
</tr>
<tr>
<td>NP 010</td>
<td>562-26-5</td>
<td>PHENOPERIDINE</td>
<td>1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NP 012</td>
<td>13495-09-5</td>
<td>PIMINODINE</td>
<td>4-phenyl-1-(3-phenylaminopropyl)piperidine-4-carboxylic acid ethyl ester</td>
</tr>
<tr>
<td>NP 013</td>
<td>302-41-0</td>
<td>PIRITRAMIDE</td>
<td>1-(3-cyano-3,3-diphenylpropyl)-4-(1-piperidino)piperidine-4-carboxylic acid amide</td>
</tr>
<tr>
<td>NP 014</td>
<td>77-14-5</td>
<td>PROHEPTAZINE</td>
<td>1,3-dimethyl-4-phenyl-4-propionoxyazacycloheptane</td>
</tr>
<tr>
<td>NP 015</td>
<td>561-76-2</td>
<td>PROPERIDINE</td>
<td>1-methyl-4-phenylpiperidine-4-carboxylic acid isopropyl ester</td>
</tr>
<tr>
<td>NR 001</td>
<td>510-53-2</td>
<td>RACEMETHERPHAN*</td>
<td>(±)-3-methoxy-N-methylmorphinan</td>
</tr>
<tr>
<td>NR 002</td>
<td>545-59-5</td>
<td>RACEMORAMIDE</td>
<td>(±)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)butyl]morpholine</td>
</tr>
<tr>
<td>NR 003</td>
<td>297-90-5</td>
<td>RACEMORPHAN*</td>
<td>(±)-3-hydroxy-N-methylmorphinan</td>
</tr>
<tr>
<td>NR 005</td>
<td>132875-61-7</td>
<td>REMIFENTANIL</td>
<td>1-(2-methoxy-carbonyl)ethyl]-4-(phenylpropionylamino)-piperidine-4-carboxylic acid methyl ester</td>
</tr>
<tr>
<td>NS 001</td>
<td>56030-54-7</td>
<td>SUFENTANIL</td>
<td>N-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NT 001</td>
<td>466-90-0</td>
<td>THEBACON</td>
<td>Acetyldihydrocodeinone (acetylated enol form of hydrocodone)</td>
</tr>
<tr>
<td>NT 002</td>
<td>115-37-7</td>
<td>THEBAINE</td>
<td>(an alkaloid of opium; also found in Papaver bracteatum)</td>
</tr>
<tr>
<td>NT 005</td>
<td>1165-22-6</td>
<td>THIOFENTANY</td>
<td>N-[1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NT 003</td>
<td>20380-58-9</td>
<td>TILIDINE</td>
<td>(±)-ethyl-trans-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate</td>
</tr>
<tr>
<td>NT 004</td>
<td>64-39-1</td>
<td>TRIMEPERIDINE</td>
<td>1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine</td>
</tr>
</tbody>
</table>

* Dextromethorphan and dextrorphan are not under international control.
AND the isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the specific chemical designation;
the esters and ethers, unless appearing in another Schedule, of the drugs in this Schedule whenever the existence of such esters or ethers is possible;
the salts of the drugs listed in this Schedule, including the salts of esters, ethers and isomers as provided above whenever the existence of such salts is possible.

Section 2. Narcotic Drugs Included in Schedule II of the 1961 Convention

<table>
<thead>
<tr>
<th>IDS CODE</th>
<th>CAS NO.</th>
<th>NARCOTIC DRUG</th>
<th>CHEMICAL NAME/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA 002</td>
<td>3861-72-1</td>
<td>ACETYLIDihYDROCODeINE</td>
<td>(derivative of codein)</td>
</tr>
<tr>
<td>NC 005</td>
<td>76-57-3</td>
<td>CODEINE</td>
<td>3-methylmorphine (derivative of morphine, alkaloid contained in opium &amp; poppy straw)</td>
</tr>
<tr>
<td>ND 004</td>
<td>469-62-5</td>
<td>DEXTROPROXYPHene</td>
<td>α-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanol propionate (Dextro-rotary isomer of propoxyphene)</td>
</tr>
<tr>
<td>ND 008</td>
<td>125-28-0</td>
<td>DIHYDROCODeINE</td>
<td>(derivative of morphine)</td>
</tr>
<tr>
<td>NE 005</td>
<td>76-58-4</td>
<td>ETHYLmORPhINE</td>
<td>3-ethylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NN 001</td>
<td>3688-66-2</td>
<td>NICOCOdINE</td>
<td>6-nicotinylcodeine (derivative of morphine)</td>
</tr>
<tr>
<td>NN 002</td>
<td>808-24-2</td>
<td>NICODICODINE</td>
<td>6-nicotinylidihydrocodeine (derivative of morphine)</td>
</tr>
<tr>
<td>NN 005</td>
<td>467-15-2</td>
<td>NORCODINE</td>
<td>N-demethylcodeine (derivative of morphine)</td>
</tr>
<tr>
<td>NP 011</td>
<td>509-67-1</td>
<td>PHOLCODINE</td>
<td>morpholinyethylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NP 016</td>
<td>15686-91-6</td>
<td>PROPIRAm</td>
<td>N-(1-methyl-2-piperidinoethyl)-N-2-pyridylpropionamide</td>
</tr>
</tbody>
</table>

AND the isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the specific chemical designation;
The salts of the drugs listed in this Schedule, including the salts of the isomers as provided above whenever the existence of such salts is possible.
Section 3. Narcotic Drugs Included in Schedule IV of the 1961 Convention

<table>
<thead>
<tr>
<th>IDS CODE</th>
<th>CAS NO.</th>
<th>NARCOTIC DRUG</th>
<th>CHEMICAL NAME/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA 001</td>
<td>3861-72-1</td>
<td>ACETORPHINE</td>
<td>3-O-acetyltetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-endo-ethenooripavine (derivative of thebaine)</td>
</tr>
<tr>
<td>NA 015</td>
<td>101860-00-8</td>
<td>ACETYL-ALPHA-METHYL FENTANYL</td>
<td>N-[1-(α-methylphenethyl)-4-piperidyl]acetanilide</td>
</tr>
<tr>
<td>NA 016</td>
<td>79704-88-4</td>
<td>ALPHA-METHYL FENTANYL</td>
<td>N-[1-(α-methylphenethyl)-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NA 017</td>
<td>103963-66-2</td>
<td>ALPHA-METHYL THIOFENTANYL</td>
<td>N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NB 009</td>
<td>78995-10-5</td>
<td>BETA-HYDROXY FENTANYL</td>
<td>N-[1-(β-hydroxyphenethyl)-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NB 010</td>
<td>78995-14-9</td>
<td>BETA-HYDROXY-3-METHYL FENTANYL</td>
<td>N-[1-(β-hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NC 001</td>
<td>8063-14-7</td>
<td>CANNABIS AND CANNABIS RESIN</td>
<td>The flowering or fruiting tops of the cannabis plant (resin not extracted) The separated resin, crude or purified, obtained from the cannabis plant</td>
</tr>
<tr>
<td>NC 008</td>
<td>6465-30-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ND 002</td>
<td>427-00-9</td>
<td>DESOMORPHINE</td>
<td>dihydrodesoxymorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NE 007</td>
<td>14521-96-1</td>
<td>ETORPHINE</td>
<td>tetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-endo-ethenooripavine (derivative of thebaine)</td>
</tr>
<tr>
<td>NH 001</td>
<td>561-27-3</td>
<td>HEROIN</td>
<td>Diacetylmorphine (derivative of morphine)</td>
</tr>
<tr>
<td>NK 001</td>
<td>469-79-4</td>
<td>KETO BEMIDONE</td>
<td>4-m-hydroxyphenyl-1-methyl-4-propionylpiperidine</td>
</tr>
<tr>
<td>NM 017</td>
<td>42045-86-3</td>
<td>3-METHYL FENTANYL</td>
<td>N-[3-methyl-1-phenethyl-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NM 024</td>
<td>86052-04-2</td>
<td>3-METHYL THIOFENTANYL</td>
<td>N-[3-methyl-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NM 018</td>
<td>13147-09-6</td>
<td>MPPP</td>
<td>1-methyl-4-phenyl-4-piperidinol propionate (ester)</td>
</tr>
<tr>
<td>NF 003</td>
<td>90736-23-5</td>
<td>PARA-FLUOROFENTANYL</td>
<td>4’-fluoro-N-[1-phenethyl-4-piperidyl]propionanilide</td>
</tr>
<tr>
<td>NP 026</td>
<td>64-52-8</td>
<td>PEPAP</td>
<td>1-phenethyl-4-phenyl-4-piperidinol acetate (ester)</td>
</tr>
<tr>
<td>NT 005</td>
<td>1165-22-6</td>
<td>THIOFENTANYL</td>
<td>N-[1-[2-(thienyl)ethyl]-4-piperidyl]propionanilide</td>
</tr>
</tbody>
</table>

AND the salts of the drugs listed in this Schedule whenever the formation of such salts is possible.
Part 2. Preparations of Narcotic Drugs Exempted from Some Provisions and which are Included in Schedule III of the 1961 Convention

Preparations of

1. ACETYLDIHYDROCODEINE, CODEINE, DIHYDROCODEINE, ETHYLMORPHINE, NICOCODINE, NICODICODINE, NORCODEINE, PHOLCODINE
   *when compounded with one or more other ingredients* and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 per cent in undivided preparations.

2. PROPIRAM
   *Containing not more than 100 milligrams of PROPIRAM per dosage unit and compounded with at least the same amount of methylcellulose.*

3. DEXTROPROPOXYPHENE
   For oral use containing not more than 135 milligrams of DEXTROPROPOXYPHENE base per dosage unit or with a concentration of not more than 2.5 per cent in undivided preparations, *provided* that such preparations do not contain any substance controlled under the 1971 Convention on Psychotropic Substances.

4. COCAINE
   Containing not more than 0.1 per cent of cocaine calculated as COCAINE base; and OPIUM or MORPHINE
   *Containing* not more than 0.2 per cent of MORPHINE calculated as anhydrous MORPHINE base *and compounded with one or more other ingredients* and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

5. DIFENOXIN
   Containing, per dosage unit, not more than 0.5 milligram of DIFENOXIN *and a quantity of atropine sulfate equivalent to at least 5 per cent of the dose of DIFENOXIN.*

6.
7. **DIPHENOXYLATE**
   Containing, per dosage unit, not more than 2.5 milligrams of DIPHENOXYLATE calculated as base and a quantity of atropine sulfate equivalent to at least 1 per cent of the dose of DIPHENOXYLATE.

8. **Pulvis Ipecacuanhae Et Opii Compositus**
   10 per cent OPIUM in powder;
   10 per cent *ipecacuanha* root, in powder well mixed with
   80 per cent of any other powdered ingredient containing no drug.

9. Preparations conforming to any of the formulas listed in this Schedule and mixtures of such preparations with any material which contains no drug.
ANNEX B. SUBSTANCES LISTED IN THE CONVENTION ON PSYCHOTROPIC SUBSTANCES OF 1971

International Narcotics Control Board      FORM P

ANNUAL STATISTICAL REPORT ON SUBSTANCES LISTED IN THE CONVENTION ON PSYCHOTROPIC SUBSTANCES OF 1971

To be furnished to the International Narcotics Control Board (INCB) pursuant to Convention on Psychotropic Substances of 1971: articles 1, 2, 3, 12 and 16 Resolution I of the United Nations Conference for the Adoption of a Protocol on Psychotropic Substances and Economic and Social Council resolutions 1576 (L), 1985/15 and 1987/30)

<table>
<thead>
<tr>
<th>Country or Territory:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent office:</td>
<td></td>
</tr>
<tr>
<td>Title or function:</td>
<td></td>
</tr>
<tr>
<td>Responsible officer’s name:</td>
<td>E-mail:</td>
</tr>
<tr>
<td>Telephone number(s):</td>
<td>Fax number(s):</td>
</tr>
<tr>
<td>Signature:</td>
<td>Calendar year:</td>
</tr>
</tbody>
</table>

The present form can also be downloaded from the INCB website: http://www.incb.org/documents/Psychotropics/forms/P/Form_P_2015/Form_P ENG_2015_New.pdf. Please consider submitting this form using XML format.
The present form should be completed as soon as possible and not later than 30 June of the year following the year to which the statistical data relate.
This form should be completed and sent to:
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 or 26060-5868
E-mail: secretariat@incb.org, Psychotropics@incb.org   Home page: www.incb.org
Instructions
(to be read carefully before completing the form)

General
1. All psychotropic substances under international control are listed in the
annex to the annual statistical report ("Green List"), which is distributed
to Governments annually by the International Narcotics Control Board
(INCB).

2. This form is divided into three parts:
   - **Part one.** Statistical data on the manufacture, utilization, stocks, imports
     and exports of substances in Schedules I, II, III and IV of the 1971
     Convention and their salts;
   - **Part two.** Trade details: statistical data on imports and exports of
     substances in Schedules I, II, III and IV of the 1971 Convention;
   - **Part three.** Statistical data on the use of substances in Schedules I, II, III and
     IV of the 1971 Convention for the manufacture of other psychotropic
     substances.

3. In order to ensure the accurate completion of the form, it should be borne
in mind that the terms used have the same meanings as those given in
article 1 of the Convention on Psychotropic Substances of 1971, for
example:
   - (a) "Export" and "import" mean in their respective connotations the
     physical transfer of a psychotropic substance from one State to another
     State;
   - (b) "Manufacture" means all processes by which psychotropic substances
     may be obtained, and includes refining as well as the transformation
     of psychotropic substances into other psychotropic substances. The
     term also includes the making of preparations other than those made
     on prescription in pharmacies;
   - (c) "Psychotropic substance" means any substance, natural or synthetic,
     or any natural material in Schedule I, II, III or IV of the Convention. The
     schedules are amended from time to time according to a procedure
     established in article 2 of the Convention;
   - (d) "Region" means any part of a State that, pursuant to article 28, is
treated as a separate entity for the purposes of the Convention. The term “region” corresponds to the term “territory” used in the other statistical forms of INCB;

(e) “Schedule I”, “Schedule II”, “Schedule III” and “Schedule IV” mean the correspondingly numbered lists of psychotropic substances annexed to the Convention, as altered in accordance with article 2.

4. The statistical data entered on the form should be expressed in terms of the pure anhydrous base of each psychotropic substance contained in salts and preparations, excluding the weight of any non-psychotropic substance that may be combined or mixed with it. The weight should be reported in grams for psychotropic substances listed in Schedules I and II and in kilograms for substances listed in Schedules III and IV. A table of the conversion factors needed to convert quantities of psychotropic substances in salt form into quantities of pure anhydrous base content is provided in part three of the “Green List”.

5. In the case of preparations containing two or more psychotropic substances, data relating to each substance should be entered separately.

Remarks

6. In the space provided for remarks on page 1, the reporting authority may communicate to INCB any information facilitating the proper understanding of the reported statistical data. Such information may, for example, refer to a substance that was put under international control only during the year to which the report relates, in which case the reporting authority may wish to inform INCB that statistical data relating to that substance cover only the period following the date on which the inclusion of the substance in the relevant schedule of the 1971 Convention became fully effective (see article 2 of the Convention) and not the whole calendar year. Other information such as losses in the manufacturing process or seizures of psychotropic substances may also be reported under “Remarks.”
Part one. Statistical data on the manufacture, utilization, stocks, imports and exports of substances in Schedules I, II, III and IV of the 1971 Convention and their salts

Column 1 (Substance)
7. The psychotropic substances are referred to either by their international non-proprietary names (INN) or by the other non-proprietary or trivial names indicated in the schedules of the 1971 Convention. The chemical name of each psychotropic substance may also be found in the schedules or in part one of the “Green List”.

Column 2 (Quantity manufactured)
8. For each psychotropic substance, the reporting authority should indicate the total quantity manufactured domestically between 1 January and 31 December of the year to which the statistical data relate. The quantities of psychotropic substances used for the preparation of pharmaceutical dosage forms should not be included under column 2 (Quantity manufactured). However, in the case of a continuous manufacturing process that does not go through the intermediate stage of the manufacture of psychotropic substances in bulk form, but uses non-psychotropic starting material and directly leads to the final preparations containing psychotropic substances, the data on quantities manufactured under column 2 should include the quantities of the psychotropic substances contained in the manufactured preparations.

Column 3 (Quantity used for the manufacture of non-psychotropic substances or products)
9. For each psychotropic substance listed in Schedules II, III and IV, the reporting authority should indicate the quantity used for the manufacture of non-psychotropic substances or products (permitted under article 4, paragraph (b), of the 1971 Convention). That quantity should include the total amount placed in the manufacturing process during the year to which the statistical data relate, even if the manufacturing process was not completed by the end of that year. Not applicable for substances in Schedule I.
Column 4 (Quantity used for the manufacture of preparations exempted under article 3, paragraphs 2 and 3)

10. For each psychotropic substance listed in Schedules II and III, the reporting authority should indicate the total quantity used for manufacture of preparations exempted from certain measures of control (permitted under article 3, paragraphs 2 and 3, of the 1971 Convention). That quantity should include the total amount placed in the manufacturing process during the year to which the statistical data relate, even if the manufacturing process was not completed by the end of that year. The quantities reported with respect to substances in Schedule II should be expressed in grams and those reported with respect to substances in Schedule III in kilograms. Figures for psychotropic substances in Schedule IV may also be reported (in kilograms). Not applicable for substances in Schedule I.

Column 5 (Manufacturers’ stocks as at 31 December)

11. For each psychotropic substance listed in Schedules I and II, the reporting authority should indicate (in grams) the quantity held in stock by manufacturers on 31 December of the year to which the statistical data relate. Figures for psychotropic substances in Schedules III and IV may also be reported (in kilograms).

Columns 6 (Imports) and 7 (Exports)

12. Statistical data should be based, to the extent possible, on actual movements across borders.

13. For each psychotropic substance listed in Schedules I and II, the reporting authority should indicate (in grams) the total quantity imported in column 6 and the total quantity exported in column 7; these quantities must be detailed by country or region of origin in section V and by country or region of destination in section VI.

14. For each psychotropic substance listed in Schedules III and IV, the reporting authority should indicate (in kilograms) the total quantity imported in column 6 and the total quantity exported in column 7. Pursuant to Economic and Social Council resolution 1985/15 of 28 May 1985, the quantities reported in column 6 may be detailed by country or region...
of origin in section VII, entitled “Trade details: import of substances in Schedules III and IV, by country or region of origin”, and the quantities reported in column 7 may be detailed by country or region of destination in section VIII, entitled “Trade details: export of substances in Schedules III and IV, by country or region of destination”.

**Column 8 (Consumption)**

15. For each psychotropic substance listed in Schedules I, II, III and IV, the reporting authority should indicate (in grams or kilograms, as applicable) the quantity consumed during the year in question, i.e., supplied to any person or enterprise for retail distribution, medical use or scientific research.

**Part two. Trade details: statistical data on imports and exports of substances in Schedules I, II, III and IV of the 1971 Convention**

16. The term “import”, as used in the 1971 Convention, is intended to include, as far as possible, the entrance of goods from abroad into a bonded warehouse, free port or free zone; similarly, the term “export” is intended to include the dispatch of goods abroad from a bonded warehouse, free port or free zone, although such transactions may not be treated by the national customs laws as imports and exports. However, care should be taken to ensure that goods passing through customs from a bonded warehouse, free port or free zone into the country or region itself are not recorded as imports, and that goods transferred from the country or region itself into a bonded warehouse, free port or free zone situated in the country or region are not recorded as exports. However, if a consignment passes in transit through a country or region to another country, it should not be considered by the country or region through which it passes as an import and subsequent export, even if the consignment is placed temporarily in a bonded warehouse, free port or free zone.

17. Goods returned by a country or region, for any reason whatsoever, to the original exporting country or region shall be entered as an export by the former and as an import by the latter.

18. In section V, entitled “Trade details: import of substances in Schedules I and
II, by country or region of origin”, for each substance listed in Schedules I and II, indicate the name of the substance, the total quantity imported as reported in column 6 (in grams) in sections I and II and, under “Imported from”, the name of the exporting country or region.

19. In section VI, entitled “Trade details: export of substances in Schedules I and II, by country or region of destination”, for each of the substances reported in Schedules I and II, indicate the name of the substance, the total quantity exported as reported in column 7 (in grams) in sections I and II and, under “Exported to”, the name of the importing country or region.

20. In section VII, entitled “Trade details: import of substances in Schedules III and IV, by country or region of origin”, for each substance listed in Schedules III and IV, the quantities reported in column 6 in sections III and IV may be detailed by country or region of origin. In section VIII, entitled “Trade details: export of substances in Schedules III and IV, by country or region of destination”, for each substance listed in Schedules III and IV, the quantities reported in column 7 in sections III and IV may be detailed by country or region of destination.

Part three. Statistical data on the use of substances in Schedules I, II, III and IV of the 1971 Convention for the manufacture of other psychotropic substances

21. Countries and territories are requested to provide information, on a voluntary basis, on the use of psychotropic substances listed in Schedules I, II, III and IV for the manufacture of other psychotropic substances, indicating the name of the source substance, the quantity used in the manufacturing process, the name of the other psychotropic substance derived from the manufacturing process and the quantity of that substance derived from the manufacturing process.

Part one. Statistical data on the manufacture, utilization, stocks, imports and exports of substances in Schedules I, II, III and IV of the 1971 Convention and/or their salts
I. Statistical data on substances in Schedule I and/or their salts (Grams)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Quantity manufactured</th>
<th>Quantity used for the manufacture of non-psychotropic substances or products</th>
<th>Quantity used for the manufacture of preparations exempted under article 3, paragraphs 2 and 3</th>
<th>Manufacturers’ stocks as at 31 December</th>
<th>Total imports (these quantities must be detailed by country or region of origin in section V)</th>
<th>Total exports (these quantities must be detailed by country or region of destination in section VI)</th>
<th>Quantity consumed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD 009 Brolamfetamine (DOB)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PC 010 Cathinone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>PT 002 Tetrahydrocannabinol, the following isomers and their stereochemical variants: Δ⁶⁵¹⁰(α), Δ⁶⁵⁷, Δ⁷, Δ⁸, Δ⁹ and Δ⁹(α)</td>
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(Not applicable)

Requested on a voluntary basis, pursuant to Commission on Narcotic Drugs resolution 54/6.
### II. Statistical data on substances in Schedule II and/or their salts (Grams)

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<th>Substance</th>
<th>Quantity manufactured</th>
<th>Quantity used for the manufacture of non-psychotropic substances or products</th>
<th>Quantity used for the manufacture of preparations exempted under article 3, paragraphs 2 and 3</th>
<th>Manufacturers' stocks as at 31 December</th>
<th>Total imports (these quantities must be detailed by country or region of origin in section V)</th>
<th>Total exports (these quantities must be detailed by country or region of destination in section VI)</th>
<th>Quantity consumed</th>
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<td>PD 010&lt;sup&gt;*&lt;/sup&gt; Delta-9-THC</td>
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<sup>c</sup> This refers to delta-9-tetrahydrocannabinol and its stereo chemical variants from synthetic origin. Information on delta-9-tetrahydrocannabinol originating from the cannabis plant (Indian hemp) should be reported as a narcotic drug in Form C (Annual statistics of production, manufacture, consumption, stocks and seizures of narcotic drugs) in terms of cannabis resin or cannabis extract. Requested on a voluntary basis, pursuant to Commission on Narcotic Drugs resolution 54/6. By its decision 56/1, the Commission decided to transfer gamma-hydroxybutyric acid from Schedule IV to Schedule II of the Convention on Psychotropic Substances of 1971. In accordance with article 2, paragraph 7 of that Convention, the decision became fully effective with respect to each Party on 4 December 2013.

### III. Statistical data on substances in Schedule III and/or their salts (Kilograms)

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105
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<th>Substance</th>
<th>Quantity manufactured</th>
<th>Quantity used for the manufacture of non-psychotropic substances or products</th>
<th>Quantity used for the manufacture of preparations exempted under article 3, paragraphs 2 and 3</th>
<th>Manufacturers’ stocks as at 31 December (voluntary)</th>
<th>Total imports</th>
<th>Total exports</th>
<th>Quantity consumed*</th>
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*Requested on a voluntary basis, pursuant to Commission on Narcotic Drugs resolution 54/6.
IV. Statistical data on substances in Schedule IV and/or their salts (Kilograms)

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<th>Quantity used for the manufacture of preparations exempted under article 3, paragraphs 2 and 3 (voluntary)</th>
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### National Medicine Policy For Narcotic and Controlled Medicines

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*Requested on a voluntary basis, pursuant to Commission on Narcotic Drugs resolution 54/6.*
ANNEX C. MODEL FORM OF CERTIFICATE FOR CONTROLLED MEDICINES CARRIED BY TRAVELERS

This is Model form of a certificate for travelers under treatment who have been legally prescribed medical preparations containing narcotic drugs and/or psychotropic substances.

https://www.incb.org/incb/en/psychotropic-substances/travellers_guidelines.html#annex1

A. Country and place of issue
Country:
Place of issue:
Date of issue:
Period of validity *:

B. Prescribing physician
Last name, first name:
Address:
Phone: country code, local code, number
Number of license:

C. Patient
Last name, first name:
Sex:
Place of birth:
Date of birth:
Home address:
Number of passport or of identity card:
Intended country of destination:

D. Prescribed medical preparation
Trade name of drug (or its composition):
Dosage form:
Number of units (tablets, ampoules etc.):
International name of the active substance:
Concentration of active substance:
Total quantity of active substance:
Instructions for use:
Duration of prescription in days:
Remarks:
E. Issuing authority
Official designation (name) of the authority:
Address:
Phone: country code, local code, number
Official seal of the authority:
Signature of responsible officer: