National Policy for Waste Management and Safe Disposal of Pharmaceutical Products
PREFACE

This is the overall policy document for Waste Management and Safe Disposal of Pharmaceutical system for Afghanistan’s pharmaceutical sector. This policy constitutes part of ongoing efforts by the Ministry of Public Health (MoPH) and other stakeholders to ensure from safe disposal and quite protection of environment; the goal of this document is to provide a comprehensive waste disposal system for medicines so as to ensure their safe destruction in a cost-effective and efficient manner; and to do this whilst also providing full protection of the environment.

This comprehensive policy of medicines waste disposal covers the entire process of waste pharmaceuticals disposal from identification, classification, write-off disposal authorization (WODA) accounting, and inventory management procedures; to ensuring that generally accepted accounting practices are fully maintained; to detailed methods of physical destruction and discharge to minimize the potential environmental impact. It takes full cognizance of international treaties on environmental protection to which Afghanistan is a signatory, as well Afghan environmental protection laws and regulations. Strategies for maintaining international technical cooperation to face both regional and international developments—especially in handling the rapid development of newer medicines and the need for their eventual disposal—are included together with systems for monitoring and evaluating implementation with a role of reducing the volumes of future waste generation.

This National Policy for Waste Management and Safe Disposal of Pharmaceutical Products was developed through a systematic and internationally accepted process by using a task force of key technical stakeholders—the Waste Management and Safe Disposal of Pharmaceutical Products Policy Task Force (WMSDPPTF)—established under the direct supervision and leadership of the MoPH. The WMSDPPTF consulted widely and reviewed the current pharmaceutical and environmental protection situation in Afghanistan. An initial draft National Policy for Waste Management and Safe Disposal of Pharmaceutical Products was developed. 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-upon components of this policy.

I am very optimistic that all stakeholders involved in the development of 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 pharmaceutical sector. 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 United States Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH) for the tremendous technical support; I also thank the WMSDPPTF, MC and NMFB members and all those who contributed to developing this policy.

Dr. Ferozuddin Feroz
Minister of Public Health
ACKNOWLEDGMENTS

This policy naturally drawn upon (and been developed based on) the outline provided in the National Medicine Policy, closely follows all World Health Organization (WHO) recommendations and Afghanistan NEPA requirements for waste management and safe disposal of pharmaceutical, and is in accordance with the realities of the criteria and needs the pharmaceutical sector in Afghanistan. It has been drafted through a systematic process that provided consultative access to all concerned and involved stakeholders.

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 Zekria Fatehzada, Head of Inspection Department/ GDPA
- Pharmacist Mohmmad Naim Yaqobi, Representative from HLIED
- Mr. Mohammad Osman Mohahed, Representative from NEPA
- Pharmacist Mohammad Shamim Nabil, Representative from BDN
- Pharmacist Mohammad Nazir Heidarzad, GDPA
- Pharmacist Noor Ahmad Zulal, Regulatory Consultant/GDPA
- Pharmacist Nematullah Nawrozian, NMFB Advisor,
- Pharmacist Hashmatulla Sadat, NMFB Advisor

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- Pharmacis Mohammad Basir, Regulatory Systems Advisor/SPS
- Pharmacist Mohammad Zafar Omari, Chief of Party/ SPS
- Pharmacist Sayed Murtaza Sadat, Technical Office/SPS
- Dr. Andy Barraclough, SPS consultant in 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 (GDPA) further expresses its gratitude to the Strengthening Pharmaceutical Systems (SPS) Project for providing technical support in development of this policy document, with the financial assistance of US Agency for International Development (USAID).
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<th>Description</th>
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<tbody>
<tr>
<td>API</td>
<td>Active pharmaceutical ingredient</td>
</tr>
<tr>
<td>BPHS</td>
<td>Basic Package of Health Services</td>
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<td>CM</td>
<td>Controlled medicine</td>
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<tr>
<td>DDP</td>
<td>Delivered, duty paid (INCO term)</td>
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<tr>
<td>DHO</td>
<td>District Health Office</td>
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<td>DTC</td>
<td>Drug and therapeutics committee</td>
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<td>EML</td>
<td>Essential Medicines List</td>
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<tr>
<td>EPA</td>
<td>Environmental Protection Agency (US)</td>
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<tr>
<td>EPHS</td>
<td>Essential Package of Hospital Services</td>
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<tr>
<td>FBO</td>
<td>Faith-based organization</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration (US)</td>
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<td>FOB</td>
<td>Free on board (INCO term)</td>
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<tr>
<td>FPP</td>
<td>Finished pharmaceutical product</td>
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<tr>
<td>GDPA</td>
<td>General Directorate of Pharmaceutical Affairs</td>
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<td>GM</td>
<td>Geiger-Müller</td>
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<td>HPW</td>
<td>Hazardous pharmaceutical waste</td>
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<tr>
<td>IDPIG</td>
<td>International Drug Price Indicator Guide (from MSH)</td>
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<tr>
<td>IFRS</td>
<td>International Financial Reporting Standards</td>
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<tr>
<td>INCB</td>
<td>International Narcotics Control Board</td>
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<tr>
<td>INCO</td>
<td>International Commercial Terms</td>
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<tr>
<td>INN</td>
<td>International Nonproprietary Name</td>
</tr>
<tr>
<td>IUD</td>
<td>Intrauterine device</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>LD50</td>
<td>Lethal Dose 50%; The amount of a material, given all at once, which causes the death of 50% of a group of test animals</td>
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<tr>
<td>LML</td>
<td>Licensed Medicines List</td>
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<tr>
<td>MoF</td>
<td>Ministry of Finance</td>
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<tr>
<td>MoPH</td>
<td>Ministry of Public Health</td>
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<tr>
<td>NEPA</td>
<td>National Environmental Protection Agency</td>
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<tr>
<td>NGO</td>
<td>Nongovernmental organization</td>
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<tr>
<td>n-HPW</td>
<td>Non-hazardous pharmaceutical waste</td>
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<tr>
<td>NMP</td>
<td>National Medicine Policy</td>
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<tr>
<td>NMPTF</td>
<td>National Medicine Policy Task Force</td>
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<td>NMRA</td>
<td>National Medicines Regulatory Authority</td>
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<tr>
<td>NMRA-CMG</td>
<td>National Medicines Regulatory Authority–Controlled Medicines Group</td>
</tr>
<tr>
<td>PGM</td>
<td>Public-sector general medicine</td>
</tr>
<tr>
<td>PHO</td>
<td>Provincial Health Office</td>
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<tr>
<td>PRV</td>
<td>Private-sector general medicines</td>
</tr>
<tr>
<td>QC</td>
<td>Quality control</td>
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<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
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<tr>
<td>TM</td>
<td>Traditional medicine</td>
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<tr>
<td>TPE</td>
<td>Total pharmaceutical expenditure</td>
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<tr>
<td>U-list</td>
<td>US RCRA list of chemical entities known to be damaging to the environment</td>
</tr>
<tr>
<td>USD</td>
<td>United States dollar</td>
</tr>
<tr>
<td>WDPPTF</td>
<td>Waste Disposal of Pharmaceutical Products Policy Task Force</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<td>-------------------------------------------------------</td>
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<tr>
<td>WODA</td>
<td>Write-off disposal authorization</td>
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<tr>
<td>WODA-CM</td>
<td>Write-off disposal authorization for controlled medicines</td>
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<tr>
<td>WODA-PGM</td>
<td>Write-off disposal authorization for public general medicine</td>
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<tr>
<td>WODA-PRV</td>
<td>Write-off disposal authorization for the private sector</td>
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1. INTRODUCTION

1.1. Introduction to Waste Disposal of Pharmaceutical Products: General

The management and safe disposal of pharmaceutical products has been a consistent challenge throughout the world. With the marked increase in the volume of distribution of pharmaceutical products, pharmaceutical supply chains must address problems posed by the growing presence of expired and unusable products in order to ensure orderly drug distribution processes.

The process of removing pharmaceuticals for disposal from inventory and satisfying all necessary accounting functions is usually referred to as WODA, or write-off disposal authorization.

Failure to dispose of pharmaceutical products in a timely manner can seriously adversely affect the functioning of the medicines supply chain, by occupying much needed storage space and distribution capacity, and thus have a detrimental effect on the provision of healthcare.

In effect, there is a two-stage process to manage disposal of pharmaceutical products: the WODA to ensure that correct accounting and financial control and inventory management procedures are applied, and then the physical destruction process.

Products disposed of improperly have the potential to contaminate the atmosphere and water supplies, or harm communities through scavenging or diversion back to the market for resale.

Management of pharmaceutical waste is a challenge, and that challenge is increasing as the volume of pharmaceuticals in use increases.

From the outset, it must be recognized that pharmaceutical waste is not one single waste stream, but many distinct waste streams that reflect the complexity and diversity of the chemicals that comprise pharmaceuticals. Pharmaceutical waste is potentially generated through a wide variety of activities in the supply chain and distribution, within healthcare facilities, including but not limited to intravenous (IV) preparation, general compounding, spills/breakage, partially used vials, syringes, and IVs, discontinued, unused preparations, unused unit dose repacks, patients’ personal medications and outdated pharmaceuticals.

Pharmaceutical waste is complex. It arises from multiple sources.

Proper pharmaceutical waste management is a highly complex new frontier in environmental management for most healthcare facilities. A retail/commercial pharmacy generally stocks more than 1,000 different items, each of which must be evaluated for potential hazardous waste handling. Pharmacists and nurses generally do not receive training on hazardous waste management during their academic studies, and safety and environmental services managers may not be familiar with the active ingredients and formulations of pharmaceutical products.

Environmental management for pharmaceutical waste is complex. Few healthcare staff have training in environmental management, and few environmental staff have the skill sets to understand pharmaceutical products. Developing clear, simple policies and procedures for handling pharmaceutical waste is essential; and in the longer term, waste management functions must be incorporated into healthcare training.
1.2. Introduction to Waste Disposal of Pharmaceutical Products: Afghanistan

Afghanistan-Specific Information

During 2014, the Ministry of Public Health (MoPH) General Directorate of Pharmaceutical Affairs (GDPA) undertook a review and small-scale survey of the situation on waste disposal of pharmaceuticals.

Although Afghanistan already has a pharmaceutical products waste disposal operation, the current operations is generally believed to have many shortfalls:

- The current system of waste disposal is viewed as being substantially dysfunctional.
- It is believed that the current process timeline is measured in one to two years, giving rise to large stocks of unviable materials which occupy valuable pharmaceutical warehouse storage space, but which cannot be removed until authorization is received. This further contributes to inaccurate stock records.
- There appear to be seriously misplaced perceptions on the volumes of materials being destroyed, giving rise to credibility issues in the efficiency and effectiveness of the supply chain and importing.
- There appear to be public concerns on environmental issues on current destruction procedures.

A questionnaire relating to waste management of pharmaceutical issues has been developed by a GDPA task force and applied at GDPA and Pharmaceutical Importers Enterprises to collect available information.

The collected data from the questionnaires are incomplete, and at times confusing and contradictory. They cannot provide a good quantitative measurement, but they are good enough to identify what cannot be the case. The also provide enough information to act as an indication of the extent of the problem, to identify key problem areas, and to contribute to debunking some of the more serious erroneous misconceptions concerning waste disposal of pharmaceutical products in Afghanistan.

The importance of removing erroneous perceptions on waste disposal of pharmaceutical products needs to be stressed. These perceptions have proved to be pervasive and enduring. If not checked, they have the power to influence major changes to the medicines supply chain, which would be wasteful, costly, and significantly detrimental to effective operation of the supply chain.

The results of the analysis indicate that:

- Even if the entire national pharmaceutical supply to Afghanistan (including both public- and private-sector supplies) were immediately sent to wastage (i.e. 100% wastage), it would still only represent (in per capita terms), less than the pharmaceutical wastage generated in the US and Europe. Afghanistan is simply not buying or receiving enough medicine to generate a major waste disposal problem from pharmaceuticals.
- The volume of the total annual, national, estimated waste disposal requirement for pharmaceuticals in the public and private supply chain for Afghanistan is likely to be less than the current domestic garbage collection in Kabul city in two hours.
- Even if the entire annual national reported volume of seizures of sub-standard medicines were to be dumped all at one time, into the Kabul domestic garbage landfill site (an
unlikely event since it would require a convoy of 30 trucks) it would be “diluted” to less than 1% of the Kabul city domestic garbage mix within a week.

- The relative volumes between domestic garbage collection and pharmaceutical waste indicates that disposal of pharmaceutical waste in domestic garbage landfill sites can be an effective disposal method since the pharmaceutical waste will be heavily “diluted” by the domestic waste.

- Even allowing for price differentials in medicines, the potential environmental impact of pharmaceuticals in Afghanistan is still likely to be at least 10 times less than in the US/Europe on a land area per square kilometer calculation.

- There are no effective systems in operation for any part of the WODA process; that is, the process of formally accounting for the removal of the stock from inventory/financial records and authorizing its destruction.

- This situation needs to be addressed.

Concerns arise because:

- The lack of a clear WODA procedure means that stocks scheduled for destruction must be held for an inordinate length of time—typically reported as in excess of one year—until final authorization can be achieved for their destruction. These stocks are occupying badly needed warehouse space, and thereby reducing the flow capacity of the main medicines supply.

- The actual destruction process. Whilst volumes are not likely to be high, there can be a danger that if disposal is not correctly managed, then damaged/used/expired products can find their way back into the marketplace. Practically, it is a very easy process to ensure products for disposal cannot be re-used, but without adequate written procedures and monitoring oversight an element of risk remains.

Overall Conclusions

- The volume of pharmaceutical waste currently being generated is not of a high enough volume to create a significant environmental or waste management problem.

- The lack of clear WODA procedures does mean that there are long delays in obtaining the necessary authorizations for product destruction. This adversely impacts the flow of the main medicine supply, and uncertainty about destruction brings a risk of possible product re-use.

- It is strongly recommended that detailed WODA procedures for pharmaceutical products be developed and implemented, and that, in the implementation process, consideration be given to reducing misconceptions of pharmaceutical waste volumes.

Afghanistan-Specific Environmental Law

Key points from the law:

- The public has a right to information; the state has a duty to provide information.

- Liaison with and possible licensing from the National Environmental Protection Agency (NEPA) is essential.
Separation/sorting/segregation of waste, and especially of hazardous waste, is necessary.
Export of waste is not permitted (see also section 1.2.3).

Afghanistan-Specific International Agreements and Treaties

Afghanistan is a signatory to the Basel Convention on the Control of Trans boundary Movements of Hazardous Wastes and Their Disposal.

This includes two key requirements relevant to the situation in Afghanistan: Restrictions on exporting waste (Trans boundary movements) AND use of incinerators.

Whilst the exact interpretation of this convention is complex, in can be considered to imply that Afghanistan should not seek to export its pharmaceutical waste but should deal with the problem in country.

**Particular note should be taken of the Basel Convention in the event of an international pharmaceutical manufacturer product recall.**

If the medicine is considered to be hazardous or toxic, it may not be possible to return the medicine to the manufacturer (since that would constitute a trans boundary movement), and it would have to be destroyed in country. Returning medicines to an overseas manufacturer is often not a viable option because of the Basel Convention requirements.

**Previous Policies**

In the past, a range of policies/procedures has been developed to handle pharmaceutical waste disposal, but these policies have not always been seamless, and there has been less-clear direction in ensuring their implementation.

This policy seeks to draw together all pharmaceutical aspects of waste disposal of pharmaceuticals and to strike the balance between risk and cost-effectiveness in developing effective operational approaches.

The key feature of this policy—which follows both international conventions and World Health Organization (WHO) guidance—is that of the **public health imperative**.

Disruption to the medicines supply chain must be minimized so as not to jeopardize public health, and disposal must be undertaken in an environmentally secure manner so as not to threaten public health and/or the environment.

**1.3. Waste Disposal Policy for Pharmaceuticals in Context**

An effective waste disposal policy for pharmaceuticals cannot operate in isolation. It must be an integral part of and fully compatible with, overall health policies and all medicine activities, and endeavor to operate seamlessly across the different stakeholders involved.

This National Policy for Waste Disposal of Pharmaceutical Products has been formulated in full recognition of its context within the structures of MoPH commitment to the pharmaceutical sector and Afghanistan’s National Medicine Policy (NMP) of 2014.
MoPH Commitment to Strengthening the Pharmaceutical Sector

For some time now, the MoPH has demonstrated a strong commitment to strengthening the pharmaceutical sector. For example, the MoPH has continuously supported the pharmaceutical and laboratory services despite its budgetary challenges. Furthermore, various task forces, including the National Medicines Policy Task Force (NMPTF), were established at the national level to lead the development of appropriate strategies for medicines.

Building on these developments, this policy document has adopted a similar approach and proposed the use of a National Waste Disposal of Medicines Task Force to ensure the effective coordination and implementation of pharmaceutical waste disposal activities across the many different structures and active players involved in WODA and waste disposal functions.

Afghanistan National Medicine Policy (NMP) 2014

The following section appears in the NMP:

PHARMACEUTICAL WASTE DISPOSAL

Introduction

The current volume of medicines used in Afghanistan is low by world standards, and any system of disposal must be firmly in keeping with the realities of current volumes and especially with economic activity levels.

World Health Organization Guidelines in conjunction with the Afghanistan Environmental Protection Agency will be used as the guiding base for developing effective disposal policies. As a guiding principle for budgeting purposes, 1% of the cost of all medicines to be provided in Afghanistan should be allocated for pharmaceutical product waste management activities. The goal of this section is to protect the health of the public from potential harm which may result from the unsafe or ineffective disposal of expired, damaged or otherwise unwanted medical items including pharmaceuticals.

Objective

To institute and maintain a system which will ensure the safe, cost effective and controlled disposal or destruction of such items.

Disposal of expired, damaged, falsified/counterfeit or otherwise unwanted drugs and medical supplies

- The NMRA, in cooperation with relevant agencies will be responsible to establish national guidelines for the disposal of these items within the context of an overall national health care waste management plan.
- In accordance with clause 5.6 of this Policy, the Drug and Therapeutic Committees at all levels will be responsible for the implementation of the national disposal guidelines as they relate to pharmaceutical products.
- The national guidelines for disposal of pharmaceutical products will include safe and cost-effective strategies and procedures for:
Elements to be included in national pharmaceutical training curricula at academic institutions
- Training program for workers handling disposal items
- Identification of drugs and medical supplies waste
- Handling of waste products
- Collection
- Segregation of different product types
- Storage
- Transport
- Disposal/destruction
- Record keeping

NMRA will be responsible to systematically monitor and evaluate the implementation of the drugs and medical supplies waste management plan and make any necessary amendments to the national guidelines.

This draft waste disposal policy document seeks to incorporate all the relevant elements from the NMP and build on that structure to provide greater levels of detail for waste disposal policy together with an outline plan for the implementation of pharmaceutical waste disposal activities.

1.4. Defining Pharmaceuticals for Waste Disposal

For the purposes of this policy, the term “pharmaceuticals” follows the WHO definition below.

Pharmaceutical product: Any medicine, medicinal product, herbal medicine, and any substance included in any publication mentioned in the Medicines Laws of Afghanistan 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.

This policy does not apply to clinical/surgical waste.

This policy does not apply to health products and in-vitro diagnostic products.

Defining Controlled Medicines for Waste Disposal

Controlled medicines are defined as all categories of medicines determined to be controlled medicines by the National Policy for Controlled Medicines and the detailed list prepared by the National Medicines Regulatory Authority–Controlled Medicines Group (NMRA-CMG).

1.5. Defining WODA

WODA is a formalized procedure that follows International Financial Reporting Standards (IFRS) to recognize that the value of an asset is now zero, and to adjust all financial, accounting, and inventory management records accordingly.
1.6. Defining Waste Disposal

Pharmaceutical waste disposal requires two conditions to be met:

- Disposal must be undertaken so as to ensure that the product cannot be reused, scavenged, or have any realistic prospect of sale or (re) entry into the pharmaceutical marketplace.
- Disposal must be undertaken to ensure minimal environmental impact and assure public health safety.

1.7. Terminology

This policy aims to use clear, unambiguous terminology throughout this policy and to encourage such use in all policies, legislation, regulation, and procedures involving waste disposal of pharmaceutical issues.

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.

1.8. Caveats and Cautions

Clinical waste: This policy does not apply to clinical waste.

2. GOALS AND OBJECTIVES

2.1. Goals

The goals of this National Policy for Waste Management and Safe Disposal of Pharmaceutical Products 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 by providing mechanisms and procedures to:

- Reduce the potential for the accumulation of waste pharmaceutical products to adversely affect the efficient functioning of the medicines supply chain, and especially to avoid restricting available storage space.
- Prevent products scheduled for destruction to (re)enter the marketplace and/or supply chain, by ensuring that they are degraded beyond all reasonable possibility of reuse.
- Minimize the possibility that pharmaceutical disposal/destruction has any significant environmental or public health impact, by ensuring use of environmentally sound and proven techniques.
- Ensure correct accounting and financial management to adequately account for the value and physical presence of the medicines to be destroyed, and to ensure medicines control procedures, especially for controlled medicines.

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

The objectives of this document are to provide the policy, mechanisms, and systems to ensure the efficient and cost-effective management of the waste disposal functions for pharmaceutical products, in keeping with maintaining full public health and environmental safety considerations.

These policies will apply to:
- All importers, wholesalers, stock-holders, stores, retail pharmacies handling medicines
- Public, private, nongovernmental organization (NGO), and faith-based organization (FBO) sectors
- All pharmacists, physicians, dentists, nurses, and other recognized health professionals dispensing or providing medicines
- Academia handling medicines
- Healthcare professionals’ organizations
- Organizations whose area of work or interest involves the provision of medicines

2.3. Scope of the Policy and Implementation Guide

This guide covers all medicines scheduled for disposal.

Special, additional conditions apply for controlled medicines.

Different conditions apply to the application of WODA activities in the public and private sectors, but physical disposal methods are common to all operational sectors throughout the policy.

3. APPLICABILITY OF THIS POLICY

3.1. Pharmaceutical Products

This policy applies to the following:

**Medicines as Finished Pharmaceutical Products (FPPs):** All medicines that are presented in a finished dosage form, having undergone all stages of production, including packaging in a final container and labeling. A medicine is defined 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.

**Medicines as Active Pharmaceutical Ingredients (APIs):** APIs include any medicine, substance, or mixture of substances intended for use 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 Medicines:** Prepared or compounded medicines are comprised of 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. These medicines are prepared by compounding, mixing, admixing, modifying, or adjusting an API or FPP (usually within a pharmacy setting) that contains any listed medicine or API.

**Traditional/Herbal Medicines:** As defined within the health laws and regulation of Afghanistan, traditional medicine (TM) is a comprehensive term used to refer to any preparation intended for use on humans, developed from either TM systems—such as traditional Chinese medicine, Indian ayurveda, and Arabic unani medicine—and to various forms of indigenous medicine. TM therapies include medication therapies that may involve the use of herbal medicines, animal parts, and/or minerals.¹

### 3.2. Organizations and Bodies

This policy will apply to all bodies, organizations, structures, pharmaceutical manufacturers, pharmaceutical retailers, and pharmaceutical dispensing operations which are involved in manufacturing, compounding, selling, storing, transporting, distributing, sampling, testing, analyzing, dispensing, administering, and receiving medicines for human use in Afghanistan.

### 3.3. Persons, Officers, and Operatives

This policy will apply to all persons who are in possession of, and or/involved in manufacturing, compounding, selling, storing, transporting, distributing, sampling, testing, analyzing, dispensing, and administering medicines for human use in Afghanistan.

### 4. KEY PRINCIPLES

#### 4.1. Openness and Transparency

To ensure the principles of honesty, openness, and transparency are enshrined in all pharmaceutical waste disposal operations and procedures, whilst recognizing the security concerns that are an integral part of such process (especially for controlled medicines), and the need to protect staff, officers, and operatives from security threats and external pressures.

**Openness**

Wherever possible:

- Minutes of waste disposal meetings and operations will be open and available to the public, BUT
  - For controlled medicines, details of specific quantities, importers/wholesalers, locations, transportation, storage sites, and disposal sites will not (normally) be released.
  - For all medicines, exact details of disposal locations will not be released; general details (e.g., Kabul municipal waste disposal site Dashte Chemtala plains) could be permitted.
  - For any cases/products that are intended for, or are undergoing legal action (e.g., seized/confiscated products), any announcements or release of information relating to these items should be delayed (for legal and regulatory reasons) until the conclusion of the legal/regulatory procedures.

¹ [http://www.who.int/medicines/areas/traditional/definitions/en/](http://www.who.int/medicines/areas/traditional/definitions/en/)
An annual summary report should be prepared and released to the public, detailing the total volumes and values destroyed, and relating these figures to total import/use medicines values so as to provide:
- An average wastage figure (percent) for different operations (public/private sectors)
- Value of ceased/confiscated medicines destroyed, by broad categories (e.g., counterfeit or sub-standard)

**Avoidance of Conflict of Interest**

Because of the diversity of interests and perspectives represented by those key players and stakeholders who will implement pharmaceutical waste disposal 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) a transparent and open manner.

This policy shall be interpreted so as to be consistent with the applicable laws and regulations in Afghanistan.

This policy shall apply to all persons and officers undertaking waste disposal of pharmaceutical 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 waste disposal of pharmaceutical activities are required to complete and sign a “no conflict of interest declaration,” and to declare a potential conflict of interest if a situation arises in which such a potential conflict might 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, the 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 particular/specific task.

**4.2. Overall Approach**

Overall approaches to waste management are normally based on the Hierarchy of Waste Management Principles shown in figure 1, which the highly preferred approach is Avoid and Reduce, Reuse and Recycle to least preferred which is Treat and Disposal. All the relevant organizations providing medicine and related services in addition to research centers must be encouraged to design and implement specific method for the further reduction of pharmaceutical waste production. Employees in the organizations must be trained on the reduction of waste production, recycle and reuse of waste.
Whilst such principles naturally form a sound basis for overall approaches for general waste management, unfortunately within the specific status of industrial development and pharmaceutical waste management in Afghanistan at this time, few can be applied to any great practical extent to pharmaceutical waste management. Rather, at this time, the focus should be on ensuring minimum environmental impact on treatment and disposal functions. However, these principles should be acknowledged as overall long-term guidance; as the industrial base develops and total pharmaceutical expenditure (TPE) increases in Afghanistan, they should be reconsidered, as to which practical elements may be included in future waste pharmaceutical management policy reviews.

The overall approach for this policy is therefore to focus on treatment and disposal requirements for pharmaceutical waste.

4.3. Basis for Procedures

All procedures and methodologies will have a clearly documented source:

- For all WODA functions, the basis of the procedures will be IFRS, as defined by financial procedures of the MoPH for the public sector, and the Ministry of Finance and Laws of Afghanistan for the private sector.
- Destruction process for pharmaceutical products will follow WHO guidelines.

Intended destruction procedures relating to environmental discharge, especially for hazardous products, will be discussed and agreed upon with the NEPA.
4.4. Recognition of the Need for Additional Procedures for Controlled Medicines

This policy recognizes the need to ensure that adequate regulatory control is maintained on controlled medicines, and that care must be taken to ensure that disposal of controlled medicines does not become a route for their potential misuse and abuse. This is to be achieved by the inclusion of additional requirements specific to controlled medicines in the WODA procedures and physical destruction requirements of this policy.

Detailed requirements specific to controlled medicines are included in individual policy sections.

4.5. Recognition of the Need for Risk-Management and Cost-Effectiveness Approaches

This policy recognizes the central principle of achieving balance in all issues related to waste disposal of pharmaceuticals.

The central principle of balance represents a series of obligations to establish:

- **Accurate, trustworthy, and credible WODA accounting and inventory adjustments systems**, which are in accordance with IFRS, but still simple and quick to operate. These qualities help to minimize any potential for financial abuse whilst ensuring no serious accumulation of waste products, which could adversely affect storage space and supply chain for viable medicines. The prime method for achieving this balance will be delegation of WODA authority to local drug and therapeutics committees (DTCs) as stated in the National Medicines Policy, so that prompt action at the local level can be taken to secure the rapid disposal of medicines scheduled for destruction.

- **More rigorous systems of regulatory supervision and oversight for controlled medicines** that also remain efficient will help effectively secure the rapid disposal of genuinely scheduled products for destruction. The prime method for achieving this will be centralized collection of all controlled medicines with quarterly destruction schedules under the direct supervision of GDPA/NMRA-CMG.

- **Ensuring minimal environmental impact from disposed pharmaceutical waste at realistic cost levels.** The prime methods for ensuring this will be a risk-management and cost-effectiveness approach involving the separation of waste to clearly identify hazardous methods and selection of destruction methods appropriate to the volumes encountered.

4.6. Designation of a National Body to Ensure Full Coordination with NEPA and Oversee Waste Management of Pharmaceuticals Activities

In accordance with the NMP 2014, GDPA will act as the prime agency from the MoPH to liaise with NEPA and oversee development of waste management of pharmaceuticals procedures.

4.7. Affordability of Pharmaceutical Waste Disposal Procedures

In determining, developing, and implementing all policy, legislative, regulatory, licensing, and procedural requirements for waste management of pharmaceuticals, all parties are to be fully aware of the cost implications of such requirements and seek to minimize the cost impact without compromising environmental and public health safety.
In accordance with the NMP 2014 Section 12, waste management of pharmaceuticals should be undertaken for less than 1% of total medicine costs.

4.8 Protection of Staff Handling Pharmaceutical Waste

All workers disposing of pharmaceuticals should wear appropriate protective equipment including overalls and boots at all times, and gloves, masks, and caps when appropriate.

4.9 Classifications of Pharmaceutical Waste

It is proposed that six categories of pharmaceutical waste be used:

- Non-hazardous pharmaceutical waste
- Hazardous waste
- Cytotoxic and cytostatic waste
- Controlled medicines waste
- Bio-hazardous waste (essentially arising from vaccines)
- Radioactive waste (essentially arising from pharmaceuticals for radiotherapy)

The key feature and use of these classification is to ensure full observation of all environmental and public health protection requirements whilst to also simplifying the handling of waste products, minimizing the sorting required, and (as far as possible) adopting the fewest number of disposal processes.

A similar methodology has been applied to the other categorizations so that only two disposal methodologies become necessary: non-hazardous pharmaceutical waste and hazardous pharmaceutical waste.

Quite a number of products listed in the various classifications are either not in use, or are only used in minute quantities in Afghanistan at this time (e.g., radio-pharmaceuticals). They have been included in this policy so that mechanisms are in place for when such products are eventually introduced into the country.

5. WRITE-OFF DISPOSAL AUTHORIZATION (WODA) PROCEDURES

5.1 WODA Procedures Development: Responsible Bodies

For the purposes of this policy, and all subsequent regulation and requirements relating to this policy:

WODA procedures for controlled medicines will be developed by NMRA in consultation with NMRA-CMG, judicial agencies, and other stakeholders as deemed appropriate, and will apply to both public and private sectors and all operators handling controlled medicines (as defined by NMRA-CMG). Special WODA procedures (to be known as WODA-CM) will apply to controlled medicines. WODA procedures for controlled medicines will include destruction and disposal.

WODA procedures for all medicines (except controlled medicines) for use in the public sector and for all organizations, agencies, and operators receiving public-sector medicines or funding, funding administered through the public sector (e.g., all implementers of the Basic Package of Health Services [BPHS] and Essential Package of Hospital Services [EPHS]), or donor funding
will be developed by NMRA and designated as WODA-PGM. WODA procedures for all medicines (except controlled medicines), which have not been funded by the public sector, or for which the funding is not administered through the public sector, and which are for use in the private sector (i.e., by manufacturers, importers, wholesalers, distributor, retail pharmacy and private healthcare establishment operators) will be designated WODA-PRV.

THEN:
- NMRA will specify the reporting requirements for WODA activities to be undertaken by the operators.
- NMRA will produce guidelines for WODA functions in the private sector.

The operator may develop their own WODA procedures but must observe the NMRA reporting requirements, and are recommended to follow the NMRA WODA guidelines for private-sector operators.

5.2. Applicability of WODA Procedures Development for Controlled Medicines

For the purposes of this policy, and all subsequent regulations and procedures, the WODA procedures for controlled medicines will apply to medicines; organizations and bodies; and persons, officers, and operatives.

Applicability of WODA Procedures Development for Controlled Medicines: Medicines

Controlled Medicines as Finished Pharmaceutical Products (FPPs): All controlled medicines that are presented in a finished dosage form, having undergone all stages of production, including packaging in a final container and labeling. A controlled medicine FPP is defined 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.

Controlled Medicines as Active Pharmaceutical Ingredients (APIs): Controlled medicine APIs include one or more controlled medicines as a substance or mixture of substances intended for use 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 or for veterinary use.

Prepared/Compounded Controlled Medicines: Prepared or compounded controlled medicines are comprised of 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, or for veterinary use. These medicines are prepared by compounding, mixing, admixing, modifying, or adjusting an API or FPP (usually within a pharmacy setting) that contains any controlled substance.
All controlled medicines that have been seized/confiscated or sequestered by National Medicine Regulatory Authority (NMRA), GDPA, MoPH or any other regulatory or judicial authority in Afghanistan.

It is stressed that this guidance applies only to controlled medicines as defined by the categories FPP, API, and compounded medicines (described in detail above), and does not include any other controlled substances that may have been seized by regulatory/judicial authorities.

Different regulations apply to seized medicines which are not controlled medicines.

*Rationale*: Although seized/confiscated medicines have no formal inventory/accounting value within the public-sector accounting system of Afghanistan—and so technically do not require WODA functions—it is necessary to record and report the disposition of all controlled medicines, regardless of their source. Such medicines do need to be destroyed, and the controlled medicines WODA procedures provide a convenient way of adequately recording/documenting the destruction process.

**Applicability of WODA for Controlled Medicines: Organizations and Bodies**

The WODA procedures for controlled medicines will apply to all bodies, organizations, structures, pharmaceutical manufacturers, pharmaceutical retailers, and dispensing operations involved in manufacturing, compounding, selling, procuring, storing, transporting, distributing, sampling, testing, analyzing, prescribing, dispensing, administering, and receiving controlled medicines for human or veterinary use in Afghanistan.

**Applicability of WODA Procedures for Controlled Medicines: Persons, Officers, and Operatives**

The WODA procedures for controlled medicines will apply to all persons who are in possession of, and or/involved in manufacturing, compounding, selling, procuring, storing, transporting, distributing, sampling, testing, analyzing, prescribing, dispensing, or administering controlled medicines for human or veterinary use in Afghanistan.

**5.3. WODA Procedures for Controlled Medicines**

Controlled medicines shall be defined as any items on the list of controlled medicines for Afghanistan as produced by NMRA-CMG in accordance with the National Controlled Medicines Policy.

**WODA Procedures for Controlled Medicines: Key Points**

The key points of WODA-CM, and the essential differences from WODA procedures for other medicines, follow:

- For controlled medicine APIs, WODA should be conducted at the manufacturing premises/store. APIs should not be transferred or moved for WODA.
- For FPPs, WODA activities should be centralized to a limited number of points. Generally, these include Provincial Health Offices/stores or Central Medical Stores in the public sector, and major wholesalers/distributors/importers in the private sector.
- The WODA process for controlled medicines requires a greater degree of inspection/oversight than for other drugs. At least two registered healthcare staff (usually...
senior pharmacists) approved by GDPA/NMRA-CMG must witness the whole process, including the physical destruction.

- All detailed information relating to WODA and destruction of controlled medicines should remain confidential. The location of storage sites for medicines awaiting WODA and eventual disposal (usually to landfill site), in particular should not be disclosed. Summary collated information on aggregated quantities, volumes, and values may be released provided that no individual location or operator or staff members are identified.

**WODA Procedures for Controlled Medicines: Approved Premises**

Only premises approved by GDPA/NMRA-CMG for undertaking WODA procedures for controlled medicines may be used for undertaking WODA-CM activities.

Such premises must already be approved by NMRA-CMG for the handling of controlled medicines. In accordance with Sections 10 and 12 of the National Policy for Controlled Medicines, “Those operators/precincts which wish to undertake WODA of controlled medicines may apply as part of the WODA procedure for controlled medicines to be granted permission.”

**WODA Procedures for Controlled Medicines: Collection of Waste Medicines**

Controlled medicine APIs designated as waste should not be moved or relocated. WODA should be conducted only at the manufacturing premises/store.

Controlled medicine FPPs and compounds designated as waste should be collected in the original packaging, cartons, boxes, packets, etc. Packaging should only be removed after the WODA inspection and during the destruction stage of the process.

Generally FPP medicines should not be collected on less than a provincial basis.

Health clinics in the public sector, funded by the public sector, or managed by the public sector (i.e., all BPHS, EPHS operators), or donor-funded health clinics, hospitals, and other health care operational units should return waste controlled medicines to either the Provincial Health Office/store, or to Central Medical Stores.

Large NGO/FBO operators may collect waste controlled medicines centrally and apply for controlled medicine WODA at a centralized store IF their central store has already been licensed for handling controlled medicines.

Private-sector operators should return their waste controlled medicines to their wholesale supplier, Provincial Health Office/store, or Central Medical Stores.

Retail pharmacies should return all waste controlled medicines to their wholesale supplier.

Pharmaceutical manufacturers, importers, distributors, and wholesalers of controlled medicines should apply for WODA-CM at their operational sites/stores. Large operators may request more than one site.

Large operators of premises for methadone maintenance therapy or other substance addiction substitution/treatment programs may apply for WODA-CM on their premises if they have large
volumes of medicines. Large volumes are generally considered to be preparations totaling more than more than 300 grams of API equivalent, or more than 100 liters of dilute solutions.

ALL movements of controlled medicines designated as waste must be fully documented using the forms for standard transfer of controlled medicines as specified by NMRA-CMG.

Any registered pharmacy in either the public or private sector may accept unused control medicines dispensed to and then returned from the intended user. This refers ONLY to unused medicines.

For the purposes of this activity, and all subsequent regulations and guidelines resulting from this activity, the term “unused medicines”—pharmaceuticals that are not administered/consumed—shall be considered to include dispensed medicines which are date expired or damaged.

This includes all unused preparations and formulations of medicines: tablets, capsules, powders, vials, ampoules, pessaries, suppositories, creams, ointments, lotions, IV solutions, unused pre-loaded syringes, unused pre-loaded liquid medicine delivery devices, dermal patches, etc.

This may include medicines that have been dispensed to a patient and returned unused; opened (partially used) bottles of tablets/capsules; partially opened blister strips; partially used multi-dose vials/ampoules; partially used IV solutions; partially used powders; and partially used, pre-loaded, non-liquid medicine delivery devices.

This does not include:
- Partially used, pre-loaded syringes, partially used liquid delivery devices
- Empty vials, ampoules, bottles, tubes, containers, IV bags/bottles, blister strips, dispensing cups, etc.
- Any delivery devices, such as syringes (other than unused, pre-loaded syringes), needles, IV administration sets, trocars, catheters, swabs
- Clinical waste

No dispensed medicines that are returned to a pharmacy can be accepted for re-use. All must be destroyed.

Dispensed controlled medicines returned to a pharmacy should be sealed in an envelope and marked “returned from intended user” and sent with other controlled medicines to either a distributor or one of the public sector collection centers for WODA activity.

**WODA Procedures for Controlled Medicines: Frequency of WODA Activities**

For controlled medicines, WODA should be conducted at least every three months.

*Rationale:* Secure storage space for controlled medicines is limited at all facilities in both public and private sectors. Large stocks of designated waste controlled medicines should not be allowed to accumulate. They represent a security risk and could adversely affect supply chain functioning by blocking much needed secure storage space.
WODA Procedures for Controlled Medicines: Target Time for Completion of WODA Activities

For controlled medicines, a WODA process should be completed in not more than 30 days from first application for WODA to certified destruction of the medicines.

Rationale: Secure storage space for controlled medicines is limited at all facilities in both public and private sectors. Large stocks of designated waste controlled medicines should not be allowed to accumulate. They represent a security risk and could adversely affect supply chain functioning by blocking much needed secure storage space.

WODA Procedures for Controlled Medicines: Detailed SOPs

WODA Procedures for Controlled Medicines: Detailed SOPs: Responsible Body

NMRA, working in conjunction with NMRA-CMG, will be responsible for developing detailed standard operating procedures (SOPs), forms, and other formats for undertaking WODA-CM. NMRA is responsible for institutionalizing and sharing information on the detailed procedures.

WODA Procedures for Controlled Medicines: Examining Officers

NMRA, working in conjunction with NMRA-CMG, will be responsible for appointing and authorizing officers to undertake WODA-CM assessments and supervisions.

All such officers must:

- Be at least 21 years old
- Not out of civil right, 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 NMRA
- Not have been convicted of a misdemeanor or felony by any court in Afghanistan
- Not be, and not have been, a habitual user of narcotics or any other habit-forming drugs
- Be a qualified and registered medical practitioner or pharmacist with at least five years of post-graduation experience

NMRA, in conjunction with NMRA-CMG, at its discretion may delegate responsibility for appointing/assigning officers for WODA-CM to either the Provincial Health Office or a DTC for a specified geographical area, but all regulations relating to the quantification and activities of the examining officers will still apply.

All examining officers must agree to sign confidential agreements and No Conflict of Interest Statements in accordance with normal Government of Afghanistan Civil Service regulations.

Examining officers may not undertake WODA-CM duties on any medicines with which they have or have had a commercial interest (e.g., owned, possessed, handled as a controlling officer) or in which a close family relative has/had a commercial interest.

It is not necessary that examining officers be full-time governmental employees, but they must fulfill all regulatory requirements.
As a minimum requirement, the following information is to be collected on the application for WODA and during the WODA process, and returned to GDPA/NMRA-CMG.

- **Applicant**
  - Name of responsible officer making the WODA application
  - Name of organization (manufacturer, importer, wholesaler, NGO, Provincial Health Office/store)
  - Address of organization, including e-mail and telephone

- **Location**
  - Physical location of the premises where the medicines are to be stored
  - Physical location where WODA to be conducted (normally in the store)
  - Physical location of destruction of medicines
  - Physical location of discharge to landfill site

- **Dates**
  - Date of application for WODA
  - Proposed date of WODA inspection
  - Actual date of WODA inspection
  - Date of physical destruction (normally same as WODA inspection)
  - Date of discharge to landfill site (normally 3 to 7 days after WODA inspection, for container method)

- **The name of the medicine using the approved generic name (International Nonproprietary Name, or INN) as it appears in Afghanistan’s Essential Medicine List (EML) or Licensed Medicine List (LML)**

- **The total quantity of the substance submitted for inspection (as detailed below) and certified by the inspection team as being present (as detailed below).**
  - For controlled substances in bulk form (API)
    - To the nearest metric unit weight (usually grams) consistent with unit size
  - For each controlled substance in finished form (FPP)
    - Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per milliliter)
    - The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or three-milliliter vial)
    - The number of full/opened commercial containers of each such finished form (e.g., four 100-tablet bottles or six three-milliliter vials); AND
    - For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: An exact count or measure of the contents (e.g., number of tablets)
  - A calculation of the total quantity of active ingredient in grams (e.g., 900 tablets of 10 mg = 9 grams)
  - Estimated total weight/volume of the medicines (including packaging)
  - If weight not known and no weighing scales are present, use volume.
  - Volume in cubic meters (approximate measure of height, width, and length multiplied together)

- **Value of the medicine**
  - Unit price from invoices/purchase orders/supply documents
  - If unit price not known, use International Drug Price Indicator Guide (IDPIG) FOB (free on board) median price, plus 25% for DDP (delivered, duty paid) in-country
  - Extended price for each item (price multiplied by quantity)
  - Total value of medicine to be destroyed

- **Reason for the disposal**
National Policy for Waste Management and Safe Disposal of Pharmaceutical Products

- E.g., date expired, damaged, returned from intended user
- **Examining officers**
  - Minimum two must be present through the entire process
  - Name, title, and position
- **Signatures**
  - Applicant
    - Certification of readiness of medicines for destruction
    - Agreement to any adjustments made by the examining team
  - Examining team
    - Verification of medicine name
    - Verification of physical count of the medicines and quantities present
    - Witnessing of completion of destruction process
    - Witnessing of discharge to landfill site
- **Notes and observations**
  - To record any happening during the inspection destruction process
  - To record and certify any minor adjustments made during verification and destruction

**WODA Procedures for Controlled Medicines: Review of WODA Applications**

Applications for WODA-CM should be submitted to NMRA.

NMRA will review all applications jointly with NMRA-CMG.

For applications that are unclear or appear unusual, GDPA may request further information and detailed explanations.

For large volumes of WODA of controlled medicines, GDPA may request a detailed explanation of how such a circumstance arose and what measures have been enacted to prevent a recurrence.

In the absence of clear explanations and details of remedial actions, GDPA may recommend that NMRA-CMG review the license of the applicant (organization/body/company) to handle controlled medicines.

After review and acceptance of the WODA-CM application NMRA will assign relevant staff to undertake the WODA process, and mutually agree a date with the applicant.

**WODA Procedures for Controlled Medicines: Responsibility of WODA Applicants**

Applications for WODA-CM can only be made by organizations, bodies, companies, and other operators who are registered to store controlled medicines by NMRA-CMG.

A registered medical practitioner or senior pharmacist (more than five years post-graduation) must sign applications for WODA-CM; they will be held accountable for the accuracy of the information provided.

Applicants are responsible for ensuring that complete information is provided on the WODA-CM application and that all information relating to formulations and quantities is accurate.

Applicants are responsible for all costs of storing the medicines, handling the medicines during verification (providing warehouse/laboring staff and equipment if necessary), and the physical
National Policy for Waste Management and Safe Disposal of Pharmaceutical Products

destruction process (e.g., containers, cement, protective clothing) including transport of the waste materials to landfill site and any applicable fees relating to use of the landfill site.

Applicants are responsible for ensuring that protective clothing is available for the staff who will undertake the physical destruction process and also for the WODA inspection team who will verify the process.

At a minimum this must consist of:

- Waterproof feet covers: wellington ‘rubber’ boots, galoshes, or waterproof safety shoes
- External clothing: overalls
- Plastic aprons
- Gloves: domestic ‘rubber’ gloves
- Eye protections: clear goggles, wrap-around spectacles
- Face masks: disposable surgical masks
- Head covers: disposable caps

*Information note:* The majority of FPP controlled medicines do not require any special handling in regards to maintenance of personal toxicity safety. The main purpose of the protective clothing is to provide protection from the cement dust used in the destruction process, breaking glass fragments, and liquid splashes.

Controlled medicine API disposal does present a greater challenge, and greater consideration to protective clothing (especially advanced face masks) should be given to higher volume API disposals. Since such personal protection equipment will normally be available as routine wear at any pharmaceutical manufacturing facility, this should not present a problem.

Applicants are responsible for ensuring that the stock scheduled for WODA-CM is clearly separated from all other controlled medicines material (e.g., distance or dividing screens, labeling), is neatly arranged (to permit easy of counting and verification), and is safely stacked (not more than 2.5 meters high).

Applicants are responsible for security arrangements throughout the WODA and disposal process.

For FPP controlled medicines disposal, no additional security arrangements are normally necessary, beyond the normal requirements for the storage of controlled medicines.

For API controlled medicines, disposal security arrangements should be in keeping with the volumes of medicines to be destroyed.

Access should be restricted to the area being used for WODA verification and physical destruction of controlled medicines.

Applicants are responsible for arranging transport of the encapsulated destroyed material to an approved domestic garbage landfill site, and for arranging its full incorporation into the landfill.

**WODA Procedures for Controlled Medicines: Presence of Witnesses**

Additional persons may be invited to witness the WODA process for controlled medicines, for example: donors, NGOs, judicial agencies, representatives of International Narcotics Control
Board (INCB) and other narcotic control agencies, representatives of MoPH and NMRA, staff in training, and staff and representatives invited by the WODA applicant.

Both the applicant and the verification team must jointly agree to the presence of the witnesses.

Not more than a total of four additional witnesses should be present.

All such witnesses, must:
- Be at least 21 years old
- Not out of civil right, 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 NMRA
- Not have been convicted of a misdemeanor or felony by any court in Afghanistan
- Not be, and not have been, a habitual user of narcotics or any other habit-forming drugs
- Be able to present photographic, certified identification (passport/ID card) to the WODA verification team

All such witnesses must sign the confidential agreement and agree not to disclose the location of the landfill site.

Witnesses may sign the WODA verification forms as additional proof of activities.

Witnesses should not take part in the verification or destruction processes. They may observe, but should not be actively involved.

**WODA Procedures for Controlled Medicines: Photographic Records**

Photographic records of the WODA verification and destruction processes may be made, BUT care should be taken to ensure that:
- None of the WODA verification team members can be identified
- The location of the storage site cannot be identified
- The location of the landfill site cannot be identified

**WODA Procedures for Controlled Medicines: Authority Levels**

Levels of authority and approval for controlled medicines WODA will be established by GDPA and reviewed at least every three years.

The levels will be established so as to enable rapid and easy WODA for low-value disposals.

Higher-value WODA applications for controlled medicines will need to be reviewed jointly by GDPA and NMRA to determine if additional supervision and investigation is required during the WODA process.

*Note:* These guideline authority levels apply only to controlled medicines. Different procedures apply to general medicines.

**Table 1:** Controlled Medicine WODA Guideline Approval Value Levels

<table>
<thead>
<tr>
<th>Estimated total value of</th>
<th>WODA signatory authority</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>Afghani</td>
<td>WODA</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>All values</td>
<td>GDPS <em>plus</em> one senior (NMRA-CMG <em>plus</em> one external monitor</td>
<td>Applicant has not accepted quantity determination by a WODA inspection team. Re-inspection is to be conducted by full GDPA/NMRA representation <em>plus</em> an external monitor.</td>
</tr>
<tr>
<td>All values</td>
<td>GDPS <em>plus</em> one senior one NMRA-CGM representative <em>plus</em> one external monitor</td>
<td>All controlled medicines seized/confiscated/sequestered by a regulatory of judicial authority of Afghanistan</td>
</tr>
<tr>
<td>Less than 10,000</td>
<td>Two officers appointed by NMRA</td>
<td>Previous experience of undertaking controlled medicine WODA activities from this operator and on these premises.</td>
</tr>
<tr>
<td></td>
<td>Two officers appointed by NMRA <em>plus</em> one senior NMRA-CGM representative</td>
<td>For all operators and premises new to controlled medicines WODA</td>
</tr>
<tr>
<td>More than 10,000 less than 50,000</td>
<td>Two officers appointed by NMRA</td>
<td>Previous experience with operator and premises, and WODA application reviewed by GDPA/NMRA with no obvious abnormalities or unusual circumstances</td>
</tr>
<tr>
<td></td>
<td>Two officers appointed by NMRA <em>plus</em> one senior NMRA-CGM representative</td>
<td>New operator premises or WODA application is unclear or abnormal</td>
</tr>
<tr>
<td>More than USD 50,000</td>
<td>Two officers appointed by NMRA <em>plus</em> senior NMRA-CGM representative</td>
<td>Previous experience with operator and premises, and WODA application reviewed by GDPA/NMRA, and there is clear and credible explanation and justification for high value disposal</td>
</tr>
<tr>
<td></td>
<td>Two officers appointed by NMRA <em>plus</em> one senior NMRA-CGM representative</td>
<td>WODA application reviewed by GDPA/NMRA and explanation and justification for high value disposal is not clear and/or credible</td>
</tr>
</tbody>
</table>

**WODA Procedures for Controlled Medicines: Application Review Procedures**

NMRA- GDPA working jointly with CMG will review all applications for WODA-CM.

NMRA will establish detailed guidelines for the application review team, which will be reviewed at least every three years.

Tables 2 and 3 outline guidance for review of volumes of controlled medicines for WODA.
### Table 2: Controlled Medicine WODA Guideline Application Review Volume Levels: FPP

<table>
<thead>
<tr>
<th>Active Ingredient (grams)</th>
<th>Tablets</th>
<th>Vials/ampoules</th>
<th>Condition</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No limits</strong></td>
<td><strong>Tablets</strong></td>
<td><strong>Vials/ampoules</strong></td>
<td>All controlled medicines seized/confiscated/sequestered by a regulatory or judicial authority of Afghanistan</td>
<td>Provide evidence of destruction to regulatory/judicial authority</td>
</tr>
<tr>
<td><strong>More than 500g</strong></td>
<td><strong>More than 5000</strong></td>
<td><strong>More than 500</strong></td>
<td>Operator with no previous controlled medicine WODA experience</td>
<td>Detailed examination of volumes of controlled medicines handled, THEN follow conditions below.</td>
</tr>
</tbody>
</table>
|                           |                  |                | Operator with a turnover of controlled medicines less than the equivalent of 10% of national supply | • Detailed explanation as to why such volumes are subject to WODA.  
• Confirmation of source of controlled medicines and approvals for importation.  
• Proposed steps to reduce waste generation in future. |
|                           |                  |                | In-country manufacturer OR operator with a turnover equivalent to more than 10% of the national supply | Explanation of source of medicines (e.g., CMS acting as collecting center) and review of volumes based on extent of source collection. |
|                           |                  |                | Two officers appointed by NMRA plus one senior NMRA and one GDPS representative | WODA application reviewed by GDPA/NMRA and explanation and justification for high value disposal is not clear and/or credible |
### Table 3: Controlled Medicine WODA Guideline Application Review Volume Levels: API

<table>
<thead>
<tr>
<th>Single API</th>
<th>Condition</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active ingredient (grams)</td>
<td>Less than 2,000g</td>
<td>Established in-country manufacturer of controlled medicines</td>
</tr>
<tr>
<td></td>
<td>More than 2,000g</td>
<td>Attempt to confirm identity of medicine API through rapid, on-site testing (Minilab or RLIR) OR witness identity test at manufacturers own quality control (QC) laboratory.</td>
</tr>
<tr>
<td></td>
<td>Less than 500g</td>
<td>Other agency (non licensed manufacturer) holding API (e.g. compounder, academic, research institute, laboratory)</td>
</tr>
</tbody>
</table>
| | More than 500g | Confirm source of medicines and import permissions:  
  - IF sealed containers: Review application to identify any abnormalities  
  - IF opened containers: Attempt to confirm identity of medicine API through rapid, on-site testing (Minilab or RLIR) OR witness identity test at site laboratory |

### WODA Procedures for Controlled Medicines: Identity and Quantity Verifications

**FFP**

Product identification should be undertaken by verifying the product labeling, packaging and any invoice, purchase order, delivery note and stock record information available.

For large quantities (see table 2/ 5.3.14), one should consider undertaking on-site rapid analysis to confirm identity of medicine.

Sealed containers should have stated content recorded (e.g., “bottle of 100 tabs”).

Unsealed containers (or any containers which are in doubt as to whether they are still factory sealed) should be treated as unsealed containers, and should have contents physically counted and recorded.

Quantities in used multi-dose vials should be estimated from liquid content level.

The total number of containers should be counted.

The total quantity of product and total quantity of active ingredient should be calculated.

IF there is any discrepancy between the application quantity and the observed quantity, THEN the applicant should be invited to conduct a joint re-count with the inspection team.

IF, after a re-count, there are still discrepancies between the application quantity and the inspection team determined quantity, THEN:
• IF the discrepancy for a particular item is less than 15%, AND the applicant accepts the quantity determined by the inspection team, the applicant should sign the WODA form in agreement and acknowledge acceptance of the revised quantity.
• IF the discrepancy for a particular item is less than 15%, AND the applicant does not accept the quantity determined by the inspection team, the WODA process should be stopped and referred back to NMRA for resolution.
• IF the discrepancy for a particular item is more than 15%, a new application showing a revised quantity should be made to NMRA.

API

Product identification should be undertaken by verifying the product labeling, packaging, and information available from any invoice, purchase order, delivery note invoice, purchase order, delivery note, and stock record.

For large quantities (see table 3), one should consider undertaking on-site rapid analysis to confirm identity of medicine.

Sealed containers should have stated content recorded (e.g., “drum of 5kg”) and be weighed using stated drum tare weight.

Unsealed containers (or any containers which are in doubt as to whether they are still factory sealed) should be treated as unsealed containers and should have contents weighed.

Appropriate personal safety equipment should be used when weighing powders.

Liquid contents should be estimated from liquid content level.

The total number of containers should be counted.

The total quantity of product and the total quantity of active ingredient should be calculated. (Usually this is the same figure, unless premix formulated API are being used.)

IF there is any discrepancy between the application quantity and the observed quantity, the applicant should be invited to conduct a joint re-count with the inspection team.

IF, after a re-count/re-weighing there are still discrepancies between the application quantity and the inspection team determined quantity, THEN:
• IF the discrepancy for a particular item is less than 5%, AND the applicant accepts the quantity determined by the inspection team, the applicant should sign the WODA form in agreement and acknowledge acceptance of the revised quantity.
• IF the discrepancy for a particular item is less than 5%, AND the applicant does not accept the quantity determined by the inspection team, the WODA process should be stopped and referred back to NMRA for resolution.
• IF the discrepancy for a particular item is more than 5%, a new application showing a revised quantity should be made to NMRA.
5.4. WODA Procedures for Controlled Medicines: Physical Destruction

**Physical Destruction of Controlled Medicines: General**

No physical destruction process should begin until the WODA inspection and verifications procedures are complete, and the necessary forms and documentation have been signed by all parties involved in the process.

As described in section 6.7 (Controlled Medicines Pharmaceutical Waste), for the purposes of this policy guide and waste management activities in Afghanistan: **All controlled medicines are to be classified as hazardous waste.**

Therefore the standard hazardous pharmaceutical waste (HPW) destruction and disposal methodology will be applied for all controlled medicines.

**Physical Destruction of Controlled Medicines: Basic Principles**

The basic principles to be used for the destruction of controlled medicines are:

- Denaturing (inertization)
- Encapsulation (in a concrete medium)
- Disposal to landfill site

Low-temperature burning is not recommended, and should be used only in extreme cases where no landfill site is available.

High-temperature incineration in waste incinerators may be used if there are adequate quantities of disposal to justify the expense (generally in excess of one 20-foot shipping container load).

**Physical Destruction of Controlled Medicines: Determine Maximum Disposal Container Size**

The maximum size of disposal container that can be used will depend on the availability of mechanical handling equipment at the destruction site and the landfill disposal site.

The applicant should clearly state the size of disposal container they propose to use.
Table 4: Guideline Weights of Disposal Containers Filled with Concrete

<table>
<thead>
<tr>
<th>Container type</th>
<th>Volume</th>
<th>Weight with concrete</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liter</td>
<td>Cubic meter</td>
<td>Kilogram</td>
</tr>
<tr>
<td>Concrete truck, rotating mixing drum</td>
<td>5</td>
<td>25</td>
<td>12,000 of concrete laden truck 25 tons</td>
</tr>
<tr>
<td>Metal 50 gallon oil drum</td>
<td>250</td>
<td>0.25</td>
<td>480</td>
</tr>
<tr>
<td>Plastic bulk chemical container</td>
<td>200</td>
<td>0.20</td>
<td>400</td>
</tr>
<tr>
<td>Large plastic bucket/drum</td>
<td>25</td>
<td>0.025</td>
<td>50</td>
</tr>
<tr>
<td>Household plastic bucket/nappy pail with lid</td>
<td>5</td>
<td>0.005</td>
<td>12</td>
</tr>
</tbody>
</table>

For large volumes of disposal—especially if other hazardous waste is present—the concrete mixing truck method can be highly beneficial since it negates the need for additional mechanical handling equipment and most landfill sites have large-vehicle access for their regular domestic waste tipping.

Physical Destruction of Controlled Medicines: Determine Encapsulation Materials Required (Cement)

The WODA applicant is responsible for ensuring that disposal containers and encapsulation materials (concrete mix) are available.
Table 5: Guideline Concrete Requirements

<table>
<thead>
<tr>
<th>Container type</th>
<th>Cubic meter</th>
<th>Bags of ready mix sand/cement/lime</th>
<th>Cement</th>
<th>Sand</th>
<th>Lime</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>20 kg bags</td>
<td>kg</td>
<td>kg</td>
<td>kg</td>
</tr>
<tr>
<td>Concrete truck</td>
<td>3 to 5</td>
<td>Mixture of lime, cement, and water in the proportions 15:15:5 (by weight)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 gallon oil drum</td>
<td>.25</td>
<td>25</td>
<td>100</td>
<td>280</td>
<td>100</td>
</tr>
<tr>
<td>Plastic bulk container</td>
<td>0.20</td>
<td>15</td>
<td>80</td>
<td>140</td>
<td>80</td>
</tr>
<tr>
<td>Large plastic bucket</td>
<td>0.025</td>
<td>2.5</td>
<td>10</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Household plastic bucket</td>
<td>0.005</td>
<td>0.5</td>
<td>2</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>

Physical Destruction of Controlled Medicines: Determine Quantity of Disposal Containers Required

The normal requirement for disposal of hazardous pharmaceuticals is that the disposal container should not be more than 75% full of disposed pharmaceuticals (i.e., base layer of concrete, mid-layer of mixed pharmaceuticals and concrete, top layer of concrete).

**Controlled Medicines as FPPs**
- IF, controlled medicines disposal is being mixed with other hazardous waste pharmaceutical waste disposal (often because of the low volume of controlled medicines to be disposed of), then the 75% rule may be applied.
- IF only controlled medicines are being disposed of, it is better to limit the waste pharmaceutical content of the container to not more than 50% unless the concrete mixing truck method is being used, in which case the 75% rule may be used.

**Controlled Medicines as APIs**
- The controlled medicines disposal should not account for more than 10%, by weight, of the filled container weight.
- The concrete mixing truck can be beneficial for disposal of large quantities of controlled medicines API.

**Physical Destruction of Controlled Medicines: Destruction Process**

In order to reduce the physical volume of hazardous waste:
- Remove the packaging materials, paper, cardboard, and plastic wrap from the pharmaceuticals.
- Pills need to be removed from their bottles, but do not open blister packs.
- Do not open vials/ampoules. Do not empty liquid preparations. Place them whole into the concrete mixture.
- Use personal protection equipment when emptying bottles (because of dust hazard).

The packaging material must be destroyed.
- It can be mechanically shredded, burnt, or otherwise rendered unusable.
- To render unusable, place in a tank of water with domestic liquid chlorine bleach (one liter of bleach to 50 liters of water) and soak for at least three days.
• Use the same process for any printed plastic wrap, empty bottles, or other empty containers. This will destroy any printing on the packaging and bottles/cartons.
• After three days, the solid waste may be treated as standard household waste and sent to landfill site.

**If using the concrete truck revolving drum method:** The use of the truck must be explained to the supplier of the concrete so that they can ensure they have adequate water on board for complete flushing/rinsing of the mixing drum of the truck after use, and also so that they realize that the concrete will not be used for structural construction use, but will go straight to waste.

When the truck arrives, load the materials for destruction into the truck.

When loading is complete, the drum should be rapidly revolved for at least three minutes (rapid mixing stage; water may be added).

The truck then drives to the landfill site and discharges the load into a prepared trench, which should be immediately covered with domestic waste. The mixture that results from rinsing the mixing drum can be emptied onto the domestic waste. The discharge area should be protected to deter scavengers for approximately one hour after discharge. (The cement/lime mixture hardens very quickly.)

**If using a container method:** Place a layer of the concrete mixture in the bottom of the container for around 10% of the container height. Load the waste materials into the container, but do not fill more than 80%. Pour the concrete mixture into the container to fill the container and cover/seal.

After three days, the container may be sent to the landfill site where it should be discharged into a prepared trench, which should be immediately covered with domestic waste.

The disposal to landfill site must be witnessed by the WODA-CM verification team.

Upon completion of the disposal process, the WODA-CM forms should be signed and returned to NMRA.

### 5.5. **Applicability of WODA Procedures Development for Public-Sector General Medicines (PGM)**

For the purposes of this policy guide, and all subsequent regulations and procedures, the WODA procedures for public-sector general medicines (PGM) will apply to medicines; organizations and bodies; and persons, officers, and operatives.

**Applicability of WODA Procedures Development for PGM: Medicines**

WODA-PGM procedures apply to all medicines, except controlled medicines, for use in the public sector, and for all organizations, agencies, and operators receiving public-sector medicines, or funding, or funding administered through the public sector (e.g., all BPHS and EPHS implementers), or donor funding.

• WODA-PGM procedures do not apply to controlled medicines and do not apply to private-sector operations.
• WODA-PGM procedures do not apply to general medicines that have been seized/confiscated or sequestered by NMRA and MoPH, or any other regulatory or
judicial authority in Afghanistan. Different regulations apply to seize controlled medicines.

Rationale: Such medicines have no formal inventory/accounting value within the public-sector accounting system of Afghanistan and so do not require WODA functions. Such medicines do need to be destroyed, and regular destruction process can be applied.

WODA-PGM procedures apply to each of the following situations.

- **All medicines, except controlled medicines, as FPPs:** All non–controlled medicine presented in its finished dosage form, having undergone all stages of production, including packaging in a final container and labeling. A medicine as FPP is defined 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.

- **All medicines, except controlled medicines, as APIs:** Non–controlled medicines 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 or for veterinary use.

- **All medicines, except controlled medicines, as prepared/compounded medicines:** Prepared or compounded medicines are comprised of 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, or for veterinary use. These medicines are prepared by compounding, mixing, admixing, modifying, or adjusting an API or FPP (usually within a pharmacy setting) that does not contain any controlled substance.

**Applicability of WODA Procedures for PGM: Organizations and Bodies**

The WODA procedures for PGM will apply only to public-sector bodies, organizations, structures, and dispensing operations which are involved in manufacturing, compounding, procuring, storing, transporting, distributing, sampling, testing, analyzing, prescribing, dispensing, administering, and receiving PGM for human use in Afghanistan.

**Applicability of WODA Procedures for PGM: Persons, Officers, and Operatives**

The WODA procedures for PGM will apply to all public-sector operatives who are in possession of and or/involved in manufacturing, compounding, procuring, storing, transporting, distributing, sampling, testing, analyzing, prescribing, dispensing, or administering PGM for human use in Afghanistan.
5.6. WODA Procedures for PGM

WODA Procedures for PGM: Key Points

The key points of WODA procedure for PGM, and the essential differences from WODA procedures for other medicines, follow:

- WODA procedure for PGM applies only to the WODA process. It is not necessary for external, central-level appointed supervisors to witness the destruction and disposal of PGM.
- Supervision of destruction and disposal for PGM is the responsibility of the local DTC.
- The necessary degree of inspection/oversight: At least two NMRA-approved, registered healthcare staff (usually senior pharmacists) must undertake the WODA-PGM process.

WODA Procedures for PGM: Approved Premises

WODA-PGM may be undertaken at any premises that are operated by the public sector or receiving public-sector funding or medicines, and suitable for the storage of medicines.

WODA-PGM can be conducted at small clinics or dispensing pharmacies, however, it is better to collect waste medicines from such units and undertake larger volume WODA.

WODA Procedures for PGM: Collection of Waste Medicines

As a general guide, waste PGM should be collected to at least the district level: district hospital stores, district hospitals, or DHOs. It is not normally practical to conduct WODA-PGM at small clinics.

Finished Pharmaceutical Products, Compounded Medicines
Medicines should be collected in the original packaging, cartons, boxes, packets, etc.

Packaging should only be removed after the WODA inspection and during the destruction stage of the process.

Health clinics in the public sector, funded by the public sector, or managed by the public sector (i.e., all BPHS, EPHS operators), or donor-funded health clinics, hospitals, and other health care operational units should collect waste PGM at any convenient point, for example: DHOs, district stores, or district hospitals.

NGO/FBO operators may similarly collect waste PGM at any convenient point in their organization.

All movements of PGM designated as waste must be fully documented as if they were viable medicines, using the standard transfer of forms for PGM, until the WODA process is complete.

Key point: PGM designated as waste is subject to normal inventory procedures (as if they were viable medicines) until such time as the WODA process is complete. All transfers must be fully documented, and all storage must be fully reflected in accurate inventory records. Only after the WODA has been certified, may they be treated as waste and destroyed.

Dispensed Medicines/Returned from Intended User
Any registered pharmacy in either the public or private sector may accept unused medicines returned from the intended user.

This refers only to unused medicines.

For the purposes of this activity and all subsequent regulations and guidelines resulting from this activity, the term unused medicines (pharmaceuticals that have not been administered/consumed) shall be considered to include dispensed medicines that are date-expired or damaged.

This includes all unused preparations and formulations of medicines: tablets, capsules, powders, vials, ampoules, pessaries, suppositories, creams, ointments, lotions, IV solutions, unused pre-loaded syringes, unused pre-loaded liquid medicine delivery devices, dermal patches, etc.

This may include medicines that have been dispensed to a patient and returned unused, opened (partially used) bottles of tablets/capsules, partially opened blister strips, partially used multi-dose vials/ampoules, partially used IV solutions, partially used powders, and partially pre-loaded non-liquid medicine delivery devices.

This does not include:
- Partially used pre-loaded syringes, partially used liquid delivery devices
- Empty vials, ampoules, bottles, tubes, containers, IV bags/bottles, blister strips, dispensing cups, etc.
- Any delivery devices, e.g., syringes (other than unused pre-loaded syringes), needles, IV administration sets, trocars, catheters, swabs
- Clinical waste

No dispensed medicines that are returned to a pharmacy can be accepted for re-use. They must all be destroyed.

**WODA Procedures for PGM: Frequency of WODA Activities**

WODA-PGM should be conducted at least every six months.

*Rationale:* Storage space for PGM is limited at all facilities in both the public sectors. Large stocks of designated waste PGM should not be allowed to accumulate. They could adversely affect supply chain functioning by blocking much needed secure storage space.

**WODA Procedures for PGM: Target Time for Completion of WODA Activities**

For PGM, a WODA process should be completed in not more than 60 days from first application for WODA to certified destruction of the medicines.

*Rationale:* Storage space for PGM is limited at all facilities in both the public and private sectors. Large stocks of designated waste PGM should not be allowed to accumulate. They could adversely affect supply chain functioning by blocking much needed secure storage space.
WODA Procedures for PGM: Detailed SOPs

WODA Procedures for PGM: Detailed SOPs: Responsible Body

NMRA will be responsible for developing detailed SOPs, forms, and other formats for undertaking WODA-PGM. GDPA is responsible for institutionalizing and sharing information on the detailed procedures.

WODA Procedures for PGM: Examining Officers

NMRA will be responsible for setting the guidelines for appointing and authorizing officers to undertake WODA-PGM assessments and supervisions.

Actual assignment of officers to undertake PGM will be undertaken by local DTCs.

All such officers must:
- Be at least 21 years old
- Be a qualified and registered medical practitioner or pharmacist with at least three years post-graduation experience

All examining officers must agree to sign confidential agreements and No Conflict of Interest Statements in accordance with normal Government of Afghanistan Civil Service regulations.

It is not necessary that examining officers be full-time governmental employees, but they must fulfill all regulatory requirements.

WODA Procedures for PGM: Minimum Information Requirements

As a minimum requirement the following information is to be collected on the application for WODA-PGM and during the WODA process, and returned to NMRA.

- Applicant
  - Name of responsible officer making the WODA application
  - Name of organization (clinic, hospital store, NGO site)
  - Address of applicant, including e-mail and telephone
- Location
  - Physical location of the premises where the medicines are to be stored
  - Physical location where WODA to be conducted (normally in the store)
- Dates
  - Date of application for WODA
  - Proposed date of WODA inspection
  - Actual date of WODA inspection
- The name of the medicine using the approved generic name (INN) as it appears in Afghanistan’s EML or LML
- The total quantity of the substance submitted for inspection (as detailed below) and certified by the inspection team as being present (as detailed below).
  - For each PGM in finished form (FPP)
    - Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per milliliter)
The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or three-milliliter vial)

The number of full/opened commercial containers of each such finished form (e.g. four 100-tablet bottles or six three-milliliter vials); AND

For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: An exact count or measure of the contents (e.g., number of tablets)

- Estimated total weight/volume of the medicines (including packaging)
- If weight not known and no weighing scales are present, use volume.
- Volume in cubic meters (approximate measure of height, width, and length multiplied together)

- Value of the medicine
  - Unit price from invoices/purchase orders/supply documents
  - If unit price not known, use IDPIG FOB median price, plus 25% for DDP in-country
  - Extended price for each item (price multiplied by quantity)
  - Total value of medicine to be destroyed

- Reason for the disposal
  - E.g., date expired, damaged, returned from intended user

- Examining officers
  - Minimum two must be present through the entire process

- Name, title, and position

- Signatures
  - Applicant
    - Certification of readiness of medicines for destruction
    - Agreement to any adjustments made by the examining team
  - Examining team
    - Verification of medicine name
    - Verification of physical count of the medicines and quantities present

- Notes and observations
  - To record and certify any minor adjustments made during verification

**WODA Procedures for PGM: Review of WODA Applications**

Applications for WODA-PGM should be submitted to local DTC and copied to NMRA.

For applications that are unclear or appear unusual, DTC may request further information and detailed explanations.

For large volumes of WODA-PGM, NMRA or DTC may request a detailed explanation of how such a circumstance arose and what measures have been enacted to prevent a recurrence.

After review and acceptance of the WODA-PGM application, DTC will assign relevant staff to undertake the WODA process, and agree on a date with the applicant.
WODA Procedures for PGM: Responsibility of WODA Applicants

Only organizations, bodies, companies, and other operators who are authorized to possess PGM can submit applications for WODA-PGM (i.e., the private sector should not be requesting WODA of government medicines).

Applications for WODA-PGM must be signed by a registered medical practitioner or senior pharmacist (more than three years post-graduation) who will be held accountable for the accuracy of the information provided.

Applicants are responsible for ensuring that complete information is provided on the WODA-PGM application and that all information relating to formulations and quantities is accurate.

Applicants are responsible for all costs of storing the medicines, and handling the medicines during verification (providing warehouse/laboring staff and equipment if necessary).

Applicants are responsible for ensuring that protective clothing is available for the staff who will undertake the verification, especially if there are damaged/leaking medicines to be inspected.

At a minimum this must consist of:
- External clothing: lab coat or overalls
- Gloves: domestic ‘rubber’ gloves
- Eye protections: clear goggles, wrap-around spectacles
- Face masks: disposable surgical masks

Applicants are responsible for ensuring that the stock scheduled for WODA-PGM is clearly separated from all other PGM materials (e.g., distance or dividing screens, labeling), is neatly arranged (to permit easy of counting and verification), and is safely stacked (not more than 2.5 meters high).

Access to the area being used for WODA verification of PGM should be restricted until the WODA process is complete.

Applicants are responsible for arranging for the safer disposal of the medicines in accordance with the relevant sections of this policy guide after WODA verification is complete.

WODA Procedures for PGM: Presence of Witnesses

Additional persons from other stakeholders may be invited to witness the WODA process for PGM, for example, donors, NGOs, judicial agencies, Ministry of Finance (MoF) staff, representatives of MoPH, staff in training, media, and staff and representatives invited by the WODA applicant.

Both the applicant and the verification team must jointly agree to the presence of the witnesses.

Not more than a total of four additional witnesses should be present.
All such witnesses, must:

- Be at least 21 years old
- Be able to present photographic, certified identification (passport/ID card) to the WODA verification team

Witnesses may sign the WODA verification forms as additional proof of activities.

Witnesses should not take part in the verification processes. They may observe, but should not be actively involved.

**WODA Procedures for PGM: Photographic Records**

Photographic records of the WODA verification, and destruction processes may be made, but care should be taken to ensure that the location of the storage site cannot be identified.

If media are present (invited as witnesses) particular care should be taken to supervise photography.

**WODA Procedures for PGM: Authority Levels**

Levels of authority and approval for WODA-PGM to be followed by DTCs will be established by NMRA and reviewed at least every three years.

The levels will be established so as to enable rapid and easy WODA-PGM for low-value disposals.

Higher-value WODA applications for PGM may need to be reviewed jointly by DTC with NMRA to determine if additional supervision and investigation is required during the WODA process.

*Note:* These guideline authority levels apply only to PGM. Different procedures apply to controlled medicines and private-sector medicines.
### Table 6: WODA-PGM Guideline Approval Value Levels

<table>
<thead>
<tr>
<th>Estimated total value of WODA</th>
<th>WODA signatory authority</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US $</strong></td>
<td><strong>Afghani</strong></td>
<td></td>
</tr>
<tr>
<td>All values</td>
<td>NMRA representative <strong>plus</strong> one monitor</td>
<td>Applicant has not accepted quantity determination by a WODA inspection team. Re-inspection is to be conducted by NMRA representation <strong>plus</strong> a monitor.</td>
</tr>
<tr>
<td>Less than 25,000</td>
<td>Two officers appointed by DTC</td>
<td>Public-sector or NGO operator</td>
</tr>
<tr>
<td>More than 25,000 and less than 50,000</td>
<td>Two officers appointed by DTC</td>
<td>WODA application reviewed by DTC and NMRA with no obvious abnormalities or unusual circumstances</td>
</tr>
<tr>
<td></td>
<td>Two officers appointed by DTC <strong>plus</strong> one Provincial Health Office (PHO) or NMRA representative</td>
<td>WODA application is unclear or abnormal</td>
</tr>
<tr>
<td>More than USD 50,000</td>
<td>Two officers appointed by DTC <strong>plus</strong> one NMRA representative</td>
<td>WODA application reviewed by NMRA and there is clear and credible explanation and justification for high-value disposal</td>
</tr>
<tr>
<td></td>
<td>Two officers appointed by NMRA</td>
<td>WODA application reviewed by NMRA and explanation and justification for high-value disposal is not clear and/or credible</td>
</tr>
</tbody>
</table>

### WODA Procedures for PGM: Application Review Procedures

DTC will review all applications for WODA-PGM, and refer high-value WODA to NMRA for further review.

NMRA will establish detailed guidelines for the application review team, which will be reviewed at least every three years.

NMRA may delegate review authority to PHO or DHO at their discretion.

### WODA Procedures for PGM: Identity and Quantity Verifications

**FFP**

Product identification should be undertaken by verifying the product labeling, packaging and any invoice, purchase order, delivery note and stock record information available.

Sealed containers should have stated content recorded (e.g., “bottle of 100 tabs”).

Unsealed containers (or any containers which are in doubt as to whether they are still factory sealed) should be treated as unsealed containers, and should have contents physically counted and recorded.

- Quantities in used multi-dose vials should be estimated from liquid content level.
The total number of containers should be counted.

The total quantity of product and the total quantity of active ingredient should be calculated.

IF there is any discrepancy between the application quantity and the observed quantity, THEN the applicant should be invited to conduct a joint re-count with the inspection team.

IF, after a re-count, there are still discrepancies between the application quantity and the inspection team determined quantity, THEN:

- IF the discrepancy for a particular item is less than 20%, AND the applicant accepts the quantity determined by the inspection team, the applicant should sign the WODA form in agreement and acknowledge acceptance of the revised quantity.

- IF the discrepancy for a particular item is less than 20%, AND the applicant does not accept the inspection team determined quantity, then the WODA process should be stopped and referred to NMRA for resolution.

- IF the discrepancy for a particular item is more than 20%, a new application showing a revised quantity should be made to DTC

5.7. Applicability of WODA Procedures Development for Private-Sector General Medicines (PRV)

For the purposes of this policy guide, and all subsequent regulations and procedures, the WODA procedures for private-sector general medicines (PRV) will apply to medicines; organizations and bodies; and persons, officers, and operatives.

Applicability of WODA Procedures Development for PRV: Medicines

- WODA-PRV procedures apply to all medicines, except controlled medicines, for use in the private sector.

- WODA-PRV procedures do not apply to controlled medicines and do not apply to public-sector operations.

WODA-PRV procedures apply to each of the following situations.

- **All medicines, except controlled medicines, as FPPs:** All non–controlled medicine presented in its finished dosage form, having undergone all stages of production, including packaging in a final container and labeling. A medicine as FPP is defined 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.

- **All medicines, except controlled medicines, as APIs:** Non–controlled medicines 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 or for veterinary use.

- **All medicines, except controlled medicines, as prepared/compounded medicines:**
  Prepared or compounded medicines are comprised of 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, or for veterinary use. These
  medicines are prepared by compounding, mixing, admixing, modifying, or adjusting an
  API or FPP (usually within a pharmacy setting) that does not contains any controlled
  substance.

**Applicability of WODA Procedures for PRV: Organizations and Bodies**

The WODA procedures for PRV will apply only to private-sector bodies, organizations,
structures, and dispensing operations which are involved in manufacturing, importing
compounding, procuring, storing, transporting, distributing, marketing, wholesale and retail
selling, sampling, testing, analyzing, prescribing, dispensing, administering, and receiving PRV
for human use in Afghanistan.

**Applicability of WODA Procedures for PRV: Persons, Officers, and Operatives**

The WODA procedures for PRV will apply to all private-sector operatives who are in possession
of and or/involved in manufacturing, compounding, procuring, storing, transporting, wholesale
and retail selling, distributing, sampling, testing, analyzing, prescribing, dispensing, and
administering PRV for human use in Afghanistan.

**5.8. WODA Procedures for PRV**

WODA procedures for PRV apply to all medicines, except controlled medicines, which have not
been funded by the public sector, or for which the funding is not administered through the public
sector, and are for use in the private sector. That is, by manufactures, importers, wholesalers,
distributors, retail pharmacies, and private healthcare establishment operators. After designation
as WODA-PRV, THEN:

- NMRA will specify the reporting requirements for WODA activities to be undertaken by
  the operators (generally none for WODA, only for disposal).
- NMRA will produce guidelines for WODA functions in the private sector.
- The operator may develop their own WODA procedures but must observe the NMRA
  reporting requirements, and are recommended to follow the NMRA WODA guidelines for
  private-sector operators.

**WODA Procedures for PRV: Key Points**

The key features of the WODA procedure for PRV, and the essential differences from WODA
procedures for other medicines, follow:
The private sector is entirely responsible for designing and implementing its own WODA procedures for all medicines except controlled medicines, but is recommended that they follow the NMRA-developed guidelines.

It is not necessary for NMRA or any other public-sector pharmaceutical operatives to oversee the WODA-PRV process, but operators may request DTCs and/or NMRA to be present as witnesses. But, such presence will not exclude the operator from observing or having verified any accounting, financial reporting, and tax-related issues.

Private-sector operatives should be aware of any financial and accounting procedures they must observe during the WODA process (e.g., verification by tax/VAT authorities).

It is not necessary for private-sector operations to report their WODA activities to DTC or NMRA but they must report their destruction and disposal of all pharmaceutical waste to DTC and GDPA. (see Section 7 of this policy)

PRV WODA applies only to the WODA process.

**WODA Procedures for PRV: Premises**

WODA-PRV may be undertaken at any premises that are operated by the private sector and are suitable for the storage of medicines.

**WODA Procedures for PRV: Collection of Waste Medicines**

The private sector may establish its own procedures but is recommended to be guided by:

Finished Pharmaceutical Products, Compounded Medicines
Medicines should be collected in the original packaging, cartons, boxes, packets, etc.

Packaging should only be removed after the WODA inspection and during the destruction stage of the process.

Only after the WODA has been certified, should the medicines be treated as waste and destroyed.

**WODA Procedures for PRV: Frequency of WODA Activities**

The private sector may establish its own procedures but is recommended to be guided by:

WODA-PRV should be conducted at least every six months.

**WODA Procedures for PRV: Target Time for Completion of WODA Activities**

The private sector may establish its own procedures but is recommended to be guided by:

For PRV, a WODA process should be completed in not more than 30 days from first decision to certified destruction of the medicines.

**WODA Procedures for PRV: Detailed SOPs**

**WODA Procedures for PRV: Detailed SOPs: Responsible Body**
NMRA will be responsible for developing guidelines, SOPs, forms, and other formats for undertaking WODA-PRV. NMRA is responsible for institutionalizing and sharing information on the detailed procedures.

The private sector is responsible for developing its own detailed SOPs for WODA-PRV.

**WODA Procedures for PRV: Examining Officers**

The private sector is responsible for determining the qualifications of the WODA-PRV examining officers required but it is recommended that:

- At least two officers undertake the process
- At least one officer is a registered pharmacist

**WODA Procedures for PRV: Responsibilities of WODA Operators**

Operators are responsible for ensuring that protective clothing is available for the staff who will undertake the verification, especially if there are damaged/leaking medicines to be inspected.

At a minimum this must consist of:

- External clothing: lab coat or overalls
- Gloves: domestic ‘rubber’ gloves
- Eye protections: clear goggles, wrap-around spectacles
- Face masks: disposable surgical masks

*Information note:* The majority of FPP PRV does not require any special handling in regard to maintenance of personal toxicity safety. The main purpose of the protective clothing is to provide protection from leaking liquids.

Operators are responsible for arranging for the safer disposal of the medicines in accordance with the relevant sections of this policy after WODA verification is complete.

**WODA Procedures for PRV: Presence of Witnesses**

Additional related persons may be invited to witness the WODA process for PRV (e.g., NGOs, judicial agencies, media, MoF staff, tax authorities, representatives of MoPH, staff in training).

Not more than a total of four additional witnesses should be present. All such witnesses, must:

- Be at least 21 years old
- Be able to present photographic, certified identification (passport/ID card) to the WODA verification team

**WODA Procedures for PRV: Photographic Records**

Photographic records of the WODA verification, and destruction processes may be made, but care should be taken to ensure that the location of the storage site cannot be identified.
WODA Procedures for PRV: Authority Levels

The private sector may set its own authority levels, but are reminded of the need to observe necessary financial and tax accounting procedures.

WODA Procedures for PRV: Post-WODA

After WODA-PRV is complete, the private sector is responsible for arranging destruction and disposal of the medicines, in accordance with the relevant sections of this policy guide.

6. DEFINITION, LISTING, AND CATEGORIZATION OF WASTE PHARMACEUTICAL PRODUCTS

6.1. Waste Disposal Categories for Pharmaceuticals: Responsible Body

For the purposes of this policy, and all subsequent regulation and requirements relating to this policy guide, Waste Disposal of Pharmaceuticals Categories in Afghanistan will be defined by the Official List of Waste Disposal of Pharmaceutical Categories to be produced by the NMRA (after consultation with NEPA).

In compiling the official listing of controlled medicines, NMRA and GDPS 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, notably the Basel Convention
- The Environmental Protections Laws of Afghanistan and the resulting regulations and detailed guidelines
- Published guidelines from other countries and NMRA
- Discussion with NEPA

The established categories are to be reviewed at least every two or three years, and amended in light of the most recent information on waste pharmaceuticals classifications and the medicines in use in Afghanistan.

The categorization list is to be published and made available to the public.

6.2. Definition of Pharmaceutical Waste to Be Included in Pharmaceutical Waste Categorization and Covered by This Policy

For the purposes of this policy guide and all subsequent regulations and guidelines resulting from this policy guide, “pharmaceutical waste” shall be considered to refer to unused (i.e., not administered/consumed) pharmaceuticals.

Pharmaceutical waste is primarily intended to consist of date-expired, damaged, sub-standard, or seized/confiscated whole FFPs and APIs.

Pharmaceutical waste includes all unused preparations and formulations of medicines: tablets, capsules, powders, vials, ampoules, pessaries, suppositories, intrauterine devices (IUDs), implants, creams, ointments, lotions, shampoos, IV solutions, inhalers, aerosols, unused pre-loaded syringes; unused pre-loaded liquid medicine delivery devices, dermal patches, etc.
Pharmaceutical waste may include medicines that have been dispensed to a patient and returned unused, opened (partially used) bottles of tablets/capsules, partially opened blister strips, partially used multi-dose vials/ampoules, partially used IV solutions, partially used powders, partially used inhalers/aerosols, or other pre-loaded, non-liquid, devices used to deliver medicine to the body.

Pharmaceutical waste may include materials that have been used to clean a major medicines spill and become contaminated by the medicine (e.g., absorbent powder/sand, cloths, paper).

Pharmaceutical waste does not include:
- All medicines dispensed to patients (unless returned unused to a pharmacy)
- Partially used pre-loaded syringes, partially used liquid delivery devices
- Empty vials, ampoules, bottles, tubes, containers, IV bags/bottles, blister strips, dispensing cups, etc.

### 6.3. Categorization of Pharmaceuticals for Waste Disposal

Initially six categories are proposed for pharmaceutical waste: non-hazardous pharmaceutical waste (n-HPW), hazardous pharmaceutical waste (HPW), cytotoxic and cytostatic, controlled medicine, bio-hazardous, and radioactive; definitions for each follow.

NMRA will be responsible for preparing detailed definitions for each category and publishing a list of the detailed definitions, together with an indicative list of medicines within each category.

The established categories and medicines list are to be reviewed at least every two years and amended in the light of the most recent information on waste pharmaceuticals classifications and the medicines in use in Afghanistan.

The categorization definitions and medicines lists are to be published and made available to the public (through online media, or upon request for hard copy).

### 6.4. Non-Hazardous Pharmaceutical Waste (n-HPW)

All other pharmaceutical waste not included in one of the categories defined below.

### 6.5. Hazardous Pharmaceutical Waste (HPW)

Three main criteria are used to determine the categorization of HPW:

- Waste pharmaceuticals that meet the definition of a hazardous waste by reason of inherent toxicity to humans and/or animals. The general guideline is an oral lethal dose of 50 mg/kg (LD50) or less. (LD50 is the amount of a material, given all at once, which causes the death of 50% of a group of test animals.) It is recommended that the US Resource Conservation and Recovery Act (RCRA) “P-list” be used to determine which pharmaceuticals should be categorized this way.

- Waste pharmaceuticals that meet the definition of a hazardous waste by reason of toxicity to the environment. It is recommended that the US RCRA “U-list” be used to determine which pharmaceuticals should be categorized this way.
- Waste pharmaceuticals that are hazardous by virtue of actual or anticipated quantity/volume.

For Afghanistan, HPW classification by virtue of volume is not considered necessary at this time because the country is not using an adequate volume of medicines for disposal quantities to be used as a criterion for hazardous waste classification.

If and when the TPE per capita for medicines use in Afghanistan exceeds US $100 per year, the situation should be reviewed and anticipated destruction quantity considered as a basis for hazardous medicine classification.

- Any medicines subject to a statutory product recall notice (as defined in Section 12 of the National Quality Assurance of Medicines Policy) are considered HPW.

A guideline summary of pharmaceuticals to be classified as HPW (developed from the US RCRA P-list and U-list) is contained in Annex 1.

### 6.6. Cytotoxic and Cytostatic Pharmaceutical Waste

All known potentially cytotoxic and cytostatic pharmaceuticals are to be managed as HPW regardless of whether or not they are technically listed as hazardous waste due to their inherent toxicity by other agencies/countries.

This will include all antineoplastic pharmaceutical agents used for the treatment of cancer.

A list of known cytotoxic medicines is contained in Annex 2.

The majority of these items are not yet in use in Afghanistan.

### 6.7. Controlled Medicines Pharmaceutical Waste

For the purposes of this policy guide and waste management activities in Afghanistan, all controlled medicines are to be classified as hazardous waste.

Controlled medicines are defined by NMRA-CMG, which also is responsible for publishing lists of controlled medicines licensed for use in Afghanistan.

### 6.8. Bio-hazardous Pharmaceutical Waste

Bio-hazardous pharmaceutical waste essentially arises from date-expired or damaged vaccines.

For this policy guide, bio-hazardous pharmaceutical waste *does not* include used syringes, needles, swabs, empty vials, or any other form of a waste arising from administering a vaccine, or any form of clinical waste.

This policy guide applies only to unused vaccines and biological agents intended for human administration (e.g., human growth hormone).

For this policy guide, bio-hazardous pharmaceutical waste may include unused pre-filled syringes, injection ‘bags,’ or other unused, pre-loaded dispensing devices.
This bio-hazardous waste will require disinfection, usually by autoclave, microwave or chlorine bleach. (Procedures are outlined in Section 7: Physical Destruction Methodologies.)

After disinfection, all vaccines and human biological products are to be treated as HPW.

In effect, handling waste vaccine will require a two-stage process: disinfection (usually through temperature processing) and then the HPW management disposal procedure.

6.9. Radioactive Pharmaceutical Waste

Radioactive waste essentially arises from pharmaceuticals for radiotherapy or diagnostic use.

For this policy guide, radioactive pharmaceutical waste does not include used syringes, needles, swabs, empty vials, or any other form of a waste arising from administering radiotherapy or radiodiagnostic pharmaceuticals; any form of human body discharge/waste and/or clinical waste; corpses; or any other radioactive sources not intended for internal human administration.

Unused radioactive pharmaceuticals will primarily be disposed of by decay in storage in a locked, radiation-proof cabinet/hot lab. After decay in storage to background radiation levels, the material will be classified as HPW (regardless of actual toxicity) and disposed of accordingly. All radioactive pharmaceuticals should be stored in appropriate shielded waste containers bearing labels indicating “Radioactive Waste Do Not Dispose.” These materials shall be held for at least 10 half-lives in a radiation-proof cabinet/hot lab and surveyed with a Geiger-Müller (GM) counter meter prior to their transfer for HPW disposal.

In effect, handling radioactive pharmaceutical waste will require a two-stage process: Storage (in radiation-proof containers) until background radiation levels are achieved and then the HPW management disposal procedure.

A sample list of radio-pharmaceuticals is included in Annex 3. Most of these items are not in use in Afghanistan at this time.

6.10. Overall Effect of the Pharmaceutical Waste Classifications

The overall effect of the proposed methodology of pharmaceutical waste classification is that only two destruction procedures are necessary:

- n-HPW: Expected to be the bulk of pharmaceutical waste in Afghanistan (more than 85% by volume)
- HPW: Some of these products require pretreatment (e.g., vaccine sterilization/temperature treatment) before applying standard destruction methods (Section 7).

It is believed that this practical approach will be relatively simple to implement, and thus more effective, offering a far greater prospect of success in securing effective medicines destruction to guard public health and limiting environmental impact of waste medicines disposal.
7. PHYSICAL DESTRUCTION METHODOLOGIES

7.1. Background and Guiding Principles for Formulating Medicines
    Destruction Methodologies

The basic principles used in developing the destructions and disposal methodologies are:
- Need to protect public health
- Need to protect the environment

The range of destruction methodologies appropriate for use in a low-income country as developed by the World Health Organization has been reviewed in the light of:
- The current low TPE in Afghanistan, and the subsequent very low volumes of pharmaceutical waste anticipated
- The lack of high-technology destruction infrastructure (e.g., high temperature, dual-chamber, oxidative, environmentally certified incinerators)
- The lack of staff skilled in the technology and theory of disposal methodologies of medicines (Most pharmacists do not have environmental training, and most environmental staff do not have pharmacy training.)
- The current very low level of funding available for destruction and disposal procedures

Therefore, the chosen methodology for destruction and disposal of medicines is:
- Pretreatment (if necessary, e.g., for use in some HPW sub-categories)
- Encapsulation (as defined by WHO)
- Disposal to domestic refuse landfill site

Low-temperature burning should not be used for medicines since it can both generate and increase the spread of toxic materials.

The basic difference in the treatment of HPW and n-HPW is the encapsulation methodology that is to be used:
- For significant volumes of waste
  - HPW: A lime/concrete encapsulation medium is to be used.
  - n-HPW: A chlorine bleach soak, or lime whitewash denaturing methodologies can be used.
- For minor volumes of waste (e.g., retail pharmacy or dispensary)
  - HPW: A cement encapsulation medium is to be used.
  - n-HPW: A chlorine bleach soak, and/or coffee grounds, and/or soil/mud, and/or waste (sump) motor oil denaturing methodologies can be used.

The selection of appropriate destruction and disposal methodologies should be reviewed by NMRA jointly with NEPA every three years.

The current methodologies selected for destruction and disposal does not preclude the trial use of newer technology development such as low-cost, small-scale incinerators (provided they comply with the requirements of the Basel Convention) and alkaline hydrolysis.

Proposals for any such trials should be discussed jointly with NMRA and NEPA, and the full operational parameters agreed upon.
7.2. Special Pharmaceutical Wastes: Pretreatments

Certain classifications of pharmaceutical waste require pretreatment before they follow the standard HPW destruction and disposal methods.

Bio-hazardous Pharmaceutical Waste

All identified bio-hazardous pharmaceutical waste should be treated as if it were potentially infectious. In fact, very little is likely to pose any significant infection risk, but it is simpler to treat all such waste with one methodology.

The basic method for disinfection is through heat treatment.

It is recommended that a microbiologist or other certified/authorized sterilizer operative monitor the process.

The materials should be placed in heat-permeable, robust, inert, containers (e.g., perforated stainless steel sterilization boxes) so as to protect against any glass breakage, explosion, etc. resulting from the heat treatment.

Appropriate sterilization indicator monitors must be included in the boxes in accordance with normal sterilization monitoring procedures.

Preferred Method

- Vacuum cycle steam autoclave
- The following parameters may be used in a gravity displacement or vacuum autoclave: minimum 121 degrees C, 15 to 19 pounds of pressure/100 kPa (15 psi), for at least 20 minutes.

Alternative Method

- Dry heat oven
- These general parameters may be used for sterilization in a dry-heat oven: 170 degrees C for 1 hour, or 160 degrees C for 2 hours, or 121 degrees C for at least 16 hours.

After correct temperature processing has been verified by positive indication of the sterility/temperature monitoring indicators, a certificate attesting that the heat treatment has been carried out should be attached to the materials, and the materials should be packaged and marked “Denatured: For Destruction Only” and sent for standard HPW destruction and disposal.

Radioactive Pharmaceutical Waste

It is a normal requirement of ionizing radiation and radioisotopes regulations that reporting to the National Atomic Energy Authority or similar regulatory body is required for the destruction and
disposal of all radioactive materials. The WODA reporting requirements must be viewed as additional to the radiation control authority requirements.

The basic method of pretreatment is delay and decay.

**Delay and Decay**
- Medium-activity radioactive waste and waste with half-lives of less than one month may be stored.
- The storage space should have lead shielding of appropriate thickness (10 HVL) to prevent radiation leakage.
- The radioactive waste should be stored for a time period of not less than 10 half-lives; that is, when after decay only 0.1% of the initial radioactivity remains.

**Radiation Monitoring after Decay**
After the appropriate decay period, the waste is monitored for the residual activity (using the appropriate detection methodology for the particular isotope). If the dose limit is low—defined as being less than 1.35 microcuries (50 KBq), or if the overall package concentration does not exceed 135 microcuries / m3 (5MBq / m3)—the waste should be certified as containing no radiation threat by a registered/authorized ionizing radiation worker, labeled as such, and securely bagged to be sent for standard HPW destruction and disposal.

### 7.3. Sorting Pharmaceutical Wastes

**The Objectives of Sorting Pharmaceutical Wastes**
The objective of sorting pharmaceutical waste is to separate the pharmaceuticals into categories that require different disposal methods.

For Afghanistan only two major destruction/disposal categories are being used:
- HPW (with sub-category items requiring pretreatment)
- n-HPW

**Methodology of Sorting Pharmaceutical Wastes**

Sorting involves an overall evaluation of the waste pharmaceuticals stockpile and subsequent division of pharmaceuticals into the pharmaceutical waste categories and then into destruction categories.

NMRA is responsible for producing detailed lists of the pharmaceutical waste categories. A consolidated list of pharmaceutical waste categories is contained in Annex 4.

The sorting process includes each of the following steps:
- Identifying each item. If in doubt or uncertain, classify as HPW.
- Making a decision on which category of pharmaceutical waste it falls into.
- Separating different categories of pharmaceutical waste.
- Confirming that pretreatment of the bio-hazardous and radioactive pharmaceutical waste has occurred. If pretreatment cannot be confirmed by the presence of certificates attached to the waste, then the waste must be returned to originator for processing.
- Sorting the waste into destruction categories of hazardous or non-hazardous waste.
Practicalities of Sorting Pharmaceutical Wastes

It is essential to leave packages and boxes intact until reaching the actual start of the destruction process. Do not remove packaging during the sorting phase. The pharmaceutical waste should be separated from its packaging as late in the process as possible.

Non-Pharmaceutical Materials
It is still regrettably the case that a typical stockpile of waste drugs is not only occupied by the pharmaceuticals themselves, but rather also includes other items (such as medical material and equipment, food, clothing, boxes, pallets, and general rubbish).

The first step in dealing with these stockpiles is to remove and dispose of this non-drug, non-chemical items. All such items should be clearly separated from pharmaceuticals and chemicals.

Waste paper, packing materials, and wooden items (such as pallets) can be recycled, burned, or disposed of as normal domestic waste to a landfill.

Hazardous or Potentially Hazardous Non-Pharmaceutical Materials
All non-pharmaceutical, potentially hazardous waste (such as chemicals, cleaning solutions, batteries, and waste oil) should be separated and must be dealt with on a case-by-case basis by the hazardous waste expert. This waste must not be handled by the pharmaceutical teams unless expressly directed to do so. This waste requires separate and careful labeling and transportation to an appropriate disposal center.

Conditions for sorting:
- Sorting should be done in a well-ventilated covered structure.
- Sorting should be done as close as possible to the waste pharmaceuticals stockpile, in an orderly way, with all sorted material clearly labeled and separated at all times.
- Staff should be supplied with protective equipment (gloves, boots, overalls, dust masks, etc.), should work under the direct supervision of a pharmacist, and should receive training on the sorting criteria and health and safety risks associated with handling the materials.

Once sorted, the pharmaceuticals should be carefully stacked, with the contents clearly indicated on the outside of the containers. Until disposal is carried out, the materials should be kept in a dry, secure, and preferably separate room to avoid being confused with in-date pharmaceuticals.

7.4 Physical Destruction of HPW: Basic Principles

The entire destruction/disposal process should be conducted under the supervision of a senior responsible pharmacist.

The basic principles to be used for the destruction of HPW are:
- Volume reduction (removal of packaging)
- Denaturing (inertization) to prevent possible re-use
- Encapsulation (in a concrete medium)
- Disposal to landfill site

Recommended Method
Denaturing and encapsulation are to be implemented together by using a lime/cement concrete mixture.
National Policy for
Waste Management and Safe Disposal of Pharmaceutical Products

After the waste material has been encapsulated in a concrete mixture it may be disposed of in a normal domestic refuse landfill site.

Alternative Method
High-temperature incineration may be used for HPW destruction IF:
- The incinerator conforms to the Basel Convention Technical Guidelines on Incineration on Land,\(^2\) AND
- The incinerator has been environmentally certified by NEPA, AND
- There are adequate quantities of HPW disposal to justify the expense. (Generally in excess of one 20-foot shipping container load required.)

Low-temperature burning is not recommended as a destruction/disposal methodology, and should be used only in extreme cases where no landfill site is available.

Physical Destruction of HPW: Reporting Requirements

NMRA will specify the detailed reporting requirements required for the destruction and disposal of HPW.

It is not necessary for retail pharmacies and small dispensaries to report HPW destruction/disposal to NMRA.

It is not necessary for operations disposing of less than two cubic meters of HPW per year to report to NMRA.

If a WODA form has been used to report the WODA to DTC/NMRA (all public-sector and all controlled medicines), the same WODA form can be used to report the destruction and disposal to DTC/NMRA.

If no WODA form has been used to report the WODA to DTC/NMRA (private-sector operators), then either a WODA form can be used, or the following information should be reported to DTC and NMRA:

- Reporting officer
  - Name of reporting officer making the report
  - Name of organization/company (manufacturer/importer/distributor, and site, clinic, hospital store, NGO site)
  - Address of reporting officer, including e-mail and telephone
- Location
  - Physical location of the premises where the HPW was sorted and destroyed
  - Physical location of the landfill site used to dispose of the encapsulated waste
- Dates
  - Date of reporting
  - Date of destruction/encapsulation
  - Date of disposal to landfill site
- The name of the medicine using the approved generic name (INN) as it appears in the EML or LML of Afghanistan.
- The total quantity of each medicine (as detailed below)

For each PGM in finished form (FPP)
  - Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per milliliter)
  - The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or three-milliliter vial)
- Estimated total weight/volume of all the medicines (including packaging) being destroyed
- If weight not known and no weighing scales are present, use volume.
- Volume in cubic meters (approximate measure of height, width, and length multiplied together)

- Value of the medicine
  - Unit price from invoices/purchase orders/supply documents
  - If unit price not known use IDPIG FOB median price, plus 25% for DDP in-country
  - Extended price for each item (price multiplied by quantity)
  - Total value of medicine destroyed

- Reason for the destruction/disposal
  - E.g., date expired, damaged, returned from intended user

- Signatures
  - Supervising pharmacist

- Notes and observations
  - To record any special circumstances

### Physical Destruction of HPW: Determine Disposal Container Size to be used

The size of disposal container that can be used will depend on the availability of mechanical handling equipment at the destruction site and the landfill disposal site.

The supervising pharmacist should make a clear decision on the size of disposal containers to be used and ensure that an adequate number of containers are available.

It can be more practical to use multiple small containers rather than one large container if mechanical handling equipment is not available.

Table 7 can serve as a guide.
Table 7: Guideline Weights of Disposal Containers Filled with Concrete

<table>
<thead>
<tr>
<th>Container type</th>
<th>Volume</th>
<th>Weight with concrete</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concrete truck, rotating mixing drum</td>
<td>5</td>
<td>12,000</td>
<td>Vehicle access to destruction site and landfill disposal site</td>
</tr>
<tr>
<td>Metal 50 gallon oil drum</td>
<td>250</td>
<td>480</td>
<td>Requires mechanical handling equipment</td>
</tr>
<tr>
<td>Plastic bulk chemical container</td>
<td>200</td>
<td>400</td>
<td>Requires mechanical handling equipment</td>
</tr>
<tr>
<td>Large plastic bucket/drum</td>
<td>25</td>
<td>50</td>
<td>Can be manually handled by two workers</td>
</tr>
<tr>
<td>Household plastic bucket/nappy pail with lid</td>
<td>5</td>
<td>12</td>
<td>Easily manually handled</td>
</tr>
</tbody>
</table>

For large volumes of disposals, the concrete mixing truck method can be highly beneficial since it negates the need for additional mechanical handling equipment and most landfill sites have large-vehicle access for their regular domestic waste tipping.

For small retail shops or dispensaries, the household plastic bucket can serve as a convenient method. A concrete mix base of around two centimeters in poured into the bucket, waste is added until it is 80% full, then the bucket is filled with concrete.

It is possible and perfectly permissible to add n-HPW to HPW to make up disposal volumes. For example, if a concrete truck is ordered for convenience of handling, but only one cubic meter of HPW is present, then three cubic meters of n-HPW may be added.
**Physical Destruction of HPW: Determine Encapsulation Materials Required (Cement)**

The supervising pharmacist is responsible for ensuring that disposal containers and encapsulation materials (concrete mix) are available BEFORE starting the destruction process. Table 8 may serve as a guide.

**Table 8: Guideline Concrete Requirements**

<table>
<thead>
<tr>
<th>Container type</th>
<th>Cubic meter</th>
<th>Bags of ready mix sand/cement/lime 20 kg bags</th>
<th>Cement kg</th>
<th>Sand kg</th>
<th>Lime kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concrete truck</td>
<td>3 to 5</td>
<td>Mixture of lime, cement, and water in the proportions 15:15:5 (by weight)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 gallon oil drum (250 l)</td>
<td>0.25</td>
<td>25</td>
<td>100</td>
<td>280</td>
<td>100</td>
</tr>
<tr>
<td>Plastic bulk container (200 l)</td>
<td>0.20</td>
<td>15</td>
<td>80</td>
<td>140</td>
<td>80</td>
</tr>
<tr>
<td>Large plastic bucket (25 l)</td>
<td>0.025</td>
<td>2.5</td>
<td>10</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Household plastic bucket (5 l)</td>
<td>0.005</td>
<td>0.5</td>
<td>2</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>

**Physical Destruction of HPW: Determine Quantity of Disposal Containers Required**

The supervising pharmacists should calculate the number of disposal containers required and ensure they are available BEFORE starting the destruction process.

The normal requirement for disposal of hazardous pharmaceuticals is that the disposal container should not be more than 75% full of disposed pharmaceuticals (i.e., base layer of concrete, mid-layer of mixed pharmaceuticals and concrete, top layer of concrete).

**FPPs**
- The 75% rule may be applied.
- IF only controlled medicines are being disposed of, it is better to limit the waste pharmaceutical content of the container to not more than 50% unless the concrete mixing truck method is being used, in which case the 75% may be used.

**APIs**
- The HPW disposal should not account for more than 30%, by weight, of the filled container weight—except for controlled medicines, in which case, not more than 10% should be used.
- The concrete mixing truck can be beneficial for disposal of large quantities of HPW APIs.

**Physical Destruction of HPW: Destruction Process**

In order to reduce the physical volume of hazardous waste:
- Remove the packaging materials, paper, cardboard, and plastic wrap from the pharmaceuticals.
- Pills need to be removed from their bottles, but do not open blister packs. Do not open or break vials/ampoules. Do not empty liquid preparations. Place them whole into the concrete mixture.
• Use personal protection equipment when emptying bottles (because of dust hazard).

The packaging material must be destroyed.
• The paper/card can be mechanically shredded and then recycled, burnt, or otherwise rendered unusable.
• To render unusable, place in a container of water with domestic liquid chlorine bleach (one liter of bleach to 50 liters of water) and soak for at least three days.
• Use the same process for any printed plastic wrap, empty bottles, or other empty containers. This treatment will destroy any printing on the packaging, bottles/cartons, or labels.
• After three days, the solid waste may be treated as standard household waste and sent to landfill site through the domestic trash disposal.

If using the concrete truck revolving drum method: The use of the truck must be explained to the supplier of the concrete so that they can ensure they have adequate water on board for complete flushing/rinsing of the mixing drum of the truck after use, and also so that they realize that the concrete will not be used for structural construction use, but will go straight to waste.

When the truck arrives load the materials for destruction into the truck.

When loading is complete, the drum should be rapidly revolved for at least three minutes (rapid mixing stage; water may be added).

The truck drives to the landfill site and discharges the load into a prepared trench, which should be immediately covered with domestic waste. The mixture that results from rinsing the mixing drum can be emptied onto the domestic waste. The discharge area should be protected to deter scavengers for approximately one hour after discharge. (The cement/lime mixture hardens very quickly.)

If using a container method: Place a layer of the concrete mixture in the bottom of the container for around 10% of the container height. Load the waste materials into the container but do not fill more than 80%. Make a very liquid concrete mix so that it flows easily, pour the concrete mixture into the container to fill the container, and cover/seal.

Physical Destruction of HPW: Disposal Process

If using a container method: After three days, and the concrete has set hard, the concrete-filled container may be sent to the landfill site where it should be discharged into a prepared trench, which should be immediately covered with domestic waste.

7.5. Physical Destruction of n-HPW: Basic Principles

The entire destruction/disposal process should be conducted under the supervision of a senior pharmacist.
The basic principles to be used for the destruction of n-HPW are:

- Volume reduction (removal of packaging)
- Denaturing (inertization) to prevent possible re-use
- Disposal to landfill site

**Recommended Methods**

n-HPW can be denatured through the following methods, and then disposed of in a landfill site:
- Mixing the n-HPW with unpleasant carrier materials such as soil, mud, coffee grounds (for very small volumes), whitewash, or waste paint/dye; OR
- Soaking the n-HPW in a chlorine bleach solution; OR
- A combination of the above techniques.

n-HPW may also be incorporated into HPW destruction and disposal processing.

**Alternative Method**

High-temperature incineration may be used for n-HPW destruction IF the incinerator:
- Conforms to the Basel Convention Technical Guidelines on Incineration on Land, AND
- Has been environmentally certified by NEPA

Low-temperature burning is not recommended as a destruction/disposal methodology, and should be used only in extreme cases where no landfill site is available.

**Physical Destruction of n-HPW: Reporting Requirements**

NMRA will specify the detailed reporting requirements required for the destruction and disposal of n-HPW.

It is not necessary for retail pharmacies and small dispensaries to report n-HPW destruction/disposal to DTC/NMRA.

It is not necessary for operations disposing of less than 10 cubic meters of n-HPW per year to report to DTC/NMRA.

**Reporting**: If a WODA form has been used to report the WODA to DTC/NMRA (all public-sector medicines and controlled medicines), the same WODA form can be used to report the destruction and disposal to DTC/NMRA.

If no WODA form has been used to report the WODA to DTC/NMRA (private-sector operators), then either a WODA form can be used, or the following information should be reported to DTC and NMRA:

- Reporting officer
  - Name of reporting officer making the report
  - Name of organization/company (manufacturer/importer/distributor, company and site, clinic, hospital store, NGO site)
  - Address of reporting officer, including e-mail and telephone

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• Location
  o Physical location of the premises where the n-HPW was sorted and destroyed
  o Physical location of the landfill site used to dispose of the encapsulated waste

• Dates
  o Date of reporting
  o Date of destruction/encapsulation
  o Date of disposal to landfill site

• Estimated total weight/volume of all the medicines (including packaging) being destroyed
  o If weight not known and no weighing scales are present, use volume.
  o Volume in cubic meters (approximate measure of height, width, and length multiplied together)

• Reason for the destruction/disposal
  o E.g., date expired, damaged, returned from intended user

• Signatures
  o Supervising pharmacist

• Notes and observations
  o To record any special circumstances

**Physical Destruction of HPW: Determine Disposal Container Size to Be Used**

The size of disposal container that can be used will depend on the availability of mechanical handling equipment at the destruction site and the landfill disposal site.

The supervising pharmacist should make clear decision on the size of disposal containers to be used and ensure that an adequate number of containers are available.

It can be more practical to use multiple small containers rather than one large container if mechanical handling equipment is not available.

Table 9 can serve as a guide.
Table 9: Guideline Weights of Disposal Containers for n-HPW

<table>
<thead>
<tr>
<th>Container type</th>
<th>Volume</th>
<th>Volume</th>
<th>Weight</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liter</td>
<td>Cubic</td>
<td>Kilogram</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>meter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Domestic refuse truck with compactor system</td>
<td>8</td>
<td>2,000</td>
<td></td>
<td>Vehicle access to destruction site and landfill disposal site</td>
</tr>
<tr>
<td>Wheelie bin</td>
<td>240</td>
<td>120</td>
<td></td>
<td>Requires mechanical handling equipment to lift bin into refuse truck</td>
</tr>
<tr>
<td>Heavy duty plastic bin bags</td>
<td>50</td>
<td>30</td>
<td></td>
<td>Easily manually handled</td>
</tr>
</tbody>
</table>

For large volumes of disposals, the compacting refuse truck method can be highly beneficial since it negates the need for additional mechanical handling equipment, and most landfill sites have large-vehicle access for their regular domestic waste tipping.

**Physical Destruction of n-HPW: Denaturing/Destruction Process**

In order to reduce the physical volume of hazardous waste:
- Remove the packaging materials, paper, cardboard, and plastic wrap from the pharmaceuticals.
- Pills need to be removed from their bottles, but do not open blister packs. Do not open or break vials/ampoules. Do not empty liquid preparations.
- Use personal protection equipment when emptying bottles (because of dust hazard).
The packaging material must be destroyed.

- The paper/card can be mechanically shredded and then recycled, burnt, or otherwise rendered unusable.
- To render unusable, place in a container of water with domestic liquid chlorine bleach (one liter of bleach to 50 liters of water) and soak for at least three days.
- Use the same process for any printed plastic wrap, empty bottles, or other empty containers. This treatment will destroy any printing on the packaging, bottles/cartons, or labels.
- After three days, the solid waste may be treated as standard household waste and sent to landfill site through the domestic trash disposal.

n-HPW may be incorporated into HPW destruction and disposal processing. n-HPW also can be denatured through the following methods, and then disposed of in a landfill site:

- Mixing the n-HPW with unpleasant carrier materials such as soil, mud, coffee grounds (for very small volumes), whitewash, or waste paint/dye; OR
- Soaking the n-HPW in a chlorine bleach solution; OR
- A combination of the above techniques.

For small volumes at retail pharmacies or small dispensaries, the waste pharmaceutical can be placed in a plastic bag, mixed with coffee grounds (following the US Food and Drug Administration, or FDA, methodology), and then discarded to normal domestic waste disposal. See photo at left.

For larger volumes, the waste can be placed in either wheelie bins or plastic garbage bags, sprinkled with either mud or whitewash (mixture of lime salt and water), and then disposed of at a landfill site.

**If using the compacting refuse truck method:**
- The use of the truck must be explained to the supplier of the refuse service so they ensure the truck is available for an adequate period of time, and also so that they realize that they should go straight to the landfill site after filling.
- Denature the materials with whitewash before depletion.
- When the truck arrives, load the materials for destruction into the truck.
- If possible, mix with other (domestic) refuse (and/or the denatured packing material).
- During the loading of the waste, the compacting function should be periodically activated to ensure all the materials are crushed and compacted.
- The truck should drive directly to the landfill site and discharge the load into a prepared trench, which should be immediately covered with domestic waste.

**8. ORGANIZATION AND RESPONSIBILITIES OF KEY PLAYERS**

**8.1. Proposed Structure**

**Waste Pharmaceutical Issues: National Policymaking Bodies**

NMRA, working jointly with NEPA, should set the national policy for the handling of waste pharmaceuticals, until a body is established to make and implement operational national healthcare waste policy (which specifically includes pharmaceutical waste).
WODA Issues

NMRA will act as the national body to establish WODA guidelines and procedures. NMRA will work in conjunction with NMRA-CMG for controlled medicines WODA.

WODA and Disposal Implementation

NMRA will be responsible for the implementation of the WODA and destruction activities for controlled medicines.

Hospital DTCs will be responsible for the implementation of the WODA and destruction activities for all medicines other than controlled medicines.

8.2. WODA and Disposal Reporting

NMRA will be responsible for preparing national reports on the WODA and Disposal situation as detailed in Section 4.1.1.

8.3. HR Development and Staff Training

GDPS, working in conjunction with NEPA, will be responsible for promoting the incorporation of pharmaceutical waste management concepts into academic and professional documents, and to facilitate in-service training and short-course training for staff development.

8.4. Institutionalization and Promotion of Pharmaceutical WODA and Waste Management Guidelines and Procedures

GDPS, working in conjunction with NMRA-CMG, will be responsible for institutionalizing guidelines and procedures for controlled medicines WODA and disposal.

GDPS, working in conjunction with NEPA, will be responsible for institutionalizing guidelines and procedures for pharmaceutical WODA and disposal.

8.5. Private-Sector WODA and Waste Management Guidelines and Procedures

The private sector is responsible for developing its own procedures for undertaking WODA (except for controlled medicines), but is recommended to follow the GDPS WODA guidelines.

All sectors, including the private sector, should follow this policy guide for the disposal of waste pharmaceuticals.

9. STORAGE AND TRANSPORTATION OF DESIGNATED WASTE PHARMACEUTICALS

9.1. Conditions and Requirements of Premises

Premises for the storage of designated waste pharmaceuticals should be secure, clean, and dry. They should be under the control of a designated senior pharmacist.
Storage of designated waste controlled medicines must follow the same regulations as for viable controlled medicines.

Access to stores/stockpiles of designated waste pharmaceuticals should be restricted to workers staff involved in the WODA/disposal functions.

9.2. Transporting of Designated Waste Pharmaceuticals

Transportation of designated waste control medicines must follow the same regulations as for viable controlled medicines.

Transportation of other designated waste pharmaceuticals should be in undertaken in secure, clean, and dry vehicles.

10. FINANCING OF MEDICINES WODA AND DESTRUCTION/DISPOSAL PROCEDURES

10.1. Guiding Principle for Financing Medicines WODA and Disposal Procedures

The guiding principle for financing costs of WODA and destruction/disposal functions for public-sector medicines is that the activities should be largely self-financing with income collected from licenses, charges, and fees for medicine regulatory activities.

It is recommended that the import license charge (or, for in-country manufacturing, the marketing authorization license charge) include a fee of 1% of the medicine cost to finance WODA and destruction/disposal functions.

10.2. Guiding Principle for Financing Controlled Medicines WODA and Disposal Procedures

The guiding principle for financing costs of controlled medicines functions is that the activities should be largely self-financing with income collected from licenses, charges, and fees for controlled medicine regulatory activities.

It is recommended that the import license charge (or, for in-country manufacturing, marketing authorization license charge) for controlled medicines include a fee of 2% of the medicine cost to finance controlled medicines WODA and destruction/disposal functions.

10.3. License Fees and Regulatory Charges

At least yearly, NMRA should set the overall guidance target (budget) cost level of activities related to medicines WODA; this is generally expected to be less than 1% of the FOB cost of the total medicines annual importation.

This established target guidance (budget) level should set the charge for the licenses, import permits for medicines, and other medicine regulatory functions. That is, if NMRA-CMG establishes a budget for all medicine regulatory functions that equals X% of the estimated total value of imported medicines, then a charge equivalent to 1% of the medicine cost should be added to all import permissions/licenses to fund WODA functions.
10.4. **WODA and Destruction Disposal of Donated Medicines**

When donations of medicines occur, all medicine donors are to be requested to contribute the same import license fee value as all other suppliers; this will enable WODA activities (and other regulatory functions). That is, donor-financed products should not be exempt from license fees.

11. **LOCAL MANUFACTURERS**

11.1. **Basic Principles**

The same basic principles for WODA and disposal of designated waste pharmaceuticals as expressed in this policy will also apply to all locally manufactured medicines.

**Manufacturer Responsibility**

The manufacturer is responsible for all the costs of ensuring safe and effective disposal of all the pharmaceutical waste that is generated by its operations.

The manufacturer should develop a formal pharmaceutical waste management plan, to be reviewed by NMRA and NEPA for handling all its pharmaceutical waste.

**Promotion of Return to Manufacturer**

Local manufacturers will be encouraged to instigate and operate return-to-manufacturer systems for unused medicines, and to develop facilities and methodologies for the safe handling, recycling, and disposal of such returned products.

**Provision of Pharmaceutical Waste Management Facilities**

Local manufacturers should develop facilities and methodologies for the safe handling, recycling, and disposal of waste pharmaceutical products, and undertake necessary staff training and development in these areas.

11.2. **Specific Conditions for Local Manufacturers of Controlled Medicines**

**Provision of Plans and Facilities for Handling Waste Controlled Medicines API**

All manufacturers and all manufacturing sites undertaking the manufacture of controlled medicines in Afghanistan should develop formal plans and methodologies for handling the secure and environmentally safe disposal of waste controlled medicines API.

This plan should be reviewed jointly by NMRA, NMRA-CMG, and NEPA.
12. MEDICINES PRODUCT RECALLS

12.1. General Conditions for Product Recalls and Waste Management

Pharmaceutical product recalls will follow the conditions and regulation as specified in the National Pharmaceutical Quality Assurance Policy (Section 11):

- Medicine manufacturers, exporters, importers, import and wholesalers shall physically remove all medicines subject to a statutory recall notice from the marketplace and access to the public, and ensure that they segregated and quarantine 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 the recall to all medicines wholesalers and retailers and localities where medicines are circulated;
  - Promptly recall all violating goods items or medicine lots from these units;
  - Make medicine recall dossiers. A medicine recall dossier, made according to a set form, must show all evidence of the supply of medicines to and recall of medicines from wholesalers, retailers and users that have purchased medicines;
  - Send reports, made according to a set procedures issued by NMRA, 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:

Medicines subject to a recall notice should *not* be sent for WODA and disposal until an instruction has been received from NMRA that destruction should proceed.

*All* recalled medicines are to be treated as hazardous pharmaceutical waste.

12.2. Pharmaceutical Waste Management of Product Recalls

After being advised by NMRA that the materials subjected to a statutory Product Recall Notice may be destroyed:

- WODA should be applied in the normal way.
- The manufacturer and/or the manufacturer’s representative in Afghanistan may be invited to witness the WODA and destruction process.
- *All* recalled medicines are to be treated as HPW and should be destroyed following the standard HPW procedures.

13. MONITORING AND REPORTING

13.1. Overall Responsibility and Coordination of Data for WODA and Pharmaceutical Disposals

NMRA will have prime responsibility for overall monitoring and reporting of WODA and medicines disposals at national level.

In particular, they will determine:

- The key indicators to be used for monitoring WODA and medicines disposal
• Set the reporting frequency and data formats for reporting from all levels undertaking WODA and medicines disposal
• Collect, collate, and review the information on WODA and medicines disposals
• Analyze and seek to estimate national wastage and disposal rates for pharmaceuticals

13.2. Key Monitoring Indicators

In determining the key indicators NMRA, will take into account the requirements of NEPA and seek to monitor:
• Estimated total value, volume, and weight of HPW disposed of each year
• Estimated total value, volume, and weight of n-HPW disposed of each year
• Rate of wastage and disposal rates as a percentage of the total national pharmaceutical supply

14. PHARMACEUTICAL WODA AND DISPOSAL POLICY IMPLEMENTATION

14.1. WODA and Disposal Policy Review

It is recognized that the implementation of this policy for pharmaceutical WODA and disposal will involve many players and will require a high degree of coordination and networking between many diverse bodies, agencies, and private-sector operators.

In order to ensure the relevance and applicability of the policy, NMRA should review this policy at least every three to five years, and effect such changes as may be required for better efficiency and coordination amongst the many parties involved.

14.2. Pharmaceutical WODA and Disposal Implementation Plan

NMRHA will define priority areas for the Pharmaceutical WODA and Disposal Implementation Plan.

NMRA will develop:
• An overall guideline national implementation plan that will outline short-to-medium-to-long-term action plans with defined activities, budgets, timeframes, responsibilities, and expected outcomes and outputs, as appropriate.
• A detailed implementation plan for NMRA activities

Local DTCs will develop detailed implementation plans for WODA and disposal activities.

14.3. WODA and Disposal Enforcement

NMRA will have the primary role is setting enforcement procedures and guidelines.

DTC will have responsibility for local enforcement functions.

The key feature of the WODA and disposal enforcement activities is that, whenever possible, they should be coordinated with NEPA, and, whenever practical, they should not be undertaken as stand-alone/vertical activities. WODA and disposal enforcement activities should be integrated into all pharmaceutical enforcement activities.
For example, the general pharmaceutical retail outlet inspection/enforcement teams should inspect pharmaceutical retail outlets for compliance with disposal regulations. No separate/unique inspections teams, solely for WODA and disposal, are envisioned.

A similar approach applies to all levels of WODA and disposal activity from API manufacturers through, importers wholesalers to dispensing pharmacies.

14.4. Pharmaceutical WODA and Disposal Human Resource Development

The MoPH will be the prime body for undertaking human resource development to support the implementation of the pharmaceutical WODA and disposal policy.

NMRA will advise the MoPH on the likely human resource requirements for effective pharmaceutical WODA and disposal implementation and to undertake necessary oversight of these activities in Afghanistan.

NMRA will seek to engage with academic bodies, training institutions, and professional organizations to raise the profile and awareness of pharmaceutical WODA and disposal matters, and to seek to include adequate training on the subject in healthcare professional training and qualification programs.

These programs are to include:
- Institutionalization of this policy and its contents and requirements
- Increased understanding amongst doctors and pharmacists on the potential environmental impact of waste pharmaceuticals
- Increased understanding amongst manufacturers, importers, wholesalers, etc. on proper disposal of unused medications, including through return programs for unused medicines

14.5. Waste Pharmaceutical Management Public Awareness Development

NMRA will be responsible for integrating information and messages on waste pharmaceutical management into its existing patient-education activities.

These are to include:
- Educating the public to understand that waste pharmaceuticals do not currently pose any significant risk to public health or the environment in Afghanistan
- Spreading awareness that formal measures for waste pharmaceutical management are in place.
- Increasing patient understanding and patient counseling about proper disposal of unused medications at home, such as through return-to-pharmacy programs for unused medicines.

15. SPECIFIC ROLES AND RESPONSIBILITIES FOR PHARMACEUTICAL WODA AND DISPOSAL POLICY IMPLEMENTATION

15.1. API Manufacturers of Medicines Based in Afghanistan
API manufacturers based in Afghanistan are responsible for undertaking and bearing all associated costs for the environmentally safe destruction of all date-expired, damaged or sub-standard products, as detailed in this policy. Manufacturers should develop a clear pharmaceutical waste management plan and discuss it with NMRA and NEPA.

### 15.2. FPP Manufacturers of Medicines Based in Afghanistan

FPP manufacturers based in Afghanistan are responsible for undertaking and bearing all associated costs for the environmentally safe destruction of all date-expired, damaged, or sub-standard controlled medicines that have not been already been supplied to distributors/wholesalers or health bodies, in accordance with this policy guide.

Manufacturers are encouraged to develop and implement programs to accept the return of unused medicines for recycling or destruction.

Manufacturers should develop a clear pharmaceutical waste management plan and discuss it with NMRA and NEPA.

### 15.3. FPP Importers of 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 products that have not been provided to other authorized bodies. All such destructions must comply with the conditions of this policy guide.

Importers are encouraged to develop and implement programs to accept the return of unused medicines for recycling or destruction.

Importers should develop a clear pharmaceutical waste management plan and detailed SOPs for WODA and disposal, and discuss them with NMRA and NEPA.

### 15.4. FPP Distributors

FPP wholesalers are responsible for undertaking and bearing all associated costs for the environmentally safe destruction of all date-expired, damaged, or sub-standard products that have not been provided to other authorized bodies. All such destructions must comply with the conditions of this policy guide.

Wholesalers are encouraged to develop and implement programs to accept the return of unused medicines for recycling or destruction.

Wholesalers should develop a clear pharmaceutical waste management plan and detailed SOPs for WODA and disposal, and discuss them with NMRA and NEPA.

### 15.5. Retail Pharmacies (Shops)

Retail pharmacies are responsible for undertaking and bearing all associated costs for the return of all unused, date-expired, damaged, or sub-standard products that have not been dispensed to
patients or provided to other authorized bodies, to the wholesaler who supplied the medicine. The wholesaler is to arrange for the destruction of the medicine.

Retail pharmacy shops are encouraged to develop and implement programs to accept the return of unused medicines from patients to ensure environmentally safe destruction.

15.6. **Public/Governmental Sector: National Central Level**

The public national central level, as represented by MoPH and specifically NMRA, has the prime responsibility for coordinating and overseeing WODA and disposal activities in the country.

In the case of medicine 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 other imported medicines. Furthermore, all donors of medicines will be encouraged to donate the equivalent cost of the import license fee, and/or at least 1% of the commodity cost of the donated medicines to assist in undertaking possible WODA and disposal functions.

15.7. **Public/Governmental DTCs**

DTCs are responsible for local implementation of WODA and monitoring of pharmaceutical disposal.
GLOSSARY

**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.

**Analgesic** is a medicine that reduces pain.

**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.

**Controlled medicines** are medicines containing controlled substances.

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

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

**Diversion** refers to the movement of controlled drugs from licit to illicit distribution channels or to illicit use.

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


**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.

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

**National competent authority**, in this document, 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.

**Rational medicine 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.
REFERENCES

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The following section appears in the NMP:

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Technical Guidelines on Incineration on Land

US Policy and Guidance

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http://water.epa.gov/scitech/wastetech/guide/upload/unuseddraft.pdf

How to Dispose of Unused Medicines
Consumer Health Information / US Food and Drug Administration (FDA), April 2013.
UnderstandingOver-the-CounterMedicines/acm107163.pdf

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http://www.med.navy.mil/sites/nmcphc/Documents/policy-and-instruction/bumed-pharmaceutical-
waste-management-guidelines.pdf

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Completed for: Water, Sanitation and Health, Protection of the Human Environment, World Health
http://www.acpo.org.br/biblioteca/07_incineracao_%20aterros/s_batterman.pdf

Guidelines for the Safe Disposal of Unwanted Pharmaceuticals Interagency Guidelines
http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

Traditional Medicine
http://www.who.int/medicines/areas/traditional/definitions/en/

Waste from Health Care Activities
http://www.who.int/mediacentre/factsheets/fs253/en/

World Bank

Feasibility Study for Hospital Waste Management
http://siteresources.worldbank.org/INTUSWM/Resources/463617-1205446508156/14TOR_HEALTHCAREWASTES.DOC
US RCRA waste codes have been included to facilitate ease of reference to the environmental impact of the preparation, but are not actually required for waste disposal use in Afghanistan.

Items in italics are chemotherapy agents.

<table>
<thead>
<tr>
<th>Constituent of concern</th>
<th>Waste code</th>
<th>Prime use</th>
<th>Included in EML</th>
<th>Included in LML</th>
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<tbody>
<tr>
<td>Arsenic trioxide</td>
<td>P012</td>
<td>Leishmania control as sodium stibogluconate 100 mg/ml, injection solution [P01CB02inj] Spironolactone 25</td>
<td>Y</td>
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<tr>
<td>Chloral hydrate (CIV)</td>
<td>U034</td>
<td></td>
<td>N</td>
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<tr>
<td>Chlorambucil</td>
<td>U035</td>
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<td>Cyclophosphamide</td>
<td>U058</td>
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<td>N</td>
<td></td>
</tr>
<tr>
<td>Daunomycin</td>
<td>U059</td>
<td></td>
<td>N</td>
<td></td>
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<tr>
<td>Dichlorodifluoromethane</td>
<td>U075</td>
<td></td>
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<td>Diethylstilbestrol</td>
<td>U089</td>
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<td>Epinephrine base</td>
<td>P042</td>
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<td>Hexachlorophene</td>
<td>U132</td>
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<td>Lindane</td>
<td>U129</td>
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<td>Melphalan</td>
<td>U150</td>
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<td>Mercury</td>
<td>U151</td>
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<td>N</td>
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<td>Mitomycin C</td>
<td>U010</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Nicotine</td>
<td>P075</td>
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<td>N</td>
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<td>Nitroglycerin</td>
<td>P081</td>
<td>Cardiac: Glyceril trinitrate (nitroglycerine) 0.5 mg per tablet, sublingual-oral tablet [C01DA02or]</td>
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<tr>
<td>Paraldehyde (CIV)</td>
<td>U182</td>
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<td>Phentermine (CIV)</td>
<td>P046</td>
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<td>Phenol</td>
<td>U188</td>
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<tr>
<td>Physostigmine</td>
<td>P204</td>
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<tr>
<td>Physostigmine salicylate</td>
<td>P188</td>
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<td>Reserpine</td>
<td>U200</td>
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<td>Resorcinol</td>
<td>U201</td>
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<td></td>
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<td>Saccharin</td>
<td>U202</td>
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<td></td>
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<td>Selenium sulfide</td>
<td>U205</td>
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<td>N</td>
<td></td>
</tr>
<tr>
<td>Streptozotocin</td>
<td>U206</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Trichloromonofluoromethane</td>
<td>U121</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Uracil mustard</td>
<td>U237</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Warfarin &lt;0.3%</td>
<td>U248</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Warfarin &gt;0.3%</td>
<td>P001</td>
<td></td>
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ANNEX 2: EXAMPLE LIST OF CYTOTOXIC AND CYTOSTATIC MEDICINES


Example List of Cytotoxic and Cytostatic Drugs

<table>
<thead>
<tr>
<th>Product approved name</th>
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<tbody>
<tr>
<td>Anastrozole</td>
<td>Exemestane</td>
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<tr>
<td>Azathioprine</td>
<td>Finasteride</td>
</tr>
<tr>
<td>Bicalutamide</td>
<td>Flutamide</td>
</tr>
<tr>
<td>Bicalutamide</td>
<td>Ganciclovir</td>
</tr>
<tr>
<td>Chloramphenicol – classified as a category 2A carcinogen and as such will include eye drops with a concentration of 0.1% (the legal threshold in waste legislation)</td>
<td>Gonadotrophin, chorionic</td>
</tr>
<tr>
<td>Ciclosporin</td>
<td>Goserelin</td>
</tr>
<tr>
<td>Cidofovir</td>
<td>Interferon containing products (including peginterferon)</td>
</tr>
<tr>
<td>Coal tar containing products</td>
<td>Leflunomide</td>
</tr>
<tr>
<td>Colchicine</td>
<td>Letrozole</td>
</tr>
<tr>
<td>Danazol</td>
<td>Leuprolin acetate</td>
</tr>
<tr>
<td>Diethylstilbestrol</td>
<td>Medroxyprogesterone</td>
</tr>
<tr>
<td>Dinoprostone</td>
<td>Megestrol</td>
</tr>
<tr>
<td>Dithranol containing products</td>
<td>Menotropins</td>
</tr>
<tr>
<td>Dutasteride</td>
<td>Mifepristone</td>
</tr>
<tr>
<td>Estradiol</td>
<td>Mycophenolate mofetil</td>
</tr>
<tr>
<td></td>
<td>Nafarelin</td>
</tr>
<tr>
<td></td>
<td>Oestrogen containing products</td>
</tr>
<tr>
<td></td>
<td>Oxycodone (including syntocinon and syntometrine)</td>
</tr>
<tr>
<td></td>
<td>Podophyllyn</td>
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<tr>
<td></td>
<td>Progestosterone containing products</td>
</tr>
<tr>
<td></td>
<td>Raloxifene</td>
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<tr>
<td></td>
<td>Ribavarin</td>
</tr>
<tr>
<td></td>
<td>Sirolimus</td>
</tr>
<tr>
<td></td>
<td>Streptozocin</td>
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<td></td>
<td>Tacrolimus</td>
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<tr>
<td></td>
<td>Tamoxifen</td>
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<td></td>
<td>Testosterone</td>
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<td>Thalidomide</td>
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<td>Toremifene</td>
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<td>Trifluridine</td>
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<td></td>
<td>Triptorelin</td>
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<tr>
<td></td>
<td>Valganciclovir</td>
</tr>
</tbody>
</table>
ANNEX 3: RADIO-PHARMACEUTICALS


The main radioisotopes used in hospitals are:
- Technetium-99m (Tc-99m)
- Iodine-131 (I-131)
- Iodine-125 (I-125)
- Iodine-123 (I-123)
- Flourine-18 (F-18)
- Tritium (H-3)
- Carbon-14 (C-14)

Half-lives of some commonly used radioisotopes are:
- Technetium-99m (Tc-99m): 6 hours
- Iodine-131 (I-131): 8 days
- Flourine-18 (F-18): 110 minutes
ANNEX 4: CONSOLIDATED LIST OF PHARMACEUTICAL WASTE CLASSIFICATIONS

Please refer to the GDPA website: http://gdpa.gov.af/en