UNHCR
DRUG MANAGEMENT
MANUAL 2006

Policies
Guidelines
UNHCR List of
Essential Drugs

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United Nations High Commissioner for Refugees
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- **Policies**
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- **UNHCR Essential Drugs List**

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PREFACE

In 2005, UNHCR provided protection to approximately 20 million refugees and other persons of concern. Provision of comprehensive health care services in refugee settings is essential as population displacement and overcrowding are associated with increased risk of communicable disease transmission and excess mortality. Refugee health care systems are based on the concept of Primary Health Care (PHC) through which essential health care is made accessible to individuals, families and the community.

Health service provision is provided to refugees and other populations of concern through Implementing Partners (IP's, directly funded by UNHCR) and Operational Partners (OP's, with other sources of funding). Provision of supplies and equipment necessary for preventive and curative health care is carried out through a variety of mechanisms: centrally through UNHCR headquarters (HQ), nationally through Ministry of Health central pharmacies, and on the local market.

Drug ordering from countries in which UNHCR works is not always appropriate or efficient. There are many examples of poor prescribing practices, purchase of drugs of dubious quality, orders unrelated to actual needs, poor drug storage and distribution, and irrational drug prescribing. In addition, local purchase may not be indicated, and there is limited data on stock ruptures, wastage, and other supply management elements.

Centrally, UNHCR has developed an Essential Drugs List (EDL) to meet the immediate minimum drug needs for a basic refugee health care system. With an annual expenditure of more than $2 million US, there is an urgent need to address essential drugs management in UNHCR.

This has led to an updating of the UNHCR EDL and to this manual. The 2006 UNHCR EDL is based on the 2005 WHO Model List of Essential Medicines and will be updated every 2 years as is the WHO list. This manual is a revision of the UNHCR Essential Drugs Manual (1989) and is the result of literature research, field visits, participation at conferences, and correspondence with experts. The manual is for the use of UNHCR's health partners, and for UNHCR health programme officers who supervise drug procurement in the field. It is meant to be a practical tool for

field staff of UNHCR and partners with the aim of improving drug management in all parts of the drug management cycle.

Given that drug management is not a new concept, this manual is not meant to introduce new ideas. It is, rather, a compilation of best practices based on references from other sources. The majority of materials are taken from: the second edition of *Managing Drug Supply* (MSH in collaboration with WHO), *Guidelines for the Storage of Essential Medicines and Other Health Commodities (*John Snow, Inc./DELIVER in collaboration with WHO) and various WHO publications. A complete list of references is given at the end of each chapter.

The manual consists of: 1. Guidelines that explain drug management concepts and their rationale, and 2. Standard Operational Procedures (SOPs) that are action-oriented and guide users step-by-step through certain drug management questions such as consumption-based quantification.

The **essential drugs policy** should be a standard document available for all staff of UNHCR and partners. It indicates minimum standards in drug management and the institutional commitment of UNHCR.

The chapter on **drug selection** aims to assist senior staff of UNHCR and health partners with the selection of the most cost-effective medicines relevant to the local situation. The development and use of an essential drugs list and treatment guidelines are hereby emphasized.

The **drug procurement** chapter seeks to provide insights into best practices in drug procurement by UNHCR and by partners. Although classic procurement principles apply, issues that make drug procurement different from procurement of other commodities are listed in the 12 drug procurement principles. Obtaining medicines of good quality at an affordable price in a timely fashion is the key objective of drug procurement. General UNHCR procurement regulations also apply to drugs and medical supplies and hence need to be used in conjunction with these specific drug procurement guidelines.

The **drug distribution** chapter includes a section on medical store management which is probably the most practical and straight-forward chapter and can be used to train storekeepers with various educational backgrounds in a variety of settings.

The chapter regarding **rational drug use** aims to introduce concepts of investigating and improving drug use rather than providing a comprehensive “how to” manual.

The chapter on **quality assurance** applies to the whole drug management cycle as drug quality assurance is a cross-cutting issue, which applies not only to procurement (Obtaining good quality drugs), but also to distribution (Verifying and maintaining quality of drugs) and use (Monitoring drug quality). Everyone can contribute to drug quality assurance, regardless of one’s job description or situation. The quality assurance chapter is the most technical chapter with specific details outlined in the corresponding Standard Operational Procedures at the end of the manual.

Our aim in UNHCR is to always emphasize the importance of sound drug management in health programs for the benefit of the organization and staff, but most of all, for the beneficiaries.

ACKNOWLEDGEMENTS

Special thanks go to Dr. Richard Brennan (IRC) and Dr. Nadine Ezard (UNHCR) for their commitment to drug management in their respective organizations and for providing comments to this document. Nabil Makki and Dr. Mohammed Qassim (UNHCR) also need to be acknowledged for sharing their experiences with drug management within UNHCR. The kind assistance of all branch office, sub-office and health partner staff where field visits and testing of the manual were carried out is also greatly appreciated.

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A special thanks also goes to Dr. Souly Phanouvong (US Pharmacopeia) for reviewing the drug quality assurance chapter.

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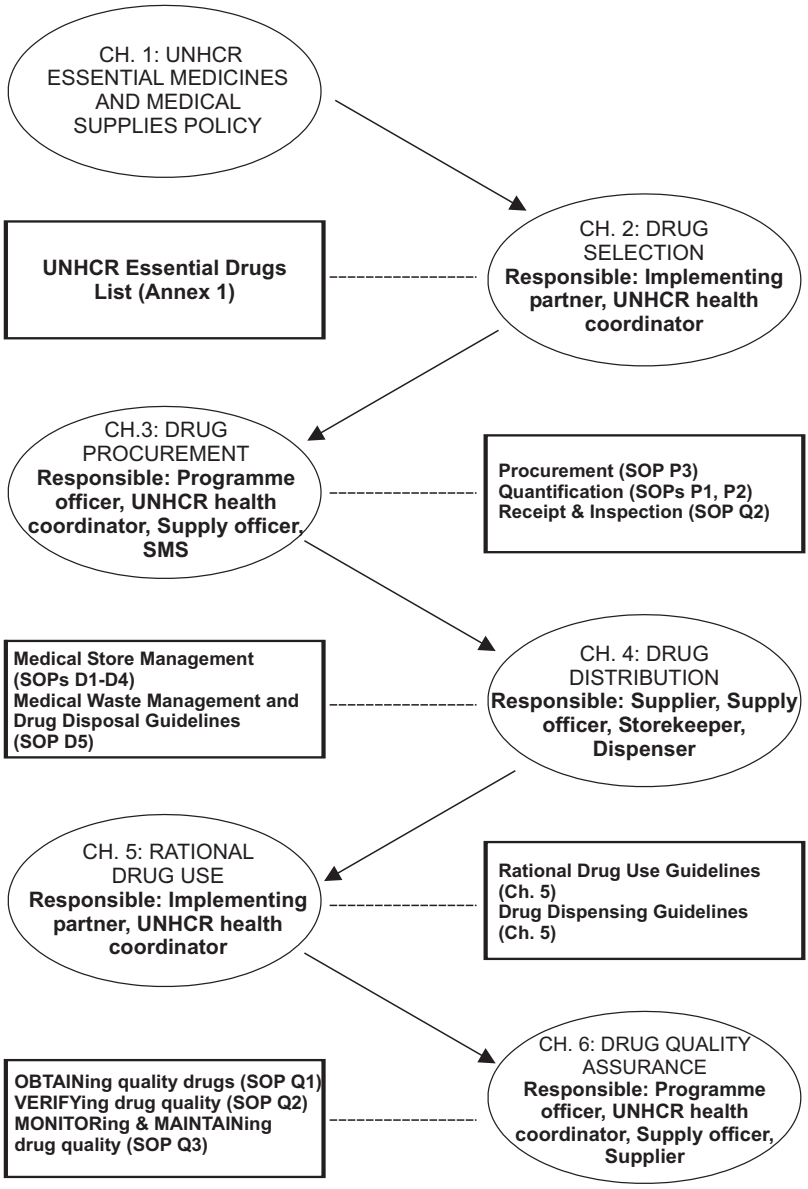
Acronyms

ADR	Adverse Drug Reaction
API	Active Product Ingredient
DRA	Drug Regulatory Authority
EDL	Essential Drugs List
FEFO	First Expiry First Out
GMP	Good Manufacturing Practice
HQ	Headquarters
ICRC	International Committee of the Red Cross
IDA	International Dispensary Association
INGO	International Non-governmental Organization
INN	International Nonproprietary Name
INRUD	International Network for Rational Use of Drugs
IP	Implementing Partner
IRC	International Resue Committee
MDR	Multi-drug Resistant
MIS	Management Information System
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NEHK	New Emergency Health Kit
NGO	Non-governmental Organization
OP	Operational Partner
PHC	Primary Health Care
PSF	Pharmaciens Sans Frontières
SMS	Supply Management Service
SOP	Standard Operational Procedure

UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
USD	United States Dollar
USP	United States Pharmacopeia
WHO	World Health Organization

UNHCR DRUG MANAGEMENT GUIDELINES



1. DRUG POLICY

UNHCR ESSENTIAL MEDICINES AND MEDICAL SUPPLIES POLICY

INTRODUCTION

Essential drugs play a crucial role in the prevention and control of diseases. After immunization for common childhood illnesses, appropriate use of essential drugs is one of the most cost-effective components of modern health care.

The primary objective of an essential drugs policy is:

> **To ensure that a selected number of high-quality essential drugs are available, affordable, and used rationally.**

Source: MSH 1997

Drugs are of particular importance because:

- ☑ Drugs **save lives** and improve health.
- ☑ Drugs promote **trust** and participation in health services.
- ☑ Drugs are **costly** (they represent the major part of a health program's budget after salaries and vehicles).
- ☑ Drugs are **different** from other consumer products: 1. neither the average **medical practitioner** nor the average **pharmacist** is equipped to independently assess the quality, safety or efficacy of each new drug, and 2. most often, the **consumer** does not choose the drug, and if so is not trained to judge its appropriateness, safety, quality or value for money.
- ☑ Substantive **improvements** in supply and use are always possible.

Despite the potential health impact of essential drugs and despite substantial spending on drugs, lack of access to essential drugs, irrational

use of drugs, and poor drug quality remain serious global public health concerns. Consider the following facts:

- Today over one-third of the world's population still lacks access to essential drugs in the poorest parts of Africa and Asia.
- Up to 75% of antibiotics are prescribed inappropriately.
- Worldwide an average of only 50% of patients take their medicines correctly.
- Anti-microbial resistance is growing for most major infectious diseases, including HIV/AIDS, tuberculosis and malaria.
- Quality & safety issues:
  - Less than 1 in 3 developing countries have fully functioning drug regulatory authorities.
  - 10 to 20% of sampled drugs fail quality control tests in many developing countries.
  - Failure in good manufacturing practices too often results in toxic, sometimes lethal, products.
  - Expanding global trade is making it increasingly difficult to implement quality assurance.

WHAT ARE ESSENTIAL DRUGS?

The concept of essential drugs was established in 1977. Every two years an expert committee updates the WHO Model List of Essential Medicines. The list serves as a model for countries to adapt to their own specific needs.

Box 1. The essential drugs concept

First introduced in 1975, the essential drugs concept is now widely accepted as a highly pragmatic approach to providing the best of modern, evidenced-based and cost-effective health care. It is as valid today as it was 25 years ago when first introduced. The essential drugs concept does not exclude all other drugs, but rather focuses therapeutic decisions, professional training, public information, and financial resources on those drugs that represent the best balance of quality, safety, efficacy and cost for a given health setting.

The essential drugs concept is also a global concept. Health systems of all types, from basic health systems in the poorest countries to highly developed national health insurance schemes in the wealthiest have recognized its therapeutic and economic benefits. Moreover, the concept is forward-looking. It promotes the need to regularly update drug selections in light of new therapeutic options and changing therapeutic needs, the need to ensure drug quality, and the need for continued development of better drugs, drugs for emerging diseases and drugs for coping with changing resistance patterns.

Source: WHO Essential Medicines Strategy 2000-2003

The essential drugs concept can be applied in all countries and at various levels (national, provincial, district, hospital). The essential drugs concept is especially valuable in resource-poor settings, as it allows one to get the best medicines for the resources available. The concentration on a few essential drugs has also lowered prices, due to economies of scale.

SCOPE

The UNHCR Essential Medicines and Medical Supplies Policy aims to give guidance on how to ensure provision of good quality essential drugs and medical supplies in all phases of the relief cycle.

POLICY STATEMENT

The United Nations High Commissioner for Refugees (UNHCR) shall:

1. Ensure implementation of the essential drugs **policy** in all UNHCR-supported health programs where drugs and supplies are selected, procured, distributed or used. It is UNHCR's role to ensure that partners:

    1.1. Base **selection** of drugs and medical supplies primarily on the **UNHCR Essential Drugs List** which is adapted to national standards. The UNHCR list is developed after cross-referencing with the WHO Model List of Essential Medicines and will be updated every 2 years.

    1.2 Use the **international non-proprietary names** (generic) in drug selection, procurement, and distribution.

    1.3 Adopt a **procurement** strategy that ensures the availability of drugs of good quality, safety and efficacy at the lowest possible price.

    1.4 Use **Emergency Health Kits** in the **acute emergency phase** to meet the needs of a population with disrupted or no medical facilities. The latest update from **UNHCR's *Handbook for Emergencies*** or the health chapter of the latest **SPHERE** handbook should also be used to ensure that minimum standards are met. **MSF** provides clinical guidelines and minimum guidelines in pharmacy management during the emergency phase.

    1.5 As soon as the acute emergency phase is over, assess specific health needs to set-up a solid drug management system that includes the establishment of an **essential drugs list**, **treatment guidelines**, a solid **drug procurement system** and proper **drug distribution procedures**. The same applies in the **reconstruction/rehabilitation phase**. This will require information about the morbidity profile, high risk groups, demographic pattern, seasonal variation of morbidity and mortality, the impact of improved public health measures, local availability of drugs and other supplies, drug resistance, usual

medical practice in the country, capabilities of the health workers and effectiveness of the referral system.

1.6 Assure drug **quality** during the procurement process through ensuring:

1.6.1 The quality of the **manufacturer** (respect for Good Manufacturing Practices-GMP).

1.6.2 The quality of the **product** (registration status, Certificate of Pharmaceutical Product,).

1.6.3 The quality of the **batch** (Certificate of analysis, labeling, appearance, packing and shelf life inspection, chemical analysis). It is the responsibility of the drug distributor to sell only drugs from GMP-compliant manufacturers and drugs that are registered in the country of destination.

1.7 Implement proper drug **storage and distribution** procedures throughout every level of the supply chain in order to ensure adequate quality of drugs and supplies at the end user level.

1.8 Take appropriate measures complying with national and/or international guidelines for the timely **disposal** of expired and unwanted drugs in a manner that does not jeopardize public health.

1.9 Support the **rational use** of drugs through the promotion of rational prescribing, dispensing and consumption of pharmaceuticals at all levels. To this effect, formulate the necessary guidelines and organize training activities for both health workers and consumers from the community.

1.10 As an integral part of rational drug use, seek to **strike a balance between preventive and curative components** of its health programs through hygiene promotion and health education.

2. Request donors to observe the obligation of providing good quality essential drugs with an acceptable range of shelf life and to adopt the WHO guidelines for **drug donations**.

3. In order to hold the drug management cycle together, the following **management support** measures will need to be taken:

   3.1 Aim to incorporate **sustainability** through a steady and reliable drug budget and through local capacity-building and staff development.

   3.2 Provide **training** options in managing drug supply for UNHCR staff and NGO-partners through conferences, field visits, staff exchange and short training courses.

   3.3 Collect and disseminate **drug management lessons** learned from the field to build institutional memory and as a commitment to the development of the field of drug management and humanitarian assistance.

   3.4 Ensure that important logistical data like inventory and consumption data are integrated in the **health information** system and used for proper procurement planning.

   3.5 Ensure that all staff and partners are well **oriented** to the rationale and content of this policy.

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2. DRUG SELECTION

Contents

SELECTING THE MOST APPROPRIATE DRUGS

1. Introduction

Rational drug selection leads to a better supply, lower costs, and a more rational prescribing and use of drugs. Selection of drugs and medical supplies should primarily be based on the UNHCR Essential Drugs List which is adapted to national standards. **The UNHCR list has been developed after cross-referencing with the WHO Model List of Essential Medicines and is updated every 2 years**. Selection should be based on the basic health needs of the target population. **A transparent and regular review of the essential drugs list is a key intervention in improving quality of care in health programs. In addition, the introduction of** standard treatment guidelines**,** reflecting the essential drugs list**, should be used in conjunction with standard symptom/disease definitions.**

Sources: IRC 2004, MSH 1997, UNHCR 1989

Drugs are expensive. In developing countries, pharmaceuticals constitute up to 40% of the health care budget and up to 90% of the household budget. For an NGO implementing health programs, drugs are the largest expenditure after salaries and vehicles.

No program can afford to purchase all drugs circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly purchased and is one of the most effective ways to control drug expenditure and overall health program expenditure. Other than the economic implications due to improved drug therapy, an effective drug formulary system will also have clinical implications.

2. Benefits

The **rationale** for selecting a limited number of essential drugs is that it may lead to:

1. a better **supply**:
    a. easier procurement, storage and distribution
    b. adequate stocks
    c. better quality assurance
    d. easier dispensing
2. more rational **prescribing**:
    a. more focused training
    b. more experience with fewer drugs
    c. no irrational treatment alternatives available
3. Lower **costs** (more competitive prices through increased competition).
4. more rational patient **use**:
    a. focused education
    b. reduced confusion and increased adherence to treatment
    c. increased availability

An **Essential Drugs List (EDL)** names the drugs considered **optimal** treatment choices to satisfy the health care needs of the majority of a target population at a cost the program can **afford**. An essential drugs list is the guiding model that indicates **priorities** in drug needs to make sure that a **regular supply** of **safe** and **effective** drugs is continuously available in sufficient quantities in a health system.

It should be emphasized to prescribers that an essential drugs list is not designed to restrict prescriber freedom but to increase access to essential drugs in settings with limited resources. A certain degree of flexibility for deviation is possible as long as this has an exceptional character and is

justified and documented. Drugs not included on the UNHCR Essential Drugs List (see **Annex 1**) can be requested using a special form (see **Annex 2**).

3. Criteria for drug selection

3.1. Emergencies

Often during the emergency phase of a refugee influx (the first two to three months) drug procurement is streamlined by the immediate provision of Emergency Health Kits. These standard health kits have been designed, tested and revised by WHO and several non-governmental organizations. Even if kits are used, normal non-emergency lines of procurement must be planned and set up from the beginning of an emergency situation so that a smooth and timely transition may be effected.

The New Emergency Health Kit (NEHK) (WHO 1998) has been developed by WHO in consultation with UNHCR, UNICEF, MSF, ICRC, the League of Red Cross and Red Crescent Societies (Geneva) and the Christian Medical Commission of the World Council of Churches. It is currently under revision as some of the drugs, such as antimalarials, are no longer effective in many settings. The new kit is expected to be available in 2006; see www.who.int/medicines for updates. The NEHK contains medicines and medical supplies in quantities sufficient for a population of 10,000 people for approximately 3 months. The NEHK has been designed to meet the needs encountered in crisis situations such as floods, droughts, earthquakes or armed conflict.

IDA always keeps sufficient quantities of the NEHK in stock to supply to relief workers in areas affected by war or natural disasters.

Composition: One complete NEHK weighs 840 kg and consists of 24 Boxes:

Source: IDA

Source: IDA

One Basic unit of 10 boxes, all identically packed. Every basic box (numbered 1-10) contains: medicines, renewable supplies and instruments destined for use by primary health care workers with limited training. Each box bears an additional green imprint, with the text "BASIC".

One Supplementary unit of 14 boxes: This Supplementary unit contains: 3 boxes of medicines (numbered 11-13), 5 boxes of IV fluids, including giving sets (numbered 14-18), 3 boxes of renewable supplies (numbered 19-21) and 3 boxes of equipment (numbered 22-24). It is destined for use by professional health workers or physicians.

Each box displays an additional green label indicating the content: medicines, IV fluids, etc. A packing list of the complete Supplementary unit is included in box number 11. The expiry date of the first item to expire is mentioned on each kit. The supplementary unit does not contain any medicines or supplies from the basic unit and can only be used when these are available as well. It should never be used alone.

Standard manuals in three languages

The kit includes the following standard manuals: *Clinical Guidelines -Diagnostic and Treatment Manual*, published by MSF. It is packed in box 24 of the Supplementary unit.

Treatment guidelines exist for the Basic unit as well. A booklet of 11 pages, containing standard diagnostics, prescription for 11 different diagnostic groups and 4 pages on dehydration/diarrhea are included. The booklet is packed in every basic box, and includes a list of contents for a complete kit as well.

For a complete list of contents of the NEHK, see **ANNEX 3.**

Reproductive Health Kits

Reproductive Health Kits for Crisis Situations also exist. These have been designed by members of the Inter-Agency Working Group on Reproductive Health to complement the Emergency Health Kits. The Reproductive Health Kits are available through UNFPA (table 1, see Reproductive Health Kits for Crisis Situations UNFPA updated 2005 or www.unfpa.org for more details). In many situations UNFPA will provide these supplies free of charge to UNHCR operations as part of the Memorandum between UNHCR and UNFPA. Please contact your national UNFPA office or UNHCR HQ at hivaids@unhcr.ch.

Table 1: Reproductive Health Kits for Crisis Situations

Block 1 : 10,000 people for 3 months, community and primary health care level	
Kit 0	administration / training supplies
Kit 1A	male condoms
Kit 1b	female condoms
Kit 2A	clean delivery kit (pregnant women)
Kit 2B	clean delivery kit (birth attendants)
Kit 3	rape treatment
Kit 4	oral and injectable contraception
Kit 5	treatment of sexually transmitted infections
Block 2 : 30,000 people for 3 months, primary health care and referral hospital level	
Kit 6	clinical delivery assistance
Kit 7	intrauterine device
Kit 8	management of miscarriage and complications of abortion
Kit 9	suture of tears and vaginal examination kit
Kit 10	vacuum extraction delivery
Block 3 : 150,000 people for three months, referral / surgical obstetric level	
Kit 11	referral level kit
Kit 12	blood transfusion kit

3.2. Post-emergency settings

The choice of drugs can depend on many factors. The most important factor is:

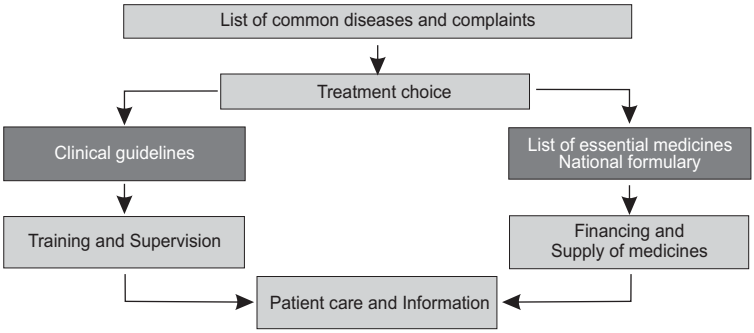
1. Relevance to pattern of ***prevalent diseases among refugees.***

   An essential drugs policy should focus on the public health needs of the population of concern.

   In primary health care settings, a **disease or health problem based approach** is more practical than a **drug-based approach** where all drugs currently used are listed, sorted by therapeutic category and drug class reviews are performed to revise the list, taking cost, safety and efficacy into consideration.

   The design of local ***treatment guidelines*** and the design of the ***essential drugs list*** are interdependent procedures; a first step is to prepare a list of common health problems. A first-choice treatment for each health problem on the list may be limited to one or more drugs or to various forms of non-drug treatment. This choice of treatment can be the basis of two important documents: the **essential drugs list** for that level of care (health post, clinic, hospital), which is a direct result of the selection, and a set of **treatment guidelines** for that level of care, which requires additional clinical information (diagnostic signs and symptoms and treatment algorithms).

Figure 3 The list of common health problems guides the formulation of clinical guidelines, the list of essential medicines, training financing, and supply – leading to improved patient care

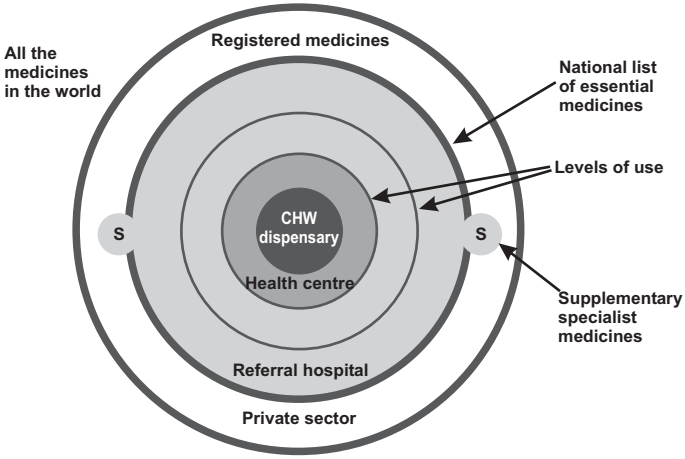


Source: WHO Policy Perspectives on Medicines – The Selection of Essential Medicines 2002

Other factors:

2. Suitability for use by health workers in the types of ***treatment facilities established in refugee settings.***

Figure 2 The essential medicines target: the national or institutional list of essential medicines is a subset of registered medicines, divided by level of care



Source: WHO Policy Perspectives on Medicines – The Selection of Essential Medicines 2002

The choice of drugs available depends on the staff's capacity to use them effectively. Consequently, it is important to know the extent of staff training and the availability of support facilities for each level of the healthcare system before deciding where individual drugs will be made available. Every program should have an essential drugs list, but this does not mean that all drugs should be made available at every level of care (health post, clinic, referral hospital). Under normal conditions, the number of drugs available at a health facility increases with the level of health services provided. In many settings, health facilities are operating beyond their capacity (e.g. a health post functioning as a health center) due to lack of resources, need, and poor geographical planning. In this case, a pragmatic approach based on the staff's capacity should be used to ensure sufficient access to essential drugs.

3. **Local considerations**.

- The effects of *local diseases* or conditions on drug effectiveness (e.g. malnutrition, liver disease);
- Local or regional differences in *sensitivity and resistance* of microorganisms, in the case of anti-infective drugs;
- Regional differences in *climate, topograpy,* and other *environmental factors;*
- *Health requirements* specified by countries of asylum/ resettlement for particular refugee groups (e.g. resettlement-related health procedures);
- *Level of services available locally* in the host country;
- *Anticipated local storage conditions (stability).*

Think twice before including drug products that are sensitive to heat, light or humidity in a setting where these factors are difficult or impossible to control (e.g. in remote health centers in Sudan). Choosing the **most stable dosage form** for a particular setting is part of the overall drug quality assurance system. Choosing tablets rather than capsules, ointments rather than creams, powder for reconstitution rather than injectable solutions and avoiding syrups is a low-cost, high impact intervention in maximizing the therapeutic lifespan of medicines in extreme climatic conditions. See Chapter 6 *"Drug Quality Assurance".*

4. Implementation issues

4.1. Developing a local Essential Drugs List

The essential drugs list developed for a refugee health program should be based on the **UNHCR Essential Drugs List (see Annex 1)** which is adapted to **national standards**. National standards are those established by the lead health authority which is usually the national Ministry of Health. A national standardized essential drugs list may have been established. Some countries do not allow importation of drugs that are not included in the national essential drugs list.

Where a national list is not available or incomplete (frequent in post-conflict settings), the **UNHCR Essential Drugs List** is the most appropriate reference. The UNHCR list has been developed after cross-referencing with the WHO Model List of Essential Medicines and is updated every 2 years. Any deviation from the national essential drugs list should be discussed with the local health authorities. *The national drugs list has legal status, whereas UNHCR or WHO essential drugs lists only remain a guideline until a country's health authorities officially adopt it.* As far as possible, essential drugs lists (and also clinical treatment protocols or guidelines) should be **standardized** across health agencies.

The **UNHCR Health Coordinator,** working with senior health staff of partner agencies, should take the lead in the development or review of the essential drugs list and standard treatment guidelines, and in the coordination process with the local authorities and other agencies. Where there is no UNHCR health coordinator, senior health staff of partner agencies should assume this responsibility in coordination with the Regional UNHCR Health Coordinator.

4.2. Organization of the UNHCR Essential Drugs List

As mentioned above, apart from developing a local essential drugs list, levels of use should be established based on the level of supervision needed for their safe and proper use. UNHCR classifies drugs as follows:

- Basic List
- Supplementary List
- Specialized List

The inclusion of a particular drug on the basic as opposed to the supplementary list is only intended for guidance: the senior health coordinator in any given situation will have to decide which medicines the different levels of health workers are able to use. This will vary according to the situation.

Basic List

This is the basic list of drugs from which a general distribution for dispensaries and health centers can be chosen. The drugs are considered appropriate for use by health workers who have completed a satisfactory training program as approved by the senior health coordinator, and for whom adequate and clearly defined supervision exists.

As a matter of principle, the Basic List does not contain any injectables. Most simple conditions can be managed with oral regimens. Choice of particular antibiotics and anti-malarials to be used by first-level health workers will be made by the senior health coordinator in consideration of local endemicity and sensitivity patterns.

Supplementary List

This list contains drugs for use by more qualified personnel such as physicians or other staff as approved by the senior health coordinator.

These drugs are for use only in more elaborate health facilities such as camp health centers/clinics, which:

- are directly supervised by a physician or senior health worker;
- allow for the care and close monitoring of in-patients whenever necessary;
- are adequately equipped to deal with reactions to the drugs listed.

Clearly, drugs used by more highly trained personnel also include those specified in the Basic List.

Specialized List

These items are intended for use in the management of specific conditions such as:

- Leprosy
- Leishmaniasis
- Contraceptive needs
- Yellow Fever
- Tuberculosis
- Malaria
- Snake bite
- Rabies
- Filariasis
- Meningococcal meningitis
- Schistosomiasis

Because many of the drugs specified in this list require careful supervision and may have serious side effects, they must be administered only:

- after a protocol for safe and proper use has been approved by appropriate supervisory personnel;
- when the approved protocol is understood and adhered to by field personnel;
- when there is access to advice from qualified health personnel who are experienced in the safe and appropriate use of the drugs listed;

- when provision exists for patients to be followed systematically to ensure:
  - adequate compliance with treatment,
  - careful monitoring of each individual's response to medication,
  - prompt recognition of side-effects.

Please note: Anti-retroviral medications (ARVs) for HIV/AIDs are considered essential drugs and refugees should have access to them. They are not, however, included on the general EDL list due to complicated issues surrounding their use. They can be ordered using the special request form (see **Annex 2**) after appropriate discussion with your Regional HIV/AIDS coordinator and/or Technical Officers at HQ, and after ensuring that the above criteria for the use of specialized drugs have been met.

Summary Chart of Essential Drugs List

List	*Who can use?*	*Where to use?*	*Needs?*
Basic List	Nurse's aid, Community health worker	• Home visiting • Simple health clinics • Basic camp dispensaries	• Training • Supervision
Basic & Suppl. Lists	Doctor, Senior nurses*	• Larger health centres • Camp health centres providing in-patient care	• Close supervision by senior health worker • Monitoring of in-patients
Specialized List	Doctors, Senior nurses*	• Larger health centres • Camp health centres providing in-patient care in regions where the specific disease entity or need exists	• Approved protocol • Adherence to protocol • Access to specialist advice • Patient supervision

*Under the direction of the supervising physician

Source: UNHCR 1989

4.3. Developing local Standard Treatment Guidelines

The introduction of ***standard treatment guidelines****,* used in conjunction with standard symptom/disease definitions, must be compulsory in all refugee health programs. This is particularly necessary given the numbers of agencies and personnel providing refugee health services, the rapid turnover of staff, and the wide range of health workers involved. These guidelines should cover the most common diseases and complaints, be differentiated for the different levels of health care, and be adapted to the competence of the health workers. For implementation of standard treatment guidelines, see Chapter 5 "*Rational Drug Use*".

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3. DRUG PROCUREMENT

Contents

I. GENERAL PROCUREMENT GUIDELINES FOR THE UNHCR SUPPLY SYSTEM

1. Introduction

Pharmaceutical procurement is a complex process that involves many steps and people. Efficient procedures should be in place: to select the most cost-effective essential drugs to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to lack of access to appropriate drugs and to waste. In many supply systems, breakdowns regularly occur at multiple points in this process due to:

- inadequate rules, regulations and structures;
- absence of a comprehensive procurement policy;
- internal procurement regulations conflicting with local regulations;
- lack of unbiased market information;
- lack of trained procurement staff.

Drug procurement for humanitarian agencies is further complicated by the following specific constraints:

- Funding which is insufficient and/or released irregularly;
- Lack of timely access to reliable logistical **data** (inventory and consumption data) for budget and procurement;
- Remote work settings in terms of **communication**, **transport** and **staff recruitment;**
- Uncertainty regarding **quality** of locally purchased drugs;
- **Delivery** (logistics, long lead-times, geographical accessibility, importation and customs procedures);

- **Quantification** (unstable population, seasonal morbidity patterns);
- Irrational **use** of drugs complicating forecasting of needs.

It needs to be emphasized that these drug procurement guidelines do not aim to replace UNHCR's general procurement guidelines (Chapter 8, *UNHCR Manual*). They need to be used as a supplement since the emphasis is not on compliance with internal accounting and procurement guidelines, but on the more technical aspects inherent to highly specific commodities such as drugs.

Also note that the procurement guidelines below do not apply to humanitarian operations in emergency or disaster settings. Other procurement mechanisms such as Emergency Health Kits apply in this case. They are discussed as a special topic in this manual in Chaper 2, Section 2.1 "*Criteria for Drug Selection, Emergencies".*

2. Strategic objectives for good pharmaceutical procurement

The twelve operational principles for good pharmaceutical procurement are based on four strategic objectives.

Four strategic objectives of pharmaceutical procurement

2.1. Procure the most **cost-effective** drugs in the right quantities.

2.2. Select reliable suppliers of **high-quality** products.

2.3. Ensure **timely** delivery.

2.4. Achieve the lowest possible total **cost.**

Source: WHO 1999

2.1. Procure the most cost-effective drugs in the right quantities.

The first strategic objective is to develop an essential drugs list to make sure that only the most cost-effective drugs are purchased. Procedures must also be in place that accurately estimate procurement quantities in order to ensure continuous access to the products selected without accumulating excess stock.

2.2. Select reliable suppliers of high-quality products.

The second objective is that reliable suppliers of high-quality products must be (pre-) selected, and that active quality assurance programs involving both surveillance and testing must be implemented wherever possible.

2.3. Ensure timely delivery.

The third strategic objective is that the procurement and distribution systems must ensure timely delivery of appropriate quantities to central stores and adequate distribution to health facilities where the products are needed.

2.4. Achieve the lowest possible total cost.

The fourth objective is that the procurement and distribution systems must achieve the lowest possible total cost. Every program can minimize the total purchasing costs by choosing the **optimal purchasing model** for their particular situation **(e.g. annual or quarterly)**, taking into consideration order interval, safety stock and the re-order formula used.

The **quality of the drugs purchased should not be compromised under any circumstances.** Unlike other commodities, drugs must always be purchased using **VFM** (Value For Money) criteria instead of Low Bid criteria.

3. Operational principles for good pharmaceutical procurement

3.1. Efficient and Transparent Management

1. Separation of key functions that require different expertise.

2. Transparency, written procedures and using explicit criteria to award contracts.

3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual audit.

4. Drug procurement should be limited to an essential drugs list defined by the recognized lead health authority, or based on the UNHCR Essential Drugs List adapted to national standards.

3.2. Drug Selection and Quantification

5. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.

6. Order quantities should be based on a reliable estimate of actual need.

3.3. Financing and Competition

7. Ensure reliable payment and good financial management.

8. Procurement in bulk.

9. Competitive procurement methods- Authorized vendors.

10. Sole-source commitment in case of authorized vendors.

3.4. Supplier Selection and Quality Assurance

11. Formal supplier qualification and monitoring.

12. Product Quality Assurance Program.

More detailed information is given in the Standard Operational Procedures (see **Annex 4**, **SOP Q1**).

4. Drug procurement in UNHCR

It is UNHCR's policy to principally purchase medical products through international suppliers. These procurement agencies have developed the expertise to ensure controlled quality at reasonable prices.

Local/regional procurement should only be considered where international procurement is impossible or does not meet programme objectives (eg. exit strategy enacted and programme in transition to handover to local partners). Procurement should aim for timely availability of drugs of good quality, safety and efficacy at the lowest available price. As mentioned above, **quality should not be compromised** under any circumstances and **Value For Money** criteria should be used, not the Lowest Bid.

Local/regional procurement requires authorization from the regional Senior Public Health Officer (or at HQ where no regional officer is available) and from SMS HQ. Authorization is given for a specific list of pharmaceuticals from a specific manufacturer in a specific country for a specific period of time.

Local/regional procurement will only be authorised where specific criteria are met. In countries where these criteria cannot be met, international procurement may be the only option and this will need to be emphasized with local officials who may argue otherwise. The criteria are:

- Approval from a trained quality assurance pharmacist that products and suppliers are quality controlled. This should be either from a partner INGO or, where the budget allows, through a UNHCR consultant.

- Selection of supplier is through a transparent bidding process. The committee deciding on the contract should include technical staff. Procurement staff can have technical input but should not have voting rights.
- Local suppliers have been pre-qualified by a committee of managers, technical staff and a pharmacist before being eligible to bid, where the annual budget is sufficient (See Ch.8, Sect. 2.4.3.5, *UNHCR Manual*). Where the budget is insufficient or adequate technical expertise is not available locally, collaboration with other health agencies (WHO, UNICEF, ICRC, and health INGOs with capacity for verification of drug quality such as MSF and PSF) is essential. Pre-qualification should check: WHO certification scheme, supplier questionnaire, reference checks, previous record of performance (quality, reliability, timely delivery of supplies), site inspection, targeted lab testing (if available), UN prequalified suppliers, test purchases.
- Suppliers are licensed with the government.
- The primary manufacturer is Good Manufacturing Practice (GMP) certified according to WHO standards and regularly inspected for GMP standards.
- The product is registered in the country of manufacture, preferably through the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving into International Commerce (http://www.who.int/medicines/organization/qsm/activities/drugregul/certification/certifsc.haplha.html).
- The product is registered in the country of import.
- The product is accompanied by Certificate of Pharmaceutical Product.
- Batch certificates of selected drugs are provided on request.
- Supplies are subject to pre- and post-shipment inspection.
- Analytical testing is conducted routinely on critical products such as life-saving drugs or IV fluids.

For more information on these points, see the Standard Operational Procedures (**Annex 4, SOP Q1).**

The following drugs available from local suppliers are likely to be automatically approved for purchase:

- Drugs also purchased by an INGO with pharmaceutical quality assurance capacity (such as MSF, PSF or ICRC).
- Drugs from local suppliers that have been purchased from international procurement agencies.
- Drugs from suppliers that have been approved by the WHO pre-qualification scheme for HIV/AIDS, tuberculosis and malaria (http://mednet3.who.int/prequal/).
- Drugs from manufacturers that have been approved by PIC/S[1] countries and that have a market authorization for these countries.

4.1 Ordering Procedures for International Procurement

An order for medicines and medical supplies is prepared in the field by senior staff of the partner agency, in coordination with the UNHCR health coordinator where present. Orders must be quantified based on consumption which is discussed in the next section and in SOPs P1 and P2 (see **Annex 4)**. The order should then be discussed with the Programme Officer to confirm the budget. Finally, all orders must be verified by a UNHCR Senior Public Health Officer. If there are any concerns it is better to seek technical advice early. The Senior Public Health Officer must verify by email that the order has been cleared and this verification must be sent with the order to SMS at HQ through the respective Desk Officer. Where an order cannot be verified at national or regional level, the Desk Officer should forward it to the Senior Public Health Officer at HQ to be cleared. After this, it will go to SMS for processing.

All orders must be completed on the **standard order forms** (excel sheets) which are available from SMS at HQ (HQSMS@unhcr.org). The sheets should not be altered in any way. They include pricing information to assist with budgeting. Narcotic drugs, such as morphine and diazepam, require import licenses which must be arranged upon request from SMS. In order to avoid delays, it is critical that such licenses be completed exactly as required otherwise the items are cancelled as suppliers cannot hold stock for extended periods of time.

1 *Austria, Denmark, Finland, Iceland, Liechtenstein, Norway, Portugal, Sweden, Switzerland, United Kingdom, Hungary, Ireland, Romania, Germany, Italy, Belgium, France, Australia, Netherlands, Czech Republic, Slovak Republic, Spain, Canada, Singapore, Greece and Malaysia.*

Orders should be accompanied by details of the partner, duration of order, size of population, and justifications (see **Annex 2)** for drugs not included on the UNHCR Essential Drugs List, which generally take longer to procure. Inclusion of this information will again avoid delays. Clear and efficient communication is important in order to avoid confusion and to have the order processed as quickly as possible. For more on this see **Annex 4 SOP P3.**

4.2 Estimating drug budget

Operational experience from a variety of field settings has shown that **drug budgets that are less than 2 USD per capita per year are in most cases insufficient to cover drug procurement for the most essential primary health care needs.** Note that this is the same amount available as in countries with the lowest pharmaceutical expenditure per capita in the world in 2000 (Democratic Republic of the Congo, Sierra Leone, etc.). Using this figure as a benchmark, it means that for a population of 50000 refugees, at least 100000 USD (50000 pers. X 2 USD/pers.) should be earmarked per year to cover most basic needs. The more efficient the procurement system and the more rational drug selection is for programs, the more this budget can be stretched. Note that for more expensive newer drug treatments such as some anti-malarials (artemisinins) or anti-retrovirals, special funds should be requested in addition to the basic amount.

Figure 1 on the following page shows that procurement is really a cycle, as good completion of one step initiates the next step. Figure 2, which follows, focuses in more detail on the procurement steps between drug selection and receipt of drugs.

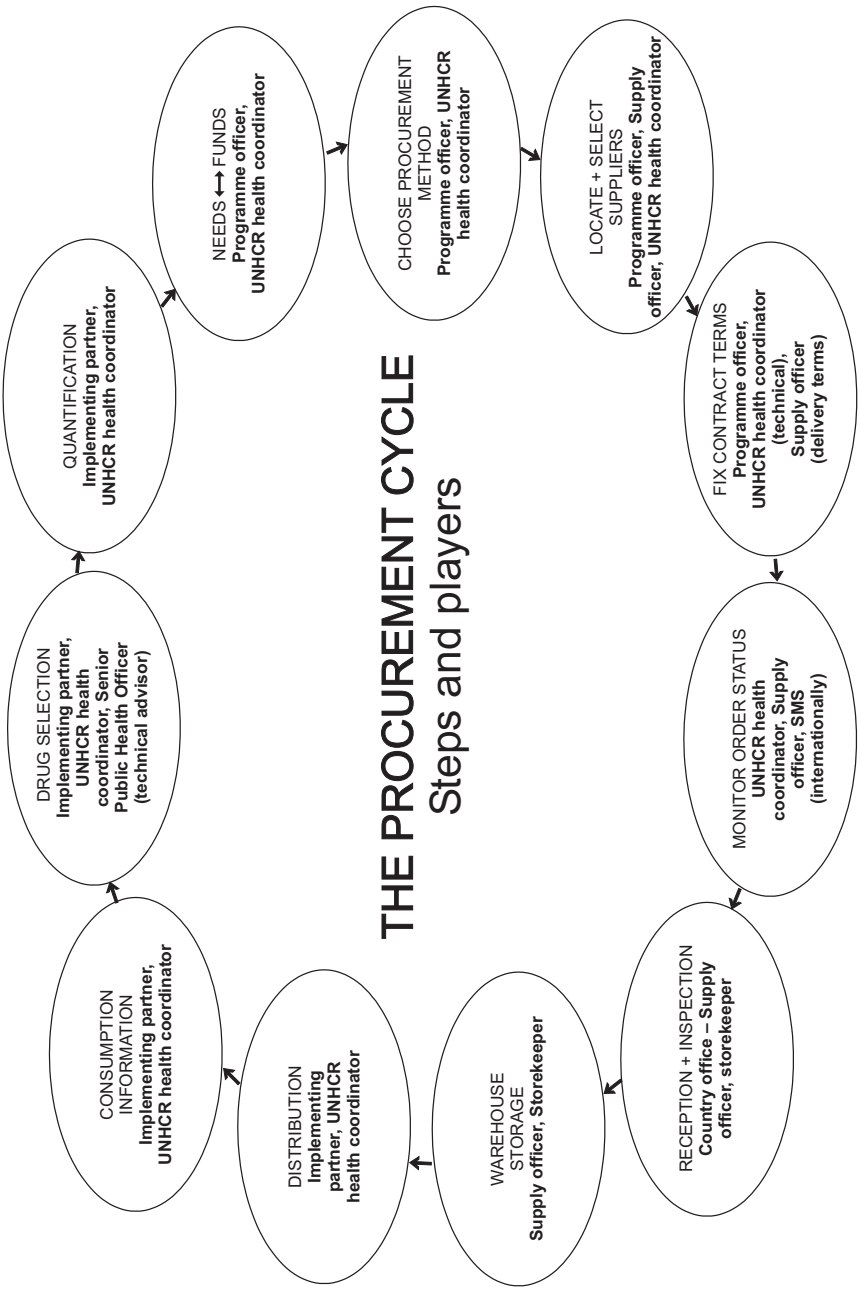
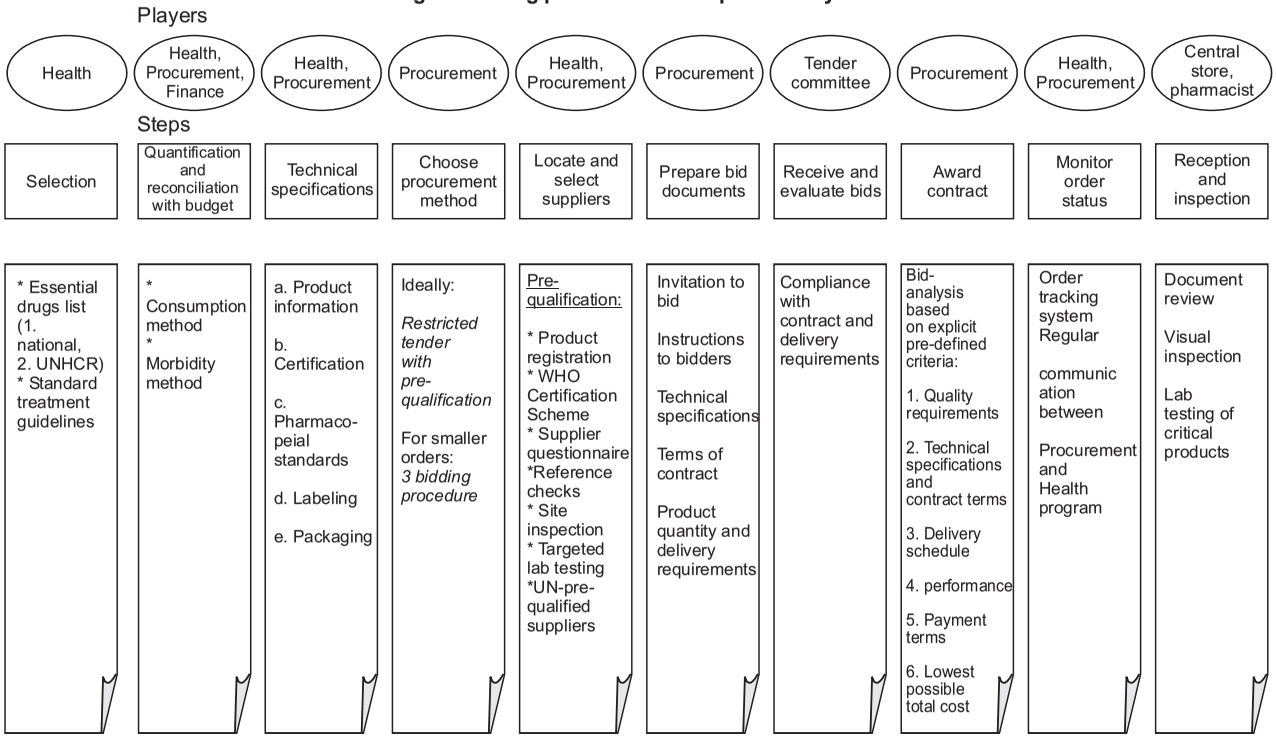

THE PROCUREMENT CYCLE
Steps and players
NEEDS ⟷ FUNDS
Programme officer, UNHCR health coordinator
CHOOSE PROCUREMENT METHOD
Programme officer, UNHCR health coordinator
LOCATE + SELECT SUPPLIERS
Programme officer, Supply officer, UNHCR health coordinator
FIX CONTRACT TERMS
Programme officer, UNHCR health coordinator (technical), Supply officer (delivery terms)
MONITOR ORDER STATUS
UNHCR health coordinator, Supply officer, SMS (internationally)
RECEPTION + INSPECTION
Country office – Supply officer, storekeeper
WAREHOUSE STORAGE
Supply officer, Storekeeper
DISTRIBUTION
Implementing partner, UNHCR health coordinator
CONSUMPTION INFORMATION
Implementing partner, UNHCR health coordinator
DRUG SELECTION
Implementing partner, UNHCR health coordinator, Senior Public Health Officer (technical advisor)
QUANTIFICATION
Implementing partner, UNHCR health coordinator

Figure 2: Drug procurement: Steps and Players



Supporting documents/standards

Note that some activities can occur in parallel with each other, such as product selection and quantification can occur while suppliers are being selected and pre-qualified.

Routine procurement tasks:

A suggested *minimum* frequency of certain procurement procedures is presented in the table below. Procurement functions that are not mentioned are either recurrent with every order or can be carried out according to internal capacity.

	Every 2 years	Annually	Quarterly	Monthly
Revision of essential drugs list	X			
Establish procurement plan		X		
Request budget for drugs and supplies		X		
Tender	X			
Pre-qualification of suppliers	X			
Collection and reporting of logistical data				X
Inventory exercise central store			X	
Collection and analysis of key procurement performance indicators		X		
ABC and/or VEN-analysis of past procurement		X		

II. QUANTIFICATION

Quantification is the process of estimating the quantities of specific drugs needed for procurement.

Indicators of poor quantification

The most common indicators of poor quantification of drug requirements are:

- Frequent shortage of drugs.
- Excess stock or expiry of large quantities of drugs due to overestimation.
- Irrational and ineffective prescribing:

  Prescribers usually either shorten treatments in an attempt to stretch their insufficient drug supply as far as possible, or substitute with inappropriate alternative drugs. In extreme cases, the treatment may be shortened to the point of ineffectiveness.
  Note that irrational prescribing can be both the cause, as well as the result of poor quantification practices.

Quantification methods

The accuracy and quality of an estimation of drug requirements will depend on the accuracy and quality of the information available.

Past consumption is the most reliable way to predict and quantify future demand, providing that the supply pipeline has been consistently full and that consumption records are reasonably accurate. Such consumption data must be adjusted in light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance. The downside of basing quantification only on past consumption is that any existing patterns of irrational drug use will be perpetuated.

An alternative way of calculating needs according to the consumption-method is to use **issue data** from the central distribution point (as opposed to consumption data reported back from the peripheral facilities). This will give information about the amount of drugs distributed to the health facilities over a given period. Consumption data is preferred above issue data because it provides a direct link with the end-users.

In cases where no reliable past consumption information exists (such as new programs), the **morbidity-based technique** may be used to estimate procurement requirements. This technique should also be used periodically to counter-check the rationality of past consumption, by comparing actual consumption with the estimated need to treat common diseases based on standard treatment protocols and epidemiological data. This **combination of consumption and morbidity methods** is also useful in programs with a high seasonal variation in consumption of certain drugs such as antibiotics or anti-malarials.

Given a well established drug supply system, good stock control, reliable distribution and rational prescribing practices, the consumption method provides the most accurate (and easiest) prediction of future needs.

Summary on when to use each method:

Quantification Method	Recommended
Consumption Method	● When adequate funds are available ● When prescribing patterns are acceptable ● When health facilities have adequate and uninterrupted drug supply ● When health facilities have reasonably good stock management, complete and accurate consumption data and stock out information ● When health facilities have low level of wastage and losses
Morbidity Method	● When available data on consumption are incomplete or unreliable ● When prescribing practices are expensive and irrational because it provides a systematic basis for improvement ● When the drug budget is unlikely to be sufficient to meet estimated requirements ● For new or rapidly changing services or when services are being substantially reorganized

Sources: ARRA & UNHCR 2002, MSH 1997

For more on how to use these methods, see the Standard Operational Procedures (**Annex 4, SOP P1 and P2).**

When funds are not available to purchase all drugs in the quantities that were estimated to be needed, it is necessary to **prioritize** the procurement list to match available financial resources. Various techniques such as **VEN (vital, essential and non-essential) analysis** and **ABC analysis** can be used to select priority drugs and to reduce the quantities of less cost-effective drugs. An ABC analysis assembles data from recent or projected procurements to determine where money is actually being spent, allowing managers to focus first on high-cost items when considering ways to reduce procurement costs. In a **VEN**-analysis, the drug budget is organized according to health priorities: **V**ital drugs (life-saving), **E**ssential (not necessarily life-saving but able to cure severe

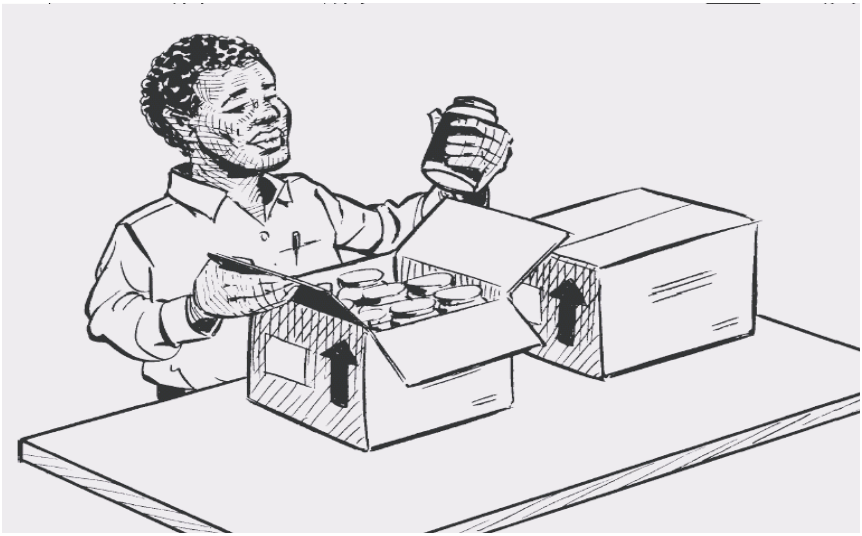
illness) and **N**on-Essential (lower therapeutic value). Vital drugs should always be purchased in sufficient quantity, no matter what, whereas for Essential and certainly for Non-Essential drugs, there is more leverage. A VEN priority list should be defined in advance of any decision related to reducing procurement**.** These hands-on tools are discussed in detail in publications listed under *References* at the end of this chapter.

III. RECEIVING AND INSPECTING HEALTH COMMODITIES

When you receive health commodities:

1. Ensure there is sufficient **storage space** (before the shipment arrives).
2. **Prepare and clean** the areas used for receiving and storing the products.
3. Count the **number of boxes** received and separate damaged and unsealed boxes from intact and sealed boxes.
4. **Inspect** all boxes for damaged or expired products. Damaged and unsealed boxes should be checked immediately and in the presence of the transporter.
5. Complete and sign the **Delivery Note** and release the transporter.
6. Send all necessary documents to **Finance** for prompt payment.
7. If appropriately trained personnel are available, take **product samples** to check for labeling, packaging and product appearance using the **checklist** below.
8. **Arrange** all products on shelves or pallets and record entries in **stock records**.

Source: MSH 1997



Source: John Snow, Inc./DELIVER 2003

Deliveries by the supplier remain the responsibility of the supplier until arrival at the warehouse of UNHCR or the partner. The supplier is responsible for insurance and all costs associated with damaged or missing goods. Since drugs are very attractive commodities, especially in developing countries or in countries at war, procedures on receiving the drugs should be carried out promptly and thoroughly.

In order to ensure a timely payment, Delivery Notes should be sent out when the goods arrive in-country. In case the goods are still under clearance, it should be clearly marked on the Delivery Note, "Not inspected, still in Customs". UNHCR or partner can pay the supplier, and still have the option to claim damaged or missing items. A paper trail is necessary to support the claim that loss or damage took place before UNHCR took delivery. Hence, it is important to note any damage to boxes, missing boxes, etc. and have all parties involved sign off. For international deliveries, the procurement department (SMS) at headquarters should be informed immediately if anything is missing or damaged.

On reception at the warehouse, the number of boxes and the state in which they are received should be checked immediately (note any signs of damage or tampering). If the contents cannot be checked immediately,

which is often the case for large shipments, the sealed and undamaged boxes should be quarantined until inspection. The contents of the boxes that are damaged or that have a broken seal should be inspected immediately against the packing list[2]. Ensure that the items delivered correspond to the items ordered, and that the quantities conform to those on the delivery note.

A thorough inspection based on predefined criteria is essential for quality assurance and as a precursor to any insurance claim. See checklists below.

Discrepancies, variations, and damage are noted on the invoice. The annotated invoice is signed and dated by a senior staff member. Observations are summarized on the delivery report. One copy of the delivery report is filed according to the purchase order to which it corresponds ("invoice matching"). Finance can usually only pay a supplier if the following documents are complete: Purchase Request (PR), a verifiable vendor receipt, Bid-analysis, Purchase Order (PO) and Delivery report.

Measures should be taken to ensure that rejected materials and pharmaceutical products cannot be use. They should be stored **separately** from other supplies while awaiting destruction or return to the supplier. All communication concerning a shipment purchased through SMS at HQ should be directed to SMS and not directly to the supplier.

After receiving procedures are completed, the drugs must be physically stored in the warehouse and entered into warehouse documentation (stock records, inventory list and warehouse register). It is important that the correct unit appears in all warehouse records, and that the same unit is used when dispensing to the patient (so tablets instead of boxes). Received goods are moved to their allocated storage positions in the warehouse, where they are stored in first-expiry/first out (FEFO) order (see Chapter 4 "*Drug Distribution, Medical Stores Management"*). Now is also the time to document **supplier performance** in the supplier file (back order, delivery time, non-compliance with contract specifications).

2 *Prepared by the seller, this document describes in detail the contents of each package in a consignment of drugs, including drug strength, pack size, number of packs per carton, and number of cartons per package. This helps the buyer check whether drugs actually shipped are in accord with the packing list and the purchase contract.*

Inspection Checklist for Drugs Received in the Warehouse:

Labeling:

1. Labeling should be **in English** and preferably one other official language of WHO.
2. All labels should display at least the following information:
   - ⇨ International Nonproprietary Name (INN) of the active ingredients
   - ⇨ Dosage form
   - ⇨ Quantity of active ingredient(s) in the dosage form (e.g. tablet, ampoule) and the number of units per package
   - ⇨ Batch number
   - ⇨ Date of manufacture
   - ⇨ Expiry date (in clear language, not in code)
   - ⇨ Pharmacopoeia standard (e.g. BP, USP,)
   - ⇨ Instructions for storage
   - ⇨ Name and address of the manufacturer
3. A printed label on each **ampoule** should contain the following:
   - ⇨ INN of the active ingredient(s)
   - ⇨ Quantity of the active ingredient
   - ⇨ Batch number
   - ⇨ Name of the manufacturer
   - ⇨ Expiry date

   The full label should again appear on the collective package.
4. Directions for use, warnings and precautions may be given in **leaflets** (package inserts). However, such leaflets should be considered as a supplement to labeling and not as an alternative.
5. For articles requiring **reconstitution** prior to use (e.g. powders for injection) a suitable beyond-use time for the constituted product should be indicated.

Packaging:

1. **Tablets and capsules** should be packed in sealed waterproof containers with replaceable lid, protecting the contents against light and humidity.
2. **Liquids** should be packed in unbreakable leak-proof bottles or containers.
3. **Containers** for all pharmaceutical preparations must conform to the latest edition of internationally recognized pharmacopoeia standards.
4. **Ampoules** must have either break-off necks, or sufficient files must be provided.

Source: MSH 1997

Expiry date:

At time of shipment the product shall have **at least 75% of its shelf life**. Write expiry date on the box in large letters and numbers, also on single containers put on the shelf. In case that the expiry date is unsatisfactory (calculate consumption until expiry date), return to supplier.

Appearance of the product:

All shipments:

Compare the goods with the supplier's invoice and original purchase order or contract. Note discrepancies on the Delivery Report. CHECK THAT:

- Number of containers delivered is correct
- Number of packages in each container is correct
- Quantity in each package is correct
- Drug is correct
- Dosage form is correct (tablet, liquid, other form)
- Strength is correct (milligrams, percentage concentration,)
- There is no visible evidence of damage (describe)

Take a sample for testing if required.

Tablets:

For each shipment, tablets of the same drug and dose should be consistent. CHECK THAT:

- Tablets are identical in size
- Tablets are identical in shape
- Tablets are identical in color (shade of color may vary from batch to batch)
- Tablet markings are identical (scoring, lettering, numbering)
- There are no defects (check for spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- There is no abnormal odor when a sealed bottle is opened

Source: MSH 1997

Appearance of the product, cont'd

Capsules:

For each shipment, tablets of the same drug and dose should be consistent. CHECK THAT:

- Capsules are identical in size
- Capsules are identical in shape
- Capsules are identical in color (shade of color may vary from batch to batch)
- Capsule markings are identical
- There are no defects (check for holes, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- There are no empty capsules
- There are no open or broken capsules

Parenterals:

Parenterals are all products for injection (IV liquids, ampoules, dry solids, suspensions for injection). CHECK THAT:

Solutions are clear (solutions should be free from undissolved particles, within permitted limits)

- Dry solids for use in injections are entirely free from visible foreign particles
- There are no leaking containers (bottles, ampoules)

Source: MSH 1997

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4. DRUG DISTRIBUTION

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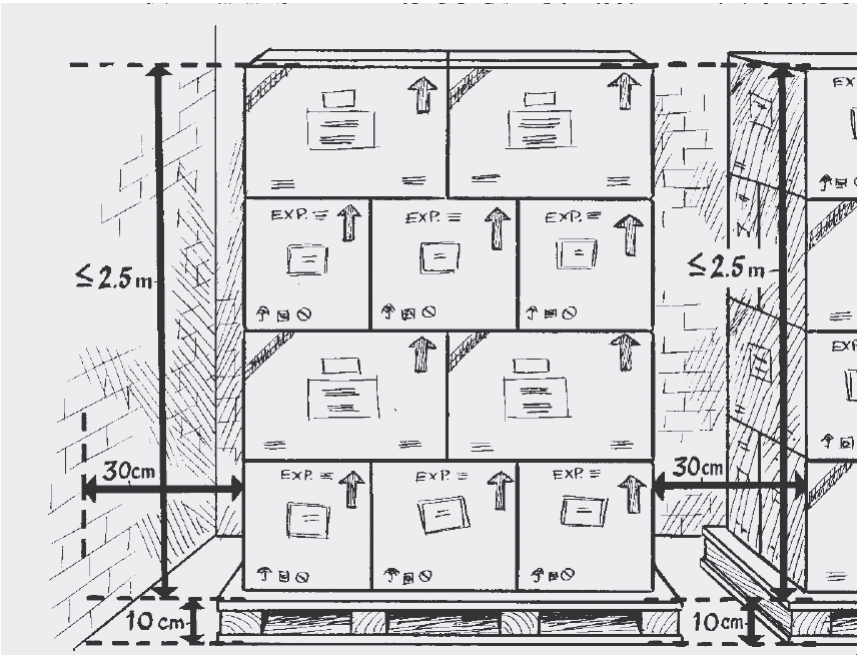
1. Objectives of Good Medical Stores Management

1. To guarantee a **continuous supply** of drugs and medical supplies.
2. To **maintain the quality** of drugs during the whole distribution process.
3. To **minimize losses** through expiration and deterioration.
4. To **control** theft and corruption.
5. To keep accurate inventory **records.**
6. To provide stock movement **information** in order to forecast needs.
7. To use **transport** means efficiently.

II. ARRANGING HEALTH COMMODITIES



Source: John Snow, Inc./ DELIVER 2003

Arrange the storeroom and shelves as follows:

If using pallets (more likely in a central facility than a health center), stack cartons on pallets:

- at least 10 cm (4 inches) off the floor;
- at least 30 cm (1 foot) away from the walls and other stacks;
- no more than 2.5 m (8 feet) high (general rule).

For all storage:

- **Follow the manufacturer's or shipper's directions** when stacking, and follow labels for storage conditions.

- Place **liquid products** on the lower shelves or on bottom of stacks.
- Store products that require **cold storage** in appropriate temperature controlled zones.
- Store **attractive and controlled** products in appropriate security zones.
- Separate **damaged or expired products** from the usable stock without delay, and dispose of using established disposal procedures.
- Always store all commodities in a manner that facilitates **FEFO ("First Expiry First Out")** rule for stock management.
- Arrange **cartons** so arrows point up and identification labels, expiry dates, and manufacturing dates are visible. If this is not possible, write the product name and expiry date clearly on the visible side.

Pharmacies without shelves or pallets are not pharmacies!!!

1. Stock Rotation

When issuing products, it is important to follow the FEFO ("First Expiry First Out") rule. Following FEFO minimizes wastage from product expiration.

- **Remove regularly** all expired items from the store and check for near-to expiry drugs which cannot be used completely.
- **Mark** all containers and boxes with the expiration date of the drug.
- Arrange stock according to **FEFO** to allow stock rotation. Put drugs with the earliest expiration date in front/on top and drugs with the latest expiration date in the back/below.
- **Do not divide** drug stocks for same products over different locations.
- Record the expiration date for every drug during **physical inventories** (provide a column for expiration date on the inventory sheet).

Remember that the order in which products are received is not necessarily the order in which they will expire. Products received more recently may expire sooner than products received earlier. So, it is extremely important

to always check expiration dates and make sure the dates are visible while the products are in storage.

Source: John Snow, Inc../DELIVER 2003

2. Organizing the store room in a logical way

- **Remove all unnecessary items** (medical + non-medical) from the store after a thorough inventory exercise.
- Stock is most easily arranged according to the following **classification:**
  - oral drugs
  - injectable drugs
  - infusions
  - drugs for external use and disinfectants

- reagents and laboratory materials
- small consumable materials classified in subcategories:
  - dressings
  - injection materials
  - sutures

Within each category, products (oral, injectable, external use) are classified **alphabetically**.

Each product should have a **designated place**, well identified by a fixed label. The label should indicate the generic name, form and dosage, e.g. AMOXICILLIN 250 MG TABLET.

Provide sufficient space between and for each drug.

Arrangement should allow fast inspection.

> *It should be possible to note the number of each box and evaluate in a few minutes, current stock or monthly consumption of a product.*

An empty space behind a label means a stock rupture.

This organizational system is indispensable for easy and efficient management. Only a few hours should be needed to do a complete inventory.

3. Special Storage Conditions

Some products need storage in an access-controlled environment. It is important to identify products that are at risk of theft or abuse or have the potential for addiction ("**controlled substances**"), and to provide increased security for these items. This includes products ("**attractive items**") that are in high demand or have the potential for resale (illicit markets). Other products such as **flammables and corrosives** pose risks of fire, product contamination or bodily injury and should be stored separately from drugs.

4. Controlled Substances

Controlled substances should be kept in a **locked cupboard** or in a safe to which only one or two persons have access. Every entry and exit should be recorded in a **register**, which can be found in the cupboard or safe. Narcotic drugs, also called "dangerous drugs" are governed by special legislation and regulations that control import, export, production, supply, possession, prescribing, record keeping, and retention of documents.

Typical examples are:

Narcotics: morphine, opium preparations, pethidine, tramadol and ketamine

Other opioid and strong analgesics: pentazocine, codeine, dihydrocodeine, dextroproproxyphene

Psychotropic drugs: usually the group of drugs called "benzodiazepines," of which diazepam is the best-known example.

Strong tranquilizing medicines, such as chlorpromazine, may also be found under this heading.

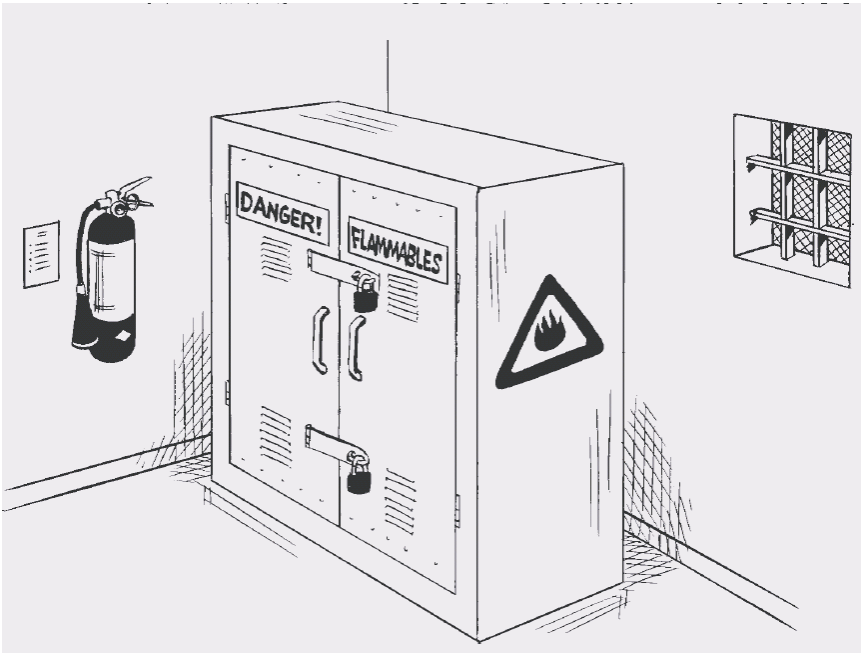
5. Attractive items

Some non-controlled items are particularly prone to theft, abuse, or misuse. These include **expensive drugs** (cimetidine, praziquantel, snake anti-venom, quinine, anti-retrovirals, artemisinin anti-malarials), certain **antibiotics, minor medical equipment** such as scissors, dressing sets, safety razors, hypodermic needles, and rolls of cotton. Such items should be stored in a separate locked area and require stricter record keeping and more frequent stock taking than other items. Periodic audits should be made of consumption (issues) against actual recorded use (outpatient registers, prescription records, or ward stock records) to expose any theft or misuse.

6. Flammables and corrosives

Bulk supplies of *flammables*, such as **alcohol, ether**, **acetone**, **kerosene** must be stored in special buildings or rooms. A separate building is best, since this greatly reduces the risk of fire spreading to the central store. **Fuel** must *always* be stored in a separate building. The flammables store must be well ventilated and fireproof, and fitted with an "explosion hatch", which may be part of the roof or part of a wall.

A small working stock of flammables may be kept in a steel cabinet in well-ventilated premises, away from open flames and electrical appliances. The cabinets should be marked "highly flammable liquid" and bear the international hazard symbol. In addition, the shelves of the cabinet should be designed to contain and isolate spillage. Always store flammables in their original container.



Source: John Snow, Inc./DELIVER 2003

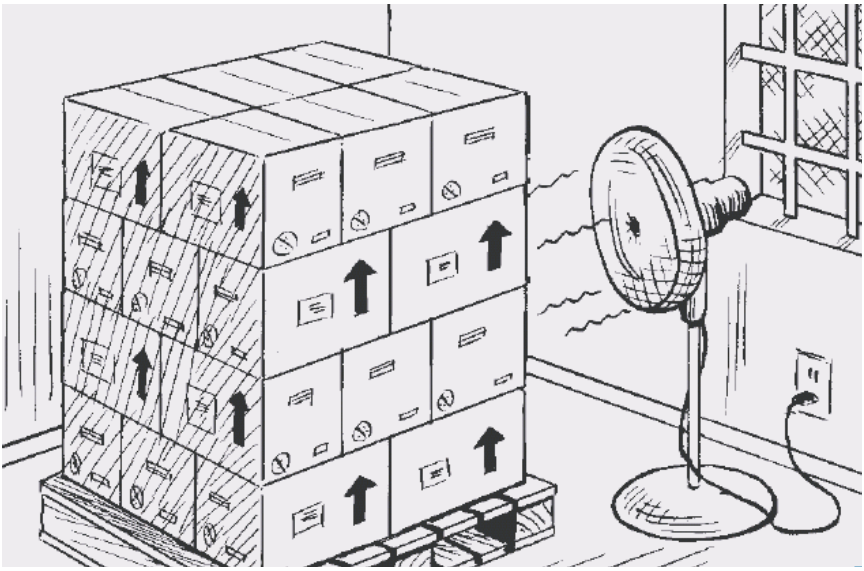
Flammable liquids each have a **flash point**, which is the minimum temperature at which the liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid. The flash point indicates the susceptibility to ignition.

- Acetone and anesthetic ether have a flash point of –18°C.
- Undiluted alcohols have a flash point of 18° to 23°C.
- The flash point for kerosene is 23° to 61°C.

It is not necessary to store flammables below their flash point, but it is very important to **store them in the coolest location possible and never in direct sunlight**. It is important to control the evaporation rate and avoid the build-up of pressure.

Corrosives or oxidant substances, such as **trichloracetic acid, glacial acetic acid, concentrated ammonia solutions, silver nitrate, sodium nitrite,** and **sodium hydroxide pellets,** should be stored away from flammables, ideally in a separate steel cabinet. Appropriate industrial-type protective gloves and face-masks should be used when handling them.

III. MAINTAINING THE QUALITY OF PRODUCTS



Source: John Snow, Inc./DELIVER 2003

1. Stability – Expiry Date – Deterioration-Quality standards.

2. Storing health commodities:
   - 2.1. Controlling temperature – The Cold Chain.
   - 2.2. Preventing damage and contamination.
   - 2.3. Protecting against fire.
   - 2.4. Protecting against pests.
   - 2.5. Protecting against theft.

1. Stability-Expiry Date-Deterioration-Quality Standards

A drug product must retain its properties within specified limits in order to be useful. The time that a drug's **stability** is guaranteed is usually established by the manufacturer. In most countries, manufacturers are bound by law to have the stability of their products tested under standard conditions. They have to be able to ensure a minimum period of preservation. This period ends with the product's **expiry date**.

The stability of a drug product depends on the active ingredient, which can be affected by its formulation and packaging. Inadequate storage and distribution can lead to physical **deterioration** and chemical decomposition, reduced potency, and occasionally, formation of toxic by-products of degradation. This is more likely to occur under tropical conditions of high ambient temperature and humidity. Being well acquainted with the normal characteristics of every drug, like color, smell, solubility and appearance, is essential. These normal characteristics or **quality standards** can also be found in *pharmaceutical references* like Martindale, Merck-Index and pharmacopeia (see Chapter 6). This method allows qualified staff to detect any changes as soon as they occur. Certain processes may however occur without any detectable change in the appearance of the products!

Damaged products should never be issued to facilities or dispensed to patients. If you are not sure if a product is damaged, check with someone who knows. Do not issue or dispense products that you suspect are damaged. Report any defects and send the defective products back to the facility that issued them to you.

Indicators of quality problems:
Products of different types show damage in different ways.
Some indicators you can use to detect damage are

Light-sensitive products (such as x-ray film)

- torn or ripped packaging

Latex products

- dry
- brittle
- cracked

All products

- broken or ripped packaging (vials, bottles, boxes, etc.)
- missing, incomplete, or unreadable label(s)

Liquids

- discoloration
- cloudiness
- sediment
- broken seal on bottle
- cracks in ampoule, bottle, or vial
- dampness or moisture in the packaging

Lubricated latex products

- sticky packaging
- discolored product or lubricant
- stained packaging
- leakage of the lubricant (moist or damp packaging)

Pills (tablets)

- discoloration
- crumbled pills
- missing pills (from blister pack)
- stickiness (especially coated tablets)
- unusual smell

Injectables

- liquid does not return to suspension after shaking

continued

Sterile products (including IUDs)

- torn or ripped packaging
- missing parts
- broken or bent parts
- moisture inside the packaging
- stained packaging

- **Capsules**
- discoloration
- stickiness
- crushed capsules

Tubes

- sticky tube(s)
- leaking contents
- perforations or holes in the tube

Foil packs

- perforation(s) in packaging

Chemical reagents

- discoloration

Source: John Snow, Inc./DELIVER 2003

Question: Can expired drugs be used?

Answer: NO!

*Expired drugs should **never** be used (unless as a last solution in case of an emergency); not only can their **potency** be decreased, but more serious effects like **increased allergic reactions** (penicillin) or even formation of **toxic** substances (tetracycline) can occur. Also **changes in formulation** (suppositories, creams) or **decrease in solubility** (oral re-hydration salts) can occur.*

*Note that the expiry date given by the manufacturer is **tentative** and marks the end of the period for which safe and effective use of the drug is guaranteed. Expiry dates are usually based on stability studies done for **moderate** climates, so it is fair to assume that many drugs stored in an extreme climate have lost most of their potency by the expiry date (if not before this date for some unstable drugs).*

2. Storing Health Commodities

It is essential to **follow the product manufacturer's storage instructions** as much as possible. The product must be kept in the most suitable conditions available and used as quickly as possible. The product manufacturer should be consulted before violating recommended storage conditions to determine how long the product will remain safe and effective under the actual storage conditions.

The use of the following labeling instructions are recommended:

On the label	Means
"Do not store over 30 °C"	from +2 °C to +30 °C
"Do not store over 25 °C"	from +2 °C to +25 °C
"Do not store over 15 °C"	from +2 °C to +15 °C
"Do not store over 8 °C"	from +2 °C to +8 °C
"Do not store below 8 °C"	from +8 °C to +25 °C
"Protect from moisture"	no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moisture resistant container.
"Protect from light"	to be provided to the patient in a light-resistant container.

If no specific storage instructions are given, **normal storage conditions** apply. Normal storage conditions for drugs have been defined as "**storage in dry, well ventilated premises at temperatures of +15ºC to +25ºC, or, depending upon climatic conditions, up to +30ºC. Extraneous odors, other indications of contamination and intense light must be excluded" (WHO 1990).** The +15ºC to +25-30ºC zone is assumed to be air-conditioned and therefore, humidity controlled. In temperate climates, this temperature range can be achieved without air-conditioning, but humidity control (dehumidifiers) may still be necessary.

2.1. Controlling temperature

Humidity

When product labels say “protect from moisture,” store the product in a space with no more than 60% relative humidity. To reduce the effects of humidity consider:

- ***Ventilation:*** Open the windows or *air vents* of the storeroom to allow air circulation. Ensure that all windows have screens to keep out insects and birds, and that all windows either have bars or are not open wide enough for anyone to climb in. Put boxes on *pallets* and ensure there is *space* between pallets and the walls of the storeroom.
- ***Packaging:*** Secure all *lids*. Never open a new container unless necessary.
- ***Circulation:*** Use a *fan* to circulate fresh (outside) air. In bigger storerooms you may need a ceiling fan. Standing fans are more useful in smaller storerooms. This requires electricity and some maintenance.
- ***Air conditioners:*** If possible, use an *air conditioner*. This is costly, depends on a constant supply of electricity, and requires regular maintenance. Depending on climatic conditions, a *dehumidifier* may be a less costly option. However, they also need a constant supply of electricity and require regular attention to empty the water containers.

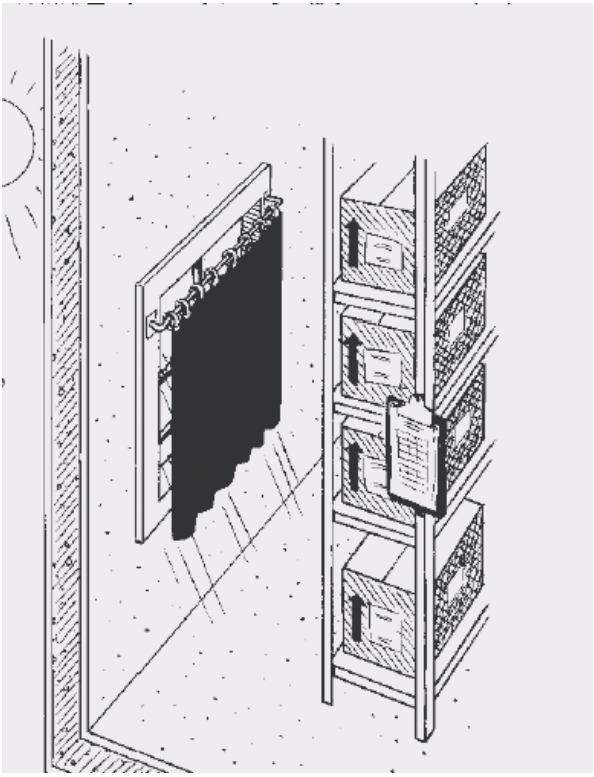
Sunlight

Some health products are photosensitive and will be damaged if exposed to light. These include multi-vitamins, furosemide, chlorpheniramine maleate, hydrocortisone, intravenous solutions in plastic bottles, rubber, cellulose, plastic or latex[1] products (such as male condoms), and x-ray film.

1 *Condoms, most sterile disposable medical devices, and surgical products such as syringes, needles, and catheters require protection from excessive humidity, cold, and strong light. Any of these conditions may make products brittle, stained, malodorous, and unusable. Sterility cannot be assured if packaging is damaged. Items remain sterile even after the expiry date as long as packaging is intact.*

To protect products from sunlight:

- Shade the windows or use curtains, if they are in direct sunlight.
- Keep products in cartons, especially injectables.
- Do not store or pack products in sunlight.



Source: John Snow, Inc./DELIVER 2003

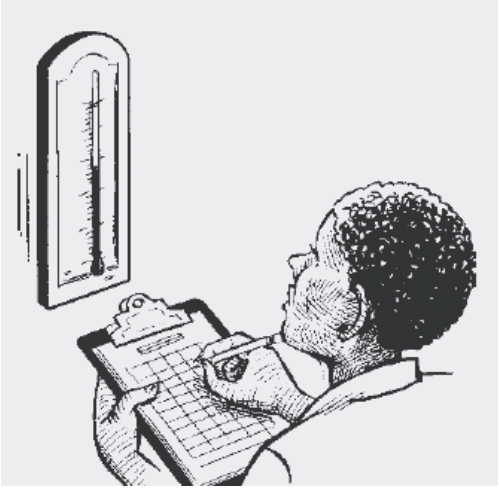
Heat

Remember that heat will affect many products. It melts ointments, creams and suppositories and causes other products to become useless. Following the guidelines listed earlier for protecting products from humidity and sunlight will also help protect products from heat.

Monitoring

Consistently monitor the temperature of the different areas within the storeroom.

Keep thermometers at the hottest places in the store and check temperatures during the hottest part of the day. If you do not have thermometers, you can still monitor the heat. If you feel hot, your products are probably hot, too. Temperature monitoring of the cold chain is even more rigorous.



Source: John Snow, Inc./DELIVER 2003

Drugs Found to Have Stability Problems under Tropical Conditions

Oral solids (tablets/powder for suspension)	Oral liquids (syrups)
Acetylsalicylic acid	Paracetamol
Amoxicillin	
Ampicillin	**Injectables**
Penicillin V	Ergometrine
Retinol (Vit. A)	Methylergometrine

Sources: Sakolchai et al. 1989: WHO/UNICEF 1991; Hogerzeil et al. 1992, 1993

Other drugs that are relatively unstable are: **cloxacillin** (tablet, capsule or powder for suspension), **nitroglycerine** (glyceryltrinitrate) tablets, **phytamenadion (vitamin K)** injection, **paracetamol** tablets (grey or black discoloration due to molding).

Freezing is as damaging as high temperatures for some items, including **injectable contraceptives, ergometrine, insulin, adrenaline.** Loss of potency in ergometrine injection because of heat has frequently been found in field studies and may also be detected visually. If the solution appears colored when compared with water, the injection has less than 90% of stated content and should be discarded.

Short periods at room temperature (during transportation or local distribution, for instance) are acceptable for many products (such as ergometrine and insulin), even though such exposure can, to some extent, reduce shelf life. Other items, such as vaccines, should always be transported in cold boxes.

2.2. Preventing damage and comtamination

Physical damage

Avoid crushing products stored in bulk. Products should be stacked no more than 2.5 m (8 feet) high, as a general rule. Heavier or fragile items (such as those packaged in glass) should be placed in smaller stacks.

Bind sharp edges or corners in the store with tape. Most importantly, ensure that nothing in the store can fall and injure staff members.

Dirt

Write and post the schedule and instructions for cleaning the storeroom in multiple locations around the facility. Sweep and mop or scrub the floors of the storeroom regularly. Wipe down the shelves and products to remove dust and dirt. Dispose of garbage and other waste often, in a manner that avoids attracting pests. Store garbage in covered containers.

Infrastructure*:* Ensure the storeroom has easy access to a water outlet for cleaning.

Cleaning materials*:* Keep a budget for buying cleaning materials. Use industrial detergents when possible, particularly for larger facilities, although imported detergents can be expensive. Try to use locally available detergents, particularly for smaller or more remote facilities. Clean with chlorine bleach at least once a month.

Outside the facility*:* Burn garden rubbish and cardboard cartons, etc. when garbage collection is not available. Use the necessary precautions to keep the fire under control, and do not burn materials close to the building. Make sure the wind is not blowing toward the building.

2.3. Protecting against fire

To prevent damage to products from fire:

- Strictly prohibit smoking in the store.
- Conduct fire drills for personnel every 6 months.
- Clearly mark emergency exits and check regularly to make sure they are not blocked or inaccessible.

- Display fire precaution signs in appropriate places in the storage facility (especially locations where flammables are stored).
- Minimize the number of flammables stored in the store. Do not allow flammable trash to accumulate.

Source: John Snow, Inc./DELIVER 2003

- Make standard fire extinguishers available in every storage facility according to national regulations.
- Visually inspect fire extinguishers every 2–3 months to ensure that pressures are maintained and that the extinguisher is ready for use.
- Service fire extinguishers at least every 12 months.
- Place smoke detectors throughout the storage facility and check them every 2–3 months to ensure that they are working properly.

- Use sand to extinguish fires where there are no fire extinguishers. Place buckets of sand near the door.

Source: John Snow, Inc./DELIVER 2003

2.4. Protecting against pests

Prevention inside the storage facility:

- Design or modify the storeroom to facilitate cleaning and prevent moisture.
- Maintain a clean environment to prevent conditions that favor pests. For example, store garbage in covered garbage bins. Regularly clean floors and shelves.
- Do not store or leave food in the storage facility. Do not allow staff to eat or drink in the storage area. Provide a designated place for eating.
- Keep the interior of the building as dry as possible.
- Paint or varnish wood, as needed.
- Use pallets and shelving.

- Prevent pests from entering the facility. Rats are known to consume certain types of IV-fluids.
- Inspect the storage facility regularly for evidence of pests.

Source: John Snow, Inc./DELIVER 2003

Prevention outside the storage facility:

- Regularly inspect and clean the outside premises of the storage facility, especially areas where garbage is stored. Check for any rodent burrows, and ensure that garbage and other waste is stored in covered containers.
- Check for still or stagnant pools of water in and around the premises, and ensure that there are no buckets, old tires, or other items holding water.
- Treat wood frame facilities with water sealant, as needed.
- Use mercury vapor lighting where possible, and locate lighting away from the building to minimize the attraction of pests.

2.5. Protecting against theft

During transport:

- Verify documents.
- Ensure packing seals are used.
- Use strong boxes/containers.
- Provide reliable/well-maintained vehicles.
- Ensure drivers are reliable.
- Ensure rapid clearance at air and sea ports and through on-land borders.

At storage facilities:

- Limit access to only designated staff.
- Limit the number of keys made for the facility; keep a list of people who have keys.
- Secure all locks and doors.
- Make unannounced spot checks.
- Provide independent stock count/inventory control.

In health centers:

- Lock the storeroom/cupboards.
- Have stock cards for each product.
- Set maximum dispensing quantities.
- Have dispensers record individual prescriptions and maintain prescription or dispensing registers (daily dispensing tally sheets, monthly consumption sheets).
- Limit dispensing to authorized staff members only.

Monitor selected products:

As additional protection against theft, monitor items that are fast moving, chronically in short supply, in high demand by patients, expensive, life saving, and easy to hide or disguise.

Most common security breaches at the hospital or health center level:

By health staff:

- petty theft ("**leakage**") by health staff for personal and family use.
- **systematic diversion** of larger quantities for illicit markets or for use in private practice.
- writing of **multiple prescriptions** to the same person or to false names ("ghost patients").
- systematic **over-ordering** of drugs for use in private practice.

By patients:

- patients **faking illness** to obtain drugs for resale (refugee camps!) or home storage.
- visits by patients to several health centers ("**drug shopping**") to obtain popular resale items (especially in refugee camps with multiple health facilities in close proximity).

Source: MSH 1997

Two techniques for monitoring medicines:

Select medicines which are likely to be stolen or misused (e.g. antibiotics, narcotics, psychotropics, anti-retrovirals).

1. Check inventory records for stock on hand. Then, conduct a physical inventory (physically count the quantities on hand) and compare the results.

2. Alternatively, compare stock records with prescription or dispensing records:

    1. Check the inventory records to determine the consumption during a specified period.
    Example, 8000 tablets were issued during a 3-month period.

2. Check medical charts or prescription ledgers and count the number of treatment courses during the same period.
   Example: 101 adults were dispensed 56 tetracycline tablets each.
3. Convert treatment courses into dose units.
   Example: 5656 tablets.
4. Compare this figure with the stock issued from the storage area.

   If you find a significant discrepancy, investigate further.

Accountability of pharmacy store staff and supervisors

Security management is as much a part of the job of a storekeeper as are drug storage and proper record keeping. In case of loss of drugs through theft or corruption, storekeepers should be held accountable. This means that they will have to demonstrate:

1. they are not involved actively or passively, and
2. they have done everything possible to have prevented this from occurring through proper store management.

Supervisors (Health Coordinators and Logistics Coordinators) will need to demonstrate regular supervision of stores and store records since security breaches are usually the result of poor supervision.

IV. KEEPING TRACK OF PRODUCTS IN A MEDICAL STORE

Source: John Snow, Inc./DELIVER 2003

1. Stock cards

The stock card is the most important record for stock management. It shows stock movement over time and gives an exact figure of the amount that is available for a certain item at a given point in time.

Stock cards should be updated in the following cases:

- With every **stock movement** (entry/exit);
- During every **physical inventory**. The physical quantity verified during the inventory should be filled out on the stock card. Every difference between physical quantity and recorded quantity should be explained under the 'Remarks' column;

- In case of **loss** (expiration, waste, theft,).

On the stock card, the following should be mentioned:

- the generic **name**, the **form** (tablet, ointment, etc.) and the **strength** of the product;
- all **movements** (entries, exits, origin, destination, stock) and the **dates;**
- **unit**: tablet, tube, bottle, piece, etc. (very important);
- **expiry date**: in bigger stores, same products with different expiry dates should have separate stock cards;
- indication of **physical inventories** and dates.

If stock cards are well kept, there will be no losses.

Very important*: update stock cards after every movement. Always use inerasable ink and never use a pencil. Every correction should be justified and reported to the supervisor. Never throw away old stock cards.*

2. The physical inventory

Before every new drug order, a comparison of the physical stock (what is counted on the shelf) and the theoretical stock (written on stock cards) should be carried out. This is called an inventory. An inventory **identifies discrepancies (or differences)** between the stock that is available and the stock that should be available according to stock records. The goal of the inventory exercise is to determine the physical stock, but also to identify and explain any discrepancies (due to miscalculation, omission, theft, unexplainable losses). Other reasons for inventory exercises can include checking the quality of the stored products, correcting records where necessary, or organizing the store room.

Example of physical inventory form

Inventory for the month of:					
Date:					
Health center:					
Item	**Expiry date**	**Quantity Stock card**	**Quantity counted**	**Difference**	**Remarks**
ASA 500 mg tablets	11/2004	2400	2346	54	Calculation error on stock card
Amoxicillin 500 mg tablets	10/2005	550	550	0	

To conduct an inventory in a central medical store:

1. ***Choose a date in advance***, and set a cut-off date several days earlier. Beyond that date, no movement of incoming and outgoing drugs should be allowed. When there is no alternative, incoming drugs should be kept aside until after the inventory (not included) and outgoing drugs should be included.

2. ***Prepare the inventory area.*** Make sure that cartons are neatly stacked so that all commodities are readily accessible, and any partial (open) cartons are visible and not concealed under full cartons.

3. ***Arrange for staff to be present*** on the day of the inventory if cartons will need to be moved and restacked. An inventory should be carried out by the pharmacy staff AND their supervisor.

4. *Collect more people* if necessary, and ***explain to non-medical staff*** very clearly how to perform the inventory and emphasize the importance of writing the exact description, unit, package size and eventually unit price.

5. **Count the usable products:**

   ➔ Begin at one end of the aisle and work to the other end before starting the next aisle.

- ➔ Go from top of the shelves to the bottom. Do not skip any stacks or rows.
- ➔ Record all counts in **basic units** rather than boxes or tins because the quantity of their contents varies according to supplier. Basic units are the smallest unit (tablets, capsules, tubes, syringes, ampoules, bottles) in which drugs can be dispensed to a patient. Be sure to count the actual quantities in partial (open) cartons.
- ➔ To be accurate, two people should do separate physical counts and then compare them. If the two counts are not the same, a recount should be made of the items in question until the cause of the discrepancy is discovered.
- ➔ Any damaged or expired supplies should be recorded on a separate sheet specifically for this purpose. These supplies are removed from the stock. Expiry dates for every item should be recorded and nearly-to-expire drugs should be marked.

6. Update the stock records:

- ➔ Record the amounts on the stock cards and write 'Physical Inventory' in the remarks column.
- ➔ If the inventory amount is different from the calculated amount, note in the remarks column that you are making a correction. For example, "Corrected by physical count" or "Found expired during inventory".
- ➔ The inventory record form should be signed and dated by the person(s) who performed the inventory and the Storekeeper. The form should be filed as a permanent record.

7. Take action based on the result of the physical inventory:

- ➔ If no discrepancies are found, congratulate your staff.
- ➔ In case a discrepancy is found, the correct physical quantity should be written on the stock card in a different color. *If discrepancies are large or frequent, further investigation should be carried out to find the cause and to take action (tighten security or repeat training in record keeping).*

Discrepancies could be caused by:

- Miscount during the current inventory or a previous inventory.
- Items previously removed from inventory or received into inventory but not recorded on the stock cards.
- Missing a carton during the inventory.
- Damaged or expired drugs recorded on a separate sheet but not deducted from the balance on the stock card.
- Items not in their proper place.
- Theft.

Record the reasons for any discrepancies on the physical inventory form.

In larger warehouses the complete physical inventory process may be disruptive to the store's activities. It is always best to choose the least busy time of the quarter to take a complete physical inventory.

An alternative method is **cycle counting** or continuous physical inventory. With this method, one or a few products are counted at a time each day, week, or month, rather than closing down the warehouse and counting everything on the same day. The sampling procedure might be simple (for example, count one product during the first week of each month, so that everything is counted at least once per year), or more targeted (count all expensive or fast-moving items twice per year, and count the rest only once). Cycle counting strategies require more thought, but are less disruptive to routine warehouse operations.

3. Summary of forms and records to keep at the central and peripheral level

Type of document	Central pharmacy	Health center pharmacy
Records	Stock card Delivery schedule Temperature monitoring sheet	Stock card Daily Consumption Tally Sheet
Forms	Waybill	Requisition form* Waybill
Reports	Quarterly inventory	Monthly Inventory Monthly Consumption**

** and ** can be combined into one form to increase efficiency*

V. REORDERING HEALTH COMMODITIES

Drugs and medical supplies should be reordered by the health facilities based on a regular re-order schedule (e.g. monthly) that will depend on staff and transportation availability. Quantities to be reordered should be based on past consumption, remaining inventory and a safety stock (see **Annex 4, SOP P1**). Note that in order to avoid emergency orders due to poor planning, storekeepers at health facilities must be trained in calculating order quantities. All supplies should be reordered on a pre-printed requisition form that is prepared by the health facility's storekeeper and authorized by the in-charge of the facility. Once the requisition form is received at the central medical store, approval from authorized health staff should be requested before releasing the products to the field. Approval of the supplies will depend on approval and justification at the health facility level. After approval by an authorized health officer, the order will be prepared by the central medical store keeper. Together with the issued supplies, a copy of the approved requisition form that indicates the issued quantities and a waybill shall be sent to the health facility. Upon arrival at the health facility, the quantity of all supplies will be verified by both the storekeeper and the driver. The waybill and requisition form are signed by both parties. One copy of the requisition form and the waybill remains at the health facility for their records, while the other copies return with the driver to be filed at the central medical store.To reduce the number of forms and records and to justify re-ordered quantities, the requisition form can include a column that indicates the quantities that have been used.

See sample Requisition form in **Sample Forms and Records**.

VI. ROUTINE MEDICAL STORE MANAGEMENT

Daily/Weekly	Monthly	Quarterly	Every 12 months
Update stock records and maintain files.	**For health center/hospital pharmacies:**	**For central medical stores:**	**For central and peripheral level:**
◆ Monitor stock levels, stock quantities, and safety stocks. ◆ Submit emergency order when necessary. ◆ Update back-up file for computerized inventory control records. ◆ Update bin cards. ◆ Separate expired stocks and move to secure area.	Conduct physical inventory or cycle count, and update stock keeping records. Assess stock situation and expiry dates. Submit monthly consumption information. Fill out requisition to central medical stores. **For central and peripheral level:** Write monthly stock report (in/out/losses/balance) !! Carry out supervisory visit (Health Coordinator/Logistics Coordinator) ◆ Run generator to ensure the system is working correctly; check the level of fuel and add fuel, if needed. ◆ Check for signs of rodents, insects, or roof leaks. ◆ Inspect the storage structure for damage, including the walls, floors, roof, windows, and doors.	Conduct physical inventory or cycle count, and update stock keeping records. Assess stock situation and expiry dates. ◆ Use established procedures to dispose of expired or damaged products. ◆ Visually inspect fire extinguishers	Conduct complete physical inventory for Finance and update stock-keeping records. ◆ Reassess maximum/minimum stock levels, and adjust if needed.

Source: John Snow Inc./DELIVER 2003

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5. RATIONAL USE OF DRUGS

Contents

I. INTRODUCTION TO THE RATIONAL USE OF DRUGS

1. Defining rational drug use

The aim of any drug management system is to deliver the correct drug to the patient who needs it. Many gains of efficient selection, procurement and distribution can be lost by irrational prescribing and by lack of adherence to treatment by the patient.

The Conference of Experts on the Rational Use of Drugs, convened by the World Health Organization in Nairobi in 1985, defined rational use as follows:

"Rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."

It is clear that there are differences in refugee settings with regard to:

- the numbers of health workers, their levels of competence, and range of nationalities;
- the specific organization of refugee health services at national levels as well as in camp settings;
- the particular treatment protocols approved for use by health authorities, and those used by agency personnel;
- the specific composition of refugee populations by age, ethnicity, socio- economic and cultural status and illness profile.

However, the effective use of drugs in all refugee settings depends on:

1. *Rational prescribing:*
    - *Appropriate indication*. The decision to prescribe a drug is entirely based on medical rationale and the drug therapy is an effective and safe treatment.

- *Appropriate drug.* The selection of a drug is based on efficacy, safety, suitability, and cost considerations.
- *Appropriate patient*. No contraindications exist, the likelihood of adverse reactions is minimal, and the drug is acceptable to the patient.

2. *Correct dispensing, including appropriate patient information.*
   Refugee patients are provided with relevant, accurate, important and clear information regarding their condition and the medication that is prescribed. Drugs are dispensed in a safe and hygienic manner.

3. *Adherence to treatment by the refugees.*
   Adherence is the degree to which patients adhere to medical advice, and take medicines as directed. A patient adheres to the treatment if he/she understands and appreciates the value of taking specific drugs for specific indications and if drugs are dispensed in a form that is acceptable to the patient.

2. Types of irrational drug use

Prescribing:

- Multiple or over-prescription (“Polypharmacy”).
- The use of drugs when no drug therapy is indicated,
  e.g., antibiotics for viral upper respiratory infections.
- The use of the wrong drug for a specific condition requiring drug therapy,
  e.g., tetracycline in childhood diarrhea requiring ORS.
- The use of drugs with doubtful or unproven efficacy,
  e.g., the use of antimotility agents in acute diarrhea.
- The use of drugs of uncertain safety status,
  e.g., use of dipyrone (Novalgine etc.).
- Failure to provide available, safe, and effective drugs,
  e.g., failure to vaccinate against measles or tetanus, or failure to prescribe ORS for acute diarrhea.

- The use of correct drugs with incorrect administration, dosages, and duration, e.g., the use of IV metronidazole when suppositories or oral formulations would be appropriate, not dispensing the full course of antibiotics.
- The use of unnecessarily expensive drugs ("extravagant prescribing"), e.g., the use of a third generation, broad-spectrum antimicrobial when a first-line, narrow spectrum agent is indicated.
- Indiscriminate use of injections,
  e.g., in malaria treatment.
- Multivitamins and tonics for malnutrition.

Dispensing:

- Incorrect interpretation of the prescription.
- Retrieval of the wrong ingredients.
- Inaccurate counting, compounding or pouring.
- Inadequate identification and labeling.
- Unsanitary procedures.
- Mistakes in delivery of drugs to patients such as wrong drug, wrong amount of drug.
- Poor quality packaging materials.

Patient adherence:

Inadequate *instructions, poor labeling* and *difficult treatment regimens* negatively influence adherence in most populations. In refugee settings, assuring compliance is particularly difficult owing to:

- the presence of language barriers, especially when expatriate or national staff must diagnose and treat refugee patients.
- lack of familiarity for some refugee populations in the use of medications, because of:
  - limited previous exposure to modern drugs,
  - previous reliance on traditional systems of healing,

- low levels of education and literacy.

- the degree of mobility in refugee groups - within camp boundaries, between encampments, and across national borders.
- the frequent disruption of established family structures arising from relocation to a refugee camp.
- the lack of an orderly household numbering system in many large refugee communities, which makes effective home visiting difficult.
- inappropriate previous exposure to drugs, e.g. reliance upon injections.
- Treatments or instructions that do not consider the patient's beliefs, environment or culture.

3. Impact of Inappropriate Use of Drugs

The impact of this irrational use of drugs can be seen in many ways:

1. Reduction in the quality of drug therapy and overall quality of health care leading to increased morbidity and mortality.

2. Waste of resources leading to reduced availability of other vital drugs and increased costs.

3. Increased risk of unwanted effects such as adverse drug reactions and the emergence of drug resistance, e.g., malaria or multi-drug resistant tuberculosis.

4. Psychosocial impacts, such as when patients come to believe that there is "a pill for every ill." This may cause an apparent increased demand for drugs.

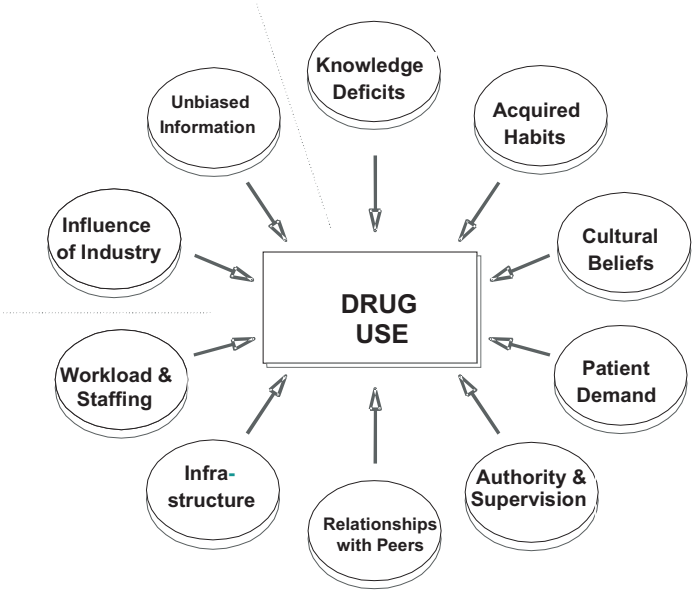
4. Factors Underlying Irrational Use of Drugs

Many different factors affect the irrational use of drugs. In addition, different cultures view drugs in different ways, and this can affect the way drugs are used.

The major forces can be categorized as those deriving from patients, prescribers, the workplace and the supply system, and combinations of these factors.

- Prescribers
  - lack of education and training
  - inappropriate role models
  - lack of objective drug information
  - generalization of limited experience
  - misleading beliefs about drug efficacy
  - lack of skill or conscientiousness
  - inadequate supervision
  - incentive to overprescribe
- Dispensers
  - inability to interpret a prescription
  - insufficient training
  - insufficient staffing
  - lack of equipment and facilities
  - lack of packaging materials
  - poor attitude about dispensing
- Patients
  - drug misinformation
  - misleading beliefs
  - patient demands/expectations
  - no labeling or no understandable labeling
  - inadequate verbal instructions
  - complex treatment regimen or long
  - duration
  - presentation of treatment
- Workplace
  - heavy patient load
  - pressure to prescribe
  - lack of adequate lab capacity
  - insufficient staffing

- Drug Supply System – unreliable suppliers.
  – drug shortages



Source: MSH 1997

5. Strategies to improve drug use

Before any strategies are developed it is essential to identify, measure and understand the problems. There are a variety of tools and methods available which can help in this.

5.1. Investigating Drug Use

Two methods should be distinguished: *quantitative methods*, to measure what is being done, and *qualitative methods*, to provide information on

why it is being done. Sources for quantitative data on drug use include indicators for health facilities and aggregated consumption and procurement data. To encourage consistency in drug use studies, the World Health Organization (WHO) and the International Network for Rational Use of Drugs (INRUD) have produced a manual for investigating drug use in health facilities. The manual defines core drug use indicators and provides a methodology for measuring these indicators. This standardized method has been used in over 40 countries and allows for a comparison between countries and regions, and for monitoring the effect of interventions.

The WHO manual defines twelve core and seven complementary drug use indicators (see Table 1 below) that measure key aspects of drug prescribing, patient care, and availability of drugs and drug information at outpatient facilities. The **core indicators** are highly standardized and do not require national adaptation. Although not comprehensive, they provide a simple tool for quickly and reliably assessing a few critical aspects of drug use. With these indicators, results should point to specific drug use problems that need to be examined in more detail. All the necessary data are collected from medical records or by direct observation at individual health facilities.

The manual also defines a set of **complementary indicators**, which are less standardized and require defining variables specific to the location. One important complementary indicator measures adherence to treatment guidelines. This indicator needs clear and explicit criteria to be reliable and informative.

TABLE 1: WHO Drug Use Indicators (Outpatient Facilities)

Core Drug Use Indicators

Prescribing indicators

1. Average number of drugs per encounter
2. Percentage of drugs prescribed by generic name
3. Percentage of encounters with an antibiotic prescribed
4. Percentage of encounters with an injection prescribed
5. Percentage of drugs prescribed from essential drugs list or formulary

Patient Care Indicators

1. Average consultation time
2. Average dispensing time
3. Percentage of drugs actually dispensed
4. Percentage of drugs adequately labeled
5. Patients' knowledge of correct dosage

Health Facility Indicators

1. Availability of a copy of essential drugs list or formulary
2. Availability of key drugs

Complementary Drug Use Indicators

1. Percentage of patients treated without drugs
2. Average drug cost per encounter
3. Percentage of drug costs spent on antibiotics
4. Percentage of drug costs spent on injections
5. Prescription in accordance of treatment guidelines
6. Percentage of patients satisfied with the care they received
7. Percentage of health facilities with access to impartial drug information.

Source: WHO/DAP 1993

The Prescribing indicators (1-5) are easily used checking prescriptions and the Health Facility indicators (11-12) are also easily verified. These indicators can be used in a study or preferably, can be included in monthly reports.

Table 2 shows results from studies using WHO indicators:

TABLE 2: Selected Results of Studies Using WHO Indicators

Country	Number of Facilities	Number of drugs Prescribed	Percent antibiotics	Percent injections	Percent generics	Consulting Time (min)	Percent who knew dosing	Percent of key drugs in stock
Africa								
Sudan	37	1.4	63%	36%	63%			
Malawi	72	1.8	34%	19%		2.3	27%	67%
Tanzania	20	2.2	39%	29%	82%	3.0	75%	72%
Nigeria	20	3.8	48%	37%	58%	6.3	81%	62%
Ghana	20	4.3	47%	56%	59%			
Uganda	127	2.4	53%	36%	86%	4.6	29%	
Asia								
Indonesia	20	3.3	43%	17%	59%	3.0	82%	
Bangladesh	20	1.4	31%	0%			63%	
Nepal	20	2.1	43%	5%	44%	3.5	56%	90%
Latin America And Caribbean								
Ecuador	19	1.3	27%	17%	37%			38%
El Salvador	20	2.2	32%	7%	72%			
Jamaica	20	2.4	30%	4%	40%			

Sources: Management Sciences for Health/INRUD

5.2. Core strategies to improve drug use

It is recommended that a combination of educational, managerial and regulatory strategies are used. The activities should be planned in such a way that they act to reinforce one another. Rules and regulations have little impact if target groups are not educated and informed and if management and supervision systems are not in place. Complementary measures and a combination of strategies that work should be identified for different target groups.

Clinical guidelines and essential drugs lists

The starting point for most, if not all, interventions to promote rational drug use is nationally or institutionally agreed standard treatment guidelines (or "clinical guidelines"). Clinical guidelines define the desired prescribing behavior and constitute the core of all educational, regulatory and managerial interventions. In addition they define the selection of essential drugs for the supply system, as expressed in the essential drugs list.

Clinical guidelines indicate the most cost-effective therapeutic approach, on the basis of valid clinical evidence. Their impact is greatest if the end-users (prescribers and, to a certain extent, patients) are closely involved in the development. As for implementation, availability of clearly printed materials, an official launch in the presence of senior health officials and initial training are key initial interventions.

The point needs to be made that availability of treatment guidelines alone will not lead to better prescribing and that reinforcement training, monitoring and supervision are essential to maintain the rational use of drugs.

A variety of printed materials can be used to further promote rational prescribing. They achieve maximum impact when used with other, more interactive interventions, such as discussion groups, problem-based learning and prescription reviews. **Printed reference materials** can include manuals, posters, and training materials. Depending on the number of treatments involved, printed references may be in the form of wall charts, pocket handbooks, or larger "shelf-size" reference books.

Some people feel that wall charts provide a better reminder to health workers, are more permanent, and help the patient better understand the treatment process. Others feel that a handbook is more effective, provided it fits into the pocket, is durable, and is well organized. Pocketbooks can also include information about individual drugs or other reference data.

Drugs and therapeutics committees

Drugs and therapeutics committees are vital structures for implementing comprehensive and coordinated rational drug use strategies in institutions and health programs. They should be responsible for developing and coordinating all policies related to pharmaceuticals (e.g. on the selection

of standard treatments, hospital formularies and drug budgets). These committees should also be responsible for adapting the national clinical guidelines and essential drugs list to the needs of the program. They should also perform drug utilization studies and prescription reviews, and develop educational strategies to improve drug use and management.

5.2.1. Educational strategies

Rational use depends on the knowledge, attitudes and practices of health care practitioners and consumers. Educational strategies for both groups are essential. It is critical to consider and to understand the environment in which drug use takes place when planning educational strategies.

In-service training of health workers

Continuing education, supervisory visits and focused lectures and workshops can be effective in increasing knowledge and changing behavior. Experience has shown that the impact on behavior is likely to be maximized if specific prescribing and dispensing behavior is targeted, if the groups are small, if known experts are involved in the teaching, and if the training is followed up with specific feedback on their actual prescribing. Face-to-face contact between prescribers and dispensers with trained educators is effective but requires considerable human and financial resources.

Note that *dispensers* are usually a neglected group of health staff in terms of having access to training opportunities. In many refugee settings, dispensers are refugees themselves, often with moderate education. Being the last step in the drug supply chain ("where the pill meets the patient"), dispensers should receive regular training and their performance should be regularly monitored.

Drug information

An underlying factor in many aspects of irrational drug use is the lack of access to independent drug information. All prescribers should have access to standard treatment guidelines, the essential drugs list and a drug formulary. In the absence of national or local guidelines, the MSF Clinical Guidelines and WHO Model Formulary can be used. Other reputable sources of independent drug information (most are available on

CD-ROM) are the British National Formulary, Martindale: The Extra Pharmacopoeia, the United States Pharmacopoeia and Harrison's Principles of Internal Medicine.

Consumer information and education

Consumer education is an important area, often neglected in developing and implementing an essential drugs policy. Most health programs tend to place greater emphasis on the supply of essential drugs to health centers and the training of health care practitioners to prescribe properly than on promoting rational use of medicines by consumers. However, drug use studies show that people commonly use medicines without health practitioners' advice, that their drug use pattern is shaped by their own experiences with medicines, and that they obtain their medicines from various sources, including the informal sector. Given this situation, more attention should be paid to educating consumers on the appropriate use of drugs.

Consumers in a refugee setting are in a context that is not conducive for the rational use of drugs. Drugs are available free of charge and are often being prescribed and dispensed by members of the same community. In war-affected areas, drugs are the equivalent of hard currency and patients have an incentive to seek health care only to obtain drugs. "Drug shopping" is a well known phenomenon in stable refugee settings with a large concentration of facilities and a lack of solid patient registration systems. The monotonous life in a refugee camp and the lack of work or entertainment can also lead to vague psychosomatic complaints that are often treated with analgesics due to lack of social services.

5.2.2. Managerial strategies to promote rational drug use

Managerial strategies are also important in promoting rational drug use and in discouraging waste. **Managerial strategies** attempt to structure information, information flow, and decision process to achieve more cost-effective use of pharmaceutical resources. The most important strategies are discussed below. In all cases, a careful analysis of the underlying problem, extensive discussions with all staff involved, a careful introduction, and intensive supervision and follow-up help to ensure maximum impact of the strategies.

Standard treatments, essential drugs lists, dispensing standards

As mentioned above, clinical guidelines should be used to define institutional or national essential drugs lists, and these should be used to guide drug procurement and reimbursement. Adherence to clinical guidelines should also be promoted by involving the end-users in their development, by introduction and training in their use, and through supervision and medical audit.

Other possibilities are a systematic review of the procurement according to and within therapeutic class, introduction of standardized or structured (pre-printed) order forms, countersigning procedures for antibiotics or expensive drugs, the use of standardized course-of-therapy packages (pre-packaging), audits plus feedback to providers, instituting self-monitoring practices among prescribers, and dispensing the first doses of treatment at the health facility.

5.2.3. Regulatory strategies to promote rational drug use

There are various regulatory strategies that support educational and managerial strategies to promote rational drug use.

Regulatory strategies are generally aimed at saving money or preventing improper use of drugs. Regulatory approaches imply a degree of arbitrariness. They tend to be focused and rather inflexible. Because of limited opportunities to make adjustments once a regulatory strategy is in place, it is important that regulatory initiatives be well-conceived and well-tested before being launched on a large scale. There are always risks of unintended adverse effects of such regulations.

Examples of regulatory strategies include the ban of unsafe drugs and prescribing and dispensing restrictions. Either type of limit is arbitrary and risks certain negative consequences. For example, a “three-drug rule” in a setting in which an antibiotic, a vitamin, and an antidiarrheal are the provider's first three preferences before oral rehydration salts (as is still the case in some places) would mean no ORS for the patient. As another example, a “three-day rule” might save money, but also contributes to underdosing, increased bacterial resistance, and giving patients the false impression that only three days supply is needed for any medicine.

Table 3 summarizes all these strategies:

TABLE 3: Intervention Strategies to Improve Drug Use

Educational strategies: TO PERSUADE

Training of Prescribers

- Continuing education (in-service)
- Supervisory visits
- Group lectures, seminars and workshops

Printed Materials

- Clinical literature and newsletters
- Treatment guidelines and drug formularies
- Illustrated materials (flyers, leaflets)

Approaches Based on Face-to-Face Contact

- Educational outreach
- Patient education

Managerial Strategies: TO GUIDE

Selection, Procurement and Distribution

- Limited procurement lists
- Drug utilization review and feedback
- Drug committees
- Providing cost information on order forms

Prescribing and Dispensing Approaches

- Structured drug order forms
- Standard diagnostic and treatment guidelines
- Course-of-therapy packaging
- Improvements in labeling
- Clinical supervision

Regulatory Strategies: TO ENFORCE

Drug selection

- Banning unsafe or ineffective drugs

Prescribing and Dispensing Controls

- Level-of-use prescribing restrictions (health post, health center, hospital)
- Restrictions on who can prescribe or dispense
- Limits on number of different drugs per patient (e.g., "3-drug rule")
- Limit on quantities of each drug (e.g., "3-Day Rule")
- Requirements for generic prescribing

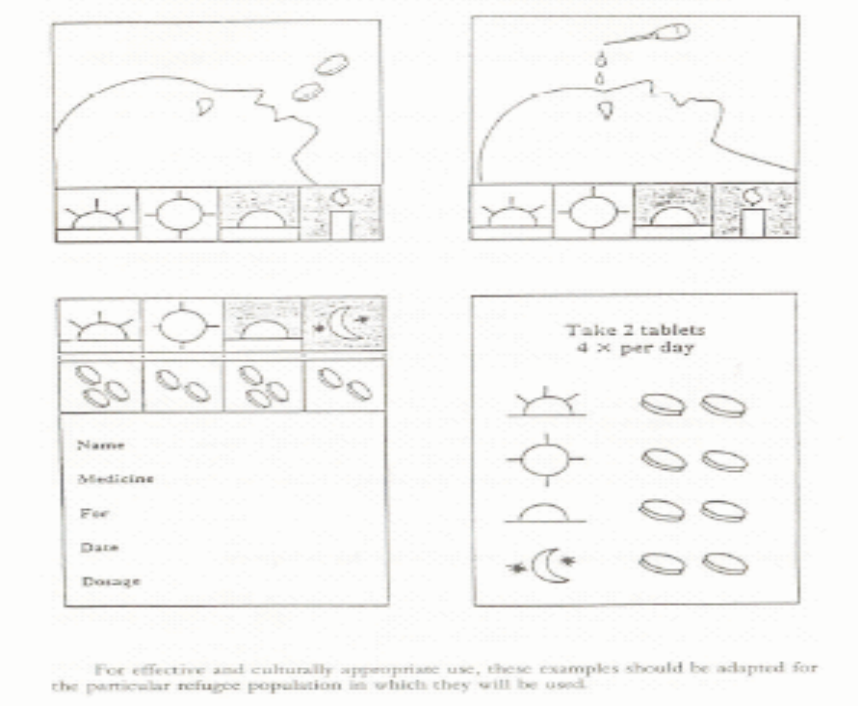
Source: INRUD 2004

5.3. Achieving patient adherence in refugee communities

To achieve adherence in refugee communities, measures should be implemented to ensure there is:

- a basic **understanding of refugee beliefs** regarding common illnesses, treatments and the effects of modern drugs. Liaison with traditional healers and midwives will assist such an understanding;
- adequate **patient education** in the use of prescribed medicines, through patient teaching and symbolic labeling for non-literate groups, for instance (see figure below);
- a mechanism for **monitoring** actual use of medications in the home (such as trained community health workers making home visits);
- a standardized individual or family **health record card** as approved by appropriate health authorities. (This is particularly important in mobile refugee populations for whom a centralized record-keeping system is clearly impractical and ineffective.)

- a provision that refugees receive instructions in a **language** that they can understand;
- the possibility for illiterate patients to have drugs dispensed in a tablet bag with a **pictogram**;
- **blister** packaging wherever possible, especially for fixed-dose combinations.



Source: UNHCR 1989

II. GOOD DRUG DISPENSING PRACTICES

Good dispensing means ensuring that an effective form of the correct drug is delivered:

- to the **right** patient;
- in the prescribed **dosage** and **quantity;**
- with clear **instructions;**
- in a package that maintains **potency.**

Dispensing is the last step in the drug pathway between manufacturer and patient. No matter how many precautions are taken to guarantee and maintain drug quality during production, packaging, transport, storage, and distribution, they will all be useless if drug quality is not preserved during this last step!

Good Dispensing Practices:

- **Safe, clean and organized working** environment
- **Disciplined use of effective** procedures
- **Qualified and** trained staff**, regular** performance **monitoring**
- **Safe and clean** dispensing/ Labeling
- **Ensuring patients'** understanding
- **Good** record keeping

Source: MSH 1997

1. Working environment

Dispensing environments must be clean because most drug products are taken internally. The working area must be hygienic and uncontaminated. The environment must also be organized so that dispensing can be

performed accurately and efficiently. The dispensing environment includes:

- **Staff**
  Must maintain good personal hygiene and should wear clean protective clothing. Facilities to wash and dry hands should be available.
- **Physical surroundings**
  These must be kept free of dust and dirt, so daily cleaning of floors and working surfaces is necessary.
- **Shelving and storage areas**
  Cupboards should only contain drugs and should be kept tidy and clean.
- **Surfaces used during work**
  Spillage of liquids (e.g. syrups) should be wiped immediately. Food and drinks are not allowed in the dispensing area.
- **Equipment and packaging materials**
  Dispensing equipment is used for measuring liquids (measuring cylinder) or counting tablets or capsules (spoons, tablet counters). Equipment should be cleaned between different products, patients and at the end of the day.

The dispensing area should be safe and large enough to allow staff movement.

Stock containers (especially in IPD) and pre-packed medicines must be stored in an organized way. **VERY IMPORTANTLY, ALL STOCK CONTAINERS IN USE MUST BE CLEARLY AND ACCURATELY LABELED** to minimize error. The repacking of one drug in a container of another drug should be discouraged and if it needs to be done, the name, dosage and batch number and expiry date should be clearly indicated.

2. Dispensing Process

The consistent and repeated use of a good dispensing procedure is vital in ensuring that errors are noticed and corrected at all stages of the dispensing process. The dispensing process:

1. Receive and validate prescription

Confirm name of patient, since there might be a risk of mixing-up prescriptions if many people have the same name.

2. Understand and interpret prescription

Read prescription and make sure that it is complete.

A prescription consists of 7 parts:

1. Name of the patient (eg. Kyaw Htoo)
2. Name of the drug and the strength to be administered (eg. ibuprofen 200 mg)
   Write the full name of the drug.
   E.g. Do not write 'para 500 mg', but 'paracetamol 500 mg'
3. Dosage of the drug (eg. 500 mg)
4. Route by which the drug is to be administered (eg. PO)
5. Time and/or frequency of administration (eg. 3 times a day)
6. Date and time when the order was written
7. Signature of the person writing the prescription

If the prescription is not complete, go back to the prescriber and ask him/her to complete the prescription before dispensing.

- Correctly interpret abbreviations used by the prescriber (e.g. IM, T.I.D.)
- Confirm that doses are in safe range (check age/sex)
- Correctly perform any calculations of dose and issue quantity
- Identify any common drug-drug interactions

In case of any doubt, check with the prescriber.
This might save a life!

3. Prepare items for issue

1. Write label
2. Select stock container
   Select by reading the label of the container and check it with the prescription. Do not keep too many containers open at the same time.
3. Measure or count quantity from the stock container
   Hands must never be in direct contact with the medicine! Counting can be done with a clean piece of paper and spatula, tablet counter, lid of the container in use or other clean surface. Immediately after counting, the container should be closed again and the container label should be rechecked for the drug name and strength.
4. Pack and label medicine
   Tablets and capsules should be packed in a sealed plastic dispensing bag. Liquids require clean bottles with effective caps. Never mix two liquids together.
   The label should indicate: *name of the patient*, *drug name and strength, dose* (amount and frequency), *quantity dispensed*. Symbols might be necessary to indicate amount and frequency of dosage (for patients who cannot read).
   Check dispensed drug against prescription and against stock containers used.

Especially in dispensaries with a high patient-load, it is better to work in teams of two for dispensing in order to double-check prescription deliveries; the first collects the drugs prescribed, the second then verifies and gives them to patients with all necessary explanations.

4. Record action taken

5. Issue medicine to patient with clear instructions and advice

Apart from emphasizing the **dose**, **frequency**, **length of treatment**, and **route of administration**, the priority is to give the patient information that will maximize the effect of the treatment. Even when a clinician prescribes an effective drug, if the patient does not believe in it, does not take it like prescribed, or even stops treatment, the ultimate goal of improving the

patient's health will not be reached. Advice should therefore concentrate on:

- **When to take** the medicine (particularly in relation to food and other medicines);
- **How to take** the medicine (chewed, swallowed whole, taken with plenty of water);
- **How to store** and care for the medicine.

Common but harmless side effects (nausea, mild diarrhea, urine changing color) should be mentioned to prevent a frightened patient from stopping the treatment.

Also important is to explain why antibiotic treatments must be taken completely, while painkillers (analgesics) should be stopped when the pain has gone.

Drugs which interact with alcohol should also be mentioned (anti-histamines, anti-depressants, metronidazole).

In case of a mono-dose treatment, the drugs should be taken on the spot under supervision. In other cases, the first dose can also be given on the spot.

Every effort should be made to confirm that the patient understands the instructions. Remember that some people pretend they understand, because they are ashamed or in a hurry! To check if a patient really understands, have them repeat what they were told.

3. Dispensing staff

Although assigned to dispenser positions, dispensing staff often do not have high levels of education. Nevertheless, they have a huge responsibility in the distribution of drugs, since most patients do not know the correct use or cannot judge the quality of drugs received and are therefore completely dependent on the dispenser.

Dispensers should have:

- Knowledge about the medicines being dispensed (common use, common dose, precautions about the method of use, common side effects, common interactions with other drugs or food, storage needs);
- Good calculation and arithmetic skills;
- Skills in assessing the quality of preparations;
- Attributes of cleanliness, accuracy, and honesty;
- Attitudes and skills required to communicate effectively with patients.

Dispensers need regular training and performance checks.

III. USE OF DRUGS IN CHILDREN, THE ELDERLY AND PREGNANCY

Drugs should be used with great care in children, older people and pregnant women.

Always check the dose for ***children***, since they take up drugs in the blood differently from adults and because their kidneys and liver have not yet fully developed. Use dosing schedules based on bodyweight rather than on age to calculate dosages for children. This is especially important for malnourished children.

Older people also need adjusted dosages since their liver and kidneys are not as functional as before. Be careful with several **antibiotics (eg. penicillin, tetracycline), digoxin, cimetidine, furosemide** and **psychotropics (eg. antidepressants, sedatives, antipsychotics).** Dispensing drugs to older people should occur with extra care. Clear information should be given about the dosage, the time of administration, the way to take the drug, and possible side-effects. Often, older people need help with taking their drugs.

Pregnant women and ***lactating women*** also need to be careful with drugs. In general, pregnant women should avoid using drugs during the first and last trimesters of the pregnancy to avoid malformations or a change in metabolism in the unborn baby.

Of course, when the health of the woman is at greater risk from not being treated, treatment should be given (example: falciparum malaria).

Never give the following drugs during pregnancy:

- **Tetracycline** (interference with bone and teeth development)
- **Doxycycline** (interference with bone and teeth development)
- **Chloramphenicol** ('Grey baby syndrome[1]')
- **Streptomycin** (vestibular and auditory damage, renal impairment)
- **Overdose of vitamin A and vitamin D** (malformations of urogenital and nervous system)
- **Certain hormones** (estrogens, progestagens, androgens, danazol)
- **Co-trimoxazole** (teratogenesis)
- **Ciprofloxacin** (interference with cartilage development)
- **Certain sulphonamides** like certain oral anti-diabetics (not during entire pregnancy), and co-trimoxazole (not during third trimester)
- **Oral anti-diabetic drugs**
- **Salicylates** (aspirin; high risk for bleeding and interference with delivery)

Drugs that are not mentioned in the above list are NOT automatically safe for use during pregnancy. A drug formulary should be consulted whenever prescribing drugs to a pregnant woman.

Through breastfeeding (lactation), a child can receive drugs that may be dangerous for its development. Certain drugs cannot be given to women who are breastfeeding. As for pregnancy, a drug formulary should be consulted when prescribing drugs to lactating women.

1 Grey Baby Syndrome: cardiovascular collapse, respiratory depression, cyanosis in unborn childen, usually near the end of the pregnancy.

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6. DRUG QUALITY ASSURANCE

Contents

I. DRUG QUALITY ASSURANCE

1. Introduction

The health and well being of **beneficiaries** should be top priority. Quality assurance of drugs assists the health program in maintaining its reputation towards beneficiaries and donors.

High world-wide standards may exist for drug regulation and quality, but implementation and enforcement vary. Consider that:

- less than 1 in 3 developing countries have well-functioning government drug regulation. Sadly enough, countries with the highest need for affordable good quality essential drugs are also the countries with the poorest regulatory capacity.
- global trade brings global quality assurance challenges for drug purchasers. Drugs manufactured in Europe, Asia and Africa may vary widely in quality and safety.
- An average of 10-45% of drugs fail quality control testing (20 countries).
- Counterfeit and substandard medicines are “freely” available (see Figs.1 and 2).

Poor drug quality means poor treatment outcomes and treatment failures, which in many cases potentially leads to drug resistance which requires more resources to treat e.g. MDR-TB, malaria. Poor quality drugs also affect the trust that beneficiaries have in the healthcare system.

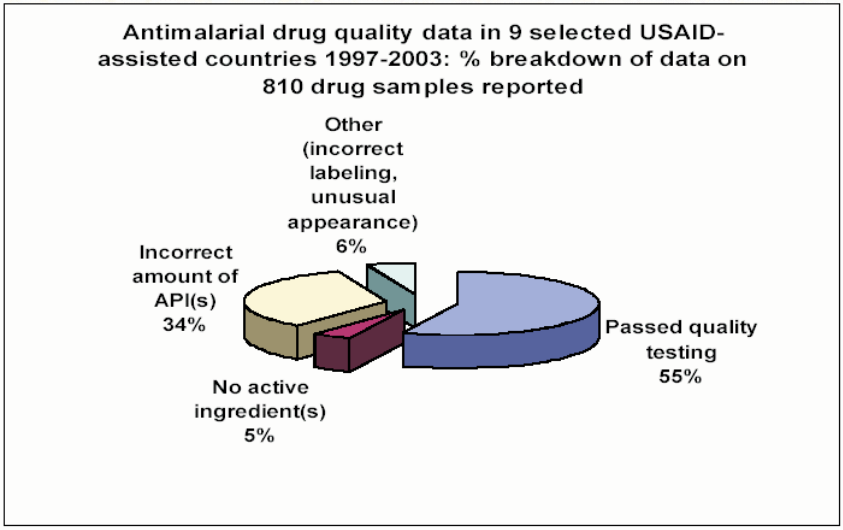
Counterfeit drugs and substandard drugs can kill:

- **Substandard: e.g. contamination/mixing up glycerol with diethylene glycol**
  - Nigeria 1990: 109 children died
  - Bangladesh 1992: 223 children died
  - Argentina 1992: 23 patients died
  - Haiti 1995/1996: 89 children died

- **Counterfeit: e.g. meningitis vaccine with no antigen**
  - Niger 1995: around 2500 deaths
    e.g. anti-malarial drugs
  - Cambodia 1999: 30 deaths (use of fake anti- malarial drugs)

Counterfeit and substandard drugs cost about 22 billion USD per year, representing about 7% of world-wide pharmaceutical sales.

Figure 1:

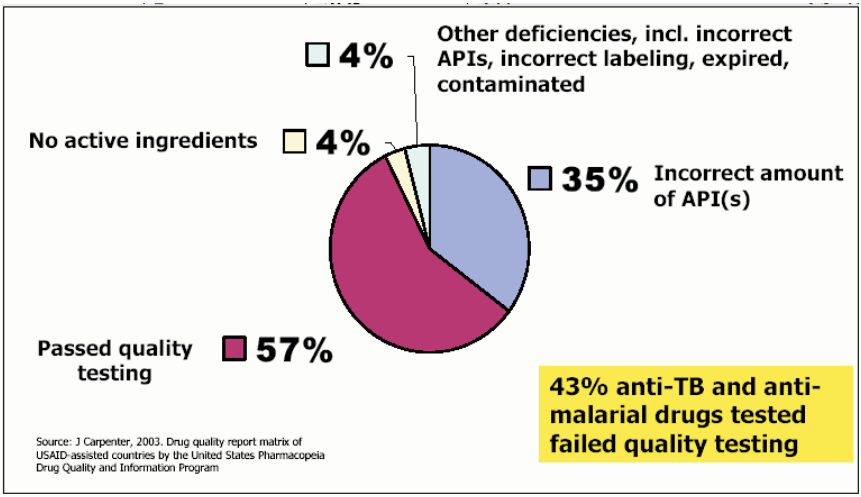


Source: Carpenter J P, 2003. Drug quality report matrix of USAID-assisted countries by the USP DQI Program

API: Active Product Ingredient

Figure 2:

% breakdown of drug quality data on 1024 anti-malarial and anti-TB drugs in selected USAID-assisted countries (1997 - 2003)



2. Objectives of drug quality assurance

The purpose of quality assurance in any drug supply system is to ensure that each drug reaching a **patient** is **safe, effective**, and of **standard quality**. For pharmaceutical procurement, drug quality is assessed as compliance with **pharmacopeial** specifications concerning a drug's **identity, purity, potency** and other characteristics like **uniformity** of the dosage form, **bioavailability** and **stability**.

Especially in regard to local drug procurement, quality assurance should be high on the priority list. A comprehensive quality assurance system includes both **technical** and **managerial** activities, spanning the entire supply process from drug selection to patient use.

Technical activities include evaluating pharmaceutical product documentation, performing or reviewing quality control laboratory tests, and monitoring product performance. The **GMP-certificate** (Good Manufacturing Practices), **batch certificates**, and **certificates of registration** are good indicators of standardized quality.

Managerial activities include **selecting suppliers**, preparing **contract terms**, monitoring **supplier performance**, and enforcing **drug inspection** procedures throughout the distribution network.

3. Characteristics of product quality

Established quality standards are published periodically in **pharmacopeias,** which provide detailed descriptions of drug characteristics and analytical techniques. The major pharmaceutical manufacturing and exporting countries publish their own pharmacopeias, for example the British Pharmacopeia (BP), the US Pharmacopeia (USP), the European Pharmacopeia and the International Pharmacopeia (published by WHO). Standards vary slightly from one pharmacopoeia to another, but efforts are made to harmonize pharmacopeial standards for drug registration.

For pharmaceutical procurement, drug quality is assessed as product compliance with specifications as described in the pharmacopeia.

Some examples of pharmacopeia:

Source: USP

4. Responsibilities of various actors

The dynamic nature of drug products and the cumulative effects of the production process, right through to packaging, handling, transport, and storage conditions, require quality assurance at all levels of the drug supply system.

Ensuring drug quality is the responsibility of all those involved - from the producers of drugs to distributers to dispensers. Both the public sector and the private sector have responsibilities.

Manufacturers are responsible for developing and manufacturing a good quality product and should adhere to Good Manufacturing Practices (GMP). They should also document their procedures and activities, to ensure the quality of the product.

The national ***drug regulatory authority (DRA)*** must ensure that drugs approved for marketing in a country are appropriately evaluated and registered; that manufacturers comply with GMP through licensing and inspection; that the quality of imported drugs is ensured, for example through the WHO Certification Scheme (see below); and that drug quality is maintained in the supply system by ensuring good storage and distribution practices, and by monitoring the quality of drugs in the distribution chain. In industrialized countries, regulatory capacity has evolved in phases over many decades. It is reasonable to expect that developing countries will also require time to develop effective regulatory capacity. Such capacity requires a firm legislative basis, trained personnel, specific technical resources, adequate funding and public commitment. Although there is noticeable improvement, in most African countries where UNHCR and partners operate, the DRAs have limited capacity to regulate and enforce quality, safety and efficacy of drug products on their market. Only DRAs from PICS/Scheme[1]

1 *PIC/S is the combination of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-Operation Scheme (PIC Scheme). Together, PIC and PIC Scheme operate under the umbrella PIC/S. The purpose of PIC/S is to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of GMP inspectors. PIC/S is a cooperative arrangement among health authorities, mainly in the European Union and contributes to a more consistent understanding of Good Manufacturing Practices in these countries. Membership in PIC/S is not automatic. An authority wishing to join is carefully evaluated to determine its inspection and licensing system, quality system, legislative requirements and inspector training. A PIC/S delegate also evaluates how well the authority's inspectors perform GMP inspections. Note that the US FDA is not a member of PIC/S. (PIC/S Website: www.picscheme.org, January 2004).*

and ICH[2] countries (EU, USA, Japan, Malaysia, Canada, Switzerland) are believed to have sufficiently stringent DRA's.

Those involved in drug ***procurement*** should ensure that drugs are carefully selected, purchased from reliable sources, inspected at the time of receipt, and transported and stored properly. Mechanisms to report quality defects and a recall procedure must be in place.

Those involved in ***distribution and dispensing*** must ensure the proper storage of products, and their appropriate handling, packaging and dispensing. They must also inform patients about the correct handling of drugs.

5. Critical elements in quality assurance

Quality assurance covers all activities aimed at ensuring that consumers and patients receive a product that meets established specifications and standards of **quality**, **safety** and **efficacy**. It concerns both the quality of the products themselves and all the activities and services that may affect quality.

A. Procedures to OBTAIN drug products that meet current quality standards (see Annex 4 SOP Q1):

1. Product Selection
2. Supplier qualification
3. Product qualification
4. Drug Regulatory Authorities
5. Contract specifications

2 *ICH: International Conference on Harmonization is a joint initiative involving both regulators and research-based industry representatives of the EU, Japan and the US in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines.*

B. Procedures to VERIFY that shipped goods meet the specifications (see Annex 4, SOP Q2):

6. Batch certification
7. Inspection of Shipments
8. Targeted laboratory testing

C. Procedures to MONITOR and MAINTAIN the quality of drug products from the moment they are received until the drug is finally consumed by the patient (see Annex 4, SOP Q3):

9. Appropriate storage, transport, dispensing and use procedures
10. Product monitoring system

Few drug management programs can effectively manage all the possible quality assurance activities for all the drug products that are procured. Consequently, realistic goals must be set to identify the combination of managerial and technical quality assurance activities that will be most effective under existing conditions.

6. Additional points in quality assurance

1. **Quality is a dynamic issue.** Drugs produced by a manufacturer may comply today but may not comply in six months. Manufacturers and suppliers should be constantly monitored and periodically re-evaluated. Quality problems detected by the monitoring system should be recorded and considered when re-evaluating a supplier. A supplier can only keep its approved supplier status for a limited duration of time after which a re-evaluation needs to take place.

2. **Quality is drug or product specific.** A manufacturer that complies with GMP-standards for oral forms (such as tablets and capsules), may not comply for more critical items such as sterile products (injectables, infusions).

3. **Quality is manufactured, not controlled.** This means that one can not simply judge the quality of a drug by *testing* the **end product** ("quality control"), but that the production **process** needs to be *validated*. One has to know the circumstances in which the drug was manufactured through inspection of Good Manufacturing Practices (GMP). Not only the finished product should be GMP-compliant, but also the raw materials used to manufacture the product. The latter is often difficult to control as most raw materials are purchased in Asia, far away from manufacturers of finished drug products or through a number of various middle-men.

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GLOSSARY OF TERMS

Active pharmaceutical ingredient (API) — A substance or compound intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient).

Adverse drug reaction (ADR) — Any unwanted effect produced by a drug that is harmful to the patient. Onset may be sudden or develop over time.

Assay — The monograph standard test, with associated method of analysis, that is designed to determine the strength of a drug product.

Basic tests — Simplified analytical tests that do not require complex methodologies and equipment. Basic tests may be used in specific circumstances to verify the identity of a drug or ascertain the absence of gross degradations or contamination.

Batch (or Lot) — A defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it could be expected to be homogenous or the quantity of a drug produced in one production run.

Batch certificate — A document containing information which normally will be issued for each batch by the manufacturer, or will be validated or issued by the competent authority of the exporting country, particularly for vaccines, sera, and other biological products. The batch certificate accompanies every major consignment.

Batch number (or Lot number) — A distinctive combination of numbers and/or letters that specifically identify a batch on the labels, the batch records, and the certificate of analysis, etc.

Bioavailability — The rate and extent of availability of an active ingredient from a dosage form as measured by its concentration/time curve in the systemic circulation or its excretion in the urine.

Bioequivalence — Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent, and their bioavailability, after

administration in the same molar dose, is similar to such a degree that their effects can be expected to be essentially the same.

Bulk product — Any product that has completed all the processing stages up to, but not including, final packaging.

Certificate of analysis (CA) — Report of the analytical test results obtained, including the final conclusion of the examination of a sample issued by the manufacturer, repacker, or trader.

Clinical trial (or Clinical research) — A research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that improve health. Interventional trials determine whether experimental treatments, or new ways of using known therapies, are safe and effective under controlled environments. Observational trials address health issues in large groups of people or populations in natural settings.

Counterfeit drug — A pharmaceutical product that is deliberately and fraudulently mislabeled with respect to identity or source. Both branded and generic products can be counterfeited. Counterfeit drugs can include products with the correct ingredient(s), with the wrong ingredient(s), without active ingredient(s), with insufficient quantity of active ingredient(s), or with fake packaging. A counterfeit drug can be a deliberate imitation or a copy of a genuine product.

Disintegration — The breaking up of a tablet or a capsule into granules or aggregates in an aqueous fluid.

Dissolution — The process by which a solid substance is broken down into molecules or ions homogeneously dispersed in an aqueous fluid to form a solution. The rate of dissolution is determined by the interaction between the substance and the medium.

Dosage form — The form—tablet, capsule, injection—of the completed pharmaceutical preparation.

Dosage (or strength) — The content of the active ingredient per dosage unit is determined by the assay of the specific monograph and expressed, generally, in milligrams or units per dosage unit.

Drug — Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

Drug formulation — The composition of a dosage form, including the characteristics of its raw materials and the operations required to process the drug.

Drug interaction — A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance or may be an adverse effect that is not normally associated with either drug. The action of one drug upon another may be harmful to the patient, depending on the drugs and the patient's medical condition.

Drug Regulatory Authority (DRA) — A national body that administers the full spectrum of drug regulatory activities, including at least all of the following functions: Marketing authorization of new products and variation of existing products; quality controlled laboratory testing (although in some countries, the lab may not be part of the DRA); adverse drug reaction monitoring; provision of drug information and promotion of rational drug use; good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers, and distribution channels; enforcement of operations; and monitoring of drug utilization.

Efficacy (of a drug or treatment) — The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which prescribed. For example, in the procedure mandated by the United States Food and Drug Administration, Phase II clinical trials gauge efficacy and Phase III trials confirm efficacy.

Expiry (expiration) date — The date given on the individual container of a drug product designating the date up to which the product is expected to remain within specifications, if stored correctly. Expiry date is established by the manufacturer for each batch by adding the shelf-life period to the date of manufacture.

Excipient —- Any component of a finished dosage form other than the claimed therapeutic ingredient or ingredients.

Finished product — A product that has undergone all stages of production, including packaging in its final container and labeling.

Fixed-dose combination — A combination of more than one active pharmaceutical ingredient in one package or single dosage form.

Generic name — The approved or international non-proprietary name of a drug given by the World Health Organization.

Generic products — A pharmaceutical product—usually intended to be interchangeable with the innovator product—is usually manufactured without a license from the innovator company and marketed after expiry of the patent or other exclusivity rights. The term should not be confused with generic names for APIs.

Good Manufacturing Practice(s) (GMP) — The part of quality assurance that ensures that pharmaceutical products are consistently produced and controlled by the quality standards appropriate to their intended use and as required by the marketing authorization. These standards include criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control, and in most cases, stability testing.

Identity — The correct chemical substance and formula of an active ingredient in a drug product.

Identity test — The selected test in the monograph to verify that the drug product has the correct identity.

Indication — A symptom or circumstance that indicates the advisability or necessity of a specific medical treatment or procedure. Indication could also refer to the degree indicated in a specific instance or at a specific time on a graduated physical instrument, such as a thermometer.

Interchangeable pharmaceutical product — A product that is therapeutically equivalent to a reference product.

Labels (according to GMP) — All finished drug products should be identified by labeling, as required by the national legislation, bearing at least the following information:

(a) the name of the drug product;

(b) a list of the active ingredients (if applicable, with the International Non-proprietary Names (INNs)), showing the amount of each present, and a statement of the net contents (number of dosage units, mass, or volume);

(c) the batch number assigned by the manufacturer;

(d) the expiry date and manufacturing date in an uncoded form;

(e) special storage conditions or handling precautions that may be necessary;

(f) directions for use, and any warnings or precautions that may be necessary;

(g) the name and address of the manufacturer or the company or person responsible for placing the product on the market.

Lead time — The time interval needed to complete the procurement cycle. This begins at the time when new stock is ordered and ends when that stock is received and available for use. Lead time varies depending on the system, speed of deliveries, availability, and reliability of transport, and sometimes, weather.

Manufacture — All operations involved in the purchase of materials and products, production, quality control, release, storage, shipment of finished products, and related controls.

Manufacturer — A company that carries out at least one step of manufacture.

Marketing authorization (product license, registration certificate) — An official document issued by a competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. The certificate must set out, *inter alia*, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INN or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. The document specifies the information on

which authorization is based. The license also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.

Method validation — Demonstrates the suitability of the analytical procedure for its intended use. The characteristics of the analytical procedures to be considered in method validation are the accuracy, precision, robustness, linearity and range, selectivity, limit of detection, and limit of quantitation.

Monograph — A set of properly selected standardized tests with associated methods of analysis that can be used to assess the integrity of drugs (including dosage forms) and starting materials. These standards, when met, assure the quality of the drug with respect to identity, purity, strength, packaging, storage, and labeling. Monographs are published in pharmacopeia.

Multi-source (generic) pharmaceutical — Pharmaceutically equivalent products that may or may not be equivalent therapeutically. Multi-source pharmaceutical products that are therapeutically equivalent are interchangeable.

New drug — A drug that has not been declared safe and effective by qualified experts under the conditions prescribed, recommended, or suggested on the label. This may be a new chemical formula or an established drug prescribed for use in a new way.

Packaging material — Any material, including printed material, used in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Primary packaging materials are those that are in direct contact with the product.

Pharmaceutically equivalent products — Products that contain the same amount of the same active substance(s) in the same dosage form, meet the same or comparable standards, and are intended to be administered by the same route.

Pharmaceutical product — Any medicine intended for human use or administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject

to control by pharmaceutical legislation in both the exporting and importing states.

Pharmacodynamic — The study of the action or effects of drugs on living

organisms.

Pharmacokinetics — The process by which a drug is absorbed, distributed, metabolized, and eliminated by the body.

Pharmacopeia — A book containing an official list of monographs and internationally acceptable standards for the potency, purity, quality, packaging, and labeling of pharmaceutical products. The major pharmacopeias in the world are: The *International Pharmacopeia*, the *United States Pharmacopeia*, the *British Pharmacopeia*, the *Japanese Pharmacopeia* and the *European Pharmacopeia*. Other countries have their own pharmacopeias.

Pharmacovigilance — All science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems. In general, pharmacovigilance aims to re-evaluate the safety and efficacy of pharmaceutical product in the market. This encompasses spontaneous adverse drug reactions, drug information reporting, promotion of rational use of drugs, risk management, and crisis preparedness.

Post-marketing surveillance of drug quality — Monitoring the quality of drugs by inspection and laboratory testing to assure that the storage is correct and that drugs are stable within their labeled shelf-life.

Potency — The extent to which a drug contains the specified amount of the active ingredient.

Pre-marketing surveillance — Monitoring the quality of drugs by inspection and laboratory testing to assure that the drugs conform to the quality standards and specifications before their marketing authorization.

Primary container — The immediate container in direct contact with the drug product, such as a jar, bottle, blister, ampoule, etc. The primary container is designed to meet the specifications for storage and protect the drug throughout its shelf-life.

Product certificate — A document containing the information set out in Annex 3 of this Guideline. The certificate is validated and issued for a specific product by the competent authority of the exporting country and intended for use by the competent authority in the importing country, or, in the absence of such an authority, by the drug procurement authority.

Purity — The extent to which drugs are free from potentially harmful contaminants, degradation products, significant quantities of other drugs, bacteria, or other microorganisms.

Quality (of drug product) — All characteristics—purity, strength, packaging, labeling—that allow the drug product to deliver its intended treatment.

Quality assurance (QA) — All matters that individually or collectively influence the quality of a product. QA's objective is to ensure that pharmaceutical starting materials and pharmaceutical products meet quality standards.

Quality control — All measures taken—including setting specifications, sampling, testing, and analytical clearance—to ensure that raw materials, intermediates, packaging materials, and finished pharmaceutical products conform to established specifications for identity, strength, purity, and other characteristics.

Quarantine — Physically isolating the starting, packaging, intermediate or bulk materials or finished products while a decision is awaiting on their release, rejection, or reprocessing.

Recall — The process of withdrawing a drug from the market because of a quality, safety, or efficacy problem.

Registration — Any statutory system of approval required at the national level as a pre-condition for introducing a pharmaceutical product to the market.

Safety — Not causing harm or injury; having a low incidence of adverse reactions and significant side effects when adequate instructions for use are given; and having a low potential for harm under conditions of widespread availability.

Sample — A portion of material collected according to a defined sampling procedure. The size of any sample should be sufficient to carry out all anticipated test procedures, including all repetitions.

Sampling procedure — A detailed and complete sampling operation to be applied to a defined material for a specific purpose. A detailed, written description of the sampling procedure is provided as sampling protocol.

Sampling unit — Discrete part of a consignment, such as an individual package, drum, or container.

Secondary container — The external container in which the primary container is placed.

Shelf-life — The period of time during which a drug product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf-life establishes the expiry date of each batch.

Specification — A detailed document describing the requirements with which the pharmaceutical products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

Stability — The ability of a pharmaceutical product to retain its chemical, physical, microbiological and biopharmaceutical properties within specified limits throughout its shelf-life.

Stability tests — A series of tests designed to obtain information on the stability of a pharmaceutical product to help define its shelf-life and utilization period under specified packaging and storage conditions.

Standard — A technical specification that addresses a business requirement, is implemented in viable commercial products, and, to the extent practical, complies with recognized standards organizations, such as ISO (International Organization for Standardization).

Standard Operating Procedure (SOP) — An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material, but of a more general nature (i.e., equipment operation, maintenance, and cleaning; validation; cleaning of

premises and environmental control; sampling and inspection). Certain SOPs can be used to supplement product-specific master and batch production documentation.

Starting material — Any substance of defined quality used in the production of a pharmaceutical product, excluding packaging material.

Substandard drug — A legal branded or generic drug that does not meet national or international standards for quality, purity, strength, or packaging.

Therapeutic equivalence — Pharmaceutically equivalent products whose effects with respect to both safety and efficacy are essentially the same, when administered in the same molar dose, as can be derived from appropriate studies (bioequivalence, pharmacodynamic, clinical, or *in vitro*).

Toxicity — An adverse effect produced by a drug that is detrimental to the patient's health. The level of toxicity associated with a drug will vary depending on the condition that the drug is used to treat.

Validated method — A method of analytical performance demonstrated by experimental data that has proven its suitability as analytical support of a specification proposed for particular drug. The nature of the method and the type of drug test determine the characteristics that should be considered to validate the method.

WHO-type certificate — A certificate of a pharmaceutical product of the type defined in the "WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce."

ANNEXES

ANNEX 1 UNHCR ESSENTIAL DRUGS LIST (2006)

PLEASE NOTE: When drugs are ordered which are not on this list, a special order form (Annex 2) will need to be completed. Procurement and delivery times will also generally be longer.

The most up-to-date list can be obtained with prices via SMS HQ (HQSMS@unhcr.org).

BASIC LIST

1 Acetylsalicylic Acid 100mg
2 Acetylsalicylic Acid 500mg
3 Acetylsalicylic acid, suppository, 50mg
4 Acetylsalicylic acid, suppository, 150mg
5 Albendazole 400mg
6 Aluminium Hydroxide 500mg, chewable
7 Amitriptyline, 25mg
8 Amoxycillin 250mg
9 Amoxicillin + clavulanic acid, 500mg+125 mg
10 Amlodipine 5mg
11 Atenolol 50mg
12 Beclomethasone oral inhaler, 250mcg/dose, 200 doses
13 Vitamin C 50mg (Ascorbic Acid)
14 Vitamin C 250mg (Ascorbic Acid)
15 Carbamazepine 100mg
16 Carbamazepine 200mg
17 Chloramphenicol 250mg
18 Chlorpheniramine Maleate 4mg

19 Chlorpromazine HCl 100mg
20 Ciprofloxacin 500mg
21 Cloxacillin 500mg
22 Cotrimazole vaginal tablet 100mg
23 Digoxin 0,25mg
24 Doxycycline 100mg
25 Enalapril 2.5mg
26 Erythromycin 250mg (as stearate)
27 Ferrous Sulphate 200mg
28 Ferrous Sulph. 200mg + Folic Acid
29 Fluconazole 50mg
30 Folic Acid 5mg
31 Furosemide 40mg
32 Glibenclamide 5mg
33 Glyceryl Trinitrate 0,5mg
34 Griseofulvin 125mg
35 Haloperidol 5mg
36 Hydralazine 25mg
37 Hydrochlorothiazide 25mg
38 Ibuprofen 200mg
39 Iodine 200mg
40 Isosorbide dinitrate 5mg
41 Mebendazole 100mg
42 Metformin 500mg
43 Methyldopa 250mg
44 Metoclopromide 10mg
45 Metronidazole 250mg
46 Niclosamide 500mg

47 Nitrofurantoin 100mg
48 Nystatin 100,000 IU, oral tablet
49 Nystatin 100.000 IU, pessaries
50 Paracetamol 100mg
51 Paracetamol 500mg
52 Paracetamol suppository, 125mg
53 Paracetamol suppository, 250mg
54 Phenoxymethylpenicillin 250mg
55 Phenytoin Sodium 100mg
56 Vitamin B6 50mg (Pyridoxine)
57 Prednisolone 5mg
58 Promethazine HCl 25mg
59 Propranolol 40mg
60 Ranitidine 150mg
61 Vitamin A 10.000 IU (Retinol)
62 Vitamin A 25.000 IU (Retinol)
63 Vitamin A 200.000 IU (Retinol)
64 Salbutamol oral inhaler, 100mcg/dose, 200 doses
65 Salbutamol 4mg
66 Senna 7,5mg
67 Spironolactone 25mg
68 Cotrimoxazole 480mg
69 Cotrimoxazole 120mg
70 Vitamin B1 50mg (Thiamine)
71 Zinc sulfate 10mg

1 Benzoic Acid comp. ointment, 800g
2 Benzyl Benzoate application 25%,
3 Benzyl Benzoate saponated 90%, 1l
4 Betamethasone 0.1% cream, 15g
5 Calamine Lotion 15%, 500ml
6 Chlorhexidine Gluconate 20%, 5ltr
7 Chlorhexidine Gluconate 5%, 1ltr
8 Chlorhexidine 1,5% + Cetrimide 15%, L
9 Fluorescein eye drops 2%, 0,5ml
10 Gentian violet 25g
11 Hydrocortisone ointment 1%, 15g
12 Miconazole 2% cream, 30g
13 Neomycin 5mg/g + Bacitracin 500 IU/g ointment, 15g
14 Silver sulfadiazine cream 1%, 500g
15 Povidone Iodine 10%, 200ml
16 Tetracaine eye drops 0,5%, 10ml
17 Tetracycline eye ointment 1%, 5g
18 Zinc Oxide ointment 10%, 800g

SUPPLEMENTARY LIST

1 Dextrose 5%, 500ml
Infusion giving set w/air inlet + filter
2 Dextrose 5%, 1000ml
Infusion giving set w/air inlet + filter
3 Dextrose 50%, 50ml
4 Haemaccel 500ml
Infusion giving set w/air inlet + filter
5 Potassium Chloride 1g/10ml

6 Ringers lactate 500ml
Infusion giving set w/air inlet + filter

7 Ringers lactate 1000ml
Infusion giving set w/air inlet + filter

8 Sodium Chloride 0,9%, 500ml
Infusion giving set w/air inlet + filter

9 Sodium Chloride 0,9%, 1000ml
Infusion giving set w/air inlet + filter

10 Oral Rehydration salt 27,9g, WHO

11 Water for inj., 2ml

12 Water for inj., 5ml

13 Water for inj., 10ml

1 Diazepam 5mg/ml, 2ml
Import license required

2 Morphine HCl 10mg/ml, 1ml
Import license required

3 Phenobarbitone 50mg
Import license required

4 Phenobarbitone Sodium 100mg/ml, 2ml
Import license required

5 Tramadol 50mg/ml, 2ml
Import license may be required

1 Oxytocin 10 IU/ml, 1ml
Cool item, store between 2-8 °C

2 Ergometrine Maleate 0,5mg/ml, 1ml
Cool item, store between 2-8 °C

3 Insulin Soluble Hm 40 IU/ml, 10ml
Cool item, store between 2-8 °C

4 Insulin Soluble Hm 100IU/ml, 10ml
Cool item, store between 2-8 °C

5 Insulin Isophane NPH HM 40 IU/ml,
Insulatard HM
Cool item, store between 2-8 °C

6 Insulin Isophane NPH HM 100IU/ml
Cool item, store between 2-8 °C

1 Adrenaline 1mg/ml, 1ml

2 Ampicillin 500mg (as Sodium)

3 Atropine Sulphate 1mg/ml, 1ml

4 Benzathine Penicillin 2,4M IU

5 Benzylpenicillin Sodium 1M IU

6 Benzylpenicillin Sodium 5M IU

7 Procaine Penicillin 3 M IU

8 Procaine Penicillin 4 M IU, fortified

9 Chloramphenicol 1g (As Sodium Suc

10 Chlorpromazine HCl 25mg/ml, 2ml

11 Cloxacillin 500mg

12 Dexamethasone 4mg/ml, 1ml

13 Digoxin 0,25mg/ml, 2ml

14 Furosemide 10mg/ml, 2ml

15 Gentamicin 40mg/ml, 2ml

16 Haloperidol 5mg, 1ml ampoule

17 Halothane inhalation 250ml

18 Hydralazine HCl 20mg (lyophilized

19 Hydrocortisone 100mg (as sod. suc

20 Ketamine 50mg/ml, 10ml

21 Lidocaine 1%, 50ml

22 Magnesium sulphate 500mg/ml, 2ml

23 Metoclopramide 5mg/ml, 2ml

24 Metronidazole infusion 5mg/ml, 100ml
25 Naloxone HCl 0,4mg/ml, 1ml
26 Phenytoin 50mg/ml, 5ml
27 Promethazine HCl 25mg/ml, 2ml
28 Salbutamol 0,5mg/ml, 1ml
29 Spectinomycin 2g w/solvent
30 Vitamin K 1mg/ml, 1ml

SPECIALIZED LIST

1 Ethambutol 100mg
2 Ethambutol HCl 400mg
3 Isoniazid 100mg
4 Pyrazinamide 500mg
5 Rifampicin 150mg
6 Rifampicin 300mg
7 Rifampicin 150mg + Isoniazid 100mg
8 Rifampicin 300mg + Isonazid 150mg
9 Streptomycin 1g
10 Thiacethazone/i.n.h. 50/100mg
11 Thiacethazone/i.n.h. 150/300mg
12 Isoniazid + Ethambutol, 150mg+400mg
13 Rifampicin + Isoniazid + Pyrazinamide, 150mg+75mg+400mg
14 Rifampicin + Isoniazid + Pyrazinamide + Ethambutol, 150mg+75mg+400mg+275mg

1 Ethinyloestradiol 0,03mg + Levonorgestrel 0,15mg
2 Ethinyloestradiol 0,035mg + Norethisterone 1mg

3 Levonorgestrel 0.75mg

4 Condoms, lubricated

5 Condoms, “Femidon”

6 Intra Uterine Device, Gyne-T 380A

7 Medroxyprogesterone acetate, depot inj, 150mg/ml, 1 ml

8 Multiload (short) cu 250 IUD

1 Amiodiaquine 200mg base

2 Amiodiaquine + artesunate 153mg+50mg, co-blister, (3+3 tabs)

3 Artemether 20mg/ml, 1ml

4 Artemether 80mg/ml, 1ml

5 Artesunate 50mg

6 Ceftriaxone 250mg w/solvent

7 Ceftriaxone 1g

8 Chloramphenicol oily 250mg/ml, 2m

9 Chloroquine 100mg base

10 Chloroquine Phosphate 250mg (unc.)
Eqv. to 155mg Chloroquine base

11 Clofazimine 50mg

12 Clofazimine 100mg

13 CoArtem (artemether 20mg + lumefantrine 120mg)

14 Dapsone 50mg

15 Dapsone 100mg
amilase 2900 IU + protease 330 IU

16 Diethylcarbamazine Citrate 50mg

17 Ivermectin 6mg

18 Mefloquine 250mg

19 Pentamidine Isethionate 300mg

20 Praziquantel 600mg
21 Primaquine 7.5 base
22 Primaquine 15mg base
23 Quinine Sulphate 300mg
24 Quinine diHCl 300mg/ml, 2ml
25 Sodium Stibogluconate 100mg/ml, 3
26 Sulfadoxine 500mg + Pyrimethamine 25mg
27 Suramin 1g
28 Meglumine Antimonate 1,5g/5ml

ANNEX 2 ORDER FORM: REQUEST FOR DRUGS NOT INCLUDED ON THE UNHCR LIST OF ESSENTIAL DRUGS

PLEASE COMPLETE ALL RELEVANT SECTIONS OF THIS FORM:

Country: _____ Location:_____

Camp: _____ Refugee population:_____

1. Generic name: _____

2. Specify the dosage form and strengths that you wish to include:

   _____

Dosage form	*Strength(s)*	*Dosage form*	*Strength(s)*
Tablet: _____		Capsule: _____	
Syrup:_____		Oral solution: _____	
Ointment/cream: _____		Injectable: _____	
Suppositories: _____		Other: _____	

3. Recommended dosages and length of treatment:

   - Paediatric:

     _____

   - Adult:

     _____

4. Clinical indications for use of drug: _____

5. State reasons for request, and explain why UNHCR list analogues not appropriate:

   _____

6. List contra-indications, precautions and side-effects associated with use/abuse of proposed drug:
   _____

7. Specify conditions under which the drug will be used:
   - camps(s) where it will be used: _____
   - level(s) of health worker(s) authorized to prescribe drug: _____
   - health facilities in which it will be used: _____
   - access to personnel skilled in use of drug: _____

(Name and title of person making request) (Signature) (Date) (Organization/Agency)

NB. This form is to be submitted for clearance to the Senior Public Health Officer through the UNHCR Field Office.

Note: Procurement and delivery time will be longer than EDL drugs.

ANNEX 3 CONTENTS OF THE NEW EMERGENCY HEALTH KIT

Basic Unit

Drugs:			
Acetylsalicylic acid 300mg	3 x	1,000	TAB
Aluminium hydroxide 500mg	1 x	1,000	TAB
Benzyl benzoate 25% application	1 x	1	L
Cetrimide 15%/chlorhexidine gluc. 1.5% (savon)	1 x	1	L
Chloroquine phosphate 150mg base (uncoated) 2 x 1.000 TAB	2 x	1,000	TAB
Co-trimoxazole 400mg+80mg scored.	2 x	1,000	TAB
Ferrous sulphate 200mg / folic acid 0.25mg	2 x	1,000	TAB
Gentian violet	4 x	25	g
Mebendazole 100mg	1 x	500	TAB
Oral rehydration salts for 1000ml water	2 x	100	SAC
Paracetamol 100mg	1 x	1,000	TAB
Tetracycline hcl eye ointment 1% 5g	1 x	50	TUB

Renewable supplies:			
Adhesive tape 2.50cm x 5m	4 x	8	ROL
Ballpoint, Bic, blue	10 x	1	PCE
Block note A6	10 x	1	PCE
“treatment guidelines ”for basic unit,engl/fr./span.	2 x	1	PCE
Clinical thermometer oral /rectal,°C+°F, stubby	6 x	1	PCE
Cotton wool absorbent BP /Eur P. 500g zig-zag	2 x	1	PCE
Elastic bandage 8cm x 5m (stretched)	1 x	20	ROL
Examination gloves latex medium disposable	1 x	100	ROL
Gauze compresses 10x10cm 12 ply, non sterile	5 x	100	PCE

Renewable supplies:			
Health card 10.000pers./ kit eng/fr/sp+plastic bag	1 x	500	PCE
Hydrophylic bandage selfedged 7,5cm x 5m	10 x	20	ROL
Note book, hard cover A4 100 pages	4 x	1	PCE
Soap unwrapped 200g	1 X	10	PCE
Tablet bags re usable 60x 80mm mini grip(+pictogram)	4 X	500	PCE

Equipment:			
Bottle, 100ml plastic (screwcap=872741)	1X	1	PCE
Cap with spout for bottle 100ml, 17 mm (code 731900)	1 x	1	PCE
Bucket, plastic 12L	2 x	1	PCE
Dish (kidney) s.s. 24cm	1 x	1	PCE
Dressing set (*)	2 x	1	SET
Drum for cotton wool and gauze diam.15cm high 15cm	2 x	1	PCE
Instrument tray 30x20x2cm	1 x	1	PCE
Forceps artery Pean 14.5cm straight (=Kocher, no teeth)	2 x	1	PCE
Gallipot s.s. without lid 300ml	1 x	1	PCE
Plastic bottle 1000ml wide neck/screw cap 731700	3 x	1	PCE
Screw cap for plastic bottle 1000ml (731800)	3 x	1	PCE
Scissors, surgical bl/bl, straight, 14.5cm	2 x	1	PCE
Syringe Luer 10ml disp	2 x	1	PCE
Surgical scrub brush, sterilisable	2 x	1	PCE
Water bag, foldable, 20Ltr strong quality with tap	1 x	1	PCE
(*) Each dressing set consists of:			
Instrument box with lid, s.s. 20x10x5cm 1 x 1 PCE	1 x	1	PCE
Forceps dissecting 14cm (dressing spring type) 1 x 1 PCE	1 x	1	PCE
Forceps artery Pean 14.5cm, straight 1 x 1 PCE	1 x	1	PCE
Scissors, surgical sh/bl, straight, 14.5cm 1 x 1 PCE	1 x	1	PCE

Supplementary Unit

Benzathine penicillin 2.4 miu	1 x	50	VLS
Diazepam 5mg/ml, 2ml	2 x	100	AMP
Epinephrine 1mg/ml, 1ml (=adrenaline)	1 x	50	AMP
Ketamine 50mg/ml, 10ml	1 x	25	VLS
Morphine 10mg/ml inj. 1ml	5 x	10	AMP
Oxytocin 10 iu/ml, 1ml	2 x	100	AMP
Phenobarbital 50mg	1 x	1000	AMP
Quinine di-hcl 300mg/ml	1 x	100	AMP
Quinine sulphate 300mg film coated	3 x	1000	TAB
Silver sulphadiazine 1% cream 50g	30 x	1	TUB
Sulphadoxine/pyrimethamin 500mg/25mg	3 x	100	TAB
Water for injection 10ml	20 x	100	AMP
Benzylpenicillin 5 miu	5 x	50	VSL
Procaine penicillin 3 miu/benzylpen. 1 miu	15 x	50	VSL
Aminophylline 25mg/ml, 10 ml	1 x	50	AMP
Amoxicillin 250mg	3 x	1000	TAB
Ampicillin 500mg	4 x	50	VLS
Atropine sulphate 1mg/ml, 1ml	1 x	50	AMP
Benzoic acid 6%+salicylic acid 3% ointment, 40gr	25 x	1	TUB
Chloramphenicol 250mg	2 x	1000	CAP
Chloramphenicol sodium succinate 1g base	10 x	50	VLS
Chlorpromazine hcl 25mg/ml, 2ml	1 x	20	AMP
Dextrose 50% 50ml	1 x	25	VLS
Doxycycline 100mg (as hyclate)	2 x	1000	TAB
Ethinylestradiol/Levonorgestrel 0.05/0.25mg	100 x	4	TAB
Folic acid 5mg	1 x	1000	TAB
Furosemide 10mg/ml, 2ml	1 x	20	TAB
Hydralazine 20mg (dry pow der for inj.)	4 x	5	AMP

Hydrochlorothiazide 25mg	2 x	100	TAB
Hydrocortisone 100mg (as sodium succinate)	2 x	25	VLS
Lidocaine hcl 1%, 20ml	2 x	25	VLS
Methyldopa 250mg filmcoated	1 x	500	TAB
Metronidazole 250mg	2 x	1000	TAB
Naloxone 0.4mg/ml, 1ml	2 x	20	AMP
Nystatin 100.000 IU vaginal	10 x	100	TAB
Nystatin 100.000 IU oral non-coated	10 x	100	TAB
Prednisolone 5mg	1 x	100	TAB
Promethazine hcl 25mg coated	1 x	500	TAB
Promethazine hcl 25mg/ml, 2ml	1 x	50	AMP
Pvp iodine 10% solution	10 x	200	ML
Salbutamol 4mg	1 x	1000	TAB
Vitamin A 200.000 iu (retinol)	4 x	1000	CAP
Vitamin C 250mg (ascorbic acid)	4 x	1000	TAB

Supplementary infusions			
Hartmann's sol. (ringer lactate) 500ml +set	3 x	20	BTL
Hartmann's sol. (ringer lactate) 500ml + set	3 x	20	BTL
Hartmann's sol. (ringer lactate) 500ml + set	3 x	20	BTL
Dextrose 5% in water 500ml + set	2 x	20	BTL
Hartmann's sol. (ringer lactate) 500ml + set	1 x	20	BTL
Dextrose 5% in water 500ml + set	3 x	20	BTL

Supplementary renewable supplies:			
Catheter Foley no.12 balloon 5-15ml sterile	1 x	10	PCE
Catheter Foley no.14 balloon 5-15ml sterile	1 x	5	PCE
Catheter Foley no.18 balloon 5-15ml sterile	1 x	5	PCE
I.v. placement unit 22G blue	15 x	1	PCE
Scalp vein infusion set 25g	3 x	100	PCE
Spinal needle 20G x 90mm disp.	1 x	25	PCE
Spinal needle 22G x 40mm disp.	1 x	25	PCE
Surgical gloves size 7.5 sterile	3 x	50	PCE
Surgical gloves size 8.5 sterile	1 x	50	PCE
Suture vicryl 2/0 , 70cm, + 3/8 ct.ndl. 30mm, V586H	4 x	36	PCE
Syringe luer 10ml disp.	2 x	100	PCE
Syringe luer 10ml synthetic autoclavable	4 x	10	PCE
Syringe luer 2ml disp	4 x	100	PCE
Syringe luer 2ml synthetic autoclavable	2 x	10	PCE
Tongue depressor wood 15cmx18mm	1 x	100	PCE
724202 Feeding tube ch5 40cm disp. luer 1 x 20 PCE	1 x	20	PCE
720903 Feeding tube ch8 40cm disp. luer 1 x 50 PCE	1 x	50	PCE
944003 Gauze compresses 10x10cm 12-ply, sterile 22 x 45 PCE	22 x	45	PCE
706300 Needle luer 21g x 1-1/2" (0.8x38mm), disp. 20 x 100 PCE	20 x	100	PCE
840774 Safety box for disp. of used syringe & needle 5L 20 x 1 PCE	20 x	1	PCE
840413 Stomach tube ch16 125cm disp. plastic 1 x 10 PCE	1 x	10	PCE
711100 Surgical gloves size 6.5 sterile 1 x 50 PR	1 x	50	PCE
901000 Syringe 50(60)ml luer dis p.(also for feeding tube) 10 x 1 PCE	10 x	1	PCE
719900 Urine collecting bag 2000ml with tap and valve 10 x 1 PCE	10	1	PCE
Autoclave tape,18mmx50mtr (for steam ster.)	2 x	1	ROL

Supplementary renewable supplies:			
Clinical thermometer oral /rectal,°C+°F, stubby	10 x	1	PCE
Examination gloves latex small disposable	1 x	100	PCE
Examination gloves latex medium disposable	1 x	100	PCE
Examination gloves latex large disposable	1 x	100	PCE
Hydrophylic gauze 90cm x 91m BP 13heavy (17g/m2)	3 x	1	PCE
I.v. placement unit 18G green	15 x	1	PCE
I.v. placement unit 24G yellow	15 x	1	PCE
Mucus extractor baby disposable	5 x	1	PCE
Needle luer 19g x 1-1/2" (1.1x38mm), disp.	10 x	100	PCE
Needle luer 25g x 5/8" (0.5x16mm), disp.	1 x	100	PCE
Scalp vein infusion set 21g	1 x	100	PCE
Sodium dichloroiso cyanurate 1.67gr (NaDCC)	6 x	200	TAB
Syringe luer 5ml disp.	5 x	100	PCE
Syringe luer 5ml synthetic autoclavable	1 x	100	PCE
Umbilical cord tie 3mm non-sterile 100m	1 x	1	ROL

Supplementary equipment:			
Battery for oto/ophth.scope penl. alkal. R6 7205/7139	12 x	1	PCE
Bulb for otoscope mini Heine(7139) XHL 056 2.5V	4 x	1	PCE
Drum for cotton wool and gauze diam.15cm high 15cm	2 x	1	PCE
Instrument tray 30x20x2cm	1 x	1	PCE
Measuring-tape, flexible 1.5m,vinyl-coated,fibregl	5 x	1	PCE
Otoscope “mini” with battery handle, small Heine	2 x	1	PCE
Scale Salter type 25kg x 100g + 3 trousers	3 x	1	PCE
Surgical scrub brush, sterilisable	2 x	1	PCE
Water filter (Berkefeld) SS3 with 3 candles 10ltr.	3 x	1	PCE
2 razor handles reusable + 100 blades	2 x	1	SET
Apron with neckband opaque plastic, disp.	2 x	1	PCE
Dish (kidney) s.s. 24cm	2 x	1	PCE

Supplementary equipment:			
Pressure cooker 21 ltr + basket (for EHK)	1 x	1	PCE
Scale metric adults bathroom type	1 x	1	PCE
Sheeting, plastic, clear 90cm x 180cm Uni 0361020	2 x	1	PCE
Sphygmomanometer, anaeroid, simple	4 x	1	PCE
Stethoscope foetal metal	1 x	1	PCE
Stethoscope, littman type double light weight + spares	4 x	1	PCE
Tape for measuring circumference (talc)	10 x	1	PCE
Abcess/suture set (packed in 734200) 2 x 1 SET	2 x	1	SET
Blade for surgical knives size 22	1 x	100	PCE
Book “guide clinique et therapeutique”(french)MSF	1 x	1	PCE
Book “clinical guidelines” (english) MSF	1 x	1	PCE
Book “guia clinica y terap eutica” (spanish) MSF	1 x	1	PCE
Dressing set (packed in 734200)	5 x	1	SET
Forceps artery Pean 14.5cm straight (=kocher, no teeth)	2 x	1	PCE
Midwifery kit (packed in 734200)	1 x	1	KIT
Prestige double-rack 7503 PHC-sterilizer + access.	1 x	1	PCE
Scissors, surgical bl/bl, straight, 14.5cm	2 x	1	PCE
Stove kerosene for sterilizer Hipolito 36	2 x	1	PCE
Tourniquet (arm), cotton white with buckle	2 x	1	PCE
Towel, huck 430 x 500mm Uni 0575000	2 x	1	PCE

Each abscess/suture set consists of:			
Instrument box with lid, s.s. 20x10x5cm	1 x	1	PCE
Forceps tissue 14.5cm 1/2 teeth (spring type)	1 x	1	PCE
Forceps artery Kocher 14cm straight	1 x	1	PCE
Forceps artery Pean 14.5cm straight	1 x	1	PCE
Scissors, curved, sharp/b lunt 14.5cm	1 x	1	PCE
Probe, grooved 14.5cm uni 0759810	1 x	1	PCE
Needle holder, mayo-hegar 18cm,straight	1 x	1	PCE

Each abscess/suture set consists of:			
Handle for surgical blade s no. 4	1 x	1	PCE
Each dressing set consists of:			
Instrument box with lid, s.s. 20x10x5cm	1 x	1	PCE
Scissors, surgical sh/bl, straight, 14.5cm	1 x	1	PCE
Forceps artery Pean 14.5cm straight	1 x	1	PCE
Forceps dissecting 14cm (dressing spring type)	1 x	1	PCE
Each midwifery set consists of:			
Instrument box with lid, s.s. 20x10x5cm	1 x	1	PCE
Scissors, surgical sh/bl, straight, 14.5cm	1 x	1	PCE
Dissecting straight Mayo 16-18	1 x	1	PCE
Forceps artery Pean 14.5cm straight	1 x	1	PCE

ANNEX 4 STANDARD OPERATIONAL PROCEDURES

SOP P1: Consumption-based quantification

SOP P2: Morbidity-based quantification

SOP P3: Ordering Procedures for International Procurement

SOP D1: Physical Inventory

SOP D2: Issuing items that expire first (FEFO)

SOP D3: Filling out stock cards

SOP D4: Storage of drugs and medical supplies

SOP D5: Removing damaged and expired stock

SOP Q1: OBTAINing good quality drugs

SOP Q2: VERIFYing the quality of shipped drugs

SOP Q3: MONITORing and MAINTAINing the quality of drugs

United Nations High Commissioner for Refugees	
Consumption-based quantification of essential drug procurement	
Nr. Of pages: 5	Procedure number: SOP P1

Objective:

Estimating the quantities of specific drugs needed for procurement to avoid shortage and excess stock based on past consumption data, adjusted for stock-outs, avoidable wastages and projected changes in drug utilization.

Responsibility:

Health coordinator in collaboration with health and logistics staff.

Resources:

Essential data are:

- general data: location, partner, name of responsible officer with UNHCR and with partner
- data on population size
- consumption and/or issue data
- data on frequency and duration of stock-outs
- projected drug costs
- review period versus desired coverage period

Consumption data	Issue data
● dispensing records ● monthly consumption reports	● stock records central distribution point ● distribution records

Note that the consumption from a stock record card is calculated by adding up all the quantities issued. The formula is:

Recorded consumption = Opening stock + Drug Received - Closing Stock.

Procedures:

Step 1: Prepare a list of drugs to be quantified.

Step 2: Determine the period of time to be reviewed for consumption.

The simplest and most practical period for which to calculate consumption is one year. This ensures that the morbidity variations of all seasons are covered. If data are available, the longest period of data should be used as can improve the reliability of the results.

The **timing** of placing an order is critical in order to avoid stock-outs. It needs to take into account the lead-time (time for procurement and delivery). For example, if an order is being placed for January – December 2006, the order must arrive in December 2005. Taking into account an average lead-time of 3 months, the order must be prepared and sent in September 2005 (or even earlier if possible).

Step 3: Enter consumption data for each drug.

For each drug, enter:

- The total quantity used during the review period (in basic units).
- The number of days (or months) that the drug was out of stock in the review period.
- The average lead-time from the last several procurements.

Step 4: Calculate the Average Monthly Consumption and adjust for stock-out.

The average monthly consumption is a key variable in the quantification formula and should be as accurate as possible. The simple approach is to divide total consumption by the number of months reviewed. If there were stock-outs during that period, the average must be adjusted to include the consumption that would have occurred if stock had been available.

Adjusted average monthly consumption:

$$C_A = C_T \div [R_M - (D_{OS} \div 30.5)]$$

C_A = Average monthly consumption adjusted for stock-outs

C_T = Total consumption during review period, in basic units

R_M = Review period in months

D_{OS} = Number of **days** an item was out of stock during the review period

Note that one must divide by 30.5 to convert to months. If the total consumption of ampicillin 250 mg capsules for a six-month review period was 89000 capsules and the drug was out of stock for 34 days during that period, the (adjusted) average monthly consumption is:

$C_A = 89000 \div [6- (34 \div 30.5)] = 18218$

Step 5: Calculate the lead-time stock needed for each drug.

This is the quantity of drug consumed during the delivery time. So if delivery time is 3 months, the lead-time stock is the monthly consumption x 3.

Step 6: Calculate the safety stock needed.

The safety stock is that which is needed to compensate for possible late deliveries, losses and increases in consumption. It is generally calculated as half of the consumption of the lead-time stock or about 20% of the total order. So if the lead-time is 3 months, safety stock is half of that or monthly consumption x 1.5.

Step 7: Convert the quantity into order pack.

Total quantities required divided by order pack size.

Step 8: Estimate costs for each drug and total costs.

In order to estimate procurement costs, multiply the price by estimated quantity for each drug by the purchase price. If for example the price per pack of Amoxicillin 250mg of 1000 capsules is 30 USD and the annual total estimated requirement is 40 packs then the cost will be =40 x 30 USD= 1200 USD.

Estimate the total cost of all drugs and add everything up.

Step 9: Prepare annual drug budget.

The annual drug budget shall include:

- All the estimated cost of the drugs & medical supplies required.

- Estimates of the cost for transportation, procurement & distribution.

Formulas for Consumption-Based Calculations

Formula Number	Objective of Formula	Calculations
1	Adjusted average monthly consumption (preferred)	$C_A = C_T \div [R_M - (D_{OS} \div 30.5)]$
2	Adjusted average monthly consumption (alternative)	$C_A = C_T \div (R_M - M_{OS})$
3	Projected average monthly consumption	$C_P = C_A \times A_U$
4	Basic safety stock requirements	$C_P \times LT$
5	Quantity to order	$Q_O = C_P \times (LT + PP) + SS - (S_I + S_O)$

C_A = Average monthly consumption, adjusted for stockouts

C_T = Total consumption during review period, in basic units

R_M = Total consumption review period in months

D_{OS} = Number of days an item was out of stock during the review period

M_{OS} = Estimated number of months an item was out of stock during the review period

C_P = Projected average monthly consumption

A_U = Utilization adjustment

LT = Average lead time (for projected supplier or worst case), in months

Q_O = Quantity to order in basic units, before adjustment for losses or program change

PP = Procurement period (number of months to be covered by order)

SS = Quantity needed for safety stock

S_I = Stock now in inventory, in basic units

S_O = Stock now on order, in basic units

Figure 1 Example of a Consumption-Based Forecast

Drug	Strength	BU	Pack Size	Total Consump-tion in Period (BU)	Days Out of Sto ck	Adjusted Average Monthly Consump-tion (BU)	Projected average monthly Consump-tion (BU)	Stock on Hand (BU)	Stock on Order (BU)	Lead-time Stock Level (BU)	Sug-gested Quantity to Order (BU)	Adjusted Order Quantity	Order Quantity (Pack s)	Probable Pack Price (US$)	Value of Proposed Order (US$)
Ampicillin	500 mg	capsule	1,000	59,500	0	9,917	10,413	32,000	42,000	31,238	50,950	56,045	57	69.30	3,950.10
Ampicillin	250 mg	capsule	1,000	89,000	34	18,218	19,129	81,000	58,000	57,387	90,548	99,603	100	35.10	3,510.00
Ampicillin sodium injection	500 mg	ampoule	100	3,879	0	647	679	111	7,600	2,036	435	478	5	29.95	149.75
Ampicillin suspension 100 mL	125 mg/ 5 Ml	bottle	1	4,128	0	688	722	1,513	3,000	2,167	4,156	4,571	4,572	0.75	3,429.00
Antihistamine decongestant elixir	250 mL	bottle	1	853	29	169	177	351	929	532	849	933	934	1.57	1,466.38
Antihistamine decongestant	(any)	tablet	500	50,000	0	8333	8,750	0	62,500	26,250	42,500	46,750	94	12.00	1,128.00
Bacitracin antibiotic ointment	—	tube	1	2,414	31	484	509	3,400	100	1,526	2,603	2,864	2,864	0.54	1,546.56
Bendrofluazide	5 mg	tablet	500	141,500	30	28,208	29,618	142,000	50,000	88,854	163,415	179,756	360	1.90	684.00
Benzathine benzyl-penicillin injection	2.4 M.U.	ampoule	50	1,318	0	220	231	1,486	0	692	1,282	1,410	29	25.00	725.00
Cephradine injection	500 mg	ampoule	100	2,695	0	449	472	2,300	1,100	1,415	2,260	2,485	25	75.00	1,875.00
Chlorhexidine gluconate solution (Hibitan)	5%	Liter	5	302	0	50	53	433	0	159	201	221	45	17.95	807.75
Chlorhexidine/ cetrimide (Savlon)	5 liter	Liter	5	438	0	73	77	418	250	230	252	277	56	14.70	823.20
Chlorpropamide	250 mg	tablet	1,000	162,000	0	27,000	28,350	169,000	0	85,050	171,200	188,320	189	8.99	1,699.11
Cimetidine (Tagamet) injection	200 mg	ampoule	10	1,090	0	182	191	2,580	0	572	0	0	0	8.36	0
Cimetidine	400 mg	tablet	1,000	24,000	0	4,000	4,200	23,500	25,000	12,600	1,900	2,090	3	42.00	126.00
Cloxacillin suspension 100 mL	125 mg/ 5 mL	bottle	1	882	0	147	154	1,446	0	463	406	447	447	1.00	447.00

Note: BU = basic unit, Consumption period = 6 months, Lead time = 3 months, Procurement Period = 6 months, Utilization adjustment for 6 months = 2.5%, Losses adjustment = 10%

United Nations High Commissioner for Refugees	
Morbidity-based quantification of essential drug procurement	
Nr. Of pages: 5	Procedure number: SOP P2

Objective:

- Estimating the quantities of specific drugs needed for procurement to avoid shortage and excess stocks in new programs or programs where no past consumption data is available.
- Countercheck procurement quantities as estimated by the consumption method.

Responsibility:

Health Coordinator in collaboration with health staff.

Resources:

Essential data are:

- data on population and patient attendances
- actual or projected incidence of health problems
- standard treatments (ideal, actual)
- projected drug costs

Procedures:

Step 1: Prepare Average Standard Treatment Schedules (ASTS).

In preparing ASTS the following information should be included:

- The name of the health problem and code number of the diagnosis.
- The patient's age and sex.
- The generic name, strength and dosage form each drug used to treat the disease.

- The average dose, number of doses/day and duration of treatment (the number of days these doses are given).
- The total average quantity of each drug used for a standard course of treatment.

ICD Code No.	Diagnosis	Treatment	Dose	Number of doses per day	Duration (total treatment days)	Quantity for course of treatment
	Pneumonia -adults	Amoxicillin 500 mg capsule	1 capsule	3	7	21 capsules
	-children	Amoxicillin 250 mg/ 5 ml suspension	5 ml	3	7	100 ml

Step 2: Estimate number of treatment episodes for each health problem.

A treatment episode is *a patient contact for which a standard course of treatment* is *required.*

The following information helps estimate the number of treatment episodes:

- Obtaining the total number of patient contacts by diagnosis.
- Recognize the diagnosis according to the health problems defined in the average standard treatment.
- Within health problems, breakdown the number of patient contacts by age, sex and severity.
- Determine the proportion of contacts for which standard treatments are required.

All patient contacts/visits may not give rise to a treatment episode as may not require a standard course of drug treatment.

A single patient contact or visit may give rise to more than one treatment episode.

Step 3: Calculate total quantity of each drug required.

a.) Calculate the total quantity of each drug required for each health problem.

A total quantity of drug for each health problem can be calculated using the following formula:

Total quantity of each drug = No. of treatment episodes of each health problem X Quantity of the drug specified for the health problem for a standard course

If the number of treatment episodes for acute diarrhea treated annually by a certain health facility was 10,000 of which 65% were children and cases were treated with ORS, the quantity can be determined as follows:

ICD Code	Diagnosis	Number of Treatment Episodes (a)	Quantity per average standard treatment (b)	Total Quantity (a x b)
	Acute diarrhea -Adult	10000 x 35%= 3500	ORS 2 sachets per 24hrs.	3500 x 2 = 7000 sachets
	-Children	10000 x 65%= 6500	ORS 1 sachet per 24 hrs.	6500 x 1= 6500 sachets
			Total	**13500 sachets**

b.) Calculate the total quantity of drug required.

When a drug is indicated for more than one standard treatment, add the quantities required for each treatment to obtain the total quantity of the drug. These all are combined to project the quantity of each drug needed for each treatment episode in each standard treatment.

Illustrative example

Drug code No.	Generic name	Health problem	Total quantity of all treatments		
			No. of treatment episodes	Qty. per average STS	Total quantity
	Metronidazole 250 mg capsule	Amoebiasis			
		Adult	600	45	27000
		Children	400	15	6000
		Giardiasis	1000	21	15000
		Trichomoniasis	1000	8	8000
Total					**56000**

STS~ means Standard Treatment Schedule

Step 4: Increase the quantity obtained to allow for possible for service expansion.

Step 5: Convert the quantity into the required order pack.

The quantity can be converted into the required number of order packs/pack size.

The Formula is:

$$\text{No. of order packs} = \frac{\text{Total quantities required}}{\text{Pack size (counting unit)}}$$

N.B: The quantity can be increased by, for example, 5% allowances for changes in consumption pattern and losses.

Step 6: Estimate the cost of the drug quantities required.

After calculating the total number of packs of each drug required, the next step is to estimate the total cost of the drug required using the formula shown below and then adding up the total costs of all drugs.

Total cost of each drug = Number packs required x Price per pack

Step 7: Prepare Annual Drug Budget.

Preparing the annual budget requires:

- Adding up the estimated cost of all drugs required;
- Estimating the cost for transportation, procurement and distribution;
- Estimating costs for preparing/printing of stock cards, bin cards, consumption reporting forms.
- Prescription Registration Book, and other necessary working documents.

United Nations High Commissioner for Refugees	
Ordering Procedures for International Procurement	
Nr. Of pages: 2	Procedure number: SOP P3

Task: To order medicines and medical supplies for use in the health centres.

Completed by: Senior health staff of Implementing partner, UNHCR health coordinator, UNHCR Senior Public Health Officer (to supervise and clear order), Programme Officer (to ensure budget), Supply Officer (to receive and transport).

Purpose: To ensure that drugs and medical supplies are appropriately ordered in terms of type and quantity and to ensure that they are available continuously without shortages or disruptions.

When to perform: At least once a year, though it could be more frequently depending on budget availability.

Steps and actions

1. The Implementing health partner must always be aware of how much stock of drugs and medical supplies it has on hand. When only six months supplies are left, they should inform the UNHCR health coordinator (where present) and the Programme officer that more supplies are needed.
2. The Programme officer should inform the Desk that funds will be needed for drugs and medical supplies.
3. Senior staff of the partner agency in coordination with the UNHCR health coordinator (where present) prepare the order for the next year (or 6 months, depending on budget) based on past consumption or morbidity methods. The order is placed on the standard order forms available from SMS.
4. The order is reviewed with the Programme Officer to confirm the budget.

5. The order is then sent to the UNHCR Senior Public Officer to be reviewed and cleared. An email should be sent to the Programme Officer that the order has been cleared.

6. The Programme Officer forwards the order and email to the Desk. If an order cannot be cleared in the field, the Desk sends it to the Senior Public Health Officer at HQ to be cleared.

7. Once cleared, the order is forwarded by the Desk to SMS for processing. When the order is ready for shipment, the supplier notifies the consignee (Country office) and SMS of the estimated date of arrival. The Supply officer at country level requests from the supplier, transport company and SMS any additional documents (eg. purchase order, packing list, final invoice, etc.) needed to start clearance procedures in-country

8. The Supply officer at country level ensures that the order is cleared through customs as quickly as possible once it arrives in-country. Once customs has been cleared, the store-keeper at the warehouse receives, inspects and stores the materials. Any discrepancies or damages are reported immediately to the Supply officer. The Supply officer arranges onward transport to the Suboffice and Implementing partner as soon as feasible.

9. The Suboffice and Implementing partner receive and verify the order. Any discrepancies or damages are reported to SMS immediately.

This task is complete when:

- drugs and medical supplies arrive in the health centre and are available for the population.

United Nations High Commissioner for Refugees	
How To Conduct a Physical Inventory	
Nr. Of pages: 2	Procedure number: SOP D1

Task: Conducting a physical inventory

Completed by: pharmacist, storekeeper, clinical officer/medical assistant

Purpose:

1. To verify the quantity of usable stock available for distribution.
2. To identify discrepancies between actual supplies and the stock balance on the stock card.
3. To detect damaged or expired items.
4. To provide opportunity for store reorganization.

When to perform:

1. Quarterly at a central medical store
2. Monthly at a health center (on the last day of the month)
3. Any time you think there may be discrepancies in the amounts of usable stocks available

Steps and actions

1. Separate and count any expired or damaged drugs, and other medical supplies.

   Record the amount of damaged or expired product in the Losses/Adjustments of the stock card. In the Remarks, provide a brief explanation for the expiry or damage.

2. Count every brand, preparation or dosage form of usable health commodity *by hand*.

   Include stock held in storerooms, cabinets, or racks. Do not count stock already issued to health facilities. Always count the smallest countable unit of the commodity. Example: condoms=piece, orals=cycle, etc.

Count unopened/complete cartons first. Multiply the number of cartons by the number of units in the carton. This will give you the total number of commodity units in the carton.

Example: You have 40 unopened cartons, each one containing 200 units.
40 x 200 = 8,000 total units in the unopened cartons.

Count open cartons. If an open carton contains unopened boxes, count the boxes and multiply the number by the number of units in a box. This will give you the total number of the commodity units in unopened boxes.

Example: You have 10 unopened boxes, each one containing 20 units.
10 x 20 = 200 total units in the unopened boxes.

Count all the units that are in open boxes, shelves, drawers, etc., and add them together.

Example: You have counted 15 units in an open box on a shelf. You have counted 4 units in a drawer.
15 + 4 = 19 total units from an open box and a drawer.

Add the total units from unopened boxes, open boxes, shelves, drawers, etc. This will give you the total number of units of the commodity available in your store (quantity on hand).

8,000 units from unopened cartons

200 units from unopened boxes

19 units from open boxes, etc.

8,219 total units = quantity on hand

3. On the next line of the stock card, write the date of the physical inventory, the words *Physical Inventory*, and the quantities counted in red ink.

Record the quantity counted in the Quantity on Hand. In the Remarks, provide a brief explanation for the loss or adjustment.

Always enter each transaction on a separate line. After recording a physical inventory on the stock card, skip a line on the stock card, leaving it blank, and begin recording the next month's transactions on the next line.

4. Mark the expiry date clearly, with large, dark numbers, on each box or carton.

5. Reorganize products according to expiry dates to comply with FEFO distribution.

These steps may have been taken during routine receipt and management of drugs and other medical supplies. However, if unmarked stocks are found during a physical inventory, proceed with these steps.

This task is complete when:

- The Quantity on Hand units of the commodity have been counted and recorded on the stock card.
- Losses and Adjustments have been calculated and recorded on the stock card.

United Nations High Commissioner for Refugees	
ISSUING ITEMS THAT WILL EXPIRE FIRST	
Nr. Of pages: 1	Procedure number: SOP D2

Task: Distributing drugs, contraceptives, and other medical supplies according to FEFO (First expiry First out)

Completed by: medical storekeeper, clinical officers/medical assistant

Purpose: To ensure that products are distributed before they expire

When to perform: Whenever health commodities are issued

Steps and actions

1. Mark expiry dates on outside of cartons or boxes.
2. Place cartons or boxes so that stocks first to expire are stacked in front on top of stocks that will expire later.
3. Issue stocks from front to back or top to bottom so stocks that expire sooner will be issued first.
   This task is complete when: All health commodities are issued according to FEFO.

United Nations High Commissioner for Refugees	
Filling Out Stock Cards for Medical Supplies	
Nr. Of pages: 4	Procedure number: SOP D3

Task: Filling out the stock card

Completed by: storekeeper, pharmacist, clinical officer/medical assistant

Purpose:

1. To maintain a continuous record of all drugs and other medical supplies transactions.
2. To record results of a physical inventory.

When to perform:

Each time you:

1. Receive or issue health commodities.
2. Record a loss or adjustment.
3. Conduct a physical inventory.

Note: Complete one stock card for each brand, preparation, or dosage form of a health commodity. Enter only one transaction on each line. After recording a physical inventory on the stock card, skip a line on the stock card, leaving it blank, and begin recording the next month's transactions on the next line. There should be one stock card for each brand, preparation, or dosage form of the health commodity you store. When you have completed both sides of a stock card for a product, attach a new stock card to the top of the old card and write the words *Balance Forward* or *B/F* on the first line. Write the quantity brought forward from the old card in the first Quantity on Hand space on the new card.

Steps and Actions

1. Description:

Enter the name of the health commodity. Use one stock card for each health commodity.

Example: Amoxicillin 250 mg

2. Unit:

Enter the smallest unit in which drugs will be dispensed to the patient (basic units), instead of packing units. Note that the same basic unit should be used a every level in the supply chain to avoid confusion.

Example: “tablet” (instead of “tin of 1000 tablets).

3. Batch number:

Enter the batch number mentioned on the product label for quality assurance purposes. Ideally, it is possible to trace back the batch number at every level of the supply chain, until the point where the drug meets the patient.

Example: 0907D

4. Expiry date:

Enter the expiry date as mentioned on the product label. Ideally, and at least at bigger medical warehouses such as a central medical store, one stock card for every expiry date should be used per product to make sure that the FEFO (First Expiry First Out) principle is being followed. One product can have several expiry dates.

Example: EXP 07/2008

5. Date:

Enter the date of the transaction.

Example: 12/4/2004

6. Issued to/Received From:

Enter the name of the facility (or supplier) that the product is coming from in case it concerns an entry. Enter the name of the facility to which the product is being sent to in case it concerns an exit.

Example: Nduta Central Camp Pharmacy (for an exit of a product from a central store)

7. Reference:

Enter the delivery note number of the item received or issued. Get this from the Requisition for Medical Supplies or issue voucher/waybill that accompanies the item.

Example: Voucher #: 0039

8. Quantity Received:

Enter the exact amount of the product received on this date in red ink. This is for stock received at the health centers from the central pharmacy, and stock received at the central pharmacy from the suppliers.

Example: Quantity received: 50,000

9. Quantity Issued:

Enter the exact amount of the product issued on any date. This is stock that has physically left the storage area.

Example: Quantity issued: 6,000

10. Balance:

Add any receipts or adjustments and subtract any issues or losses from the existing Balance to determine the new Balance (or "quantity on hand"). Write this figure in the Balance column for this date. This column should always represent the amount of this item presently in your store.

When conducting a physical inventory, always record the exact amount
counted. If the physical count does not match the amount recorded in this column, review the issues and receipts against the delivery vouchers, check the math, note *Losses and Adjustments* in a separate row (in a different ink color) and update the figure in this column.

Record the physical inventory on the stock card *in red ink*.

Example:
Balance = 143,000

Physical Inventory = 143,000
Note: *Losses/Adjustments:*

Enter the exact amount of losses or adjustments (additions) to inventory on this date.

Always use a (-) sign to indicate losses and a (+) sign to indicate adjustments (additions).

Losses include theft, expiry, damage, or items used for either training or counselling.

Adjustments include usable stock returned from lower level facilities or transferred from one facility to another.

Example: (-) 2,000 loss

11. Remarks:

1. When there is a loss or adjustment for an item, provide a brief explanation.

   Example: Damaged by water

2. When updating the stock card, sign your name.

   Example: John Makowa

3. When conducting a physical inventory, sign your name.

   Example: Physical Inventory: John Makowa

This task is complete when:

- The Product name or Description, Batch Number, Expiry Date, Date (of transaction), Reference, Quantity Received, Quantity Issued, Losses/Adjustments, Balance, and Remarks columns are correctly completed.

United Nations High Commissioner for Refugees	
Storing drugs and medical supplies at medical stores and pharmacies	
Nr. Of pages: 3	Procedure number: SOP D4

Task: Storing drugs, contraceptives, and other medical supplies

Completed by: Pharmacist-In-Charge, Pharmacy Technician, Stores Clerk, etc.

Purpose: To protect quality and package integrity while making products available for use.

When to perform: When health commodities are being stored.

Storage Guidelines and Notes

1. Clean and disinfect storeroom regularly. Take precautions to prevent harmful insects and rodents from entering the storage area.

Rodents and some insects (for example, termites and roaches) like to eat certain health commodities, like oral contraceptives. They also eat shipping cartons and inner packaging. Pest-proof your store to stop the pests from getting in. If your store becomes infested with pests, use appropriate pesticides and use cats, which are effective against termites, rodents, roaches, etc. After you clear pests from the store, keep it clean. A clean store keeps pests away. Food and drinks in the warehouse increase the risk of pests. Eliminating some pests may be difficult and beyond the storekeeper's means.

2. Store health commodities in a dry, well lit, well-ventilated storeroom—out of direct sunlight.

A hot store may cause some of the commodity supplies to spoil, which will *decrease shelf life.* For example, the shelf life of oral contraceptives and condoms is generally 4 to 5 years. However, the shelf life, particularly condoms, will probably be much shorter if the temperature inside the warehouse rises above 40ºC. Although air conditioning is ideal, it is expensive. Alternatives are ceiling fans and/or forced ventilation. Direct exposure to sunlight can also reduce the shelf life of commodities. Use roofing and windows that shade

the interior of the store from sunlight. Store supplies in their shipping cartons.

3. Protect storeroom from water penetration.

Water can destroy commodity supplies or their packaging. If packaging is damaged, the product is unacceptable to the client even if the commodity is undamaged. Repair the warehouse so water cannot enter.

Other measures include stacking commodity supplies off the floor on pallets (at least 10 cm off the floor and 30 cm away from walls), because moisture can seep through walls and floors and into the commodity supplies.

4. Keep fire safety equipment available, accessible, and functional.

Train employees to use it. Keep fire extinguishers accessible and in working order. Keep one extinguisher near the door and others throughout the inside of larger warehouses. Ensure that the right equipment is available— water works on wood and paper fires but should not be used on an electrical or chemical fire.

5. Store latex products away from electric motors and fluorescent lights.

Latex products, including condoms, can be damaged if they are directly exposed to fluorescent lamps. The lamps and electric motors create a chemical called ozone, which can rapidly deteriorate condoms. Move condom boxes away from these sources. Leave condoms in paper boxes and cartons.

6. Maintain cold storage, including a cold chain, as required.

Cold storage, including the cold chain, is essential for maintaining the shelf life of certain drugs and vaccines. After these items are removed from cold storage, they become irrevocably damaged. If electricity is unreliable, it may be necessary to use bottled gas or kerosene-powered refrigeration. During immunization campaigns, cold boxes or insulated coolers may be sufficient for rapid transport.

7. Limit storage area access to authorized personnel. Lock up controlled substances.

To ensure that all stock movement is authorized, lock the storeroom, limit access to persons other than the storekeeper and his/her

assistants, and verify that both incoming and outgoing stock matches documentation. Periodically perform a systematic physical inventory to verify inventory records. More than one key to the storeroom should be available to ensure that the storeroom can always be accessed. However, the second key should not be available for everyone. Keep the key in a centrally located lock box, under the control of the storekeeper's supervisor.

8. Stack cartons at least 10 cm off the floor, 30 cm away from the walls and other stacks, and no more than 2.5m high.

Note: This may not be possible in all health centers.

Use pallets to keep products off floors where they will be less susceptible to pest, water, and dirt damage. Stack pallets away from walls and far enough apart so an employee can walk completely around each pallet. This promotes air circulation and facilitates movement of stock, cleaning, and inspection. Using pallets is usually more efficient than using shelving, particularly for bulk items because they:

- Reduce the amount of unpacking for storage and repacking for delivery.
- Facilitate shipment in lot sizes.
- Are cheaper to construct.
- Hold more stock for the space they occupy.

Health centers are more likely to have shelving than pallets. Correct stacking of supplies will *avoid crushing cartons* at the bottom of a stack. Stack cartons no more than 2.5 meters high. This will also reduce potential injury to warehouse personnel. Keep commodities *away from walls to promote air circulation* and prevent cartons from moisture damage, which may occur if water condenses or penetrates walls.

9. Arrange cartons with arrows pointing up, with identification labels, expiry dates, and manufacturing dates clearly visible.

Arrows indicate that the commodity should be stored with the arrows pointing up. For example, if Depo-Provera® is stored on its side or upside down, caking will occur, making it difficult to mix for use. The identification labels make it easier to *follow FEFO*, and make it easier to select the right product.

If shipping cartons do not show either a date of manufacture or an expiration date, the date of receipt of supplies at the receiving warehouse should be clearly marked on the cartons and bin cards. Write large, easy-to-read numbers with a marking crayon. If the original markings are small or difficult to read, rewrite the manufacturing or expiration dates in large numbers.

10. Store health commodities to facilitate FEFO procedures and stock management.

Ensure FEFO is followed. Recently received commodity supplies may sometimes be *older* than the store's existing stock.

11. Store health commodities away from insecticides, chemicals, flammable products, hazardous materials, old files, office supplies, and equipment; always take appropriate safety precautions.

Insecticides and other chemicals may affect the shelf life for many products. To make the health commodities easy to access, keep other supplies away from health commodities. Some health commodities have a relatively short shelf life overall, and they must move quickly to the end user. Storing old junk may slow down access to products. Some medical procedures require the use of flammable products. Bottled gas or kerosene is used to power refrigerators, alcohol is used in sterilization, and mineral spirits is used to power Bunsen burners.

These products should be stored away from other products, near a fire extinguisher.

12. Separate damaged and expired health commodities from usable commodities, remove them from inventory immediately, and dispose of them using established procedures.

By separating these products, FEFO is more easily implemented.

By destroying damaged products immediately, more space will be available.

This task is complete after:

- All health commodities are stored according to these guidelines.

United Nations High Commissioner for Refugees	
Removing damaged and expired stock	
Nr. Of pages: 1	Procedure number: SOP D5

Task: Handling of damaged or expired drugs and other medical supplies

Completed by: pharmacist, storekeeper, clinical officer/medical assistant

Purpose: To remove unusable products from storage so they are not distributed to patients.

When to perform: Whenever damaged or expired health commodities are known or discovered.

Steps and Actions

1. Stack damaged or expired product separately from usable stocks in an unused box or on an unused shelf.

2. Write *Damaged* or *Expired Stock* on the box or shelf.

3. Note the quantity of expired or damaged stock as a loss on the appropriate *stock card* and subtract the quantity from the Quantity On Hand column.

4. If you are: Then:

At the health centre Inform the health facility manager of the quantity of expired or damaged stock and send the stock to the central medical store.

At the central medical store Inform the health coordinator of the quantity of expired or damaged stock and await orders for disposal.

The health coordinator Inform the donor of the quantity and value of expired stock and request approval for destruction.

This task is complete when:

- Damaged or expired stock has been separated from usable stock.
- Stock card has been updated.
- Appropriate authorities have been notified.

United Nations High Commissioner for Refugees	
Obtaining good quality drug products	
Nr. Of pages: 13	Procedure number: SOP Q1

1. Careful product selection

Objective: selecting safe and efficacious products with adequate stability, proper labeling and packaging and without bioavailability problems

Impact: medium

Cost: low

Sources:

- Technical documentation provided by the supplier on pharmaceutical characteristics of the dosage form
- Product samples to check drug product, labeling and packaging

Staff: health coordinator and logistics

Procedures:

** Choose dosage forms with longer shelf-life.*

- Powders for reconstitution instead of injectable liquids
- Powders for reconstitution instead of oral suspensions
- Tablets instead of capsules
- Ointments instead of creams

In general: the less water a product contains, the longer its shelf-life.

**Ask for product-specific stability studies from manufacturer whenever appropriate.*

**Avoid products exhibiting potential bioequivalence problems or ask for studies for a small number of drugs (certain heart, seizure, asthma drugs).*

Select products with packaging that can withstand rough transport and extreme climatic conditions.

- Plastic rather than glass containers for intravenous infusions, disinfectants, etc.
- Plastic tins rather than metal tins for tablets and capsules.
- Blister packages or small pack size containers where cost-effective.

2. Supplier qualification

Objective: To ensure that the company in question is a registered company, that the products offered are manufactured in compliance with Good Manufacturing Practices (GMP) and that marketing authorization in the country of origin has been obtained for the products offered. If the supplier is known to the procurement agency, evaluation of past performance is part of the prequalification.

Cost: high

Impact: high

Staff: quality-assurance pharmacist consultant or procurement agency

Procedures:

** Select competitively and transparently by: restricted tender with pre-qualification if sufficient budget.*

** For known suppliers: Analyze information available on supplier reliability.*

Information on suppliers' performance (from a supplier performance monitoring system) needs to be analyzed, and operational definitions and criteria must be developed and applied to assess the reliability of suppliers and avoid subjectivity. For example: suppliers should ensure that the drugs delivered have a shelf-life of at least 2 years at time of receipt.

Lack of explicit definitions and criteria provides rejected suppliers (as well as the donors) with the opportunity to question the integrity of the procurement process.

** For new suppliers:*

1. Verify if supplier can meet contract specifications such as:

   1.1. Purchasing of drugs from strictly GMP-compliant manufacturers (see under product qualification).

   1.2. Check strict GDP (Good Distribution Practices)-compliance of supplier's staff, procedures and infrastructure.

2. Follow procedures:

   2.1. **Assess reputation and reliability** according to other clients WITH A CHECKLIST: if bad reputation: STOP.
   If good reputation or no opinion; go to 2.2.

   2.2. **Assess supplier** based on:

      2.2.1. **Supplier questionnaire** (see annex 1 at end of this section): if unsatisfactory: STOP, if satisfactory; go to 2.2.2.

      2.2.2. **Technical visit** by health and logistics staff that checks Good Distribution Practices:

      Quality Assurance System: registration of the supplier in the country, organization, technical documents, general Standard Operating Procedures (SOP's), qualification procedure of the manufacturers (of raw material), handling of returns, complaints and product recalls, computerization, traceability, batch release, self-inspections.

      One important aspect of quality assurance is the concept of "traceability". The supplier must be able to trace the product to the finished product manufacturer, and the latter must be able to trace the ingredients to their producers, all in a transparent manner.

      Personnel: general qualification, job descriptions for key personnel, training.

      Documentation: registration, certificate of analysis.

      Warehouse: building, condition, suitability, monitoring (temperature, humidity), pest control, lay-out, product flow, distribution and control, labeling.

      If all points in 2.2.2 are satisfactory, APPROVED SUPPLIER.

3. Product qualification

Objective: to ensure that drug products purchased meet internationally accepted quality standards

Cost: high

Impact: high

Staff: quality-assurance pharmacist consultant or procurement agency

Procedures:

3.1. *Evaluate product questionnaire* (see annex 1at end of this section):

- Registration status
- Site of manufacture (origin)
- Active ingredients
- Finished product specifications
- Stability data

If available, type of therapeutic equivalence data

3.2. *Evaluate certificates:*

- Registration: Certificate of a Product
- GMP
- Analytical batch certificate from manufacturer ("certificate of analysis")

Many models of product certificates exist: the WHO-type and the non-WHO type product certificates (see annex 2 at end of this section). Products Certificates that are needed are based on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce otherwise known as the WHO Certification Scheme.

These certificates confirm that the products have been manufactured according to current GMP standards and that the manufacturer has been inspected by the national DRA and the products are approved for marketing in the country of origin. It further

certifies that all written product information has been approved by the national DRA. For products not approved for marketing in the country of origin, the reason(s) must be given.

In addition to the product certificate that provides information regarding registration status in country of origin, **registration status in country of use** should also be verified as it will influence product selection and quality assurance of a pharmaceutical product.

The **analytical batch certificate** should be asked for (at least for critical drugs[1]) to verify whether the individual batch of the drug that is purchased complies with the pharmaceutical specifications mentioned in the registration file.

3.3. *Take product samples* to check labeling and packaging

Samples that are taken during an audit are taken to look at the **general presentation** and labeling, but not for laboratory testing. Note that **many quality problems are detectable on visual product inspection and do not require testing!** E.g. crumbling tablets, particles in injectables.

Samples that are needed for **laboratory testing** are taken from the **local market** or from another agency having purchased from the same supplier. Having a supplier send a sample is not the best option for obvious reasons.

If 3.1, 3.2 and 3.3 are satisfactory, APPROVED PRODUCT.

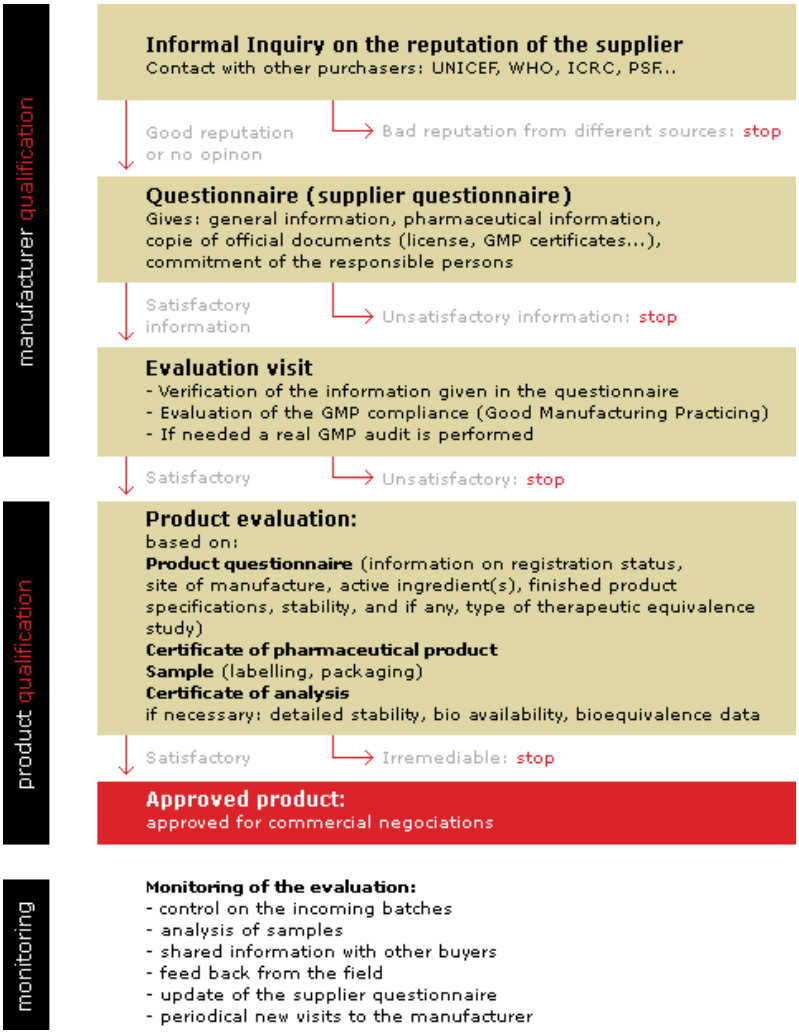
Depending on: a) these audit results, b) results of possible laboratory testing, and c) the agreement by the supplier to send all quality assurance related documents for every batch that is purchased, the suppliers are either 1. **totally** pre-qualified, 2. **partially** pre-qualified (only for certain dosage forms) or 3. **not at all** pre-qualified. In the last case, future pre-qualification is dependent on the supplier's response in points to improve.

Pre-qualified suppliers or manufacturers should be audited at least every 3 years.

1 Critical drugs may include: 1.drugs with the highest public health importance (antibiotics, antimalarials, infusions,etc), 2. drugs from new or unknown suppliers, 3. drugs with a narrow safety margin (e.g., digoxin, lithium, phenytoin, theophylline and warfarin).

Figure 1 below visualizes the procedures mentioned under 2. Supplier Qualification and 3. Product Qualification.

Figure 1: Supplier and product qualification (Transfer Belgium)



Note that in addition to procedures explained under Supplier qualification and Product Certification, an **assessment of the host country's drug policy and regulation** needs to be carried out. See annex 3 at the end of this section for suggested assessment questions. Note that WHO can also assist with providing answers. The publication "The World Medicines Situation, WHO/EDM/PAR/2004.5" also contains valuable information.

4. Contract specifications

Including specifications in a contract can help ensure that high-quality drugs are received. It is absolutely VITAL that contract specifications are made clear to the supplier and that they are enforced. UNHCR's quality standards should be clarified and suppliers made to contractually comply with them. Random checks can be carried out to verify compliance. For example, it is not realistic to have health staff of UNHCR (or implementing partners) inspect registration status of all drug products or GMP-compliance of all manufacturers. At minimum, they should carry out random checks and take action in case of non-compliance. This way, the burden of quality assurance is placed on suppliers, who: 1. should be doing this in the first place, 2. should have the technical capacity to do so (if not, UNHCR and partners should not be purchasing from them).

At a minimum, the following specifications should be mentioned in the contract (see Sample Drug Contract which follows).

- price and currency
- payment terms
- quality: Chemical and physical specifications of finished products AND raw materials, pharmacopeial standard, registration status in country of origin, batch certificates, GMP-certificate
- nomenclature, language and labeling
- storage and transport
- delivery
- packaging (suitable and sealed)
- expiry dates/shelf-life
- default
- documentation

It is vital that these conditions are not only mentioned in the contract, but that they are also being verified upon receipt of the shipment.

Example of IDA product specification (1)
S-5064 MC1. REV. no.: 00, Date: Page: 1/2
rifampicin 150 mg + isoniazid 75 mg
Form and strength
Each tablet contains 150 mg rifampicin and 75 mg isoniazid.
Producer and article code

Manufacturer:	Macleods Pharmaceuticals Ltd., India
Manufacturing site:	Plot No. 1. Near Kuldeep Nagar, Mahim Road, Palghar (W), 404 Distr. Thane Maharashtra
IDA code:	5064

Specifications
Characteristics

Colour:	Brown to reddish brown
Shape:	Round, biconvex
Coating:	Film coated
Diameter:	8.9mm~0.2mm
Thickness:	5.9mm~0.2mm
Average weight:	about 299 mg
Uniformity of Weight:	complies to BP
Disintegration:	< 30 minutes
Dissolution (both components):	75% in 45 minutes (paddle, 100 rpm, 90Oml 0.1 N HCl)

Assay at release

- rifampicin:	95.0 - 107.5 %
- isoniazid:	95.0 - 107.5 %

Assay end of shelf-life

-rifampicin:	90.0 - 107.5 %
-isoniazid:	90.0 - 107.5 %

Related substances:
- rifampicin quinone: NMT 4%
- rifampicin n-oxide: NMT 1.5%
- 3-formyl rifampicin: NMT 0.5%

```
Active raw material
- quality:       BP 2000
- Approved source
- Rifampicin:Lupin laboratories [2]
- Isoniazid: Amsal Laboratories

Storage
Store in a dry place below 25°C. Protect from light.

Shelf life
Two (2) years.

[2] Same raw material as was used to proof the
bioequivalence of rifampicin
```

Annex 1: The Model Questionnaire for Prequalification of Suppliers consists of four main sections:

MINIMAL information:

Business Information (section I),

Product Information (section 4),

Desirable information (which is a MUST if purchasing from manufacturer)

- Manufacturing Information (section 2),
- Quality (section 3)

I. Business Information

This section establishes if the company is a manufacturer or a wholesaler. It contains data to assess the size of the business in terms of staff, categories of staff, capital value, sales turnover and if the company is engaged only in export trading. Companies that do not appear viable must be avoided. It is also important to know the countries the company has

been exporting its products to. If a company has exports to countries with sophisticated drug regulatory systems, this indicates that its products comply with stringent quality standards. However, if the products are exported only to developing countries with newly-established drug regulatory systems, efforts must be directed toward ensuring that the products being offered meet quality criteria. Sales turnover from export and domestic sales help to distinguish so called “export only” companies that manufacture products that are only for export to developing countries. In such a case, the procurement agency needs to find the reason why such a company does not market its products in its country of origin. A description of the company’s quality assurance system provides useful insights on how the concept of quality assurance is understood and implemented.

Possible supplier evaluation criteria:

- the supplier holds a valid license as an importer/wholesaler;
- the supplier has been operating as a distributor for drugs and medical supplies for more than 3 years and has not ceased operations in the last 3 years;
- the supplier has clients in at least 3 regions of the country;
- sales turnover for drugs and medical supplies in the last fiscal year is at least 1000000 USD;
- the supplier has provided audited financial statements for the past 3 years;
- the average stock value for drugs and supplies in the last fiscal year is at least 80000 USD;
- annual sales to at least one customer exceeds 30000 USD;
- the supplier has a staff of at least 10 full-time employees.

II. Manufacturing Information (mainly for manufacturers)

Ideally the manufacturer should be inspected, but for some developing countries this may not be feasible due to the lack of funds and qualified inspectors. The WHO Certification Scheme can be used to ensure GMP compliance and establish if the products intended for export are approved for sale in the country of origin. It is useful to request additional information

related to the manufacture of the products to verify the information provided through the WHO Certification Scheme. This section provides information on the number and type of the professional staff involved in the manufacture of the pharmaceutical products. It discloses whether the offered products are manufactured by the company or if other manufacturers are responsible for part(s) of the total manufacturing process (manufacture under contract). **All companies involved in the manufacturing process** will have to submit information under section II (Manufacturing Information) and III (Quality Control Information). The information provided should be crosschecked with the description of the quality assurance system.

Since manufacture of pharmaceuticals involves many steps from processing of the raw materials to the late stages of packaging and labeling the products, it is important to know if more than one company is involved in the whole process and compliance with

GMP must be documented for all the manufacturing plants involved in the process.

To be able to manufacture products of acceptable quality, such products have to be produced on a routine basis. Some manufacturers have product lists containing 2000-3000 different products and it is difficult for any manufacturer to manufacture such a wide range of products routinely. Such a wide product range is also not economically viable. For a medium-sized company the ideal product range may not exceed more than 80-120 different products. This type of information can be very helpful as many companies attempt to supply any product requested by securing the products from third parties or manufacturers such products for the very first time and therefore does not have the required validation and stability studies for quality assurance. It is important to establish that the products offered have undergone bioavailability testing when required, and stability testing as is routinely required.

III. Quality Control Information (mainly for manufacturers)

This information serves to evaluate the quality assurance system of any pharmaceutical company. GMP requires companies to have quality control laboratories. Use of external laboratories is acceptable only for selected tests that require sophisticated instruments and special skills.

Efforts should always be directed towards searching for reliable suppliers of quality products and therefore, prequalification is a continuous process.

Be alert if:

- The company exports only to developing countries.
- The company's product list exceeds 200 products.
- The company has less than 100 drugs of the national essential drug list in stock.
- The company has no components of a quality assurance system suggested under 2.2.2.
- Stability studies have not been conducted.

IV. Product Information

A useful guide in formulating decisions on drug procurement is the regulatory status of a product in countries with well-established drug regulatory systems with adequate resources and capacity.

Products registered for marketing in such countries have complied with efficacy, safety and quality standards and are acceptable for procurement. Products not registered in such countries merit further investigation in light of efficacy, safety and quality issues. Many small countries require prior registration in selected developed countries as a prerequisite for the marketing authorization of products.

As previously mentioned, Certificates of Pharmaceutical Products based on the WHO Certification Scheme establishes that a product has been registered in the country of origin and its manufacturer complies with Good Manufacturing Practice (GMP) standards with regular inspections. Doubt on the authenticity of certificates may be verified by directly communicating with the issuing agency. Many countries still issue such certificates using formats different from that recommended by the WHO. In such cases the issuing agency should be requested to reissue certificates using the recommended format (see below).

Annex 2: Types of WHO and non-WHO Certificates used in drug procurement

Figure 18.6 Comparison of Certificates Used in Pharmaceutical Procurement

Type of Certificate	Uses	Limitations
WHO-type certificates		
Certificate of pharmaceutical product (WHO 1992 type) ▸ Issued by DRA in exporting country ▸ Provides licensure status of product ▸ Provides inspection status of manufacturer	▸ Essential for product licensure ▸ Ideally required for all new products ▸ Prequalification of suppliers ▸ Screening of new suppliers	▸ Is only as reliable as issuing DRA ▸ Does not provide batch-specific information
Statement of licensing status (WHO 1992 type) ▸ Issued by DRA in exporting country ▸ States that product is licensed	▸ Prequalification of suppliers ▸ Screening of new suppliers	▸ Does not provide batch-specific information
Batch certificate (WHO type) ▸ Issued by manufacturer *or* DRA in exporting country ▸ Confirms that individual batches conform to specifications ▸ Linked to certificate of pharmaceutical product	▸ Usually requested for antibiotics ▸ May be required for problem drugs	▸ Issued by few DRAs ▸ Easily falsified ▸ May require additional expense
Non-WHO-type certificates		
Free sale certificate ▸ Issued by DRA in exporting country ▸ Confirms product is sold in the country of origin	▸ Commonly used for licensure	▸ No indication that product has been evaluated for safety and efficacy ▸ No indication that product is registered for use in country of origin
GMP certificate ▸ Issued by DRA in exporting country	▸ Prequalification of suppliers	▸ Only as reliable as issuing DRA
Analytic batch certificate ▸ Issued by manufacturer ▸ Contains results of analytical tests ▸ Not linked to certificate of pharmaceutical product	▸ Postqualification of suppliers	▸ Manufacturers' certificates may be falsified ▸ Does not necessarily conform to specifications approved at time of product licensure

Source: MSH 1997

Annex 3: Assessment of drug policy, regulation and enforcement in the host-country

Policy, Legislation and Regulation

- Is there a national drug policy approved by the government? When was it last updated?
- Is there a comprehensive drug law? When was it last updated?
- Is there a functional national drug control authority responsible for the promulgation of regulations and enforcement?

Drug Selection and Registration

- Is there a system for drug registration?
- Is drug registration based on an assessment of a drug's efficacy, safety, quality, and truth of packaging information? Are pharmacological or therapeutic standards used?
- Are there different registration procedures for essential drugs, generic products, multi-source products, or imported products from selected countries?
- Is the WHO Certification scheme on quality used systematically by the drug regulatory authority?
- Is there a system for the collection of data regarding the efficacy and safety (adverse effects) of marketed drugs?

Licensing, Inspection, and Control

- Do mechanisms exist for the licensing, inspection, and control of pharmaceutical personnel and for manufacturing, distribution, and dispensing facilities?
- Do inspectors use a checklist for inspecting different types of pharmaceutical assessments?
- How many inspections were made during each of the last three years for the different types of pharmaceutical establishments?

Compliance and enforcement

- What measures exist for enforcement of pharmaceutical laws and regulations? Are they enforceable administratively or through court actions? Are statistics available about compliance and enforcement?
- During the last three years, how many drug products were eliminated from the register? How many batches of drug products were recalled from the market?
- Is there a system for reporting drug product problems? What type of and how many complaints were registered in the past three years, and what corrective actions were taken?

United Nations High Commissioner for Refugees	
Verifying the quality of shipped drugs	
Nr. Of pages: 4	Procedure number: SOP Q2

7. Inspection of Shipment

Purpose: To check:

1. Adherence to contract specifications (labeling, packing).
2. Receipt of necessary quality certificates.
3. Completeness of order.
4. Damage.
5. Quality- Physical inspection of goods (particles in injection, uniformity of appearance).

Cost: low

Impact: medium

Staff: logistics officer

Procedures:

On Receipt:

1. Count the **number of boxes** received and separate damaged and unsealed boxes from intact and sealed boxes.
2. **Inspect** all boxes for damaged or expired products. Damaged and unsealed boxes should be checked immediately and in the presence of the transporter.
3. Complete and sign the **Delivery Note** and release the transporter.
4. Send all necessary documents to **Finance** for prompt payment.
5. If appropriately trained personnel is available, take **product samples** to check for labeling, packaging and product appearance using the **checklists** below.

For labelling:

1. Labeling should be **in English** and preferably one other official language of WHO.
2. All labels should display at least the following information:
   - International Nonproprietary Name (INN) of the active ingredients
   - Dosage form
   - Quantity of active ingredient(s) in the dosage form (e.g. tablet, ampoule) and the number of units per package
   - Batch number
   - Date of manufacture
   - Expiry date (in clear language, not in code)
   - Pharmacopoeia standard (e.g. BP, USP,)
   - Instructions for storage
   - Name and address of the manufacturer
3. A printed label on each **ampoule** should contain the following:
   - INN of the active ingredient(s)
   - Quantity of the active ingredient
   - Batch number
   - Name of the manufacturer
   - Expiry date

The full label should again appear on the collective package.

4. Directions for use, warnings and precautions may be given in **leaflets** (package inserts). However, such leaflets should be considered as a supplement to labeling and not as an alternative.
5. For articles requiring **reconstitution** prior to use (e.g. powders for injection) a suitable beyond-use time for the constituted product should be indicated.

Packaging:

1. **Tablets and capsules** should be packed in sealed waterproof containers with replaceable lid, protecting the contents against light and humidity.
2. **Liquids** should be packed in unbreakable leak-proof bottles or containers.
3. **Containers** for all pharmaceutical preparations must conform to the latest edition of internationally recognized pharmacopoeia standards.
4. **Ampoules** must have either break-off necks, or sufficient files must be provided.

All shipments:

Compare the goods with the supplier's invoice and original purchase order or contract. Note discrepancies on the Delivery Report. CHECK THAT:

- Number of containers delivered is correct
- Number of packages in each container is correct
- Quantity in each package is correct
- Drug is correct
- Dosage form is correct (tablet, liquid, other form)
- Strength is correct (milligrams, percentage concentration,)
- There is no visible evidence of damage (describe)

Take a sample for testing if required.

Tablets:

For each shipment, tablets of the same drug and dose should be consistent. CHECK THAT:

- Tablets are identical in size
- Tablets are identical in shape

- Tablets are identical in color (shade of color may vary from batch to batch)
- Tablet markings are identical (scoring, lettering, numbering)
- There are no defects (check for spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- There is no abnormal odor when a sealed bottle is opened

Capsules:

For each shipment, tablets of the same drug and dose should be consistent. CHECK THAT:

- Capsules are identical in size
- Capsules are identical in shape
- Capsules are identical in color (shade of color may vary from batch to batch)
- Capsule markings are identical
- There are no defects (check for holes, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- There are no empty capsules
- There are no open or broken capsules

Parenterals:

Parenterals are all products for injection (IV liquids, ampoules, dry solids, suspensions for injection). CHECK THAT:

- Solutions are clear (solutions should be free from undissolved particles, within permitted limits)
- Dry solids for use in injections are entirely free from visible foreign particles
- There are no leaking containers (bottles, ampoules)

8. Laboratory testing

Purpose: screening of drugs before storage (either critical drugs or suspicious drugs upon receipt from supplier) or after storage.

Cost: low/medium/high (depending on type of testing)

Impact: medium

Staff: consultant pharmacist

Procedure: will not be detailed here. It will have to be developed by the consultant in consultation with TSS at HQ if any testing is to be carried out.

United Nations High Commissioner for Refugees	
Monitoring and maintaining the quality of drug products	
Nr. Of pages: 4	Procedure number: SOP Q3

9. Appropriate storage, transport, dispensing and use procedures

9a. Appropriate storage and transport

Purpose: maintaining drug quality as delivered by supplier

Cost: low-medium

Impact: medium-high (higher in extreme climatic conditions)

Staff: medical officer and logistics (supervision), storekeeper

Procedures:

- Ensure that storage premises are clean.
- Protect drug containers from direct sun.
- Temperature not exceeding 25°C (exceptionally 30°C). Install air-conditioning where necessary.
- Provide adequate ventilation.
- Monitor cold chain – keep EPI-vaccines and cool items between 2 and 8 °C, protect freeze-sensitive vaccines from freezing, check equipment and supervise staff, etc.
- Avoid overstocking.
- Items stored on shelves or in cupboards.
- All drugs stored in a predefined order (alphabetically, per dosage form, per therapeutic class).
- Containers with the nearest expiry date lined up first so as to be used first (First Expiry First Out or FEFO-rule).
- Avoid repackaging unless quality control is in place.

See SOP D4 “Storage of drugs and medical supplies”.

9b. Ensure Good Dispensing Practices

Purpose: avoid contamination and deterioration of drugs by environment, staff, insufficient packaging method and patients

Cost: low

Impact: medium (higher in extreme climatic conditions)

Staff: medical officer (supervision), drug dispensers

Procedures:

- Safe, clean and organized working environment.
- Disciplined use of effective procedures.
- Qualified and trained staff, regular performance monitoring.
- Safe and clean dispensing/ Labeling.
- Use proper dispensing containers-airtight and/or light resistant.
- Dispensing against prescription only.
- Establish the contents of a drug label (at least patient name, drug name, strength, expiry date, instructions for storage, use, dispensing date, and quantity.
- Counseling and ensuring patients' understanding.
- Good record keeping.

10. Product monitoring system

10.1. Problem reporting system

A formal system should be established which encourages health workers to report potential problems with poor product quality; ideally using pre-printed, simple reporting forms. At every level, it should be made clear who should report the perceived quality problem and to which person at the next level. All reports should be carefully assessed to establish the need for laboratory testing and appropriate follow-up action must be taken, including product recall if warranted. The reporter should be informed about the results and the action taken, even if products are not

defective, in order to encourage continued participation in the reporting program. Product defect reports and results should be recorded as part of the supplier monitoring system in both supplier as product files.

See Problem Reporting Form for Pharmaceutical Products in **Sample Forms and Records**.

10.2. Product Recalls

1. Rapid communication to facilities for quick product recall

The first step is to **recall** every batch of the same drug from the health facilities and the central pharmacy to put this batch under quarantine.

Drugs under quarantine can never be used. They will be released for use again, only if formal test results do not indicate any quality defects about the tested batch.

The recall procedure illustrates the importance of having an inventory system in place that can trace drugs back according to their lot or batch numbers (**traceability**).

2. Immediate notification of the supplier and collection of suspicious samples

For example, IDA retains samples of all distributed batches until the end of their shelf-life plus one additional year for products that are not registered in the European Union (and that are hence checked internally). This should facilitate the investigation of possible complaints. A reliable supplier always assumes full responsibility for his products and will test the suspicious product, even when it may turn out to be due to poor storage procedures and conditions. A preliminary condition is to have a functional **product problem reporting scheme** that identifies who reports what to whom e.g. a health worker in a health center reports the insolubility of penicillin procaine fortified powder for injection to the central medical store staff who in turn report the problem to the procurement office that contacts the supplier.

In case the supplier does not accept responsibility to test samples, samples for laboratory testing are collected and sent to an acknowledged **testing** facility, preferably in Europe, although in certain countries (e.g. Kenya) some private or academic institutions

also have a well-functioning quality-control laboratory. Note that the value of the stock at risk must justify testing (a relatively lower stock value in comparison with costs of laboratory testing does not justify testing). Suspicious drugs that have caused adverse reactions should always be tested however.

3. The monitoring of adverse reactions in patients that have received the suspicious drug.

   Note that **many quality problems are detectable on visual inspection and do not further require laboratory testing** (e.g. crumbling tablets, particles in injectables, oral suspensions that harden,).

SAMPLE FORMS AND RECORDS

Form F1: **Daily consumption tally sheet**

Form F2: **Monthly requisition and consumption reporting form**

Form F3: **Stock record sheet**

Form F4: **Periodic inventory report form**

Form F5: **Problem reporting form for pharmaceutical products**

Form F1: DAILY CONSUMPTION TALLY SHEET

Health Facility: _____ Date: _____ Recorded by: _____

Nr.	Drug description	Unit	Initial Stock	Quantity Dispensed														Total Dispensed	Remaining Stock

Form F2: MONTHLY REQUISITION AND CONSUMPTION REPORTING FORM

Health facility: _____ Date: _____

Request period: _____ Voucher#: _____

Nr.	Item	Unit	Closing balance	Quantity Used	Quantity Requested	Quantity Issued	Quantity Received	Remarks

Requested by: _____ Delivered by: _____

Name-Position-Signature-Date *Name-Position-Signature-Date*

Approved by: _____ Received by: _____

Name-Position-Signature-Date *Name-Position-Signature-Date*

Issued by: _____

Name-Position-Signature-Date

Form F3: STOCK RECORD

Description: ______________________________ Batch#: __________

Unit: ________________________________ Expiry date: __________

Date	Issued To/Received From	Reference	Quantity Received	Quantity Issued	Balance	Remarks/ Signature

Form F4: PERIODIC INVENTORY REPORT

Review period: _____

Location: _____ Date: _____

Item	Batch#	Expiry Date	Quantity on stock record	Quantity counted	Difference	Remarks/ Justification

Witnessed by: _____ _____

Name and position *Signature*

Reviewed by: _____ _____

Name and position *Signature*

Form F5: PROBLEM REPORTING FORM FOR PHARMACEUTICAL PRODUCTS

Reported by: _____

Sample location: _____ Date: _____

Drug description (generic name + strength)	Brand Name	Manufacturer or supplier	Batch number	Expiry date	Conditions and duration of storage	Findings

Suggested criteria for drug evaluation:

1. *Physical characteristics:* e.g. hardness, color, mixing ease for reconstitution
2. *Packaging:* expiry date, lot or batch number, package insert
3. *Labeling:* language, legibility
4. *Patient acceptability:* taste, color, size of tablet
5. *Health care provider acceptability:* e.g. is the ampoule easy to break

Guidelines for sampling:

1. Take samples from previously unopened containers
2. Minimum sample size: Tabs and caps: 100 units. Injectables (liquid and dry forms): 10 units, Syrups (liquid or dry forms): 5 units, Drugs for External use: 2 units.
3. Tab/caps must be tightly packed in plastic/glass vial (do NOT use plastic dispensing bag)
4. Enclose COMPLETE LABEL (generic name, strength, quantity, manufacturer and supplier names, lot/batch number, expiry date, date of manufacture)
5. Attach certificate of analysis where possible