



UNHCR's Essential Medicines and Medical Supplies

Policy and Guidance 2013

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ACRONYMS

EML	Essential Medicines List
GMP	Good Manufacturing Practice
IEHK	Inter-agency Emergency Health Kit
INN	International Non-proprietary Name
MDR	Multi-Drug Resistant
NGO	Non-Governmental Organization
PEP	Post-exposure Prophylaxis
PHC	Primary Health Care
PMCS	Procurement Management and Contracting Service
UNHCR	United Nations High Commissioner for Refugees
UNICEF	United Nations Children's Fund
USP	United States Pharmacopoeia
WHO	World Health Organization

INTRODUCTION

UNHCR's health programmes 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 services are provided to refugees and other persons of concern at national health centres or through health centres supported by UNHCR's implementing and operational health partners. Provision of medicines, supplies and equipment necessary for preventive and curative health services is primarily carried out through two mechanisms: centrally by UNHCR or nationally through Ministry of Health central pharmacies.

The 2013 Essential Medicines and Medical Supplies Policy and Guidance is an update of the earlier version of 2011 incorporating recent policy changes. This policy and guidance tool is designed for all UNHCR staff, notably programme officers, supply officers and Public Health Officers as well as UNHCR's health partners.

This policy contains a chapter presenting selected technical guidelines for UNHCR and partners' public health staff and pharmacists. Those technical guidelines provide detailed step by step guidance on managing procurement, storage, rational use and monitoring of medicines and medical supplies.

The Essential Medicines and Medical Supplies Policy and Guidance will remain valid until 2020. The essential medicines and medical supplies lists will be updated biennially, with the next update in 2015.

CHAPTER 1. UNHCR'S ESSENTIAL MEDICINES AND MEDICAL SUPPLIES POLICY

The UNHCR's Essential Medicines and Medical Supplies Policy provide guidance on how to ensure provision of good quality essential medicines and medical supplies in all phases of UNHCR programming.

The UNHCR Essential Medicines and Medical Supplies policy will ensure that quality essential medicines and medical supplies are available, affordable, and used rationally.

1. UNHCR will ensure implementation of the Essential Medicines and Medical Supplies Policy in all UNHCR-supported PHC programmes where medicines and medical supplies are selected, procured, distributed or used. It is UNHCR's role to ensure that UNHCR and its partners:

- 1.1 *Base* selection of medicines and medical supplies on UNHCR Essential Medicines and Medical Supplies List.
- 1.2 *Use* the international non-proprietary names (INN or generic names), not the brand name in medicine selection, procurement, and distribution.
- 1.3 *Adopt* an international procurement strategy that ensures the availability of medicines of good quality, safety and efficacy at the best value-quality price.
- 1.4 *Use* Emergency Health and Reproductive Health Kits only in the acute emergency phase to meet the needs of a population with disrupted or no access to functioning health facilities.

- 1.5 *Assess* specific health needs, after the acute emergency phase is over, to set-up a functioning medicine management system that includes the UNHCR essential medicines list, standard treatment guidelines, a solid medicine procurement system and proper medicine distribution procedures.
- 1.6 *Assure* medicine quality during the procurement process through ensuring:
 - 1.6.1 The quality of the manufacturer - respect of Good Manufacturing Practices (GMP) by providing a valid GMP certificate.
 - 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, labelling, appearance, packing and shelf life inspection, chemical analysis). It is the responsibility of the medicine distributor to supply only medicines from GMP-compliant manufacturers and medicines that are registered in the country of destination.
- 1.7 *Implement* proper medicine storage and distribution procedures throughout every level of the supply chain to ensure adequate quality of medicines and supplies at the end-user level.
- 1.8 *Take* appropriate measures complying with national and/or international guidelines for the timely and safe disposal of expired and unwanted medicines and other medicine-related waste management in a manner that does not jeopardize public health.
- 1.9 *Support* the rational use of medicines 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 *Strike* a balance between preventive and curative components of the health programmes through health and hygiene education.

2. UNHCR will follow its obligation of providing good quality essential medicines with an acceptable range of shelf life, and adopt the interagency guidelines for medicine donations¹.

3. UNHCR will uphold the medicine management cycle by applying the following management support measures:

- 3.1 *Aim* to incorporate sustainability through a steady and reliable medicine budget.
- 3.2 *Provide* local capacity-building and staff development training in managing medicines and rational medicine use for UNHCR staff and health partners through monitoring, field visits and short training courses.
- 3.3 *Ensure* that important logistical data like inventory and consumption data are integrated in the health information system and used are for proper procurement planning.
- 3.4 *Ensure* that all staff and partners are well oriented and adhere to the rationale and content of the essential medicines policy.

¹ Guidelines for Medical Donations – Revised 2010:
http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf

CHAPTER 2. ESSENTIAL MEDICINES SELECTION

Key points to remember

- Rational medicine selection leads to a better supply, lower costs, rational prescription and use of medicines.
- Selection of medicines and medical supplies in UNHCR operations should primarily be based on UNHCR's Essential Medicines List (EML) adapted to national standards.
- Any item that is not included in the EML could only exceptionally be ordered using the form in annex 1 with explicit justification and authorisations of the relevant officers.
- The UNHCR EML has been developed after cross-referencing with the World Health Organization (WHO) Model List of Essential Medicines and will be updated regularly.
- Selection should be based on the basic health needs of the target population.
- The standard treatment guidelines, reflecting the EML, should be used in conjunction with standard symptom/disease definitions.

2. 1. INTRODUCTION

Essential medicines play a crucial role in the prevention and control of diseases. UNHCR has therefore developed an EML, based on WHO's essential medicine list². The rationale for selecting a limited number of essential medicines is that it will lead to:

1. A reliable supply:
 - a. Easier procurement, storage and distribution
 - b. Adequate stocks
 - c. Better quality assurance
 - d. Easier dispensing

2 WHO Model List of Essential Medicines, March 2010.
http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf

2. Rational prescribing:
 - a. More focused training
 - b. More experience with fewer medicines
 - c. No irrational treatment alternatives available
3. Reduced costs (more competitive prices through increased competition).

4. Rational patient use:
 - a. Increased adherence to treatment
 - b. Focused education
 - c. Reduced confusion
 - d. Increased availability

It should be emphasized to prescribers that an EML is not designed to restrict prescriber freedom but to increase access to essential medicines. Medicines not included in UNHCR's EML can be requested on an exceptional basis using a special form (see Annex 1).

2.2. CRITERIA FOR MEDICINE SELECTION

2.2.1. Emergencies

During the emergency phase of a refugee influx (usually the first 2-3 months) medicine procurement is streamlined by the immediate provision of Emergency Health Kits. 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 can take place.

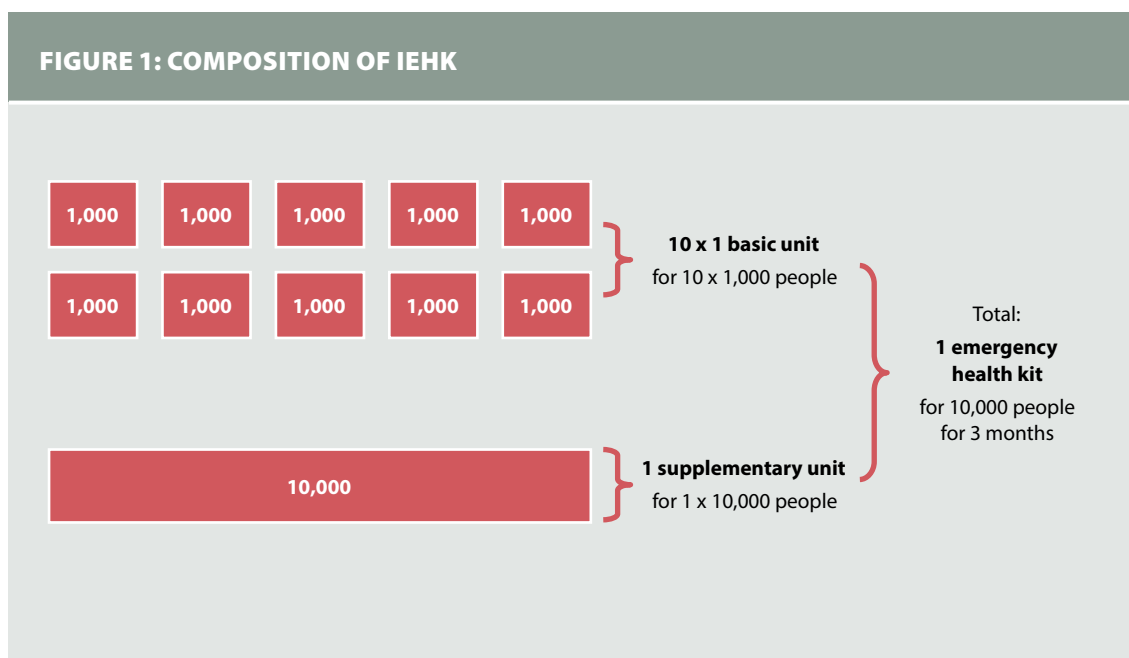
The Inter-agency Emergency Health Kit (IEHK)

The IEHK was developed by WHO in consultation with UNHCR, non-governmental organisations (NGOs), the International Federation of Red Cross and Red Crescent Societies and other UN agencies, and is updated every four years. The latest version is IEHK 2011³.

The IEHK is designed principally to meet the first PHC needs of a displaced population without medical facilities during an acute emergency. The IEHK consists of two different sets of medicines and medical devices, named a *basic unit* and a *supplementary unit*. To facilitate distribution to smaller health facilities on site, the quantities of medicines and

3 The Interagency Emergency Health Kit 2011: http://whqlibdoc.who.int/publications/2011/9789241502115_eng.pdf

medical devices in the basic unit have been divided into 10 identical units for 1,000 people each. One kit consists of 36 cartons, weighs 1,043 kg and occupies 4.8 m³ space. Please note that IEHK does not cover all Reproductive Health needs of the affected population.



Basic unit

The basic unit contains essential medicines and medical devices for PHC workers with limited training and is designed to be used at health post/health centre level. It contains oral and topical medicines, none of which are injectable.

Supplementary unit

The supplementary unit contains medicines and medical devices for a population of 10,000 persons and is to be used only by professional health workers or physicians. The supplementary unit does not contain any medicines or medical devices from the basic units. The supplementary unit should only be used together with one or more of the basic units at the field hospital level.

Both units contain malaria modules and the supplementary unit also contains Post-exposure Prophylaxis (PEP) kit. Some suppliers still consider them separate units needing explicit inclusion during ordering process.

Some international suppliers have a permanent stock of IEHK ready for shipment within 24 hours.

Reproductive Health Kits

Reproductive Health Kits for Crisis Situations⁴ have been designed by members of the Inter-Agency Working Group on Reproductive Health to complement the IEHK. The Reproductive Health Kits are available through UNFPA (table 1; see Reproductive Health Kits for Crisis Situations UNFPA updated 2010). UNFPA might provide these supplies to UNHCR operations as part of the Memorandum of Understanding between UNHCR and UNFPA.

TABLE 1: REPRODUCTIVE HEALTH KITS FOR CRISIS SITUATIONS, 2010 EDITION

Block 1 : KITS SERVING THE NEEDS OF 10 000 PEOPLE FOR 3 MONTHS	
Kit 0	Administration/training supplies
Kit 1A	Male condoms
Kit 1B	Female condoms
Kit 2A	Clean delivery, individual, for mother
Kit 2A	Clean delivery, individual, for attendants
Kit 3	Rape treatment: Basic treatment after rape, including treatment for children
Kit 4	Oral and injectable contraception
Kit 5	Treatment of sexually transmitted infections
Block 2 : KITS SERVING THE NEEDS OF 30 000 PEOPLE FOR 3 MONTHS	
Kit 6	Clinical delivery assistance (A and B)
Kit 7	Intrauterine devices
Kit 8	Management of miscarriage and complications of abortion
Kit 9	Suture of tears (cervical and vaginal) and vaginal examination
Kit 10	Vacuum extraction delivery
Block 3 : KITS TO BE USED AT THE REFERRAL/SURGICAL OBSTETRIC LEVEL SERVING THE NEEDS OF 150 000 PEOPLE FOR 3 MONTHS	
Kit 11A	Referral level kit for reproductive health: Reusable equipment
Kit 11B	Referral level kit for reproductive health: Drugs and disposable equipment
Kit 12	Blood transfusion kit

⁴ Inter-agency reproductive health kits for use in crisis situations, 5th edition, 2011. http://www.unfpa.org/webdav/site/global/shared/procurement/06_for_customers/02_gccp-erhkits/RH%20Kits%20Manual%202011.pdf

In an emergency, delivery of the reproductive health kits will take between 2–7 days after finalization of the budget allocation.

In addition, vaccine and nutritional emergency kits are available. However, in almost all instances, vaccines are provided locally through Ministry of Health with support from UNICEF and WHO.

For continued access to antiretroviral treatment in the first phase of an emergency, it is important to ensure that refugees and other persons of concern to UNHCR are included into national HIV treatment programmes⁵. Where this is not feasible, appropriate discussion with the Senior HIV Officer and the relevant bureau in headquarters is required before UNHCR procures antiretroviral medication.

2.2.2. Post-Emergency Settings

IEHK and reproductive health kits are for use only in the early phase of an emergency. These kits are neither designed nor recommended for re-supplying existing health care facilities.

Normal non-emergency lines of procurement for medicines and medical supplies must be planned and set up already during the emergency phase so that a smooth and timely transition takes place.

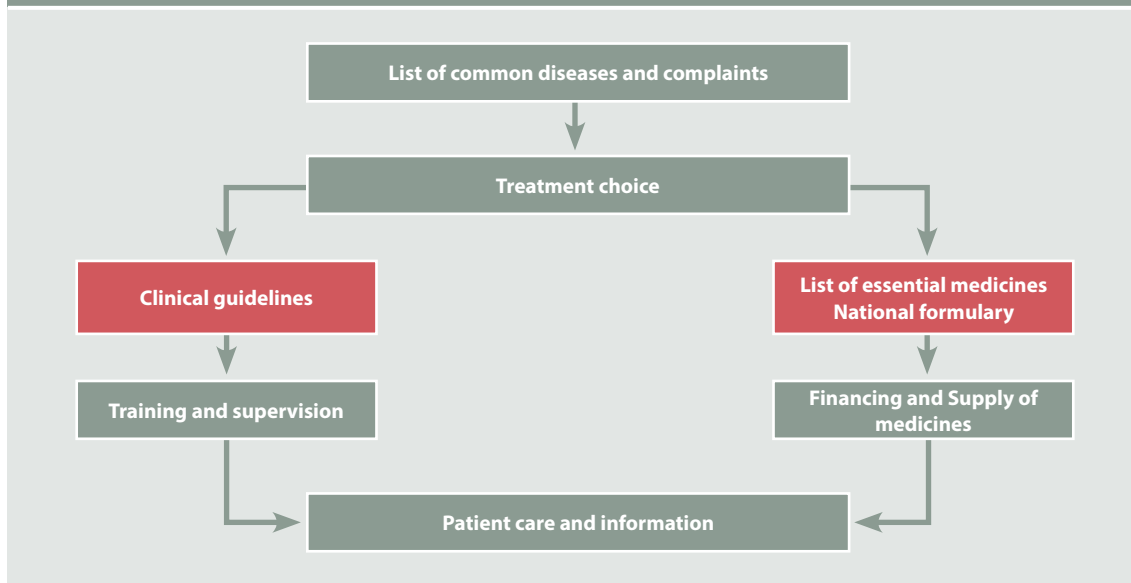
The choice of medicines depends on many factors. The most important are:

Relevance to pattern of prevalent diseases among refugees

In PHC settings, a disease or health problem-based approach is more practical than a medicine-based approach. The design of local *treatment guidelines* and the design of the EML 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 medicines or to various forms of non-medicine treatment. This choice of treatment can be the basis of two important documents: the EML 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).

5 UNHCR Antiretroviral medication policy for refugees, 2007: <http://www.unhcr.org/45b479642.html>

FIGURE 2: 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
http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.2.pdf

Suitability for use by health workers in the types of health facilities established

The choice of medicines 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 health care system before deciding where individual medicines will be made available. Every programme should have an EML, but this does not mean that all medicines should be made available at every level of care (health post, clinic, referral hospital). Under normal conditions, the number of medicines 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 centre) due to lack of resources, need, and poor geographical planning. In this case, a pragmatic approach based on the staff’s capacity and expertise should be used to ensure sufficient access to essential medicines.

Local considerations

- The effects of local diseases or conditions on effectiveness of medicine (e.g. malnutrition, liver disease);
- Local or regional differences in sensitivity and resistance of microorganisms, in the case of anti-infective medicines;
- Regional differences in climate, topography, 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).

Consideration should be given before including medicines that are sensitive to heat, light or humidity in a setting where these factors are difficult or impossible to control. Choosing the most stable dosage form for a particular setting is part of the overall medicine 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.

2.3. THE ESSENTIAL MEDICINE LISTS

2.3.1. The Global UNHCR Essential Medicine List

The UNHCR EML is available in UNHCR intranet⁶ and is updated periodically.

UNHCR EML classifies medicines as follows:

- **Emergency Kits**
 - IEHK basic
 - IEHK supplementary
 - Interagency reproductive health kits
 - Diarrhoeal disease kit
 - Immunization kit
- **Medication**
 - Oral medicines (including inhalation, sublingual, suppository, vaginal)
 - Injectables medicines
 - External use medicines (incl. eye) and antiseptics
 - Infusions
 - Vaccines, immunoglobulins
 - Psychotherapeutic + anticonvulsants + antiparkinsonians
 - Antituberculosis medicines

⁶ https://intranet.unhcr.org/intranet/unhcr/en/home/protection_and_operational/Public_Health___HIV/health/guidance/medication.html

- Contraceptives
- Antimalarials

The EML 2013-2015 includes the therapeutic action class(es), administration route, specifications for restricted use, presentation/strength, dosage forms, packing unit, need for cold chain (2-8°C) or Cool place (8-15 °C) for the different medicines are also included.

Important:

Vaccines, antiretroviral medications and second line antituberculosis medications are considered essential medicines, and refugees and other persons of concern to UNHCR should have access to these under all circumstances.

These medicines are not included in the UNHCR's EML list (except the PEP kit, which is part of IEHK) because they are supplied by the national expanded programmes on immunization through Ministry of Health in collaboration with WHO or UNICEF and the national HIV and Tuberculosis programmes.

These medicines can be ordered, but only after appropriate discussion and approval from the Regional or Global Senior Public Health Officer and the relevant bureau at headquarters.

2.3.2. Developing a National Essential Medicines List

The EML developed for a UNHCR PHC programme should be based on UNHCR's EML adapted to national standards. National standards are those established by the respective Ministry of Health. A national standardized EML may have been established. Some countries do not allow importation of medicines that are not included in the national EML, thus it is important to obtain this list.

Where a national list is not available or incomplete (frequent in post-conflict settings), UNHCR's EML is the most appropriate reference.

The national medicines list has legal status, whereas UNHCR or WHO EMLs only remain a guideline until a country's health authorities officially adopt it. Any deviation from the national EML should be discussed with the local health authorities.

The UNHCR Country Public Health Officer together with the public health staff of partner agencies and/or Ministry of Health should take the lead in the development or review of the EML, essential medical supplies and standard treatment guidelines in coordination with relevant local authorities and other agencies. Where there is no country-based UNHCR Public Health Officer, the UNHCR Programme Officer should assume this responsibility in coordination with the Regional or Headquarters Public Health Section.

Medicines not included in UNHCR's EML can be requested but on an exceptional basis and using a special form. It should be an exceptional measure needing strong and evidence-based justifications (see Chapter 3 of this manual on medicine procurement). The special request form (see Annex 1) should be used after appropriate discussion with the Regional or Headquarters Public Health Section.

2.3.3. Developing Local Standard Treatment Guidelines

The introduction of standard treatment guidelines, used in conjunction with standard symptom/disease definitions, is compulsory in all refugee health programmes. This is particularly necessary given the often large number of agencies and personnel providing refugee health services, the rapid turnover of staff, and the wide range of health workers involved. These treatment 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.

2.4. MEDICINE DONATIONS

Guidelines for medicine donations in emergencies⁷ have been developed by the WHO in cooperation with UNHCR and other major international agencies active in humanitarian programmes. The four core principles that form the basis of good medicine donation practice are:

1. Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged.
2. Donations should be given with due respect for the wishes and authority of the recipient country, and in conformity with the government policies and administrative arrangements of the recipient country.

7 Guidelines for Medical Donations – Revised 2010: http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf

3. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.
4. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

All above principles apply to UNHCR and its partners where medicine donations are being considered, but also where UNHCR is considering donating medicines. Medicine donations to emergency operations should be avoided altogether, and these operations should be supplied with the IEHK (see above). All planned medicine donations to UNHCR operations or from UNHCR operations to national health services or partner, should be cleared by the Regional or Headquarters Public Health Section.



Rwanda / Congolese refugees / Some refugees collect their medicines in the pharmacy of the Health Center in Kiziba camp. The Centre provides preventive and curative health care to the refugees and the local population surrounding the camp. / UNHCR / Frederic NOY / October 2012

CHAPTER 3. GUIDANCE FOR THE PROCUREMENT OF MEDICINES AND MEDICAL SUPPLIES

Key points to remember

- Medicine procurement should be limited to an EML defined by the recognized country health authority, or based on UNHCR's EML adapted to national standards.
- Medicines not included on a validated EML can only be requested on an exceptional basis by using a special form. Approval should be given by the UNHCR Regional Public Health Officer with subsequent clearance by Headquarters Public Health Section.
- It is UNHCR's policy to principally bid and purchase medical products through international suppliers.
- Local/regional procurement should only be exceptional, where quality is guaranteed. This requires special authorization from Procurement Management and Contracting Service (PMCS) Budapest and UNHCR Regional Public Health Officer with final clearance from Headquarters Public Health Section and should be limited to a bare minimum.
- The procurement and distribution systems must achieve the lowest possible 'best-value quality' cost and not the lowest bidder principle provided the pharmaceutical company provides a good manufacturing practice (GMP) certificate.
- The actual purchase price of medicines is important but is not the only reason for choosing a supplier or achieving the lowest possible total cost. Hidden costs due to poor product quality, poor supplier performance, low coverage rate or short shelf-life must always be taken into account.

3.1. INTRODUCTION

Pharmaceutical procurement is a structured process that involves many steps. Efficient procedures should be in place to:

- a) select the most cost-effective essential medicines to treat commonly encountered diseases;

- b) quantify the needs;
- c) pre-select potential suppliers;
- d) manage procurement and delivery; e) ensure good product quality and
- f) monitor the performance of suppliers and the procurement system.

UNHCR's medicine and medical supplies procurement chapter does not replace UNHCR's general procurement guidance as specified in UNHCR Manual, Chapter 8 on Supply Chain Management⁸ as well as UNHCR's Procurement Guidelines for Implementing Partners⁹. The specific medicine procurement guidance outlined below needs to be used as a supplement to the general UNHCR procurement regulations to comply with UNHCR's accounting and auditing procedures and standards.

3.2. STRATEGIC OBJECTIVES FOR GOOD PHARMACEUTICAL PROCUREMENT

There are four strategic objectives of good pharmaceutical procurement¹⁰

1. Procure the most cost-effective medicines in the right quantities

Procedures must be in place that accurately estimates quantities to ensure continuous access to the medicines selected without accumulating excess stock or having shortage.

2. Select reliable suppliers of high-quality products

Reliable suppliers of high-quality products must be (pre) selected. UNHCR recommends international bidding and international procurement as the standard.

3. Ensure timely delivery

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.

4. Achieve the lowest possible best value-quality cost

The procurement and distribution systems must abide by the best-value for money principle, and not the "lowest bid" principle on the basis that the pharmaceutical

8 UNHCR Manual, Chapter 8 on Supply Chain Management: https://intranet.unhcr.org/intranet/unhcr/en/home/executive_direction/official_policies/unhcr_manual/chapter_8__supply.html

9 UNHCR Procurement Guidelines for Implementing Partners, 2004: <http://www.unhcr.org/pages/49c3646c4a6.html>

10 WHO Operational principles for good pharmaceuticals procurement 1999: <http://www.who.int/3by5/en/who-edm-par-99-5.pdf>

company could provide a GMP certificate. Differences exist in terms of “reliability” between national or international GMP certificates, so the “best value-quality” principle is of paramount importance.

The price of the medicines is not the only component to achieve the lowest possible total cost. There are four main components which have equal importance:

- The actual purchase price of the medicines
- Hidden costs due to poor product quality, poor supplier performance or short shelf-life. These hidden costs are the most perfidious ones and should be always carefully taken into account.
- Inventory holding costs at various levels of the supply system
- Operating costs and capital loss by management and administration of the procurement and distribution system.

The quality of the medicines purchased should not be compromised under any circumstances. Unlike other commodities, medicines must always be purchased using “Best Value-Quality” criteria instead of “Lowest Bid” criteria



Namibia / Congolese refugees / This picture is part of a UNHCR photography project, carried out with the assistance of a professional photographer Brendan Bannon. The project is entitled “Do you see what I see?”, and gives refugee children the opportunity to learn how to use a camera and have the opportunity to give the world a vivid, emotional look into their lives. “See refugee life through the voices and visions of children, who are experts on their own lives.” - B. Bannon / UNHCR / B. Bannon

3.3 MEDICINE PROCUREMENT IN UNHCR

3.3.1 Medicine Procurement Policy

It is UNHCR's policy to bid and purchase medical products through international suppliers.

These international suppliers have developed the expertise to ensure controlled quality at reasonable prices. This will also avoid procuring counterfeit products which have flooded many unregulated markets.

Local/regional procurement is to be only exceptionally used with required authorisation. Local/regional procurement should be limited to a bare maximum of 5% for the entire medicine procurement in the operation.



Zambia / Angolan refugees / Nangweshi camp / The camp clinic, which treats both refugees and Zambians living nearby as part of a Zambia Initiative to improve conditions for everyone in the refugee-impacted areas. This should improved prospects for the local integration of those who do not return. / UNHCR / J. Redden / 10 March 2006

**Local/regional procurement requires special authorization from
UNHCR PMCS Budapest**

AND

UNHCR Public Health Section

**Local/regional procurement will only be authorized where specific
criteria are met.**

**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 should only be considered where international procurement is impossible due to legal barriers in the country or it does not meet the programme objectives (e.g. exit strategy enacted and programme is being handed over to Ministry of Health/local partners). The specific criteria that should be met under these circumstances are:

- Selection of supplier through a transparent bidding process. The committee deciding on the contract should consult the Public Health Section. The same applies if the order is managed by UNHCR implementing partners.
- Local suppliers must be pre-qualified by a committee of managers, technical staff and a pharmacist before being eligible to bid. Collaboration with other UN agencies (WHO, UNICEF) may be sought.
- Pre-qualification should be checked for following: 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; and test purchases.
- Suppliers should be licensed with the government.
- The primary manufacturer is 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. The product is registered in the country of import.
- The product is accompanied by Certificate of Pharmaceutical Product.

- Batch certificates of selected medicines 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 medicines or IV fluids.

In countries where these local/regional procurement specific criteria cannot be met, international procurement is the ONLY option and this will need to be emphasized with the national officials who may argue otherwise.

3.3.2 Quantification Guidance for Medicine Procurement

Quantification is the process of estimating the quantities of medicines and medical supplies for annual procurement. The accuracy and quality of an estimation of medicine requirements will depend on the accuracy and quality of the information available.

a) Consumption method

Past consumption is the most reliable way to predict and quantify future demand, provided 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 medicine 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 medicines 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.

b) Morbidity method

In cases where no reliable past consumption information exists (such as new programmes), the morbidity-based technique may be used to estimate procurement requirements.

c) Combination of methods

The morbidity-based 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 programmes with a high seasonal variation in consumption of certain medicines such as antibiotics or antimalarial.

There are different tools available to help estimate the needs of essential medicines. Quantimed¹¹ is a tool developed by Rational Pharmaceutical Management Plus Project, a project of Management Sciences for Health (MSH), for the quantification of pharmaceuticals, including costs, for essential medicines and supplies needed in health programmes. It can be used for a single health facility, a national programme, or a group of geographic or administrative areas. The tool can use the past consumption, morbidity, and proxy consumption methods for quantification, singly or in combination. Quantimed is based on a Microsoft Access database. The tool and its accompanying documents are available in the reference link¹².

3.3.3 Estimating the Budget for Medicines

In the future, prices in US\$ will be indicated for each item in UNHCR's EML, so that it can be used to estimate the annual medicine and medical supply budget.

11 http://deliver.jsi.com/dlvr_content/resources/allpubs/factsheets/SoftFact_Quan.pdf

12 https://intranet.unhcr.org/intranet/unhcr/en/home/protection_and_operational/Public_Health___HIV/health/guidance/medication.html?cq_ck=1373367760765

3.4 PROCUREMENT FUNCTIONS

A suggested minimum frequency of certain procurement procedures is presented in table 2 below.

TABLE 2. ROUTINE PROCUREMENT FUNCTIONS					
	Every 2 years	Annually	Quarterly	Monthly	Responsible
Revision of essential medicine list	X				Public Health Section in HQ with input from Regional Public Health Officers
Establish procurement plan		X			Country Operation (Supply and Programme Section)
Global Tender	X				PMCS Budapest
Pre-qualification of suppliers	X				Public Health Section HQ / PMCS Budapest / Contract Committee
Request budget for medicines and supplies		X			Country Office
Essential medicine monitoring				X	Health Partner
Inventory exercise central store			X		Health Partner
Collection and analysis of key procurement performance indicators		X			UNHCR Public Health Officer + health partner

3.4.1 Ordering Procedures for International Procurement

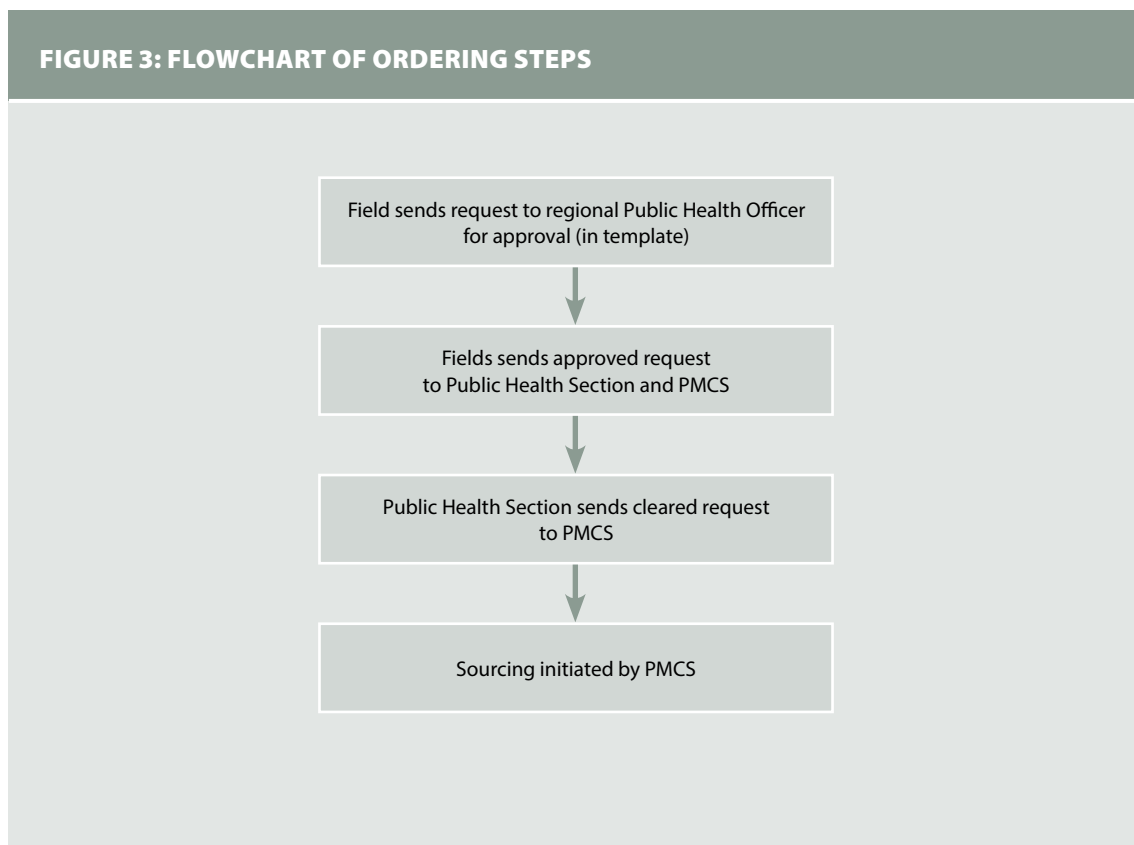
The following steps need to be followed for international procurement:

1. An order for medicines and medical supplies is prepared in the field by the public health staff of the partner agency in coordination with UNHCR's country Public Health Officer (where present).
2. In country operations, with multiple partner agencies delivering health programmes, the most cost-effective approach is to keep the medicine and supplies budget with

UNHCR and procure centrally for the entire programme for all partner agencies at the same time, once per year.

3. The order should then be discussed with the UNHCR Programme Officer to confirm the budget.
4. The completed and correct filled form in Annex 1 should be filled for all orders that are not on UNHCR's EML.
5. The regional public health officer must approve the order before submitting to PMCS and Public Health Section.
6. The Public Health Section must confirm by email that the order has been cleared and this verification must be sent with the order to PMCS in Budapest with a copy to the respective desk officer and programme officer and Public Health Officers at country and regional levels.
7. PMCS will then process the order. For planning purposes it is important to bear in mind that the time between order of essential medicines and medical supplies with PMCS and the delivery at country level will take an average of 12 weeks after the country has raised the requisition.

Following figure demonstrates the process.



To ensure efficient delivery, PMCS will endeavour that all orders are placed on Delivery at Place (Incoterms® 2010)¹³, where the delivery remains the responsibility of the supplier until arrival at the specified place. Under these conditions the supplier is responsible for insurance and all costs associated with damaged or missing goods. However, UNHCR needs to assist in the customs clearance process by providing the necessary importation VISA (if required) and exemption certificates. Since medicines are very attractive commodities, procedures on receiving the medicines should be carried out promptly and thoroughly.

To ensure a timely payment, Goods should be inspected upon delivery and delivery Note should be duly signed if consignment is in accordance with the packing list. In case the goods are still under clearance, it should be clearly marked on the Delivery Note, "Not inspected, still in Customs". This will be immediately followed by the creation of a receipt in MSRP which will enable payment to supplier. The MSRP receipt will be communicated to PMCS which will process payment. 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 section (PMCS) in Budapest should be informed immediately if anything is missing or damaged.

3.4.2. Receipt and Inspection of Medicine and Medical Supply Consignments upon Arrival

On reception at the warehouse, the number of boxes and the state in which they have been 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 list¹⁴. Ensure that the items delivered correspond to the items ordered, and that the quantities conform to those on the Delivery Note.

13 <http://www.iccwbo.org/products-and-services/trade-facilitation/incoterms-2010/>

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

A thorough inspection based on predefined criteria is essential for quality assurance and as a precursor to any insurance claim. See the checklist in table 3 below.

TABLE 3: INSPECTION CHECKLIST FOR MEDICINES RECEIVED IN THE WAREHOUSE (SOURCE: MSH 1997)

<p>Labelling</p>	<ol style="list-style-type: none"> 1. Labelling should always be in English and if required one other official language. 2. All labels should display at least the following information: <ul style="list-style-type: none"> ➤ International Non-proprietary 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: <ul style="list-style-type: none"> ➤ INN of the active ingredient(s) ➤ Quantity of the active ingredient ➤ Batch number ➤ Name of the manufacturer ➤ Expiry date <p>The full label should again appear on the collective package.</p> 4. Directions for use, warnings and precautions may be given in leaflets (package inserts). However, such leaflets should be considered as a supplement to labelling 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.
<p>Packaging</p>	<ol style="list-style-type: none"> 1. Tablets and capsules should be packed in sealed waterproof containers with replaceable lids, 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.
<p>Expiry date/ shelves-life</p>	<p>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, and also on single containers put on the shelf. In case the expiry date is unsatisfactory (calculate consumption until expiry date), return to supplier.</p>

**TABLE 3: INSPECTION CHECKLIST FOR MEDICINES
RECEIVED IN THE WAREHOUSE (CONT.)**

**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
- Medicine 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 medicine and dose should be consistent. CHECK THAT:

- Tablets are identical in size
- Tablets are identical in shape
- Tablets are identical in colour (shade of colour 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 odour when a sealed bottle is opened

Capsules:

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

- Capsules are identical in size
- Capsules are identical in shape
- Capsules are identical in colour (shade of colour 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)

Discrepancies, variations, and damages 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”).

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

After receiving procedures are completed, the medicines 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.

Uganda / Congolese refugees from DRC / Refugee woman
in the health centre with her young child in Nakivale
Refugee Settlement, Mbarara District, South West Uganda
/ UNHCR / H. Coussidis / 2006



CHAPTER 4. RECOMMENDED RESOURCES FOR THE MANAGEMENT AND USE OF ESSENTIAL MEDICINES

GUIDELINES FOR THE STORAGE OF ESSENTIAL MEDICINES AND OTHER HEALTH COMMODITIES, JOHN SNOW INC./DELIVER, 2003

This pocket guide is designed for those managing or involved in setting up a storeroom or warehouse. The guide contains written directions and clear illustrations on receiving and arranging commodities; special storage conditions; tracking commodities; maintaining the quality of the products; constructing and designing a medical store; waste management; and resources. It was written to meet the needs of district-level facilities; however, the guidelines and information it contains apply to any storage facility, of any size, in any type of environment.

This guide is available in different languages, including English, French, Arabic, Bangla, Chinese, Spanish, Russian and Urdu in the following page:

http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/

WHERE THERE ARE NO PHARMACISTS: A GUIDE TO MANAGING MEDICINES FOR ALL HEALTH WORKERS TWN AND HEALTH ACTION INTERNATIONAL ASIA PACIFIC, 2010

Where there are no pharmacists explains how to order medicines, store them, prepare them, dispense them and use them safely and effectively. This book provides advice on all these aspects for people working with medicines as well as information to help communities benefit from the use of medicines. It provides guidance for anyone who is doing the work of a pharmacist; anyone who sells, dispenses, prepares, manages, or explains to others how to use medicines.

How to Order the Book

Contact Third World Network at 131 Jalan Macalister, 10400 Penang, Malaysia.

Tel: 604-2266159

Fax: 604-2264505

Email: twnet@po.jaring.my for further information

MDS-3: MANAGING ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES, MANAGEMENT SCIENCE FOR HEALTH 2012

Managing Drug Supply (MDS) is the leading reference on how to manage essential medicines in developing countries. MDS was originally published in 1982. It was revised in 1997 with over 10,000 copies distributed in over 60 countries worldwide. The third edition, MDS-3: Managing Access to Medicines and other Health Technologies reflects the dramatic changes in politics and public health priorities, advances in science and medicine, greater focus on health care systems, increased donor funding, and the advent of information technology that have profoundly affected access to essential medicines over the past 14 years.

Individual chapters of this book could be downloaded from the following page:

<http://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies>

ESSENTIAL DRUGS – PRACTICAL GUIDELINES, MÉDECINS SANS FRONTIÈRES 2013

These guidelines are designed to give practical, concise information to physicians, pharmacists and nurses on the use of essential medicines.

This book could be downloaded from the following page

http://www.refbooks.msf.org/msf_docs/en/MSFdocMenu_en.htm

RH KITS SHELVING INSTRUCTIONAL VIDEO, UNFPA 2011

This video demonstrates practical ways to store different components of the Reproductive Health Kits. The video is available in English and French from the following web page:

<http://www.iawg.net/resources/rhkits.html>

ANNEX 1

ORDER FORM REQUEST FOR ITEMS NOT INCLUDED ON THE UNHCR ESSENTIAL MEDICINES LIST

PLEASE COMPLETE ALL RELEVANT SECTIONS OF THIS FORM:

Note: Procurement and delivery time will be longer than medicines on the Essential
Medicine List.

Country: _____ Location: _____
Camp: _____ Refugee population: _____

1. Generic name: _____

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

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 medicine:

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 medicine:

7. Specify conditions under which the medicine will be used:

- Camps(s) where it will be used:
- Level(s) of health worker(s) authorized to prescribe medicine:
- Health facilities in which it will be used:
- Access to personnel skilled in use of medicine:

(Name and title of person making request)

(Signature)

(Date)

(Organization/Agency)

NB. This form is to be submitted for approval of Regional Public Health Officer through the UNHCR Country Office and must be cleared by Public Health Section.

