Procurement and Sourcing of Medical Items

Unlike sourcing many routine humanitarian relief items – such as durable goods or NFIs – the procurement of health items comes with many of its own caveats.

Registration of Pharmaceutical Products - In most countries, companies that produce, import and sell pharmaceutical products are required to obtain prior evaluation and approval from a governing body, often called the national drug regulatory authority (NDRA), or a stringent regulatory authority (SRA). Products to be registered should be proven to be effective, safe, and of good quality. Registration is often also called Marketing Authorisation (MA). Due to the fact the quality of the medications is checked as part of the registration process, each brand (produced by different manufacturers) is registered independently. In most cases, not only the product, but also the packaging, is registered. National Marketing Authorisation often have limited validity and must be renewed with certain periodicity. Pharmaceuticals intended for import as part of the humanitarian assistance (for non-commercial use purpose) may be exempted from registration of pharmaceutical product in the host country. It is important not to assume this will be the case and verify details with respective authorities in country prior to the dispatch of goods.

Essential Medicines List - Each country defines its own essential list of medicines (EML), aiming to satisfy the priority health care needs of its own population. Essential medicines are selected with in reference to disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be always available within the context of functioning health systems in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford.

The World Health Organisation (WHO) maintains what it calls the "Model List of Essential Medicines", a list of formally recognised medications that WHO reviews and endorses for usage for populations around the world. The model list of essential medicines is reviewed every few years, and medication is either added or removed based on advice derived from the most up to date clinical data. The contents of the model list are searchable via an online database. The model list of essential medicines is not the definitive list of usable drugs in all contexts, nor is the list of all approved drugs – it merely serves as guide for national authorities, manufacturers and importers to reference. More information on now national level essential medicines are developed can be found in WHO's guide on the Selection of Essential Medicines at Country Level.

The majority of countries in which humanitarian organisations operate have adopted at least part of the model list of essential medicines, but it is very common for countries or national authorities to add or remove medications to the list to cover their own importation needs. Countries may choose to add or remove medications for sociocultural or political reasons, and some countries or regions have extremely robust and complex regimes for defining acceptable medications and dosages.

> *"Many pharmaceutical products can be registered for use in a country, but they may not be on the national EML, or on the standard treatment guidelines. Products not on the EML, but used by the private sector, can still be registered if their efficacy, safety, and quality are acceptable to the regulatory authority. Failure to follow the pharmaceutical registration protocol could lead to products being held up by customs when they enter the country. Not only does this delay the delivery of important health care products, but it wastes time and money, and risks spoilage or expiry of products while at customs."*

(USAID - The Logistics Handbook, A Practical Guide for The Supply Chain Management of Health Commodities)

National Drug Regulatory Authorities may also normalise where health products are sourced, in what shape and dosages are presented, what minimal identification and use indications shall be provided, etc.

It is often considered that the procurement is the crucial point of Quality Assurance (QA) of medicines. The source of the raw materials (active ingredient, excipients - an inert substance used to give a pharmaceutical preparation a suitable form or consistency), as well as the way the final pharmaceutical product is manufactured determines the intrinsic quality of each medicine.

Donor Regulations

A significant portion of funds used to procure health related items in an emergency comes from large scale institutional donors. Many donors have well established procedures on what and how medicines and medical support devices can be purchased using their funds.

Most major institutional donors only allow recipients of their funds to procure pharmaceuticals through pre-qualified suppliers. Pre-qualified suppliers must undergo thorough audits and must be regularly reviewed for their quality assurance standards. As a result:

- There are a limited number of pre-qualified suppliers globally, and frequently they are outside the areas of the emergency.
- Different donors don't always pre-qualify the same supplier; If an aid organisation receives funds from more than one donor, they may be obliged to buy from different sources depending on the funding type.
- Some pre-qualified vendors function as non-profits, while others are commercial enterprises. This may impact product costs and availability.

The variability and geographic specificity of donor pre-qualified vendors mean that humanitarian organisations should research their relevant donor regulations prior to purchasing pharmaceuticals and other health items. The relatively small number of suppliers also means that procurements will likely need to be imported – please reference the section on Importation and Customs for more information.

Product Names

> *"The selection of the medicines to be provided in a country affected by an emergency is of key importance because, if the medicine is not well known by the health professionals who will prescribe it, it will not achieve its intended use."*
>
> (DG ECHO - Review of quality assurance (QA) mechanisms for medicines and medical supplies in humanitarian aid)

Sometimes pharmaceutical items can be referred to by a variety of names. When ordering drugs please consider the following points.

International Non-proprietary Name - An international non-proprietary name is a unique name that is given to the product based pharmaceutical substances or active pharmaceutical ingredients and is generally globally recognised.

Brand Name - For marketing purposes, brand names are generated by a particular

manufacturer and will generally be trademarked. All brand name products will still carry an international non-proprietary name as well, as there should be no difference in chemical composition from one brand to the next. Some pharmaceuticals that hold brand names may still be under patent by one Manufacturer. These products are usually given patent protection for 20 years from the date the patent was submitted and provides protection for the innovator of the medicines to recover the initial costs incurred in research development and marketing expenses.

Generic Drug - A generic drug is a pharmaceutical that is produced and distributed without patent protection. It has the same active ingredients as brand names, but it can be manufactured by a different producer.

It's strongly recommended to use international non-proprietary names to refer to medicinal products. Using the international non-proprietary names enables you to purchase products from multiple suppliers, whether branded or generic, and manage them as the same product.

Health Kits

A common procurement strategy for health items in humanitarian emergencies is the design and use of emergency health kits. These standardised kits of medicines and medical supplies are developed by agencies to meet different health needs in humanitarian emergencies and disasters during the acute emergency phase, normally during the first 3 months, when a push model is critical to launch the operation. It's key to note that after the acute phase of an emergency is over, or during chronic emergencies, the quantity of needed medicines should be reassessed base on operational needs, and a routine supply of health items should come from consumption-based demand.

The most widespread and accepted emergency health kit is theInteragency Emergency Health Kit (IEHK) developed by WHO, however there a variety of other kits that support trauma surgery, maternal and reproductive health, newborn health, and specific infectious diseases produced and managed by different humanitarian organisations. Emergency health kits may include a mix of pharmaceuticals, medical devices and equipment, and are designed based on treatment of specific medical conditions common in emergencies. The contents of each kit are designed to attend specific diseases, for a specific number of patients during a given period of time using assumptions based on global standard treatment protocols.

The advantage of emergency health kits is that they are uniformly recognised and stocked across multiple organisations and vendors and are generally recognised by governments. A pharmaceutical manufacturer or supplier can assemble, or stock health kits based on known and pre-approved components, and customs and health officials at the national level have known documentation on what may be included. Depending on the organisation responsible for the specific kit(s), content is usually updated every few years to be compliant with updated clinical guidelines and based on other changes in the medical supply landscape.

Use of the word "kit" should not be mistaken as a singular box or bag. The majority of health kits consist of more than one box, and in some cases multiple pallets per single kit. Additionally, a number of health kits contain a mix of health product categories – such as temperature-controlled items, keep cool items, dangerous goods, or controlled substances – and management of health kits requires keen attention and the implementation of quality risk management throughout distribution.

Some larger humanitarian organisations may choose to develop their own health kits, which may or may not be available to other agencies for procurement. Prior to developing health kits,

agencies should consult what is available on the market, and keep in mind the need to conform to international standards, such as essential medicines lists, while doing so.

Advantages of Pre-Made Health Kits	Disadvantages of Pre-Made Health Kits
• Kits are pre-defined for specific health emergencies and reduce the complexity of ordering on short notice. • Kits are useful when beneficiary data is limited, and no proper demand is fully understood – this is very common in the early phases of emergencies. • Kits are fast to order – vendors have well defined and premade kit contents, and sometimes even stock them in advance. • Kits are fast to distribute – in many cases, kits will arrive in clearly marked packages, and already be segregated into easy-to-handle cartons. Kits also don't require field level users to break down and re-kit larger bulk orders.	• Kits don't always fulfill the supply needs for comprehensive services and tend to only target lifesaving needs for specific medical practices. • Kits are designed based on global averages on prevalence of clinical interventions for low- and middle-income settings, and assumptions on supply requirements for each clinical intervention based on WHO treatment protocols. As a result, the kits are not based on the national treatment protocols in a specific country or on the specific service seeking behavior of the targeted population. • Kits in their design are inherently more expensive than bulk procurement of the items contained within the kit. • Kits may have a shorter shelf life. Many kits are held in stock at the global level prior to dispatch to a specific country, and the shelf life of individual items in the kits will be shorter than items with expiration dates taken from regular vendor rotation.

Donations of Medicines and Health Supplies

There are many different scenarios for medicine and health material donations – such as emergency aid, long- term aid, or assistance to national health systems or to individual health facilities. Donations may come from pharmaceutical companies (directly or through private voluntary organisations), they may come in the form of aid from governments, or they may be donations aimed directly at single health-care facilities. The intended beneficiaries of donations of medicines range from individual facilities to entire health systems. Although there are legitimate differences between these scenarios, many basic rules for appropriate donation practice apply to them all.

WHO in cooperation with major international agencies active in humanitarian relief and development assistance, developed the Guidelines for Medicine Donations. The guidelines are intended to improve the quality of medicine donations in international development assistance and emergency aid.

The guidelines aim to describe a common core of good medicine donation practices based on a few core principles:

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,

and in conformity with the government policies and administrative arrangements of the recipient country: all donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines, if the national list of essential medicines is not updated.

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.
5. Items must not have less than minimum required shelf life upon arrival to allow timely distribution and consumption without causing unnecessary reverse logistics activities and related costs.

Different humanitarian organisations will have internal requirements and processes for the acceptance of donations of medical and health supplies which aim to ensure compliance with WHO guidelines for medicine donations.