1.8.1 Medical procurement

importers of specific medical

suppliers be registered as such.

MEDICAL PROCUREMENT		
Needs definition Clear specifications including shelf life requirements Use medicinal names rather than brand names Special requirements Include sample quantities in total order where necessary.	 Shelf life calculations paracetamol has a 30-month shelf life. Requestor asks for 90% remaining shelf life (27 months) at delivery. Import lead time = 4 months. → international procurement will not comply with requestor's requirements. → Options: lower the minimum remaining shelf life required or procure locally. 	Supply chain requirements Restricted items = stricter import rules and controls Check transport and storage conditions needs (ex: cold chain) Check who can be a consignee of imported medical supplies Check requirement for testing or sampling at arrival in country.
National regulations Check national essential medicines list for any limitations or requirements in importations. Some countries require that	Procurement agent services Procurement can be delegated to a procurement agent (at a cost). Tendering is required for procurement agent contracting.	Supplier selection Request for support from ICRC/IFRC procurement experts. All procurement of medical items done under IFRC rules must be approved at

The procurement of medical items, whether equipment (tools, machinery, diagnostics or laboratory equipment) or drugs, requires special care and consideration. Priority should be given to a PNS with medical experience or to IFRC or ICRC who hold contractual relationships with medical suppliers.

GVA level.

There needs to be careful selection and thorough investigation of suppliers - procurement will be restricted to a selected number of validated suppliers who have the required Good Distribution Practices (GDP) and Good Manufacturing Practices (GMP) certifications, follow World Health Organization (WHO) procedures in procurement and guarantee the guality of their products.

When planning to procure medical items, contact your allocated Logistics Coordinator as soon as the requisition is raised. Unless stated otherwise in the GAD between the BRC and a PNS, no medical procurement should be initiated in country without prior notification to the Logistics Coordinator or the procurement department of the IFRC.

The procurement and distribution of medical supplies requires strict quality control procedures to ensure the quality of products provided to beneficiaries. This applies particularly to the procurement and distribution of pharmaceuticals, which can be life-threatening when the quality is substandard. There are numerous ethical and legal responsibilities related to the quality of medical products offered by humanitarian agencies. The WHO Model List of Essential Medicines serves as a guide for the development of national and institutional essential medicine lists and is updated every two years by the WHO Expert Committee on Selection and Use of Medicines.

All medical supplies must have a batch number allocated by the manufacturer. Each batch must have a manufacturing date and an expiry date, both including month and year, at least. Each batch that is manufactured must have a batch certificate or a certificate of analysis that confirms that drugs from this batch have passed the necessary tests.

When procuring medical items, consider the below carefully:

Definition

- Make sure the specifications of the request are clear: what form/dosage of each drug is required. List the typical forms, with images.
- Ensure that the request states the medicine needed rather than the name of a manufactured drug. For example, if paracetamol is required the requisition should say "paracetamol" and not "Panadol".
- Ensure that any special requirement is listed on the requisition: is this molecule classified as a narcotic, restricted or dangerous goods?
- Ensure that the requisition specifies the expected shelf life for the item ordered and the minimum required shelf life at delivery. Make sure the supply chain lead time is factored into the required shelf life. The decision on this must be made in conjunction with the requestor and based on recommendations from IFRC or your allocated logistics coordinator.
- Confirm that the total estimated cost of the request captures the cost of the supplies themselves, as well as associated costs for example, packaging, shipping, sampling, testing, taxes, in-country registration fees.
- Where samples will be taken out of the consignment for analysis, make sure the total quantity ordered takes this into consideration.

National essential medicines list and legal framework

Each country holds a list of the drugs they allow in the country

- Some drugs may be prohibited in the country you are working in.
- Refer to the Food and Drug Administration of your country to confirm whether the drug requested is allowed for use in your country – most of the time these lists are in line with WHO recommendations, but they may differ.
- Each country is free to classify specific drugs as restricted medical items, and this will be specified on the national essential medicines list.
- Restricted medical items often require further documentation to be imported and must be stored with increased controls (see Chapter 3). Note that some countries will limit the quantity of narcotic drugs imported by a single consignee over a set period. The national FDA is the preferred source of information for these details.

Supply chain requirements

- See above for restricted medical items.
- Transport and storage conditions for drugs and medical supplies are generally stricter than those for other commodities. Always ensure that you or the final recipient have the capacity to store an order in the correct conditions (see Chapter 3).
- Some drugs or diagnostic supplies must be kept in temperature-controlled conditions during transport and storage (see guidance here). When receiving a request for drugs with cold chain requirements, ensure the supplier has the capacity to confirm that the supplies have been transported in the required conditions (e.g.: reefer containers with temperature loggers) and that you will be able to store them in a temperature-controlled environment at the point of delivery.
- The importation of medical supplies is often more restricted than the importation of other types of commodities. To import drugs, you will typically have to:

- Be registered as an authorised importer of drugs in the importing country.
- Submit an import application to obtain pre-approval ahead of the shipment arriving in country. This application will typically contain a letter explaining the need for importation, the registration certificate and all draft commercial documents provided by the supplier (commercial invoice, packing list, certificate of origin and certificate of analysis). Based on the application, customs and the national FDA will deliver an authorisation to ship the medical supplies.
- Humanitarian organisations can obtain tax exemptions for the importation of medical supplies. Usually this is requested from the ministry of health or finance and customs, which must each approve the request separately. To file for a tax exemption, you will typically have to submit a donation certificate certifying that the consignment has no commercial value (will not be sold once in country) and a proforma invoice for all the drugs to be imported. Tax exemption documents must be stored carefully and included in the documents submitted upon the departure or arrival of the consignment.
- Some countries require that the consignment should be inspected by a third-party service provider (often named by the ministry of health or FDA) upon arrival in country. This will usually have to be arranged by the shipper or consignee and will require sampling at port of arrival, placing the supplies in quarantine until clean results are obtained and releasing them after reception of the results. Inspection costs should be added to the estimated cost of procurement.

Selecting suppliers of medical products for procurement

See the section of the IFRC procurement manual for information about the pre-selection of suppliers for medical supplies. Note that all procurement of medical items (incl. pharmaceutical products and medical equipment) done under IFRC procurement rules MUST be approved by the Procurement authority in Geneva before issuing a contract.

Recognising that the capacity of the BRC and other PNS does not allow for the necessary thorough controls, it is recommended to use the capacity of IFRC/ICRC to assess and monitor suppliers – where they are in place and with prior notice, use existing contracts that IFRC/ICRC hold with medical suppliers.

Using a procurement agent to conduct medical procurement

In some cases, the organisation requiring the medical supplies will not have the capacity to conduct medical procurement beyond the definition of needs. Such processes can be delegated to a procurement agent against a service fee (usually a percentage of the total value of the procurement delegated by the organisation). These procurement agents often hold a list of pre-qualified suppliers who have been quality-approved. This can be a useful solution in the rare case where a programme requires a drug or piece of equipment that cannot by supplied via a known supplier. Always refer to your logistics coordinator to assess sourcing options.

An example of shelf-life calculation: paracetamol usually has a 30-month shelf life. Your requestor asks for 90 per cent remaining shelf life (27 months) at delivery, and you know that importing drugs into your country will take around four months. Based on this, you can deduct that international procurement will not comply with your requestor's requirements, so the choice is to lower the minimum remaining shelf life or procure the paracetamol locally.