Guide for Medical and Pharmaceutical Procurement

I. INTRODUCTION

This annex will serve as a guide for the Mission Procurement Focal Points and Global Procurement and Supply Unit (GPSU), in the proper medical and pharmaceutical procurement. This include but are not limited to pharmaceutical products, vaccines and cold chain products, medical supplies, medical device and medical equipment. This is also a reference to assure compliance in procurement methods when coordinating or working with different donors.

IOM evolves in response to global migration challenges and medical procurement continues to be a growing need. As part of further improvement in procurement and supply, a clear and structured process is vital to ensure cost-effectiveness, good product quality and timely deliverables.

IOM adapts best practices and follows recommendations from various health authorities such as Word Health Organization (WHO) and Centers for Disease Control and Prevention (CDC). WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, articulating evidence-based policy options, providing technical support to countries, monitoring and assessing health trends and make recommendations with respect to international health matters.

IOM's Migration Health programmes address the wellbeing and health needs of individual migrants as well as the public health needs of host communities by assisting its governmental and non-governmental partners. While doing that in the modern resource limited setting, the issues of medical procurement become especially relevant to optimize in order to maintain the supply and quality of pharmaceuticals while minimizing the costs. The medical market is heavily regulated by both national and international entities and consistency with relevant health care standards of quality is of utmost importance.

Medical and pharmaceutical procurement, same as the procurement of non-medical commodities, is not only an issue on price but it ensures adequate products are available in the right quantity and quality, at the best value for money, at the right place, at the right time from the right source.

1. Objectives

This annex will serve as additional guidance for the Mission Procurement Focal Points and Global Procurement and Supply Unit (GPSU), in the proper medical and pharmaceutical procurement. This include but are not limited to pharmaceutical products, vaccines and cold chain products, medical supplies, medical device and medical equipment. This is also a reference to ensure that IOM Migration Health programmes are able to obtain the quality medical products at the right prices in a timely manner, and assure compliance in procurement methods when coordinating or working with different donors.

As you go through this material, you will encounter underlined texts, you can click this in order to view the file, or you will be redirected to a website.

2. General Considerations

Overall procurement in IOM is regulated by IN168 "Procurement Manual" that should be consulted for any general issue related to medical or any other type of procurement. To the extent possible IOM should ensure that the procured medical product and vaccines meet national and international regulatory standards as described below:

a. In-Country Registration

Procurement for IOM migration health projects should meet regulations by corresponding authorities in each country where IOM operates or be waived by the appropriate government authority. To achieve this goal, IOM should work closely with each host country in ensuring the drugs procured are in line with the national standards set for drug quality. IOM will work closely with the host country regulatory bodies to ensure certain standards and qualifications are maintained when procuring and importing drugs for IOM programs in the various missions.

Every country has its own National Regulatory Authority (NRA) which is responsible for enforcing the rules and regulations; issuing guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products; and monitoring compliance to set standards. *See National Regulatory Authorities* for some examples.

b. International regulations

When procuring drugs or pharmaceutical supplies there are many international registries and regulatory bodies that have pre-qualified products that are already approved for use by partners of U.S. government funded programs.

i. The **WHO**, through the Quality Safety and Standards (QSS) Unit of the Department of Immunization, Vaccines and Biologicals (IVB), provides advice to the United Nations Children's Fund (UNICEF) and other United Nations (UN) agencies on the acceptability, in principle, of vaccines considered for purchase by such agencies for vaccination programs they administer. The WHO does so through its vaccine prequalification program. An important part of the program is the WHO's reliance upon the national regulatory authority (NRA) of the country of manufacture of the vaccine if the NRA meets the WHO indicators that gauge its functionality.[3] Implementing partners often require World Health Organization (WHO) pre-qualification for all vaccines and drugs for neglected diseases procured through cooperative agreements. When possible, IOM should use vaccines

and drugs that are prequalified by WHO. Please refer to the WHO Prequalification of Medicines Factsheet for more information

ii. **U.S. Food and Drug Administration (FDA)** or **Stringent Regulatory Authority (SRA).** The USFDA serves as a regulatory authority on drug quality in the US while SRAs include regulatory bodies in Japan, Europe, and Canada. When there is no prequalification by WHO then IOM should check to see if FDA or any SRA has prequalified the drug.

iii. **Global Fund** provides grants for procurement of certain antiretroviral, tuberculosis, and malaria drugs, which must be WHO prequalified or authorized by an SRA, or recommended by an independent expert review panel convened by the Global Fund when no drug is available that has been prequalified. The panel's recommendations are valid for 12 months or until the drug is WHO-prequalified or authorized by an SRA.

iv. **UNICEF**, is the leading agency for vaccine procurement. UNICEF promotes vaccine security by working with manufacturers to ensure there is a reliable supply of quality, affordable vaccines, and with governments to assess their vaccine requirements. IOM has concluded a MoU(link) with UNICEF on procurement of pharmaceutical and medical products.

3. Exceptional Approval

IOM realize that there will be incidents when a drug is required to complete the treatment recommendations as per the guidelines for overseas medical treatment and in those exceptional cases the following procedures are recommended:

a. IOM Country Medical Officer should be notified by the procurement officer of the issue
b. If no prior approval is in place by an international regulatory body then an independent review process should be conducted
c. Review process begins with notifying the MHD HQ of the discrepancy that will provide further guidance in consultation with IOM GPSU and government counterparts.
d. Pharmaceutical Checklist (see Appendix A) should be utilized for quality assurance.
e. WHO has established a list of prequalified laboratories that can be used to assure drug quality. IOM, in conjunction with CDC and other government partners can at any time in the preparation to procure certain drugs request a laboratory to confirm the drug's quality against international standards. See the list of prequalified QC labs.
f. In an instance where a new pharmaceutical manufacturing facility is being used, then IOM can utilize the Checklist for the Inspection of Pharmaceutical Manufacturers (see Appendix B) to ensure quality of certain drugs

4. MHD Procurement Support in Manila Administrative Centre (MAC)

MHD procurement position was established within the Global Procurement Supply Unit of Manila Administrative Center to assist field missions in medical procurement and to bring it on par with IOM and donor requirements. The following main activities are envisaged for this function:

a. Create, maintain and enforce medical procurement guidelines in cooperation with CDC and other donors
b. Assist GPSU in creating and maintaining a roster of reliable medical suppliers
c. Facilitate global, regional and country procurement of vaccines, anthelminthic drugs and other selected medical goods available for global procurement

d. Endorse medical procurement orders of more than 25,000 USD
e. Assist missions in their procurement requests, provide guidance on medical procurement issues as needed

II. CATEGORIES OF MEDICAL AND PHARMACEUTICAL PROCUREMENT

Recognizing that there are multiple interpretations for the categories listed below, they are defined as follows by WHO:

1. **Pharmaceutical products** – more commonly known as medicines – are a fundamental component of both modern and traditional medicine. It is essential that such products are safe, effective, and of good quality, and are prescribed and used rationally. Rational use of medicines refers to the correct, proper, appropriate use of medicines before the expiry date. Rational use requires that beneficiaries/patients receive the appropriate medicine, in the proper dose, for an adequate period of time, and at the lowest cost to them and their community. Lowest cost should not be the main criteria for purchasing medicines, it should always be based on best value or quality. Expiration date of the pharmaceutical products shall be always verified before purchase and shall be kept in the conditions recommended for each product.

2. **Vaccine** – is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters. Vaccines distributed through the UN Agencies are prequalified by the WHO, to ensure that the product complies with the quality and safety standards established by the WHO. Prior to procurement of vaccines, check if there are existing frameworks for developing countries. Search for negotiated prices from GABI and FIND.

> ❖ *Important Note:*
> **Lot Release Certificate**
> The responsible national regulatory authority (NRA) is required to issue a lot release certificate for vaccines that are distributed through the UN Agencies. The lot release certificate is issued by the NRA and sent to the manufacturer confirming that the particular lot meets the approved specifications and related provisions. The lot release certificate/s from the NRA (or from the national control laboratory) of the producing country are considered to be the ***only*** evidence that the lots have been released by the producing country.

3. **Medical supplies** – refers to non-durable commodities that are disposed after treating a patient. These are items that healthcare personnel wear or use for personal protection from infection. Examples are bandages, blades, caps, face shield, gauze, gowns, glasses, masks, single-use syringes, surgical and examination gloves, suture materials, and tongue depressors.

4. **Medical devices** – an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical devices include but are not limited to blood glucose monitoring device, canes, crutches, wheelchairs, walkers, sphygmomanometer, ophthalmoscope, otoscope, stethoscope and thermometer. Medical devices intended for global use should follow international standards Ex. ISO 13485. This standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices. A standard can be recognized fully or partially, provided this is clearly specified. Conformity of a device can be assessed by third party agencies, such as a notified body. In some countries, the publication of government recognized standards mandates product compliance.

5. **Medical equipment** - is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; these require calibration, maintenance, repair, user training, and decommissioning − activities usually managed by clinical engineers; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment includes medical monitors, medication pumps-devices programmed to dispense medications to a patient at a specified rate, medical imaging machines, medical ventilators, anesthesia machine, heart-lung machines and dialysis machines.

When purchasing medical equipment, consider vendors which have the capacity to provide after- sales service - qualified technicians to perform periodic preventive maintenance, availability of spare parts and timeliness of delivery.

The table below shows a summary of documents that can be encountered during medical procurement.

What are the necessary documents?	Where is this applicable?					Who will accomplish/provide this document?	Who will approve this document?	Remarks
	Pharmaceutical products	Vaccines	Medical supplies	Medical device	Medical equipment			
Internal documents								
Purchase Request Form (PRF)	X	X	X	X	X	Program staff	Project Manager/Head of Unit/RMO/COM	
Request for quotation (RFQ)	X	X	X	X	X	GPSU, PFP	Head of Unit/Mission Proc. Unit	
Bids Analysis Summary (BAS)*						GPSU	Project Manager/Head of Unit/RMO/COM	purchases over USD 3,000 up to USD 25,000
Declaration of Non-conflict of Interest/BEAC Resolution*						BEAC Members	Project Manager/ RMO/COM/GPSU/MAC Director	purchases above USD 300,000; for urgent purchases
Purchase Order	X	X	X	X	X	GPSU, PFP	PFP, POA	
Note for File*						GPSU		for exceptional approvals
Request for Payment	X	X	X	X	X	GPSU, PFP	Project Manager/Head of Unit/RMO/COM	
External documents								
Airway Bill	X	X	X	X	X	Vendor/Shipper	N/A	
Application for Import Permit	X	X	X	X	X	Vendor	National Regulatory Authority of the country of destination	
Application for Export Permit	X	X	X	X	X	Vendor/Shipper	National Regulatory Authority of the country of origin	
Bill of Lading	X	X	X	X	X	Vendor/Shipper	N/A	
Certificate of Analysis	X					Vendor	N/A	
Certificate of Conformity				X	X	Manufacturer	National Regulatory Authority of the country of origin	
Certificate of Good Manufacturing Practice	X	X				Vendor	National Regulatory Authority of the country of origin	
Certificate of Origin	X	X	X	X	X	Vendor	National Regulatory Authority of the country of origin	
Certificate of Product Registration	X					Manufacturer	National Regulatory Authority of the country of origin	
Certificate of Sterilization*			X			Manufacturer	N/A	for sterile medical supplies
Customs Clearance	X	X	X	X	X	Vendor/Shipper	Customs' Authority of the country of origin/destination	
Materials Safety Data Sheet*	X		X			Manufacturer	N/A	for hazardous chemicals
Lot Release Certificate*		X				Manufacturer	National Regulatory Authority of the country of origin	for vaccines
Packing List	X	X	X	X	X	Vendor/Shipper	GPSU / PFP	
Technical specifications				X	X	Vendor	GPSU / BEAC Members	
Pro Forma Invoice (invoice)	X	X	X	X	X	Vendor/Shipper	GPSU	
Quotations/proposals	X	X	X	X	X	Vendor	GPSU / BEAC Members	

**see remarks*
BEAC-Bids Evaluation Committee PFP-Procurement Focal Point RMO-Resource Management Officer COM-Chief of Mission POA-Purchase Order Approver MAC-Manila Administrative Centre

Table 1. Summary of significant documents in medical and pharmaceutical procurement

II. MEDICAL AND PHARMACEUTICAL PROCUREMENT PROCESS

Upon approval of the working budget structure and other financial requirements of the project, the following phases and steps provide guidance on medical and pharmaceutical procurement.

1. **Phase I, Procurement Planning and Preparation**

   The importance of planning must never be taken for granted as this will unveil available options and methods that will enable the organization to reach its objectives. Planning is a repetitive process that requires continuous review and input from experts, good communication and coordination between participants and flexibility in approach.

   Medical and pharmaceutical requests amounting to USD 25,000 and above should be sent for procurement review to GPSU prior to issuance of purchase order.

   Introduce IOM in a global perspective to potential medical and pharmaceutical vendors. This will eliminate their regional approach which can result to better price of goods to be purchased.

   Below has to be taken into consideration when procurement of medical or pharmaceutical products is planned.

   Common terms related to pharmaceutical procurement:
   a. Proprietary medicines (original or brand-name medicines)
   b. Generic medicines
   c. International Non-proprietary Name (INN)
   d. Trade Name Generics

   According to WHO Essential Drugs and Medicines Policy Interagency Pharmaceutical Coordination Group, there are four strategic objectives of pharmaceutical procurement:
   a. Procure the most cost-effective drugs in the right quantities
   b. Select reliable suppliers of high-quality products
   c. Ensure timely delivery
   d. Achieve the lowest possible total cost

   Procurement Planning and Preparation, is completed with the following steps:

   a. Identification and description of products

   In procuring pharmaceutical products, identified items should be written in their **international nonproprietary name (INN)**. The INN is an international scientific generic reference name uniquely identifying a particular product. It is widely accepted as the standard for describing drugs on a procurement list or tender request. Health authorities such as WHO and USAID/OFDA have a limited list of drugs for procurement. *(See WHO Model List of Essential Medicines and USAID/OFDA Essential Medicines List).* These were developed to simplify pharmaceutical selection and expedite review and approval of pharmaceuticals requested. Products must also be specified in terms of dosage form: Solid (oral tablets), liquid (oral solution), injection, accurate dosage quantity of the active substance.

Selection is the first stage in the procurement and supply cycle; it is a rational, evidence-based process of choosing a limited number of products to be purchased, managed and used. The complete description should be written on the Request for Quotation (RFQ) or Bidding Documents.

The specifications of a **pharmaceutical product** should always include the following elements:

- Generic name, International Non-proprietary Name (INN), or parallel medicine
- Form: For example tablet, capsule, injection, vial
- Dosage: For example 150mg, 50mg/ml
- Packaging: For example box of 60 tabs, blister of 30 tabs

Example: ranitidine 150mg tablet, 100 tabs/blister

Technical specification (TS) is a document required for the procurement and acquisition process of medical devices and equipment. It serves as a tool guide for the medical staff to understand and to know what is appropriate for each medical device.

The technical specifications of a **medical device and medical equipment** contains the following elements:

- Name, category and coding
- Purpose of use
- Physical or chemical characteristics
- Utility requirements
- Accessories, consumables, spare parts and other components
- Packaging, environmental requirements
- Training, installation and utilization
- Decommissioning
- Safety standards

TS must state the exact nature of the regulatory approval (also termed as registration, certification or licensing) from country of origin that is required. Supportive documents must be submitted as part of the bidding process to verify the exact regulatory status of the item to be purchased.

b. Identification of suppliers

Planning procurement of medical devices and equipment has several considerations, which includes the following:

i. Specify the required certifications for both vendor and manufacturer to be attached in the bidding documents.
ii. Specify delivery Incoterms and delivery place.

Due to the wide range of medical and pharmaceutical items, it is recommended that a list of prequalified vendors should be utilized in procurement. Prequalified vendors are those who comply with the WHO Good Manufacturing Practice Guidelines (GMP). This will save a lot of time when sourcing. The Vendor Information Sheet (VIS) is a document that contains all pertinent data about the company and includes a requirements checklist. This will help the procurement

staff in verifying vendor's qualifications *(See Vendor Information Sheet at https://intranetportal/resources-management/procurement).*

Although conforming to certain internationally recognized standards for manufacturing may increase confidence, procurement staff should be aware that some vendors may not be authorized or meet international standards during their assessment process, beware of false certificates.

Regardless of whether a vendor is prequalified, background checking and information should be collected to ensure that the vendor is capable and legible of supplying. At the point of vendor selection, the procurement staff should note any embargos enforced by the country of origin, and country of destination. It would be helpful to include a statement in the bidding documents that requires vendors to check legal obligations for international trade.

c. Determination of Expiration Dates

To ensure that pharmaceutical products retain their good quality and effectiveness (especially for pharmaceutical products), shelf-life/expiration date should be more than a year from date of order placement. Expiration date is the date during which a drug may be expected to meet the requirements of the pharmacopoeial monograph provided it is under the prescribed conditions. When the expiration date is marked with only month and year, a drug maybe used up to and including the last day of the month indicted. If a day is included with month and year, the drug may only be used through that day.

Figure 1. Medicine or vaccine may be used up to and including the expiration date.

important to specify required shelf-life upon delivery in the purchase order. Freshly produced or manufactured items are preferred. Option for staggered deliveries should be considered when vendors do not guarantee a longer shelf-life.

Vaccines and biological products are normally short-dated (expires after 18 months). Storage and handling of vaccines will be discussed further on Phase VI.

Some medical supplies have expiration dates too such as those stated as *sterile*. Sterile medical supplies are safe to use as long as the integrity of the package is not compromised, the outside of the package requires special attention.

Figure 2. Sterile latex surgical gloves showing the expiration date

> ***Sterile** means the product underwent a sterilization process which makes it totally clean, free form bacteria or any other microorganism.*

If the sterile package is not 100% intact, the pack should not be used. Sterile medical supplies such as catheters and surgical gloves may require a **certificate of sterilization** to assure that the products underwent proper sterilization procedures.

This photo shows that that the surgical gloves packaging is still intact, sterile, and can be used up until June 30, 2017.

d. Quantification

Quantification is the calculation of required quantities of medicines, tests or services to correctly treat patients for a certain period of time. It is essential to ensure that enough products are available to avoid supply shortages; prevent ordering more than necessary to avoid wasting of products; forecast the funding necessary to cover needs and to carry out the procurement; and organize the procurement and supply program.

Order quantities should be based on reliable estimate of actual need. An important and practical consideration during quantification is past consumption. It is one of the most reliable way to predict and quantify future demand. Such consumption data must be adjusted in the light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance, and project expectations.

Budget is an important consideration to purchase all drugs in the quantities which were estimated to be needed, it is necessary to prioritize the procurement list to match available financial resources.

Techniques such as VES (vital, essential and nonessential) Analysis, Therapeutic Category and ABC Analysis, Morbidity and Adjusted Consumption Methods can be used to select priorities and reduce quantities less cost-effective drugs. (*See Quantification Methods* for more detailed information and the summary of steps for each method). If not familiar, please contact GPSU or MHD. Here are several quantification methods recommended by WHO and UNDP:

i. *ABC Analysis*, is the analysis of annual medicine consumption. It can reveal high usage items for which there are lower-cost alternatives on the list available in the market. This information can be used to choose more cost-effective alternative medicines; identify opportunities for therapeutic substitution; and negotiate lower prices with vendors. The major advantage of ABC analysis is that it identifies those medicines

on which most of the budget is spent. It is most useful in established programs with a well understood and predictable consumption pattern. Because the method is not very flexible, it is not suitable for new programs with no consumption track record. A major disadvantage is that it cannot provide information to compare medicines of differing efficacy.

ii. *Therapeutic Category Analysis,* building on the ABC Analysis this method can identify therapeutic categories that account for the highest consumption and greatest expenditures; mission procurement focal point/GPSU/authorized medical staff can choose the most cost-effective drugs within a therapeutic class and to choose alternative medicines for therapeutic substitution.

iii. *Vital, Essential and Non-essential (VEN) Analysis,* this method can be used when there are insufficient funds to buy all desired medicines. VEN Analysis is a well-known method to set up priorities for purchasing medicines and keeping stock. Drugs are divided, according to their health impact, into vital (V), essential (E) and non-essential (N) categories. This allows medicines of differing efficacy and usefulness to be compared, unlike ABC and therapeutic category analyses, where only drug of similar efficacy or action can be compared.

iv. *Morbidity Method,* relies on epidemiological prevalence data, taking also into account the distribution of patients by treatment regimen. This method also requires an informed professional opinion about the population targeted for treatment and the use of products by clinicians.

v. *Adjusted Consumption Method,* this method is generally used at the start of new program when there is no consumption track record or complete morbidity data. Consumption statistics from similar situations, including from other countries, are used as basis for the estimations. This method is difficult to use if there are changes in demand and use, and if the situation is very different from other experiences, for example, demographic variations between regions and countries and different prescription practices.

e. Consultation and coordination with MHD and other authorized medical personnel

It is recommended for mission procurement focal point/GPSU/authorized procurement staff to seek consultation from the Medical Health Department (MHD) for every medical procurement *(MHDCMHO@iom.int).* MHD has a pool of expert doctors with different specializations (X-ray equipment, vaccines, etc.). The procurement staff shall check with MHD if any information is missing, illegible, questionable or vague. For example, when the requested item with an original generic name is not available, but a parallel medicine is, and no information on that has been shared, MHD can be consulted for their expertise in this case.

f. Significant Documents

The procurement staff should provide assurance that the host country's responsible national regulatory authority has approved the importation and use of the proposed medicines. Therefore, the need for the following documents may vary according to country of destination, country of origin, national policies, and

requirements of the participating donor. Generally, they are similar. Examples of these documents are listed in Table 1.

An ***import permit*** is necessary for medical procurement. This should be secured by the Mission on the country of destination. The original import permit should be sent to the country of origin, so the vendor can apply for their ***export permit***. *Example,* Mission requested for a medical equipment. Needed medical equipment will originate from a registered IOM global vendor. GPSU/mission procurement focal point coordinates this with the Mission Level. IOM Mission applies for the approval of import permit by the NRA (country of destination). Approved original copy will be sent to vendor at the country of origin. The vendor will then secure their export permit to the NRA (country of origin) by attaching the approved import permit.

Dangerous Drugs are those listed in the 1961 and 1971 UN Convention on Narcotic Drugs and Psychotropic Substances, DDB Regulation and 1988 UN Convention against Illicit Traffic of Narcotic Drugs and Psychotropic Substances. (*See UN Controlled Narcotic Drugs and Psychotropic Substances*). Procurement of these products may require additional permits.

2. Phase II, Procurement Processes

The procurement process should not happen independently. Rather, a number of participants should be involved, all of whom have important expertise to share to the decision-making process, regardless of whether procurement is coordinated at a local or global level. Technical experts and end-users at Mission level must be able to communicate their needs to those responsible for procurement through frequent and open communication.

Medical and pharmaceutical procurement is completed through the following steps:

a. Once items are selected and quantities/specifications are defined, they should be included in the request for quotation (RFQ) or invitation for bids (IFB)
b. Send/publish RFQ or IFB
c. Issue general instructions or bid documents to vendors
d. Quote/bid submission
e. Quote/bid evaluation. The Bid Analysis Summary (BAS) form is used for this purpose in addition to other technical evaluation documents the Mission used, and needs GPSU clearance if cost is greater than USD 25,000. Please see also Procurement Manual Annex 20.2, BEAC Guide on the Conduct of Competitive Bidding, if procurement is through competitive bidding, which is required over USD 300,000 or Annex 20.4 for the Purchase Authorization Matrix for Field Mission
f. Award of purchase order (PO) or contract supply agreement

Important Note for Phase II:
Review procurement requests received for completeness and accuracy. Ensure availability of funds and that the WBS indicated in the Purchase Requisition Form (PRF) is valid and complete. Coordinate with the end-user and RMO in cases of invalid WBS. Ensure that the PR is approved up to Head of Office/Chief of Mission. Forms mentioned can be viewed at *https://intranetportal/resources-management/procurement.*

Review and evaluate quotations/proposals as against the specifications/terms of reference/statement of work. For local procurement, ensure that quotation covers all shipping cost until delivery to required destination (office, camp, hospital). In case of global procurement, ensure that quotation includes requested INCOTERMS, warranty details (if applicable), delivery lead-time and payment terms. In simple terms, INCOTERMS cover who does what, who pays for what, when does the risk pass from seller to buyer, and when does the delivery occur. Please *see Procurement Manual Annex 20.3* for the Guide on the Use of International Commercial Terms.

Online Procurement

Low-value medical supplies amounting to less than USD 2,000 can be purchased with the use of a credit card, through Global Procurement and Supply Unit.

3. Phase III, Order Processing and Monitoring

Once the Bids Analysis Summary (BAS) is completed, approved or agreed according to technical specifications, the next step would be Purchase Order (PO) creation by the mission procurement focal point/GPSU using materials from PRISM.

Mission procurement focal point and GPSU's critical roles are to oversee the supply chain; arrange shipment; ensure shipping documents to Missions worldwide with different courier service providers based on best rates and Mission preference. Efficient monitoring entails regular and good coordination with the vendor, shipper (sender, consignor), carrier and the receiver (consignee). In most cases, *the vendor is also the shipper*.

The need for cold chain should also be emphasized at this phase, especially during procurement of vaccines.

Such coordination depends upon well-established communications and a good working relationship between the three parties. These three parties have specific responsibilities in ensuring successful transportation.

a. The shipper (sender, consignor)

i. Makes advance arrangement with the receiver including investigating the need for import/export permits
ii. Makes advance arrangements with the carrier to ensure that the shipment will be accepted for appropriate transport and that the shipment (direct transport if possible) is undertaken by the most direct routing
iii. Prepares necessary documentation, including permits, dispatch and shipping documents
iv. Notifies the receiver of transportation arrangements once these have been made, well in advance of the expected arrival time

b. The carrier

i. Provides advice to the sender regarding the necessary shipping documents and instructions for their completion
ii. Provides advice to the sender about correct packaging
iii. Assists the sender in arranging the most direct routing and then confirms the routing Maintains and archives the documentation for shipment and transport

c. The receiver (consignee)

i. Obtains the necessary authorization(s) from national authorities for the importation of the material
ii. Provides the sender with the required import permit(s), letter(s) of authorization, or other document(s) required by the national authorities
iii. Arranges for the most timely and efficient collection on arrival
iv. Should acknowledge receipt to the sender

It is important to consider insurance of goods prior to procurement. Insurance will safeguard challenges that can be encountered during handling and transportation.

Shipments should not be dispatched until:

Advance arrangements have been made between the sender, carrier and receiver.
The shipper has confirmed with the national authorities that the material may be legally exported.
The receiver has confirmed with the national authorities that the material may be legally imported.
The receiver has confirmed that there will be no delay incurred in the delivery of the package to its destination.

4. Phase IV, Acceptance of pharmaceutical products, medical supplies/devices/equipment

After issuance of approved PO to the vendor and continuous shipment monitoring, the next phase would be acceptance of products at required destination. Mission procurement focal point/GPSU/authorized medical staff shall receive, inspect and shipment of goods if sourced locally; confirms goods receipt with Mission if sourced internationally, and performs Goods Receipt (MIGO) using materials in PRISM.

General principles in accepting goods include: verifying if the items delivered are included in the approved PO according to the agreed technical specifications; delivered items match the pro forma invoice; deliveries are not expired, if short-dated, justification from vendor is valid and GPSU was informed in advance; for items with cold-chain requirement, temperature reading from the monitoring device should fall within normal range, in accordance with the product's storage condition.

The mission procurement focal point/GPSU/authorized medical staff shall consider and check the following during acceptance of medical devices/equipment:

a. Designated staff shall evaluate if the items are in good condition, check consistency of the goods and services supplied respecting the contract conditions and technical specifications.
b. The vendor shall deliver the original software license, in the name of the final beneficiary, where applicable, together with the equipment.
c. The vendor shall make available all the consumables, measurement and calibration instruments used during commissioning operations including the didactic material for maintenance and user training courses.
d. The vendor/installer shall install the device or equipment according with the installation requirements.

e. The vendor/installer shall test, calibrate and commission the goods as appropriate in a way that they are fully operational and can be used. The mission procurement focal point/procurement staff/authorized medical staff reserves the right to witness the testing and commissioning.
f. The vendor/installer shall orient and train authorized medical staff/technicians made available by IOM in the most frequent problems that could occur during equipment utilization.

5. Phase V, Payment of Orders

After inspection and acceptance of products, mission procurement focal point/GPSU/authorized medical staff shall prepare request for payment (RFP) for submission to Accounts Payable Unit for processing of payment to vendors.

Payment of goods can be made through advance payment. This is strongly discouraged but can be considered in exceptional circumstances such as emergencies. See sections 5.6 and 5.7 of the IOM Procurement Manual for a more detailed discussion.

6. Phase VI, Storage and handling of pharmaceutical products, vaccines, medical supplies/devices/equipment

Proper storage and handling ensures that all pharmaceutical products, vaccines, and other medical items used are stored according to standards and best practices so as not to compromise the product's integrity, stability and efficacy. Please see Warehouse Manual for a more detailed discussion on Inventory Management.

Make sure that insurance is in place. Estimated insurance premium rate ranges from 0.75% - 2.75% of total insured value, excluding government tax and stamp duty. Should you need assistance on this matter, you may send your inquiries to GPSU at fpu@iom.int).

Storage and handling

a. General principles in storage and handling

i. Proper storage and handling of all products are necessary so as not to compromise the product's integrity, stability and efficacy.
ii. Fill shelves/cabinets in a manner that stocks are rotated following the "first-in-first-out" or the "first-to-expire-first-out" FIFO/FEFO principle.
iii. Products for external use (creams, ointments, eye and ear drops) should be stored separately from products for internal use (capsules, tablets, syrups).
iv. Storage of food are not allowed in the storage and medication preparation areas including pharmaceutical refrigerators/chillers.
v. "Protect from light" products shall be stored in its original packaging and direct exposure to sunlight must be avoided.
vi. All pharmaceutical products and medical supplies should be protected from excessive heat, moisture and freezing temperature. It shall also be safeguarded against rodents and other pests.
vii. Items purchased as sterile should be used according to manufacturer's directions. The sterility of a packaged item is event-related and depends on the quality of a wrapper material, the storage conditions, conditions during transport, and the amount of handling.
viii. Refer to manufacturer's product information and package inserts for specific, detailed storage and handling protocols.
ix. Correct cold-chain procedures must be observed during transit, warehousing, shipping and storage.

b. Best practices in storage and handling vaccines

A vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition. It begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, then delivery and storage at the provider facility, and ends with administration of vaccine to the patient. The cold chain relies on three main elements: well-trained personnel, reliable transportation and storage equipment and efficient management procedures.

Failure to store and handle vaccines properly can reduce vaccine potency. This may result in inadequate immune responses in patients and poor protection against disease. Storage and handling errors can also result in significant financial loss if these products cannot be used. Below are best practices recommended by WHO, Centers for Disease Control and Prevention (CDC):

i. Arrange for a constant electrical supply to the cold storage or alternative supply of electricity for cold rooms and refrigerators if the main source of electricity is not reliable (Ex. UPS, solar panel generator). If the generator is not solar-powered, maintain a stock of fuel sufficient to run the generator for at least a few days. Run the generator on a regular basis (at least once a month) to ensure the system is working properly. Larger facilities may want to contract out the maintenance of the generator and electrical system.
ii. Always have enough frozen icepacks to transport items requiring cold storage in cold boxes and/or vaccine carriers. Use only icepacks filled with water. Do not use icepacks prefilled with other liquids, which are usually blue or green. When ordering cold chain equipment, larger facilities should reassess the needs for icepacks and icepack freezer space.
iii. Vaccines must not be transported with any radioactive products, food products (fish, meat) and shall not be stored in deli, fruit and vegetable drawers, or in the refrigerator door. The temperature in the door is not stable and differs from that of the inside unit.
iv. Check vaccine temperatures upon arrival at the storage facility and ensure immediate storage at manufacturer-recommended temperatures. Vaccines' physical appearance is NOT a reliable indicator that vaccines have been stored under appropriate conditions.
v. It is important to follow the manufacturer's recommended storage conditions for all products. Different terms of storage conditions can be viewed in *Guidelines for the Storage of Essential Medicines*.

Designated personnel maintain temperature log (monitor temperature at least twice daily for vaccine storage) and ensure alternative storage method is in place in the event of power or refrigerator failure. Any temperature reading outside ranges of the recommended temperature is considered a temperature excursion. If temperature monitoring device indicates a reading outside the recommended range, first check that device is appropriately placed.

Figure 3. Vaccines printed with a vaccine vial monitor (VVM)

In addition, one of UNICEF's best practice is that vaccines are delivered with a vaccine vial monitor (VVM). A vaccine vial monitor is a circular indicator, with an inner square made of heat-sensitive material. It is initially light in color and turns darker when exposed to heat over time. By comparing the color of the square to the surrounding reference ring, health workers can determine the extent to which the vaccine has been exposed to heat and if it has been spoiled. The vaccine can be used as long as the color of the square is lighter than that of the ring. VVM helps health workers to determine whether the vaccines are still usable.

c. Access-controlled storage

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, and to provide increased security for those items. This includes products that are in high demand or have the potential for resale (black market value). WHO Model List of Essential Medicines include several narcotics and psychotropic medicines, typical examples are:

i. Opioid analgesics: codeine, morphine and oxycodone
ii. Medicines for other common symptoms in palliative care: amitriptyline, diazepam, cyclizine, fluoxetine, haloperidol and midazolam
iii. Anticonvulsants/antiepileptics: lorazepam, carbamazepine, phenobarbital

Some of the medicines mentioned earlier are controlled substances, which are medicines handled under international control. Access-controlled storage include storing products in a separate locked room, cabinet or safe or a locked wire cage within the storage facility. These medicines need greater attention. There are specific procedures in place for the procurement, reception, storage, dispensing, and administration of controlled substances. Special ordering forms that needs approval should be used such as the Stock Withdrawal Request Form and Stock Card (Ask GPSU for a copy of these forms).

Other medicines, including antiretrovirals used to treat HIV/AIDS, may need storage in a controlled facility, because they are scarce, expensive, and in high demand.

Organizations donating medicines may require that those medicines be stored in a controlled environment. These may be products donated for a specific condition that can also be used for other conditions. Examples include medicines used to treat opportunistic infections for HIV/AIDS and medicines used to treat sexually transmitted infections that might also be on the NEML and used for other conditions; or HIV test kits that may be donated for use in specific programs, such as preventing mother-to-child transmission, but can be used for other purposes, such as ensuring blood safety.

d) Storage and handling of medical devices and equipment

Medical devices and equipment are provided with a product manual/package insert/CD. Information written in these materials aim to provide consumers or end-users with clearer, more comprehensive product and usage information.

They contain the product name; performance, indication for use, efficacy and/or effectiveness; instructions for use; instructions for storage; instructions for cleaning/disinfection; cautions; principle of operation; maintenance instructions; clinical studies; name, address and contact details of manufacturer and importer.

7. **Phase VII, Distribution**

Distribution of pharmaceutical products, vaccines, and medical supplies is centered on safe dispensing and labelling of medicines, and on providing a good service. Doctors are responsible for prescribing the right drug with the right dose to the right patient based on the right diagnosis at the right time. The pharmacist on the other hand has to exercise an independent judgment to ensure that the medicine is safe and appropriate for the patient, as well as it conforms to the prescriber's requirements. All medicines shall be written in a clear, legible, accurate and complete manner to prevent or minimize medication error. This shall apply to medical practitioners including doctors, pharmacists and other healthcare personnel.

All dispensed pharmaceutical products shall be properly labelled. Label shall include the following information: name of the dug, dosage form, dosage strength, frequency, expiration date, storage. For medically-related concerns or clarifications, mission procurement focal point/procurement staff can consult GPSU or MHD.

8. **Phase VIII, Disposal of Health Care Waste**

It is very important to dispose of pharmaceuticals properly because there can be very negative consequences to improper disposal. Improper disposal can result in contaminated water supplies, the diversion and resale of expired or inactive medicines, and improperly incinerated products, which can release toxic pollutants into the air.

Types of health care waste

a) *Sharps waste* – single-use disposable needles, needles from auto-disable delivery systems, scalpel blades, disposable trocars, sharp instruments requiring disposal, and sharps waste from laboratory procedures

b) *Other hazardous chemical waste* – waste contaminated with blood, fluids, human tissue; compounds such as mercury; pressurized containers; and wastes with high heavy metal content

c) *Pharmaceutical waste* – expired, damaged, or otherwise unusable medicines and items contaminated by or containing medical substances

It is recommended to use a medication disposal form to record expired and damaged pharmaceuticals. Proper personnel protective equipment such as gloves, mask, and eye goggles and apron should be used during disposal.

For methods of health care waste disposal please refer to local country regulations

Important Note:

Waste types not to be incinerated:

- Pressurized gas containers
- Large amounts of reactive chemical waste
- Silver salts and photographic or radiographic wastes
- Halogenated plastics such as polyvinyl chloride (PVC)
- Waste high with mercury or cadmium content, such as broken thermometers, used batteries and lead-lined wooden panels
- Sealed ampules or ampules containing heavy metals

The World Health Organization has set Guidelines for Safe Disposal of Unwanted Pharmaceuticals In and After Emergencies. The disposal methods for various categories of pharmaceuticals are identified in the following table.

CATEGORY	DISPOSAL METHODS	COMMENTS
Solids	Landfill	No more than 1% of the daily municipal waste should be disposed of daily in untreated form (non-immobilized to a landfill).
Semi-solids	Waste encapsulation	
Powders	Waste inertization Medium and high temperature incineration (cement kiln incinerator)	
Liquids	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics not to sewer
Ampules	Crush ampules and flush diluted fluid to sewer	Antineoplastics not to sewer
Anti-infective drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to sewer.
Antineoplastics	Return to donor or manufacturer Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator) (chemical decomposition)	Not to landfill unless encapsulated. Not to sewer. No medium temperature incineration.
Controlled drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Not to landfill unless encapsulated.
Aerosol canisters	Landfill Waste encapsulation	Not to be burnt: may explode.
Disinfectants	Use To sewer or fast-flowing watercourse: small quantities of diluted disinfectants (max. 50 liters per day under supervision)	No undiluted disinfectants to sewers or water courses. Max. 50 liters per day diluted to sewer or fast-flowing watercourse. No disinfectants at all to slow moving or stagnant watercourses.
PVC plastic, glass	Landfill	Not for burning in open containers.
Paper, cardboard	Recycle, burn, landfill	

Table 3. Disposal Methods for pharmaceuticals

Safety Boxes

Safety boxes or sharps containers are puncture- and water-resistant, impermeable containers. When used correctly, they reduce the risk of skin-puncture injuries that may spread disease.

- Do not recap syringes before disposal.
- Place the syringe and needle in the sharps box **immediately** after use.
- Keep the sharps box where the injections are given.
- Do not overfill the sharps containers (about ¾ full).
- When ¾ fill, close the box tab completely to cover the opening and tape it shit.
- Store the box in a safe and secure location until ready for final disposal.
- Do not empty and refill sharps boxes. Fill once and discard immediately.

Managing health care waste is a comprehensive program that requires support at all levels of the health care system. Staff involved in health care waste management must be given training and support. Check with local officials about laws that pertain to health care waste management and environmental protection before instituting a disposal technique.

IV. DONORS

IOM works closely with the donor community as well as migrants, governments and other partners in the international community to address today's many and complex migration challenges. To carry out these activities, IOM's main financial resources come directly from governments. In addition to Member donor governments, IOM also works with UN agencies, the private sector and foundations. Over the years, IOM has extended its donor base and developed a variety of approaches with partners to secure funding to implement project activities. In addition to the IN168 conditions, there may be more stringent procurement requirements for medical supplies by the Donor which we have to always check and comply.

Important Note:
Always check which procurement guidelines, donor or IOM, will apply for every medical and pharmaceutical procurement process.

V. GLOSSARY

Generic medicines, simply called "generics" are medicines that are exact copies of the proprietary medicine; they contain the same active ingredient in the same dosage and have the same pharmaceutical form. They are said to be bioequivalent. Therefore, they have the same treatment efficacy. They can only be manufactured and sold once the patents protecting the proprietary medicine have expired. Generic medicines are generally much cheaper than the proprietary medicines.

Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice'), is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.

International Non-proprietary Name (INN), is the internationally agreed scientific name of the active ingredient contained in the medicine. It uniquely identifies a particular product.

Lead time, is the total period of time needed from the time a decision is made to use a particular product until it is available for use.

Lot release certificate, is the official document that authorizes the manufacturer to release the specific lot onto the market. The certificate may include the following information: name and address of manufacturer; Site(s) of manufacturing; trade name and/common name of product; marketing authorization number; lot number(s) (including sub-lot numbers, packaging lot numbers if necessary); type of container; number of doses per container; number of containers/lot size; date of start of period of validity (e.g. manufacturing date) and/or expiry date; storage condition; signature and function of the authorized person and authorized agent to issue the certificate; date of issue of certificate; and certificate number.

Material Safety Data Sheet (MSDS). It is a detailed informational document prepared by the manufacturer or importer of a hazardous chemical. It is intended to provide workers and emergency personnel with procedures for handling or working with that substances in a safe manner

Sterile, free from bacteria or any other living microorganisms

Therapeutic substitution, takes place when a different drug is given, usually a cheaper drug within the same therapeutic class to the drug that was originally prescribed by the doctor

Vaccine vial monitor (VVM), a circular indicator, with an inner square made of heat-sensitive material. It is initially light in color and turns darker when exposed to heat over time.

VI. APPENDICES

Appendix A: Pharmaceutical Checklist

Adapted from the content of the WHO Technical Report Series, No. 937, 2006

Prequalification of pharmaceutical supplies	
Solicit and Receive Expressions of Interest	
Specifications for the product has been established with the following details:	
☐	The name of the active pharmaceutical ingredient (s)
☐	Pharmacopoeia reference (if any)
☐	Strength per dose and dosage form
☐	Dosage form (route of administration)
☐	Pack size
☐	Packing material
☐	Labeling requirements
☐	All specifications required were detailed as part of the invitation for EOIs (Expression of Interest)
Product Information and sample for analyses submitted for review:	
☐	A product dossier is available and submitted for consideration for multisource (generic) products, if applicable.
☐	A product dossier is available for innovator products which have been on the market for less than five years (if applicable)
☐	A product dossier is available for products containing substances that have specific properties that may have explicit impact on the safety, efficacy or quality of the product.(if applicable)
☐	A standard product dossier as prepared for a **national** drug regulatory authority can be submitted.
For products manufactured and registered in countries where regulatory requirements are in line with international regulations the following should be submitted:	
☐	A WHO-type certificate of a pharmaceutical product issued by one of the regulatory authorities of an International Conference on Harmonisation (ICH) region, together with a summary of a product characteristics
☐	An assessment report issued by the regulatory authority
☐	A WHO-type batch certificate from the manufacturer: If packaging of the product is different from that approved by a regulatory authority of an ICH region, stability testing should be submitted. If the formulation, strength or other specifications are different from the product for which the WHO-type product certificate (CPP) was issued, data to support the applicability of the certificate despite the differences should be submitted.
☐	If required, a pharmaceutical product questionnaire is available
Screening Product Information for completeness as part of the review process:	
Information to be checked and recorded:	
☐	Date of Receipt
☐	Name of Manufacturer
☐	Address of Manufacturer
☐	Name of the Product
☐	Country of Manufacturer
☐	Product Number
☐	Outcome of the Screening
Analyses of Samples when applicable	
☐	Samples for analysis is accompanied by product information packages

☐	Samples were analyzed with the finished product specifications
☐	Quality laboratory that is accredited and complies with GMP and good practices for control laboratory is available for analyses
Existing Certificates	
☐	Information in addition to the CPP is available (do not rely solely on the CPP)
☐	Compliance with the WHO GMP is verified
☐Yes ☐ No	Inspection of the Manufacturing site is required (see cGMP checklist)
Pre-Qualification Product Information Checklist on Received Product	
☐	INN of active ingredients
☐	Strength of product
☐	Dosage form
☐	Pack size
☐	Shelf-life
☐	Storage Conditions
☐	Name of Supplier
☐	Name of Manufacturer and Manufacturing Site
☐	Product has been inspected upon arrival to ensure that expiration dates are consistent with purchase order and there is no damage to goods.

Appendix B: Checklist for the Inspection of Pharmaceutical Manufacturers

Developed from the Troutman Sanders Current Good Manufacturing Practices Checklist for Pharmaceutical Manufacturers

Site: _____ *Country:*_____

Current Good Manufacturing Practices for Pharmaceutical Manufacturers	
Records and Reports	
☐	Pharmaceutical Manufacturer maintains the production, control and distribution records and retains the records for a minimum period of time after the expiration date of an active ingredient, a batch of a drug product, or other set marker
	Retained records are readily available for inspection
☐	Manufacturer evaluates records and data contained within, at least annually, to determine quality standards of each drug product
☐	Manufacturer maintains a master production and control records for each drug product
☐	Manufacturer maintains batch production and control records
☐	Manufacturer maintains all data derived from all tests necessary to assure compliance with established specifications
☐	Manufacturer maintains component, drug product container, closure and labeling records
☐	Manufacturer maintains distribution records which include the name and strength of each product and describes the dosage form, name and address of the consignee, data and quantity shipped, and control number of the drug product
☐	Manufacturer requires the establishment and following of written procedures for the handling of written and oral complaints
Production and Process Controls	
☐	Has established and follows written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality and purity they are purported to contain.
☐	Has documentation of performance of compliance with established written procedures for production and process controls at the time of performance.
☐	Has established and follows written procedures that detail in-process controls, tests, or examinations to be conducted to assure batch uniformity and integrity of in-process materials of each batch and the final drug product.
☐	Has established and follows written procedures of a system for reprocessing batches found not to conform to specifications and actions necessary to ensure that the reprocessed batch conforms to established specifications.
Laboratory Controls	
☐	Has established and follows scientifically sound and appropriate specifications, standards, sampling plans, and/or test procedures designed to assure identity, strength, quality and purity.
☐	For each batch of drug product, there is appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release.
☐	Has established and follows written testing programs designed to assess the stability characteristics of drug products.
☐	Has appropriately identified reserve samples that is representative of each lot in each shipment of each active ingredient and has retained them.
Quality Control Unit	
☐	Manufacturer has established a Quality Control Unit with written procedures and responsibilities with authority to approve or reject everything from drug components to the final drug product
☐	Quality Control Unit has adequate laboratory facilities for the testing and approval or rejection from drug components to the final drug product.
☐	Quality control unit is also responsible for approving or rejecting procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

Packaging and Labeling Controls	
☐	Has established and follows written procedures describing the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials.
☐	Has established and follows control procedures for the issuance of labeling.
☐	Has established and follows written procedures designed to assure that correct labels, labeling and packaging materials are used for drug products and incorporates important features.
☐	Requires the examination of packaged and labeled products during finishing operations to assure that containers and packages in the lot have the correct label.
☐	Bears an expiration date determined by appropriate stability testing to assure it meets identity, strength, quality, and purity at the time of use.
Holding and Distribution	
☐	Has established and follows written procedures describing the warehousing of drug products, including description of procedures for quarantine of drug products before release by the quality control unit; and storage of drug products under appropriate conditions of temperature, humidity and light so that identity, strength, quality, and purity of the drug products are not affected.
☐	Has established and follows written procedures describing the distribution of products including a procedure whereby the oldest approved stock of a drug product is distributed first and the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.
Building and Facilities Control	
☐	Has clearly defined separate areas of operations within buildings or buildings to prevent contamination or mix-ups
☐	Has equipment which provides for adequate control over air pressure, micro-organisms, dust, humidity and temperature for the manufacturing, processing, packing or holding of a drug product.
Equipment Controls	
☐	Has established and follows written procedures for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product.
☐	Equipment and utensils are cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.
☐	Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems used in the manufacture, processing, packing and/or holding of a drug product must be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibrations and inspections must be maintained.

VII. REFERENCES

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