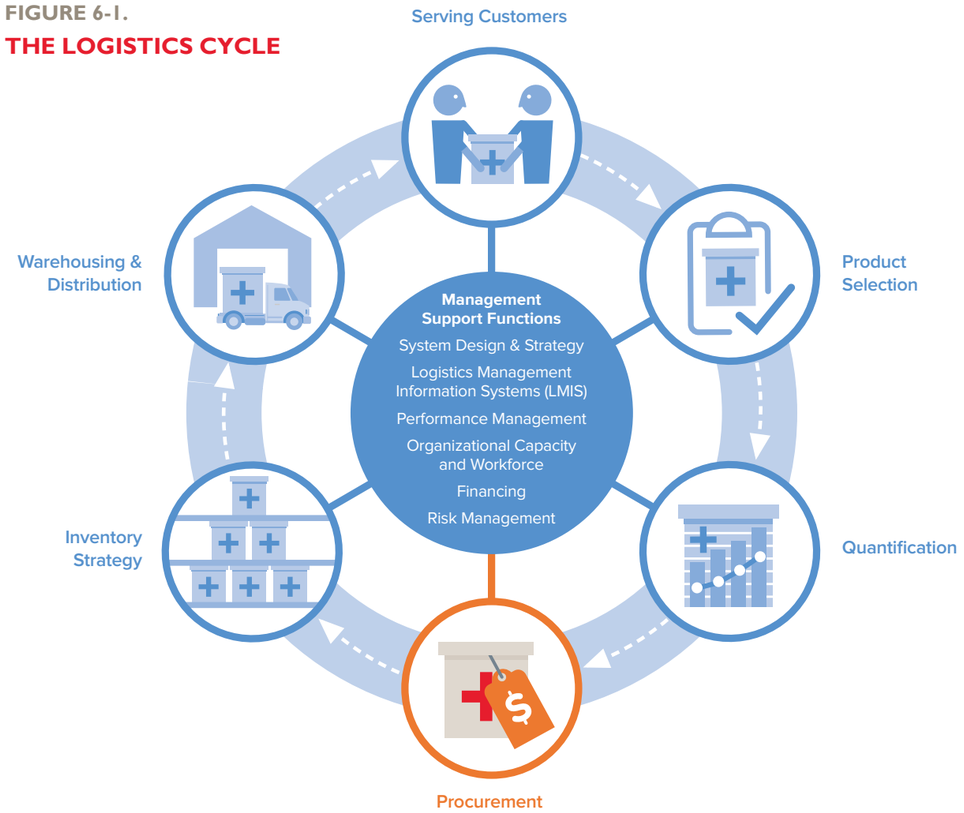
CHAPTER 6

HEALTH COMMODITY PROCUREMENT

FIGURE 6-1.
THE LOGISTICS CYCLE



WHAT A SUPPLY CHAIN MANAGER NEEDS TO KNOW:

The supply chain manager needs to know the following about health commodity procurement, which are covered in this chapter:

- The key challenges of procuring health commodities
- Key elements and considerations in crafting the procurement strategy
- The procurement cycle for public health sector systems
- The main steps to conduct a procurement

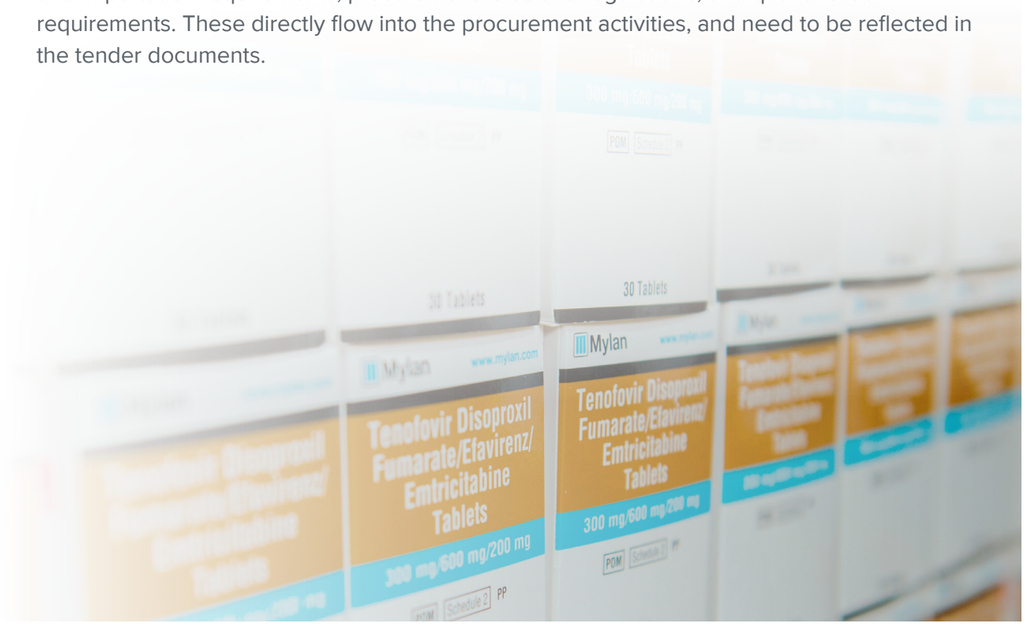
Procurement is a critical part of the logistics cycle (see figure 6.1) because it ensures that:

- Correct products are procured
- Products are of good quality
- Value for cost is maximized
- Supply of products is reliable and meets the demand
- Procurement process follows the rules and regulations of the local government and the funding agency

6.1 THE COMPLEXITY AND CHALLENGES OF PROCUREMENT

Only effective and rigorous procurement policies, processes, and procedures can ensure a reliable flow of commodities into the supply chain, and can effectively respond to any contextual or operational changes in the supply chain.

The procurement function is affected by preceding elements of the logistics cycle and the regulatory context. Factors include the characteristics of the products, registration, quality and importation requirements, procurement rules and regulations, and quantification requirements. These directly flow into the procurement activities, and need to be reflected in the tender documents.



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However, the procurement activities are also shaped by downstream activities in the logistics cycle, including distribution plans, whether they need to be pre-packed for dispatching or kitted, and whether there are specific brands or models that users or service providers have been trained to use.

6.1.1 THE KEY STAKEHOLDERS

The procurement process involves many different parties, whose decisions and requirements have a direct impact on the way the procurement can be conducted:

The in-country government program unit (i.e., the Family Health Division, National Malaria Control Program, etc.) or the Ministry of Health usually determines which products need to be procured to support their programs. Most of the time, the national essential medicines list and the national standard treatment guidelines must be consulted to select the needed products.

The National Drug Regulatory Agency (NDRA) has the most up-to-date information on requirements for:

- Product registration (including the product categories requiring registration, registration expiration dates, or submissions pending approval)
- Quality, such as international pre-qualifications and potential local product testing
- Importation requirements

Understanding these requirements is critical as they will feed the technical requirements of the tender.

The funding agency (e.g., donor, granting, or lending organization, or national government) has procurement rules, regulations, and requirements attached to the use of the funds and has its own timeline for the release of funds. (refer to Chapter 10).

The supply chain partners in country that are responsible for the warehousing and distribution of the commodities. Their operational and distribution plans may have a direct impact on the packing requirements, the final destination, etc., which need to be specified in the tender document.

The suppliers and manufacturers who will be responsible for manufacturing the commodities and for carrying out the registration with the NDRA. Their past performance is standard evaluation criteria in the tender document.

6.1.2 SPECIFIC PROCUREMENT CHALLENGES

Given the scope, high profile, and value of the purchases, the nature of the commodities, the number of stakeholders, or the strict nature of public procurement procedures, challenges often arise during the procurement process. While a wide range of issues can affect procurement, the most common and critical procurement challenges revolve around the following:

LENGTHY PROCUREMENT PROCESS AND EXTENSIVE LEAD TIME

Each step of the process requires a certain amount of time to complete. While some steps can be done in parallel and will vary in the time required, some are often fixed for a set period, and may require validation or concurrence of one or several stakeholder(s).

PRODUCT QUALITY ASSURANCE

Counterfeit and substandard products are in the marketplace, creating significant product quality risks for the supply system. To address this risk, public sector procurement processes and national regulatory agencies must implement appropriate quality assurance measures to ensure that only good quality products enter the supply system. Procurement addresses this responsibility through the technical specifications, issued in the tender document, which identify key product quality requirements, such as product certification requirements, pharmacopeia standards (when applicable), labeling and packaging requirements, shelf life requirements, etc.

TRANSPARENCY, EQUITY, AND INTEGRITY THROUGHOUT THE PROCUREMENT PROCESS

The procurement unit must support an open procurement process by consistently applying relevent procurement regulations and procedures, and international best procurement practices that promote transparency and accountability.

PROJECTIONS AND ESTIMATES

Cost projections and lead time estimates are often difficult to make. The procurement unit should be aware of the main market trends, although it cannot readily gather information specific to a tender prior to the publishing of the tender document and receipt of the bids.

6.2 DEVELOPING THE PROCUREMENT STRATEGY

6.2.1 UNDERSTAND THE CONTEXT OF THE PROCUREMENT

Procurement activities should be conducted in the context of the overall health program and supply chain: procurement is one piece of the logistics cycle with many challenges and stakeholders. To best align procurement activities with the overall health program goals and supply chain strategy, the procurement unit should be aware of the following:

- Program information: goals, targets, timelines, stakeholders
- Importance of the program for the organization, the client
- How procurement activities align operationally with other elements of the logistics cycle

6.2.2 RESEARCH THE SUPPLY AND DEMAND MARKETS

In order to design the procurement strategy, the procurement unit develops a good understanding of the market by covering the following areas:

- **Market structure**
  What is the size of the market? How many suppliers are in the market? What is their size (production, capacity, market share)? Where are suppliers located? What is the degree of market concentration? What are the market trends?

- **Competition**
  What are the competition criteria (price, quality, service, other?) What are the barriers to entry? What are the key competitive advantages?

- **Supply chain**
  How complex is the supply chain from raw material to finished product? How stable is that chain; what are the vulnerabilities?

- **Products**
  Are there any alternatives or substitute products or suppliers? What is the extent of product differentiation? Specifically for health commodities, are there branded (patented) products or generic products? Are there any quality standards segmenting the products?

- **Value as a customer**
  What is the procurement's market share and attractiveness and hence the leverage as a customer for the suppliers?

- **Prices**
  Inputs on pricing are valuable, especially for budgeting purposes. The procurement unit can research pricing using reference prices, historical prices, and existing relationships with players in the market other than the suppliers. Even if the procurement has existing relationships with suppliers, they should refrain from directly reaching out to these suppliers before and during the bidding period until a contract is awarded because of the transparency and fairness requirements in public procurement.

The Request for Information (RFI) and Request for Expression of Interest (RFEOI) are very useful tools similar to Request for Quotes (RFQ) and Request for Proposals (RFP), except that the RFI's purpose is strictly to get information, and both do not directly lead to the award of a contract. The RFI's and the RFEOI's main purposes are to:

- Develop a clearer understanding of the market
- Stimulate interest and assess the market for interested parties
- Align the technical requirements with the market's capacity
- Help determine the most appropriate procurement approach

6.2.3 IDENTIFY THE APPLICABLE RULES AND REGULATIONS, AND REQUIREMENTS

Depending on the stakeholders, various sets of rules and regulations (regarding procurement, importation and distribution, use of funds) and quality assurance requirements apply to the procurement activities, namely those flowing from:

- The funding entity
- The organization conducting the procurement activities
- Local regulatory requirements
- Applicable standard treatment guidelines

The funding donor or the procuring organization may pre-qualify sources for its procurement activities. If there are no prequalified sources, the following quality criteria and certifications are often considered as the most reliable:

- Products approved by a Stringent Regulatory Authority (SRA)
- WHO Prequalified (WHO PQ) products
- Products reviewed by the WHO Expert Review Panel with a category 1 or 2 result

Photo courtesy of John Snow, Inc.

Alternatively, the following criteria are valuable sources to gauge the quality of the products:

- Pre-qualification and/or recent use of the suppliers by international organizations (USAID, UNICEF, UNFPA, the Global Fund, etc.)
- Confirmation that the product is manufactured in a current Good Manufacturing Practice (cGMP) certified site
- CE, ISO certifications.

Good Manufacturing Practices (GMPs)
"GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine; insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects. GMP covers all aspects of production, from the starting materials, premises, and equipment to the training and personal hygiene of staff. GMP requires detailed, written procedures for each process that could affect the quality of the finished product and systems to provide documented proof that the correct procedures are consistently followed. Many countries have formulated their own requirements for GMP based on WHO GMP. Others have harmonized their requirements, for example, in the Association of Southeast Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention."

Registration
Most health commodities and especially pharmaceuticals need to be registered in the destination country to be imported and distributed in country. Active registration or ability to obtain an import waiver should therefore be a requirement in the bidding documents, and should be verified with the manufacturer and/or the national drug regulatory authority (NDRA). In case a product is not registered in country, the product will need to have the government's approval for importation and distribution in country via a waiver. Waivers normally require proof of product quality, although the document set is not as comprehensive as that for registering a product.

Some countries participate in WHO-supported regulatory harmonization initiatives which may be a good source of information regarding national regulatory policy and registration status in country. Examples include African Vaccine Regulatory Forum and the African Medicines Regulatory Harmonization (AMRH) initiative.

Custom clearance and importation

In addition to registration requirements, customs clearance and importation requirements should be clarified with the in-country regulatory agency and reflected in the tender documents. While the incoterms (shipping terms, responsibilities and costs) may vary, it is the responsibility of both the purchaser and supplier to support the customs clearance and importation process by ensuring that the necessary documentation is provided. Insufficient or incorrect documentation can cause unnecessary delays in clearance, which frequently leads to charges.

6.2.4 RISK MANAGEMENT

Risk management is the systematic application of management techniques (policies, procedures, practices) to identifying, analyzing, and prioritizing risks, and to mitigating the likelihood and/or the consequence of a risk happening. Risk management is, therefore, a way to anticipate, avoid, and/or mitigate the negative impact the occurrence of an event can have on the outcome of the procurement (See chapter 11).

At a minimum, the following list should be put together and reviewed through the end of the procurement activities:

- Hierarchized list of the potential risks based on the likelihood of each risk to occur (low, medium, high) and the impact of each risk in case of occurrence (low, medium, high)
- Mitigation plan for each risk (against occurrence and/or impact), or at least for any medium-high and high-high combinations

Any disruption in the supply chain results in a potential risk and change for the procurement activities, so it is important that risk management is conducted throughout the supply chain and that the procurement unit is associated in this work to evaluate the potential impact on the procurement activities and to design a way to mitigate it.

In addition, the procurement activities are themselves subject to specific risks, divided in three main categories:

Technical risks
Typical technical risks are non-technical conformance, quality issues. They are mainly mitigated in the technical specifications of the tender document..

Commercial risks
Typical commercial risks are the supplier's financial viability, capacity to perform the contract (in time, at the agreed price, etc.). They are mainly mitigated in the tender document's requirements (specifications around past experience and financial statements, weight of these criteria in the evaluation), and in the contractual terms and conditions (with clauses such as liquidated damages, price variation clauses, termination clauses).

Administrative risks
Typical administrative risks are funds availability, obtaining the necessary clearance and concurrence from the relevant stakeholders through the procurement cycle. They are mainly addressed by carefully planning the administrative tasks associated with the purchase and determining the associated timeline.

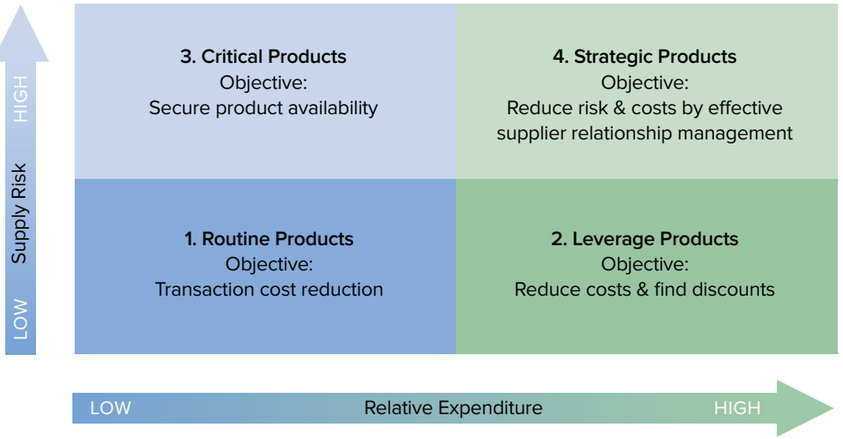
6.2.5 BUILD THE PROCUREMENT PLAN

6.2.5.1 IDENTIFY THE OVERALL PROCUREMENT OBJECTIVES

Based on the previous section, the procurement unit has enough information to be able to classify the procurement according to the matrix below, which in turn provides the overall procurement objectives and the type of relationship to develop with the supplier.

The supply positioning matrix figure 6-2 evaluates each major category of products to be procured according to the supply risk (difficulty of securing supply) and its relative expenditure (compared with the total value of products procured; this can be fine-tuned with considerations of how urgently the products are needed or how strategic they are for the program or the organization).

FIGURE 6-2.
SUPPLY POSITIONING MATRIX



For **routine products**, the objective is to reduce the transaction costs, e.g., simplifying the ordering system; the relationship with the supplier is usually transactional only. The contract is usually based on a fixed price, either reduced to a simple purchase order, or a long-term contract with indefinite quantity.

For **leverage products**, the objective is to reduce costs and find discounts. The market is dynamic and there is little supply risk which constitutes an opportunity to maximize the competition to get attractive prices and conditions. The contract type is usually a long-term contract with several suppliers which are then invited to competitively bid regularly for release orders.

For **critical products**, the objective is to secure product availability. Otherwise, failure to secure supply means a potential bottleneck in the supply chain. A close relationship and strong communication with the supplier should be maintained. The contract is usually a long-term contract, with a fixed price and quantity (or with a minimum quantity).

For **strategic products**, the objective is to focus on optimal supplier and contract performance management. A strategic relationship with the supplier needs to be maintained (long-term focused, partnership based). The contract is usually a long-term contract, with a fixed price and indefinite quantity with a ceiling.

6.2.5.2 SELECT THE PROCUREMENT METHOD AND THE CONTRACT TYPE

Depending on the value of the procurement and/or the nature of the products to be procured, the following are the main methods of procurement.

- **"Shopping"**: there is usually a threshold under which organizations authorize the procurement unit to simply buy the products without any formal competitive bidding
- **Limited-competitive bidding**: only a limited number of suppliers are invited to participate to the bidding process. This occurs when the funder and procurement agency have rules and regulations limiting procurement of certain products from only pre-selected suppliers. In this scenario, it is important that the procurement unit carefully documents the rationale behind the limited-competitive bidding.
- **Sole-source procurement**: only one single supplier is invited to participate in the bidding process. This occurs when only one source is able to supply the requested product. In this scenario, it is important that the procurement unit carefully documents the rationale behind the sole-source justification.
- **Competitive bidding**: Suppliers are invited to submit formal bids in response to a tender which is publicly published, advertising the scope, specifications, and terms and conditions of the proposed contract, as well as the criteria by which the bids will be evaluated. The procurement unit creates a tender document, to solicit formal offers from suppliers.

Depending on the nature of the program and the procurement (one-time procurement versus a multi-year supply program), and the market environment (sole-source versus competitive supply), the procurement unit needs to identify the contract type that will be best suited for the activity. It is important to think about the contract type early in the procurement planning as the contract sets the framework in which the transactions and the interactions between the buyer and the supplier will take place. In addition, the contract type as well as the terms and conditions (general and specific) need to be mentioned in the tender document.

Every contract is different, as it should be uniquely adapted to the product category, the supply chain requirements, and the procurement strategy. The following are the main contract types and aspects to consider:

Duration:

- Some contracts are **one-off** contracts, capturing one single purchase order (PO). The contract can be reduced to the PO, provided that it captures the elements listed further below and references documents (such as the tender document or the bid) and agreements made during the procurement cycle by the two parties. Prices of such contracts are usually fixed (see below).
- On the other side of the spectrum, **long-term** contracts are in place for several years, thus giving a framework for a potential long-term relationship between the parties. Prices of such contracts can be fixed or variable (see below).

Price:

- The price in a contract for the supply of health commodities is usually **fixed**, and firm (compared to **adjustable prices** – for example, in the case of a price linked to a raw material's price). The advantage for the buyer is to be able to manage the value of the procurement more easily.

Quantity:

- A **minimum** quantity in the contract helps secure the supply
- An **indefinite** quantity in the contract (though usually with a minimum and a ceiling quantity) gives the flexibility to respond to changing demand
- A **firm** quantity in the contract usually helps the supplier to offer the most possible competitive price although it increases the buyer's risk if there is a change in demand

A contract should capture the following as agreed between the parties:

- Key technical specifications of the product
- Quality-assurance requirements
- Quantity
- Delivery schedule
- Delivery terms (INCOTERMS)
- Contract value
- Contract duration
- General terms and conditions
- Special terms and conditions (such as liquidated damages)
- Payment conditions
- How changes to the terms of the contract should be managed

6.2.5.3 DETERMINE THE PROCUREMENT TIMELINE

Procurement is often a lengthy process, with a lot of steps and stakeholders at every stage. A full timeline should be developed, updated, and communicated with the stakeholders (internal and external) to ensure an efficient integration within the whole supply chain, to plan and support the procurement cycle, avoid stockouts, and manage stakeholders' expectations.

The procurement timeline should capture at least the following:

- Key activities and milestones (such as specifications development, tender advertising, bids evaluation, contract award, product availability, transit, etc.)
- Estimated dates for completing each activity
- The name of the responsible parties for each activity
- The name of the parties who should receive the timeline updates

The supply plan and timeline, which is the final output from the quantification exercise, provide critical inputs to the procurement plan and timeline. The procurement activities should be started 24–36 months ahead of when products will be needed and the timeline should be updated regularly. This is usually a rolling activity given the cyclical nature of health products procurement—rarely is it a one-time activity. This process also ensures that all activities are accounted for, to ensure that the right products arrive in the right quantities, at the right time, in the right condition, at the right price, and to the right place.

Photo courtesy of C. Keddem, Myanmar

6.3 STEPS IN PROCUREMENT (FOCUS ON COMPETITIVE TENDERING)

In public procurement, each step is standardized and regulated according to the requirements of the various stakeholders and relies on thorough documentation and transparency throughout the process. This ensures that the whole process is fair and competitive, that stakeholders are engaged, and concur when needed.

It is critical to manage the procurement process effectively to ensure that procedures are followed and the process is well documented. An open and transparent process will increase competition and fairness while decreasing the risk of bidder protests.

The main steps in a procurement are captured in figure 6-3. These are the standard steps only; they do not include administrative steps linked to the stakeholders' specific requirements (for example, if approval to contract is needed from the funding entity) which need to be developed and incorporated in the procurement timeline.

FIGURE 6-3.
PROCUREMENT STEPS

6.3.1 DEVELOPING THE SPECIFICATIONS

Specifications are at the heart of procurement.
A specification is a statement of needs to be satisfied by the procurement. Good product specifications need to be complete, comprehensive, and accurate as they:

- Define the customer's needs
- Tell the procurement unit what to procure
- Tell the potential supplier what is required
- Establish the standards against which evaluation, inspection, tests, and quality checks would be made

There are three types of specifications:

- Functional specifications, such as the purpose, duty, role, or function of the product to be procured
- Performance specifications, such as the capability, input/output criteria, performance characteristics
- Technical specifications, such as the detailed physical characteristics

The basic product information is usually provided by program managers, but the procurement unit should also be sure to have the following confirmed as they are key specifications:

For pharmaceuticals:

- Generic name
- Dosage and formulation
- Shelf life
- Packaging (primary, secondary, tertiary, and for specific shipping)
- Adequate protection for cold-chain products
- Language on the inner and outer packaging, labels, and inserts
- Quality assurance specifications:
  - o Proofs of certifications and approvals (GMP/CE/ISO certification, WHO PQ, etc.)
  - o Manufacturing records, testing data, regulatory certificates, registration certificates, etc.
  - o Certificate of Analysis (COA), Certificate of Conformance (COC), Certificate of Origin (COO), testing results, etc., associated with the actual production batches when the contract is awarded
  - o Testing requirements including plans for inspection by the procurer or its contractor, product sampling procedures, testing requirements, retain samples requirements, etc.

For devices and equipment:

- Warranty
- Spare parts
- Customer service
- Training and installation

For products where there can be more than one supplier, specifications must be product-neutral and not written to favor one supplier or brand and model over another. Specifically, performance specifications should mention minimum requirements and acceptable tolerances whenever possible. In case a specific brand and product or model is requested, the rationale should be clearly explained, validated by the relevant stakeholders, and documented. In addition, waivers to restrict competition will usually need to be obtained.

Supplier's capacity
The specifications capture the requirements requested for the product. But it is critical to also be able to assess the supplier's capacity to perform. The following are the main criteria that can be used for this purpose:

- Past and similar experience,
- Financial viability (by requesting the last three years' financial statements, for example)

- Past performance with the procuring organization
- Organizational resources
- References who can share their experience with the bidder

6.3.2 THE TENDER DOCUMENTS

For effective competitive procurement, it is important that the tender document lays out in detail the following:

- Background and context of the procurement
- Quantities of the desired products
- Specifications of the desired products
- Quality assurance requirements of the desired products
- Delivery dates
- Incoterms and required destination of the shipment
- Instructions, bid submission forms and templates if applicable
- evaluation criteria and method which will be used to evaluate and select suppliers
- The procurer's General Terms and Conditions (GT&C)
- The procurer's Specific Terms and Conditions (ST&C)

The tender document needs to be publicly advertised (on organizational and government websites, in newspapers, trade bulletins, journals, and local bulletin boards). Additionally, the procurement unit can send invitations directly to suppliers it would like to bid.

6.3.3 EVALUATION CRITERIA AND EVALUATION METHODS

The evaluation of bids is the process of assessing offers in accordance with the established evaluation method and evaluation criteria, with a view to obtaining best value for the organization. The process needs to be conducted in a fair and transparent manner to ensure equal treatment of all bidders.

The evaluation of the bids received should be carried out based on the evaluation criteria and method detailed in the tender document. The following are the main phases of the evaluation:

- **Responsiveness of the bid:** This phase evaluates whether a bid is complete (all required documents and information were shared), was submitted in time, and follows the instructions laid out in the tender document.
- **Technical review:** This phase evaluates the bid against each technical requirement that was set out in the tender document. Bids which do not comply technically should be rejected and no longer considered.
- **Business review:** This is the evaluation of the proposed cost. Depending on the procurement, the business review considers the offered price only, or adopts a more total cost approach.

The main methods of evaluation are the following:

- Each bid is reviewed on a meet/does not meet criteria for every requirement in the tender document. Bids meeting all the requirements are deemed compliant, all non-compliant bids should not be further considered. The compliant offers are compared based on the offered price. The compliant bid with the lowest cost is the winning bid.
- The same method can be used with a hierarchized list of the key requirements based on the context of the procurement (for example, registration in country or lead time can be the differentiating criteria)
- Each bid is scored or scaled for every requirement and for the offered price. The winning bid is then the bid with either the highest technical score and the lowest cost, or the highest overall cumulative technical and business score.

The main activities in the evaluation phase are the following:

- Establishing an evaluation team if applicable
- Assessing the bids against the evaluation criteria
- Getting and reviewing clarifications from bidders if applicable/if needed
- Leading negotiations if applicable
- Completing the evaluation report with the recommendation for the contract award

Total cost and best value

Too often lowest cost is deemed the most important criteria to selecting a supplier while a program's success depends on selecting the supplier who will be able to deliver quality-assured products within the required timeframe for the best value.

Total cost of ownership (TCO) measures all the cost components (fixed and variable, direct and indirect) of supplying the needed products from a specific source. This calculation can be a complex one, encompassing costs such as installation, maintenance, doing business, etc.
For procurement of health commodities for the public sector, at a minimum, the following should be included in the calculation of the total cost:

- Purchasing price
- Shipping and insurance costs to the destination in country
- Custom clearance costs
- Storage costs during transit to the destination in country.

In addition, the procurement team should evaluate the bids with a best value approach. Again, a best value approach can be a complex evaluation. But in the case of health commodities, at a minimum, the reliability of the supplier around the following should be taken into account on top of the technical requirements and the price:

- Quality
- Country requirements such as registration and or pre shipment inspection
- Delivery schedule
- Continued existence
- Lowered risk

The approach should be described in the tender document.

6.3.4 CONTRACT AWARD

The contract is the outcome of the bidding process; it is the document which legally binds the purchaser and supplier to an agreed-upon set of commitments made through the tender document, the bid, and the subsequent communications, negotiations, and agreements between the parties.

The procurement unit should inform unsuccessful bidders in order to:

- Foster good relations with the suppliers
- Establish a reputation for openness and transparency
- Encourage unsuccessful bidders to bid in the future
- Help prevent costly and time-consuming protests

6.3.5 CONTRACT AND PERFORMANCE MONITORING

Contract monitoring and performance are necessary to ensure that the supplier is ultimately meeting its obligations so that products arrive on time and in good condition. A contract monitoring system:

- Ensures that the technical specifications and contract requirements are met, especially in terms of quality, price, schedules
- Enables the purchaser to identify any potential issues, changes, and conflicts
- Evaluates the supplier's overall performance

This system should include the following at a minimum:

- Timeline of the key milestone of the products' supply
- Pre-shipment document review

- Pre-shipment sampling, inspection, and testing
- Review of the Proof of Delivery (POD) which captures the delivery, receipt, and good condition of the products at the required destination
- Key performance indicators (KPIs)
- Procedures for addressing issues or disputes

Establishing a contract performance monitoring system and implementing it early in the contract process ensures that problems are identified and resolved early, before they become bigger problems. It also means that if there is an issue with production, the purchaser and supplier can work together to identify alternatives sooner, rather than later, when options may most more because the need is more urgent.

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