CHAPTER 21

Managing the tender process

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SUMMARY

The primary function of a procurement office is to obtain the required items at the right time, in the correct quantities, and at the most favorable prices. The procurement office compiles a list of requirements, identifies potential suppliers, selects the most cost-effective supplier for each product, secures firm supply contracts, and makes sure that the suppliers and the health system comply with contract terms. Competitive tenders are recommended for most pharmaceutical procurement in public-sector pharmaceutical systems, so this chapter addresses the principles of efficient tender management, focusing on the most common tendering models.

To maximize the benefit of pharmaceutical purchases, corruption and favoritism in procurement must be minimized. Equally important is avoiding the appearance of favoritism, so the tender process should be as transparent as possible under national procurement laws.

A formal tender process includes medicine selection, quantification, preparation of tender documents and contracts, notification and invitation to bid, formal bid opening, collation of offers, adjudication and supplier selection, contract award, performance monitoring of suppliers and clients, and enforcement of contract terms if necessary. Reliable suppliers are the cornerstone of effective procurement, and a prequalification process is recommended; tender adjudication and selection of suppliers is the critical step that determines the costs of medicines and defines the integrity of the procurement process. Adjudication should be based on formal written criteria and must be free from influence by special interests.

Accurate and timely information is critical at each stage of the process, and lack of effective information systems is a main cause of procurement delays and inefficiencies. The information system must be able to—

- Produce information for quantification and tender documents
- Collate offers for adjudication
- Issue notifications of award and purchase orders
- Track order status and compliance with contract terms
- Manage communications with contract suppliers
- Track suppliers' performance for future tenders

21.1 Introduction to tender management

Many of the major policy and management issues relevant to pharmaceutical procurement were covered in Chapter 18. Several types of procurement methods are used for pharmaceuticals, but the procurement method chosen for each medicine should—

- Obtain the lowest possible purchase price for high-quality products
- Ensure suppliers' reliability, in terms of both quality and service
- Maintain transparency in the process and minimize the opportunity for illicit influences on procurement decisions
- Achieve these objectives with the least possible professional and clerical staff time and within the shortest possible lead time

Table 21-1 summarizes the most frequently used methods to purchase pharmaceuticals.

This chapter focuses on the management of competitive tenders. Some global procurement mechanisms, such as the United Nations Children's Fund (UNICEF), the Supply Chain Management System, and the Global Fund's voluntary pooled procurement system, use negotiation as a primary tactic to establish contracts on high-use and high-cost items; as discussed in Chapter 18, these large procurement systems need to ensure multiple source options to assure steady supply and to be certain that multiple suppliers stay in the particular market. However, most modern laws and regulations covering public-sector procurement require competitive procurement methods. Negotiation can be legitimate when only a few suppliers are available for a particular product, but negotiation is not generally recommended when using public funds.

Country Study 21-1 shows how El Salvador lowered costs by making its tendering process more efficient.

This chapter discusses the best practices in managing the standard tender processes used to purchase pharmaceuticals. Historically, the tender process has been an annual cycle in most public-sector health systems. In some situations, tenders are conducted two or three times per year; however, some procurement offices have begun entering into multiyear framework contracts to reduce the administrative burden of managing frequent tender cycles. Global procurement systems such as UNICEF and USAID's Supply Chain Management System also use these sorts of framework contracts for selected products.

As discussed in Chapter 18, Internet-based approaches, including "e-procurement" with "reverse auctions," have been advocated for public-sector procurement, with the

most experience occurring in Latin America. These methods, however, have not yet been proven for pharmaceutical procurement.

The standard steps in the normal tender cycle are—

1. Determine the tender format and scope.
2. Define requirements—select and quantify medicines and supplies.
3. Select suppliers to participate in the tender.
4. Prepare and send tender documents.
5. Receive and open offers.
6. Collate offers for adjudication.
7. Adjudicate the tender.
8. Issue contracts to winning bidders.
9. Monitor performance and product quality.
10. Enforce contract terms as needed.

Each of these steps requires informed decisions about which of several possible procedures best fits the particular situation. In most countries, options will be limited by procurement laws and regulations, but even in the most restrictive legal settings, the procurement program has several choices to make. The goal of this chapter is to provide information to help procurement managers make the best choices for their own situations.

21.2 Determining the tender format and scope

Some countries have procurement regulations that specify the tender format for pharmaceutical purchasing. The World Bank and some bilateral donors may mandate specific tender formats for procurement financed by loans or donated funds (see References and Further Readings). However, in many cases, flexibility exists in structuring the tender; in those situations, options include—

- Restricted versus open tender
- Local or international scope
- Estimated or fixed tender quantities
- Split or single tender awards
- Primary/secondary contracts or rebids
- Required or optional use of local agents in international tenders
- Annual or biannual tenders versus multiple tenders during the year

Table 21-1 Comparison of procurement methods

Procurement method	Brief description	Effect on price	Procurement lead time	Workload for procurement office	Need for evaluating suppliers	Conditions favoring use
Open tender	Bidding is open for all interested suppliers	Usually lowest prices	Moderate to long	High	High	• When many reputable suppliers are available and likely to be interested • If prequalification is not feasible or not allowed by regulation or donor's provisions
Restricted tender	Participation of suppliers is limited to those who have registered with the government or who have prequalified	Favorable	Moderate to long	High	High	• When substantial list of registered suppliers has been developed • When capacity exists to manage prequalification and supplier monitoring
Competitive negotiation	The buyer approaches a small number of potential suppliers and negotiates for specific price or service arrangements	Can be favorable	Short to moderate	Moderate	High	• Experienced purchasing office with good access to market intelligence • Low-price or small-volume items • When there are few suppliers • When special terms or specifications are required by the buyer for items not widely available • Emergency purchases to supplement tender
Direct procurement	Purchase is made directly from a single supplier at the quoted price	Usually highest prices	Short to moderate	Low	High	• Emergency purchases when negotiation is not possible • Purchase of single-source pharmaceuticals • Low-price or small-volume items

Country Study 21-1
El Salvador: Improving efficiency through joint tendering

In El Salvador, the Strategies for Enhancing Access to Medicines (SEAM) Program's 2001 assessment found that some essential medications were lacking in both public health care facilities and those of nongovernmental organizations (NGOs). At the Ministry of Public Health and Social Welfare (MSPAS, from its initials in Spanish), purchasing had been decentralized, decreasing the ability to negotiate prices for pharmaceuticals in large volumes and providing little management capacity for inventory management. Although the NGO sector was small, these organizations provided services in rural areas that did not have access to MSPAS services. Because they bought small volumes, the NGOs could not negotiate favorable prices for their medicines, which limited the availability of essential medicines.

On the basis of the SEAM assessment and recommendations, MSPAS authorities developed a pharmaceutical procurement system based on joint tendering for medicines from the national Essential Medicines List to select products, their suppliers, and unit prices for the thirty hospitals and 362 public and NGO health units.

From late 2002 to 2005, MSPAS held three joint tender processes. The 2003 purchases resulted in a lower number of tenders, a 45 percent decrease in the median unit prices for the medicines, and greater efficiency in spending on medications and use of the budget appropriation.

The three-year experience showed that a joint bidding program based on the national Essential Medicines List could be implemented, and the following lessons were learned—

- The active participation of hospitals in the program's design contributed to its acceptance and to ensuring transparency in the evaluation of tender bids.
- Joint tendering within the network of public hospitals resulted in greater efficiency in spending on medications, a reduction in the number of tender processes, and improved quality assurance of medicines.
- To optimize the benefits of joint purchasing, an effective logistics system must accompany it.

Restricted or open tender

One of the most important decisions to make is whether the tender will be restricted to suppliers who are prequalified because they have demonstrated reliability, or whether the tender will be open to any supplier who is interested. This decision is required whether the tender is local or international.

A restricted tender with *prequalification* involves developing a list of registered suppliers based on past performance, references from previous clients, and documentation of product quality. Then, only those registered suppliers may participate in tenders. This process avoids the necessity of trying to decide whether the lowest bidder is eligible to be awarded the contract. With prequalification, by definition, the lowest bidder should be qualified for the contract.

When prequalification works well, substandard suppliers are kept out of the tender process entirely. Prequalification is not beneficial, however, if it protects favored suppliers from competition. In some countries, a new supplier finds surviving the prequalification process virtually impossible, no matter how reliable the new supplier may actually be.

Prequalification can be extremely time-consuming, especially if policy requires that suppliers be prequalified separately for each medicine. This problem can be mitigated through ABC analysis and prequalifying only high-demand, category A medicines while prequalifying low-demand products by lot (see Chapter 40 for details). As noted below, however, proper postqualification requires just as much time. The policy question is where the time should be allocated in the tender process.

To help countries procure quality pharmaceuticals, the World Health Organization (WHO) operates a prequalification program for HIV/AIDS, tuberculosis, and malaria medicines. See Box 21-1 for more information. Many international donors that provide procurement funding accept WHO prequalification or documentation of a supplier's or product's approval by a so-called stringent regulatory authority as evidence that the supplier is eligible for prequalification in a tender (see Chapter 19).

Although a country's laws may require that a pharmaceutical supplier and its products be registered in the procuring country, procurement managers may wish to follow WHO's international standards for prequalifying potential bidders first and then add a requirement that successful bidders must register their products locally.

An open tender with *postqualification* makes the tender available to all interested bidders. Suppliers' bids and documentation are solicited, received, and reviewed with respect to registration status, product quality, technical and financial capacity, and past performance.

An open tender can arguably increase the pool of prospective suppliers, but complications and delays in postqualification often occur. In addition, a well-managed prequalification process can generate good competition. Pharmaceuticals are unlike some other commodities, in that product quality is both crucial and difficult to ensure. Therefore, the success of open tenders with postqualification depends on the capacity of the procurement program to winnow out unqualified suppliers and poor-quality products after bids have been received, in some cases, from all over the world. The procurement office must go through a process similar to that used in prequalification. The difference is the need to screen many more suppliers and products. Moreover, bids are usually submitted with a time limit on price validity (see Chapter 39). Screening all suppliers and products after bid opening and within the period of price validity may be difficult. In one Indian state, for example, price validity was specified as 180 days, while the contract award typically took twelve to fifteen months (Heltzer et al. 2008). If delays like this occur, prices have to be reconfirmed, and in some cases, rebidding may be needed.

Poorly defined criteria for postqualification can also exclude qualified bidders, especially when the criteria favor developing local industry over assuring medicine quality. Finally, postqualification may be used for fraudulent purposes, if, for example, someone in the procurement agency wants to tilt business toward preferred companies.

Prequalification is generally accepted as an essential procurement practice. The *Interagency Guidelines for Establishing a Model Quality Assurance System* specifically state that prequalification is a key element in ensuring product quality (WHO et al. 2007). Following this lead, many countries have formally incorporated prequalification and restricted tendering into their procurement regulations; for example, Tanzania's Public Procurement and Regulatory Authority has published regulations and bid documents for use in the health sector that explicitly provide for restricted, prequalification-based tendering. Such practices have also been a feature of many successful pharmaceutical procurement programs around the world.

As these arguments make clear, the eventual goal of most procurement programs should be tenders limited to registered, prequalified suppliers. Prequalification avoids wasting time on suppliers that do not perform according to contract and helps minimize the possibility of introducing substandard products. However, aggressively seeking out potential new suppliers that may wish to become registered is important for maintaining competitive pressure on established suppliers.

International versus local procurement

In most developing countries, the national pharmaceutical industry produces only a limited range of products.

Box 21-1
WHO's prequalification program

The World Health Organization set up the Prequalification of Medicines Progamme in 2001 to facilitate access to quality medicines for HIV/AIDS, malaria, and tuberculosis. Originally, the program was intended to give UN procurement agencies, such as UNICEF, a range of quality medicine suppliers from which to choose. Over time, the program has become a useful tool for anyone purchasing medicines on a large scale, including countries themselves. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria disburses money for medicines that have been prequalified through the WHO process.

Manufacturers applying to the program must present extensive information on their product to allow qualified assessment teams to evaluate its quality, safety, and efficacy. The manufacturer must also open its manufacturing sites to an inspection team that assesses working procedures for compliance with WHO good manufacturing practices. The assessment teams work with regulators from the developing countries where the medicines will be used to make sure that the process is transparent and trusted by the end users. The program also prequalifies quality-control laboratories.

WHO's prequalification process takes a minimum of three months if the product meets all the required standards. When products do not meet the appropriate standards, the process can be longer and ultimately result in no prequalification for a product. WHO also carries out random quality-control testing of prequalified medicines that have been supplied to countries.

Medicines on the prequalification list include both brand-name and generic products. Since 2001, reproductive health products and zinc (for childhood diarrhea) have been added to the program. Also included are fixed-dose combinations, which are assessed based on the same principles used by the European Agency for the Evaluation of Medicinal Products and the U.S. Food and Drug Administration.

Source: WHO 2010b.

Therefore, most products must be procured via international markets. Nevertheless, countries with a local industry often require that public tenders give it some preference, such as following the World Bank example of granting a 15 percent price preference to locally manufactured products. However, greater price preferences make it difficult to achieve value for money—which is critical when national pharmaceutical budgets are limited. In all cases, the quality assurance requirement must be maintained. A strong national drug regulatory authority uses its product registration process to assure quality.

For many items, an international competitive tender, whether open or restricted, almost always results in lower prices than a tender limited to the local market. For some inexpensive items that cost a lot to ship, such as parenteral solutions, purchasing locally may be cheaper if the manufacturing plant meets acceptable quality standards. Facility licensing through a strong, independent drug regulatory authority is crucial.

In countries with a large pharmaceutical industry, such as India, international tendering is largely unnecessary; however, some countries that have an enormous number of companies licensed to manufacture pharmaceuticals may only have a few that meet international production and quality assurance standards. In such circumstances, establishing sufficiently stringent prequalification criteria to assure product quality while supporting national economic development demands is a challenge. Failure in this difficult balancing act can result in substandard products entering the health system.

One common constraint on international procurement is pharmaceutical registration. Countries with pharmaceutical registration systems normally require that all medicines purchased through public tender be registered locally. Both restricted and open tenders can be limited to products registered in the purchasing country. This requirement may limit or eliminate international procurement if the registration process is complicated and time-consuming, but in most countries, some flexibility is available to assure access to essential medicines.

Some countries expedite or even waive registration for new medicines that are considered vital to public health, such as antiretroviral medicines. In many cases where registration is waived, a donor is financing the purchase and helps make the case for a waiver.

Countries in some regions, particularly Latin America, have attempted to move toward regional harmonization of pharmaceutical registration, with virtually automatic registration granted if the product is either registered within the region or originates from a country recognized as having effective pharmaceutical regulatory systems. In an example of such harmonization, Namibia accepted products already registered in International Conference on Harmonization countries or South Africa to streamline its registration of antiretrovirals. However, regional harmonization generally faces many barriers, including concerns that products from the region's stronger economies could have an unfair advantage.

In sum, much has been debated about regional harmonization, but the discussions have not advanced very far. Time will determine whether meaningful harmonization can be achieved.

Estimated- versus fixed-quantity contract

Two basic options exist for defining purchase quantity: the traditional *fixed-quantity, scheduled-delivery* purchasing contract, and the *estimated-quantity, periodic-order* contract.

The *fixed-quantity contract* specifies guaranteed quantities (with a small variation sometimes allowed) and delivery in either one large shipment or smaller, separate shipments over the life of the contract. The purchaser accepts the risk that quantities for specific items may be too high (resulting in overstocks) or too low (resulting in shortages). If the purchaser actually needs more than the projected quantity (plus permitted variation), the price may be adjusted for additional quantities, depending on the contract.

With the second type of contract—the *estimated-quantity, periodic-order (draw-down) system*—the tender quantity is just an estimate rather than a firm order. A contract price is negotiated for each medicine, and the purchaser or members of the purchasing group order periodically from contract suppliers at the contract price throughout the contract term. In a pooled procurement system, orders can be placed directly by group members or channeled to the supplier through a central procurement office. Purchasers order only the quantities of each item needed, regardless of the quantity stipulated in the original tender estimate.

The supplier delivers to purchasers at the contract price throughout the term of the contract, regardless of the variation between projected and actual total quantity purchased under the contract. The supplier takes the risk that actual quantities will differ from those estimated: if the quantities are higher, it is not a problem (assuming the supplier has the necessary capacity), but if purchases are significantly lower than estimates, the supplier may not participate in future tenders. This system benefits the purchaser, because the purchaser's financial liability is limited to each order, and if demand changes, the purchaser is not burdened with unneeded stock or pressed to cover shortages. However, in the interest of maintaining a mutually beneficial relationship with a supplier, the purchaser must make every effort to reliably estimate demand and should communicate any significant changes—either increases or decreases—in projected order quantities.

Pharmaceutical tenders for most developing countries have been made for many years as fixed-quantity, scheduled-

delivery tenders, and suppliers serving these procurement programs might be expected to resist the change to estimated-quantity contracts. However, many large-scale procurement programs serving developing countries successfully use the estimated-quantity, drawdown contract.

When the draw-down system is used, prices should be guaranteed for the entire period of the contract. If possible, prices should be negotiated as CIF (cost, insurance, and freight) or CIP (carriage and insurance paid), with no extra charges for freight and insurance (see Chapter 39).

In the 1970s and 1980s, when inflation was a persistent problem around the world, tendering more than once a year or including an escalator clause effective after a certain number of months, based on inflation, was often necessary. Although inflation is no longer a severe problem in most places, circumstances in some countries, such as Yugoslavia in the mid-1990s and Zimbabwe in the 2000s, can warrant adding an inflation factor to tender agreements. In such contexts, a guaranteed-quantity tender or a procurement system policy to make most purchases at the lowest contract price possible (that is, before an escalator clause takes effect) may produce the best results for the health system. Guaranteed access to foreign currency greatly helps to manage procurement in high inflationary situations.

In countries where access to funds and foreign exchange is sporadic and uncertain, tendering on a periodic basis, as funds become available, may be necessary. This procedure almost always requires a fixed-quantity, scheduled-delivery tender format.

Similarly, if most products must be imported and lead times are extremely long, fixed-quantity, scheduled-delivery contracts are best, because the drawdown system requires reasonable access to contract suppliers. This type of contract functions acceptably with lead times of up to four to five months, but it would be difficult to manage where lead times are routinely greater than one year. One option is to limit tender participation to suppliers that can provide shorter lead times (assuming such sources are available). This strategy might produce an overall price increase but could potentially reduce waste. A total cost analysis exercise (described in Chapter 40) would help model the potential impact of such a change.

In some situations, combining the formats might be best: negotiating fixed-quantity contracts for products that can be purchased most cost-effectively in large single quantities and using estimated-quantity contracts for other products.

Splitting tender awards

Some procurement programs routinely split contract awards among two or three suppliers, with the rationale of maintaining capacity with several suppliers or avoiding dependence on one supplier for a critical medicine. However, any health system procurement program that routinely splits tenders is almost certainly not getting the best possible pricing, and the opportunity exists for "bid rigging"—suppliers agreeing beforehand what bids will be offered, with the realization that all will benefit from a share of the pie.

Split tenders may be desirable in some circumstances—for example, when a country is making one huge annual purchase of essential medicines, the risk of supplier default is real, and the public health consequences will be severe if default occurs and the medicines are not available. In addition, large global procurement programs may determine that split awards are needed to modulate the global market and maintain competition and assure access to essential products (Chapter 18).

Primary/secondary contracts versus rebids

When a supplier defaults, delays in receiving medicines have usually already occurred by the time the problem is understood. Rebidding contracts through the entire tender procedure will likely result in stockouts or high-priced emergency purchases, or both. A primary/secondary contract system can avoid rebidding delays by providing an immediate option if the contract winner cannot perform. This sort of system is used by the Organisation of Eastern Caribbean States (OECS) Pharmaceutical Procurement Service and is common to many pharmaceutical purchasing groups.

In a primary/secondary system, two contract awards are made, with the primary award to the bidder offering the lowest price and the secondary award to the second-lowest bidder, provided that the secondary supplier is one that is expected to be able to supply under all conditions. The secondary contract should be used only when the primary supplier is unable to perform.

Primary/secondary awards are useful *only* if two requirements are met: the second-lowest price is reasonably close to the lowest and thus worth locking in, and a reliable secondary supplier is prepared to accept that status and guarantee the price in case the primary supplier defaults. If either condition is not met, a secondary award is not worthwhile.

Some countries have regulations prohibiting these types of contracts, requiring that a new tender be made in the case of default. World Bank international competitive bidding tender procedures call for rebids when a supplier defaults, but some flexibility for local purchasing and local competitive bidding usually exists in such cases.

Use of local agents in international procurement

Multinational manufacturers and exporters are commonly represented by local representatives in developing countries. The decision to require, encourage, or avoid buying through local agents in international tenders affects the range of foreign suppliers, the efficiency of communication between the buyer and the supplier, and the choice of trade and

Box 21-2
Advantages and disadvantages of buying through local agents

Potential advantages

1. *Speeds and improves communication.* Local agents may be authorized to make decisions without a special contact with the foreign supplier. When necessary, the local agent may be better able to contact the appropriate person at the foreign supplier's office.
2. *Locates least-expensive acceptable supplies.* In competitive tenders, the interest of the local agents lies in locating inexpensive suppliers, including sources that might not otherwise have come to the attention of the purchaser.
3. *Facilitates payment.* Local agents can sometimes accept local currency and allow deferred payment. Currency conversions can be troublesome, and some countries specify that payments be made in local currency to local agents.
4. *Expedites delivery.* Local agents often handle port clearing. For instance, when port-clearing fees require negotiation, local agent knowledge and experience can frequently save money and time.
5. *Speeds receipt of emergency supplies.* Local agents often maintain stocks within the country, which speeds receipt of emergency supplies and may reduce the amount of warehouse space required.
6. *Affords greater legal recourse.* The presence of an in-country agent affords greater opportunity for legal action if the supplier defaults.
7. *Introduces new products.* Occasionally, new products or formulations are introduced that are cost-effective alternatives to existing products. The agent is necessarily biased but may provide scientific articles in support of the product. Other information sources should be sought to supplement the introductory information provided by the agent.
8. *May offer potential for using primary distributor.* In some countries, government warehousing and distribution costs possibly may be eliminated by implementing a prime vendor contract with a local distributor that will warehouse and distribute medicines directly to public health facilities.

Potential disadvantages

1. *May slow and confuse communication.* If untrained, unmotivated, poorly supervised, or part time, a local agent may lengthen and confuse arrangements with the foreign supplier. In addition, if the purchaser requires specific product information, a local agent may impede communication.
2. *May increase cost.* Local agents may add as much as 15 to 30 percent to the visible cost, even though their commission is often much less. Higher unit prices are also paid for low-volume purchases through local agents, compared to direct purchase.
3. *Serves as a source of black-market pharmaceuticals.* Licensed importers can be a major source of pharmaceuticals for illicit use, and local agents need to be regulated through licensure and regular inspection of records and stocks.
4. *May completely default on an order.* Local agents who are not financially stable may go out of business and disappear. Two or three local suppliers should be kept available as backup for emergency tenders.
5. *Attempts to increase medicine consumption.* Local agents employ detail men or company representatives to visit health system physicians to encourage product use, as well as to request new medicines.

payment terms. Major advantages and disadvantages of buying through local agents are listed in Box 21-2.

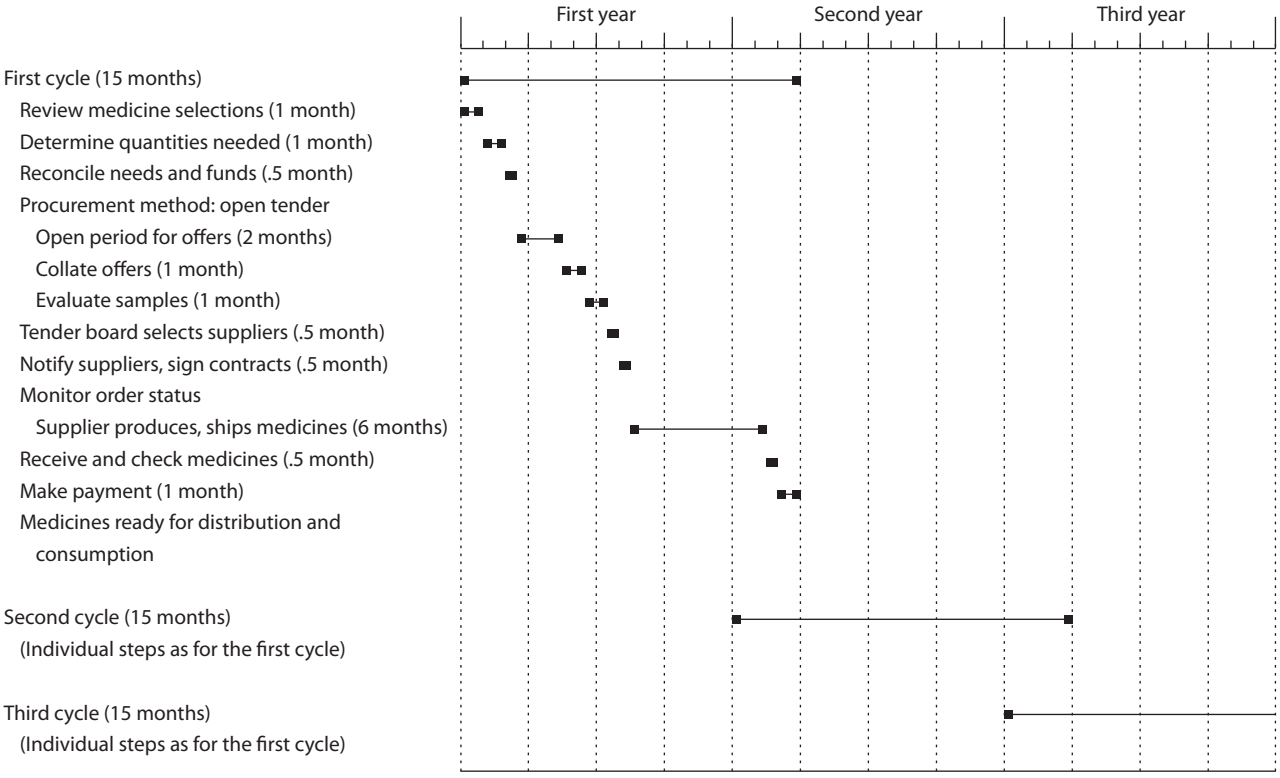
Chapters 8 and 39 further discuss the potential for contracting with local distributors to provide warehousing and transport services.

Tender frequency and timing

Tender planning must take into account the time required for each step. The time required to develop or revise a tender list, including medicine selection and quantification, varies widely, but may require two to six months in some settings. The time required to select suppliers for tender participation can also be considerable; in one African country, the first prequalification process took more than one year.

If standard documents are not available, preparing documents for tender can take at least a month after quantification is completed. Some countries, such as Tanzania and Uganda, have overcome this problem by developing standard bidding documents. The time spent waiting for tender offers depends on geographic scope (local versus international) and in some cases on regulations of the government or the funding agency. A reasonable response time for local tenders is likely to be fifteen to twenty days, and for international tenders, forty-five to sixty days. Collating offers is quicker with computerized systems, but at least one month

Figure 21-1 Example of a timetable for an annual tendering system



should be allowed for this process. Some online tendering systems capture supplier bids through the procurement agency's Web portal, which can greatly facilitate collection and collation of bids (note that this is not the same process as in e-tendering with reverse auction). Adjudication and contract award should also be faster in computerized systems, but again, one month should be allowed, and at least two months with manual systems. After contracts are awarded, the lead time between orders to the supplier and initial deliveries may be a month or less with local tenders, but international suppliers' lead times usually range from three months to one year, and on occasion even longer.

Efficient procurement offices spread the tender workload throughout the year, with overlap from one tender cycle to the next; when contracts have been awarded for the first cycle, planning for medicine selection for the next cycle should begin. Frequent communication with clients and with suppliers is needed to make sure that the tender proceeds according to schedule. Many procurement offices use spreadsheets to simplify tender tracking, but all procurement staff members need to use a common spreadsheet format to avoid misunderstandings that can result from different people developing their own. Figure 21-1 illustrates an annual tender cycle of fifteen months, with overlap.

The frequency of tendering should be attuned to the funding cycle, and for international tenders, to the availability of foreign exchange (particularly if inflation is an issue). Tendering once a year is not appropriate when funds, including foreign exchange, are released in monthly installments, because bids will expire before the funds for the actual awards become available. This can also be a problem where funds are released late from the government treasury but revert back if not spent by the end of the fiscal year.

21.3 Defining needs

As discussed in Chapter 18, restricting the number of pharmaceuticals on a procurement list can increase effective procurement volume for those pharmaceuticals. A central agency will usually be more efficient than a large number of health facilities operating independently when it comes to selecting a restricted list of essential medicines. If selection is totally decentralized, the benefits of group purchasing will be lost. On the other hand, if the health facilities do not have real input into which medicines are selected, they will not feel that their needs are being served and will lose a feeling of ownership, which may result in facilities making direct purchases outside the tender contracts, undermining the integrity of the system. A balance needs to be struck between centralized and decentralized elements of procurement.

Selection of medicines for the tender

The medicine selection committee (see Chapter 16), which is often known as the formulary committee, should meet before each tender to finalize the list of medicines. If, for example, a tender is scheduled for June and quantification takes three months plus one month for clarification and tender document preparation, the medicine selection committee would meet in January.

Requests for additions or changes to the procurement list should be compiled throughout the year by the procurement agency, the selection committee, or both. Often, provisions are in place to obtain special approval for purchasing items not included on the essential medicines list.

Requests for additions to the list should be made in writing with justification for the addition and (if applicable) the name of the product to be replaced. Members of the technical staff of the procurement agency or medicine selection committee should compile information from the medical literature on the new product (and on the therapeutic category the product represents) for the selection committee. Some procurement programs require that for each addition to the list a similar product be deleted, unless the proposed addition represents a new therapeutic category. Usually, however, the list of products continues to grow, which can present problems in both managing and financing procurement.

Analyses of past procurements using methods such as VEN (vital, essential, nonessential), ABC, and therapeutic category analysis (see Chapter 40) should be compiled before the meeting of the medicine selection committee to focus deliberations and help in rationally limiting the procurement list.

After the selection committee has met, the procurement office develops a list of the approved medicines for quantification. In computerized procurement agencies, this process may take one or two weeks.

Quantification

As discussed in Chapter 20, the procurement office is responsible for producing a reasonably accurate estimate of pharmaceutical requirements for each tender, but much of this responsibility can be decentralized. Some health systems ask each level with decision-making authority to compile its own list of estimated quantities required for medicines on the procurement list. The central procurement office then compares the lists with past consumption, checks for any known changes affecting demand, clarifies questions directly with the client, and compiles the overall list for procurement.

Quantification can consume considerable time in programs that are decentralized but require multiple layers of review. With four levels of management authority (health area, regions/districts, provinces, and national) involved in reviewing estimates, developing a list of medicine needs for procurement may take six to nine months. If the quantification process extends to six months or more, a full year may pass by the time the pharmaceuticals are actually received. In that time, needs may change, and money is wasted if the pharmaceuticals purchased no longer match current needs.

Methods for procurement quantification—consumption-based, morbidity-based, and proxy consumption—are discussed in Chapter 20. The choice of method is based largely on the type and reliability of data on medicine usage, patient use, and morbidity patterns.

Countries should avoid making one major effort to quantify medicines and then relying on the same data for several years thereafter. No matter how accurate the original quantification may have been, given changes from year to year, the earlier projections become increasingly unreliable guides to later procurement needs.

When the quantification has been completed, the responsible committee (it may be a tender board or a special procurement committee) should review and approve the list of medicines and the quantities proposed. Having the procurement office estimate the actual cost before the list is sent to the committee for review, and definitely before the actual tendering is executed, is important. If cost estimates are not done, the subsequent evaluation of tender offers may indicate that costs exceed funding.

21.4 Selecting suppliers for tender participation

The selection of suppliers has a profound effect on the quality and cost of pharmaceuticals acquired. Inadequate safeguards in supplier selection may result in the purchase of medicines that are ineffective, unsafe, or even deadly. As discussed in Chapter 18, hidden costs resulting from late deliveries, complete default on confirmed orders, losses caused by poor packaging, or short expiration dates—common problems with unreliable suppliers—may raise the actual medicine cost to several times the original contract cost.

New suppliers are constantly coming into the market, while others are changing to new fields, merging, or going out of business altogether. New companies may have difficulties with quality control and packaging for export during their first years of production but later become reliable, low-cost producers. At the same time, a company long known for high-quality products and prompt service may become seriously deficient as a result of changes in management or regional distributors. A multinational company offering an attractive price may provide excellent service in one country and poor service in a nearby country, solely because of its choice of in-country representatives.

An efficient procurement office must therefore be able to closely monitor supplier performance and consider the relevant information during both prequalification or postqualification.

Types of potential pharmaceutical suppliers

Government pharmaceutical factories, local private manufacturers, and foreign manufacturers are *primary* sources of pharmaceuticals, because these companies do the manufacturing themselves. Donors, international procurement services, independent foreign exporters, and local importers and distributors are *secondary* sources; they obtain pharmaceuticals from manufacturers for resale.

As discussed, both donor financing and national procurement laws and regulations may determine the options for supplier selection.

Pharmaceutical manufacturers. Pharmaceutical manufacturers can be classified as *research-based* and *non–research-based* producers. The well-known multinational pharmaceutical companies are research based in that their reputation and, to a large extent, their profitability depend on new pharmaceuticals developed through research. These pharmaceuticals are patented and vigorously promoted by brand name. Nevertheless, many such firms also produce a line of pharmaceuticals that they sell by generic name at a lower price than their brand-name products. These pharmaceuticals are often made on the same production line and sometimes in the same batch as the brand-name product. Quality standards are identical; only the packaging and appearance of the medicine are different.

Non–research-based firms range from small, one-factory, local companies to large national or multinational generic pharmaceutical manufacturers that frequently market pharmaceuticals only by their nonproprietary names. Although they may have less name recognition, many generic manufacturers produce products equal in quality to those of any brand-name company.

International procurement services. International procurement services are sometimes nonprofit companies or arms of international agencies. Sometimes these services operate as private, for-profit entities. They provide services from one or more warehouses, and they vary with regard to selection of medicines, prices, means of quality assurance, payment terms, restrictions placed on the buyer, and nature and timeliness of service provided. Some well-established international procurement agencies are listed in the annual *International Drug Price Indicator Guide* (MSH). Some procurement agencies, such as Crown Agents, do not maintain inventory but are ad-hoc purchasing agents that must go through the sometimes lengthy process of negotiating prices with individual manufacturers and then arranging shipment from the manufacturer to the purchaser.

These agencies can play a valuable role in international tenders, providing competitive international prices for a range of products and access to small quantities of pharmaceuticals—sales that may not interest primary manufacturers. Their proposals should be evaluated by the same criteria used for other sources of supply, and they should specify the name of the manufacturer and the mechanism for quality assurance, like any commercial distributor.

Independent international wholesale exporters. Independent international wholesale exporters—sometimes known as "jobbers"—purchase pharmaceuticals from a variety of manufacturers for resale. Many of these companies around the world specialize in exports to developing countries. Most exporting countries exercise less strict control over jobbers than over manufacturers, a practice that can open purchasers to risk of procuring poor-quality products. Hence, it is essential to get the name of the primary manufacturer and make sure that the distributor provides bona fide quality assurance documents and certifications from the exporting-country regulatory agency with each registration request, tender offer, and shipment. Forged certification documents have been received in some countries from less reliable foreign exporters. WHO has developed prequalification procedures related specifically to wholesalers. Procurement offices should consider adapting the WHO procedures when qualifying wholesalers as suppliers.

Local importers and distributors. Local importers and distributors—also known as wholesalers—are often major forces in the local pharmaceutical market, both financially and politically. Like foreign distributors, these companies may not closely examine the quality of the products supplied by the manufacturers with which they work. In many countries, these companies have exclusive rights to represent certain manufacturers, and tender offers for these manufacturers' products come through the local distributor. Again, the procurement office may wish to adapt and apply the WHO wholesaler prequalification criteria when qualifying this type of supplier.

Locating and contacting qualified suppliers

Generally, identifying qualified suppliers should be done through a systematic prequalification process or by advertising an open tender followed by a rigorous postqualification evaluation.

Open public tenders can be publicized through local newspaper notices and Internet tender portals, such as dgMarket (http://www.dgmarket.com). Increasingly, procurement agencies are posting tender notices to their own websites (for example, Tamil Nadu Medical Services Corporation and Tanzania's Medical Stores Department). Notices can be sent to international newspapers, trade directories, and journals with wide circulation. The World Bank

has published guidelines on e-tendering for programs that it finances (World Bank 2009).

Agencies that are required to purchase only from prequalified suppliers may still publicize their intent to purchase through an international notice, in addition to contacting prequalified suppliers directly. This "safeguard" practice informs the prequalified suppliers and may also arouse the interest of new suppliers.

Even when all foreign suppliers in a tender are represented by local agents, notice through international channels may be faster and more reliable than depending on local agents to alert foreign suppliers. Earlier notification allows suppliers more time to prepare offers and thus increases the probability of competitive offers.

Contacts with international agencies. Contacts with international agencies may be an effective way for a procurement office with little international experience to identify potential suppliers. This arrangement may be especially useful in places without central government authority, such as in the early days of East Timor's independence, when UNICEF procured pharmaceuticals on behalf of the interim government.

The WHO prequalification scheme can guide countries to suppliers that provide quality-assured products, and the Global Fund's voluntary pooled procurement mechanism also helps countries access quality products at competitive prices. Other global initiatives, such as Stop TB and the Global Drug Facility, Roll Back Malaria and the Affordable Medicines for Malaria program, and WHO's AIDS Medicines and Diagnostics Service, offer information on suppliers of specialized products, and in some cases, on comparative pricing.

Contacts with other procurement offices. As discussed in Chapter 18, even where a formal, regional multicountry pooled procurement system is not realistic, countries in a region may be able to develop a coordinated information-sharing process among their national procurement offices—sharing information on prices and supplier performance.

Information on international prices. To know whether potential suppliers are offering competitive prices, procurement offices need a point of reference or sufficient experience in the market to make accurate cost estimates. One such reference for international prices for essential medicines, the annual *International Drug Price Indicator Guide,* contains the catalog prices from several international procurement agencies and actual tender prices received by developing-country procurement agencies. The Global Fund's Global Price Reporting Mechanism is an important source of comparative pricing data from countries that purchase medicines through Global Fund grants. Reference prices can also come from one of the nonprofit international procurement agencies, and most of them provide a price catalog on request. The global initiatives discussed above can provide pricing information related to their specific mandates. Chapter 18 lists various price-reporting references.

Evaluating new suppliers

When considering contract awards to previously unknown suppliers, establishing how product quality will be assured is essential. If the procurement office does not have a way to test products, it may argue against an award to a foreign supplier whose products are either not approved through the WHO prequalification process or not registered by a stringent regulatory authority. As noted, procurement laws, regulations, or policies may require that national suppliers be given preference (or at least access to the tender), but in many cases, these suppliers do not have international certification. The procurement office is still responsible for excluding substandard suppliers from the tender.

In addition to deciding whether a supplier is generally reliable, which of the supplier's products are of acceptable quality must be determined. Some suppliers may produce good-quality liquids but not tablets or injections. A supplier may have difficulty producing certain medicines because of a lack of quality raw materials or a lack of certain equipment.

Some procurement programs establish a list of critical medicines for which potential quality issues exist and limit suppliers for those products. Trying to qualify each supplier separately for each medicine on the tender list certainly will add substantial time to the pre- or postqualification process. In a West African country that decided to prequalify suppliers separately for each medicine, the prequalification process for one tender took nearly eighteen months.

Procurement staff must develop a formal system of determining suppliers' reliability to eliminate suppliers that are substandard. Two aspects are involved: evaluating potential new suppliers (for pre- or postqualification) and rating the performance of current and past suppliers.

Evaluation of new (unknown) suppliers should be approached through formal prequalification and through testing products received when feasible, followed by performance monitoring.

Formal prequalification. As mentioned, prequalification is the process of developing a list of registered suppliers based on past performance, references from previous clients, and documentation of product quality before they are invited to submit bids on tenders. Although establishing an initial list of prequalified suppliers can be time-consuming, it expedites the tender evaluation because every bidder is qualified. A rigorous prequalification process will include references from past clients and inspections of manufacturing sites by quality experts (WHO 1999).

Annex 21-1 lists information one should check when considering a new supplier. Sample registration forms used by the international nonprofit procurement agencies can be requested from the agencies.

Test performance on trial purchases. As part of their monitoring process, procurement programs should, if possible, test samples of products received. Products from new suppliers should be tested more often than products from established, trusted suppliers. Purchasers should generally not procure products that are needed to treat critical illness or that absolutely require timely delivery from completely new suppliers. For example, an unknown supplier might be awarded a contract for vitamin B complex, but not for gentamicin.

Monitoring and evaluating supplier performance

After a contract is awarded, monitoring the supplier's service and quality should provide the basis for decisions regarding future purchases. In many countries, monitoring is done informally and without written records, which makes assembling data for review by procurement committees difficult. Successful purchasing agencies use a formal monitoring system, as described in Section 21.9 on procurement information.

In general, suppliers that have performed poorly should be excluded from the next tender. Some procurement agencies give a probationary re-approval to suppliers that have had problems, such as too many partial shipments or excessive lead times, but offer high-quality products at competitive prices. If problems recur, the nonperforming suppliers are then barred from the next tender. If a supplier's problems are sufficiently grave, it can be barred for a two-year period and then be forced to prequalify again.

Some procurement offices use a point system, assigning values to performance criteria such as those shown in Annexes 21-1 and 21-2. The relative weights of each category vary; for example, in some situations, the lead time may be very important and be given a high weight; in other situations, it may be a minor factor. In countries with strong regulatory control of the pharmaceutical market, product quality may be given a low weight, because all registered products are assumed to be of acceptable quality.

Rating systems offer two options for ranking applications: in one, a minimum passing score is used; in the other, suppliers are ranked from top to bottom overall, and contract preference is given to higher-ranked suppliers when prices are equivalent. A supplier with a much higher rank might get the contract despite a competitor's offer of lower prices.

Because ratings of supplier reliability and quality have a tremendous effect on the number and quality of suppliers that participate in a tender, the ratings must be as impartial as possible, with criteria written into the tender adjudication process. Ratings will always be subjective to some extent, so to ensure impartiality, the entire procurement committee, or at least a multiperson team, should be responsible for assigning supplier ratings.

21.5 Preparing and issuing tender documents

After selection, quantification, and preparation of the tender list are completed, bid packages are sent out to suppliers or posted on a website. For restricted tenders, packages are made available to all prequalified bidders; in open tenders, they are made available to all interested bidders. The tender package typically includes the documents discussed below. (See References and Further Readings for sources of tender documents that can be adapted.)

Invitation to bid. This describes the scope of the procurement, the purchasing group that is soliciting offers, the conditions under which bids will be accepted, the address for submission, the date and time bids are due, and the dates to be covered by the contract.

Instructions to bidders. These cover how to submit documents, including how to state prices; dates of bid validity; what currencies to use; what documents are required in addition to bid forms; bid and performance bonds (if applicable; see Chapter 39); precautions against undue contact with procurement office staff; format for submitting offers; domestic preference (if any); criteria for bid evaluation; and procedures involved in adjudication, award, and notification. Forms should be appended for performance and bid bonds and for documenting domestic preference and value added, if applicable.

In addition, the procurement manager should indicate in the tender document itself how suppliers' offers will be evaluated. This step shows all suppliers the importance of the various requirements specified in the tender. Figure 21-2 shows an evaluation matrix introduced by Papua New Guinea to assess the potential suppliers for pharmaceutical tenders.

Bidding documents usually include a statement indicating that the procurement committee may reject any or all bids. Rejection of all bids is justified when no effective competition exists or bids are not substantially responsive.

Conditions of contract. These discuss general conditions in the contract that will be signed with successful bidders and any special conditions applicable to the current procurement (see Chapter 39).

General technical specifications. These provide information on good manufacturing practices (GMP) standards, pharmacopoeial standards, nomenclature and description required for each product, shelf life and expiration date parameters, labeling instructions, packaging instructions, GMP and quality assurance certificates required, and other evidence of product quality to be submitted with the tender and with each shipment.

Specific pharmacopoeial standards should be listed for each product; if any of a range of standards is adequate (*British Pharmacopoeia, U.S. Pharmacopeia, European Pharmacopoeia,* or *International Pharmacopoeia*), it

Figure 21-2 Papua New Guinea pharmaceutical tender

TENDER EVALUATION SHEET

Indicator	Weight	Comment
1. Financial	**30%**	
1.1 Form of bid	30%	Lowest
2. Performance	**30%**	
2.1 Delivery	5%	Within specified time—5%
2.2 Years experience supplying Papua New Guinea (PNG)	5%	2 years or more—5%
2.3 Past contracts	5%	PNG—3%; developing countries—2% (within last 5 years)
2.4 Packaging	5%	As specified in tender—5%
2.5 Financial capacity	5%	Acceptable bid bond supplied—5%
2.6 Evidence of financial capacity	5%	Banker's details and financial records—5%
3. Quality	**40%**	
3.1 Product documentation submitted as per conditions of bid	15%	Documents submitted for all pharmaceutical and medical equipment products—15% > 80% required documentation—10% 60–80% required documentation—7.5% 30–60% required documentation—5% 0–30% required documentation—0%
3.2 Manufacturer's certifications submitted as per form of bid	15%	Manufacturer's certifications received for all pharmaceutical and medical equipment products—15% > 80% required documentation—10% 60–80% required documentation—7.5% 30–60% required documentation—5% 0–30% required documentation—0%
3.3 Manufacturer's labeling submitted as per form of bid	10%	Manufacturer's labeling received for all pharmaceutical and medical equipment products—15% > 80% required documentation—10% 60–80% required documentation—7.5% 30–60% required documentation—5% 0–30% required documentation—0%

should be noted. If special packaging or labeling is required for a subset of products, this requirement should be indicated on the schedule of requirements (see below), but a generic statement of packaging and labeling applied to all products should be included in the general technical specifications. Instructions about labeling (contents and language) and package inserts can be included in the technical specifications, unless specific requirements exist for a subset of products. These should be indicated on the tender list.

If all products are to be shipped to the same destination, on the same delivery schedule, by whatever means is most efficient and cost-effective, this specification can be stated in the conditions of contract. If different instructions apply to certain products, they should be stipulated in the schedule of requirements.

Schedule of requirements, or tender list. This provides a concise description of each product and the quantity required, along with any technical specifications unique to that item. If it can be printed with sufficient space for suppliers to enter offers, having suppliers use this space for bids greatly simplifies the collation of offers. Sufficient space should be provided so that the supplier can enter all relevant information, including the name of the original manufacturer.

The schedule of requirements should include the International Nonproprietary Name (INN), or generic name (for combination products, the name of each generic component), the strength in metric units for each component, the basic unit (tablet, capsule, vial, bottle), the package size, and the number of packages needed. Some tenders list both the total number of packages

and the total number of basic units needed, to avoid misunderstanding and to allow for the possibility that a supplier may offer a different (but acceptable) package size representing the same number of basic units. The tender should specify whether the listed package sizes are the only ones acceptable; some procurement agencies request offers on all package sizes available.

Each unique product should have a separate inventory code number, used only for that product. This code is useful in compiling product catalogs and is essential for computerized information systems. It can also be helpful in making sure that all parties are referring to the same item when clarifying issues with client facilities or with suppliers. For therapeutic category analysis, a supplementary code can be used to assign each drug product to a therapeutic category (see Chapter 40).

To simplify future procurements and make sure that all staff use the same terminology in procurement and tender functions, compiling all information about each tender product into a procurement catalog is useful. With a computerized system, developing a catalog is simple; updating a product catalog manually is more difficult, but the effort may be worthwhile to save time in compiling future tender lists.

21.6 Adjudicating the tender

The most important aspect of adjudication is that it is an open and transparent process that assures all participants that the tender was conducted fairly. Tender adjudication involves several separate activities and stages—

- Prepare for adjudication during the open period.
- Receive and open bids.
- Collate bids for adjudication.
- Adjudicate offers and award contracts.

Preparing during the open period

The length of the open period (time between the invitation to tender and the closing date) typically varies from four to eight weeks. A longer open period lengthens the total lead time for obtaining pharmaceuticals but may also increase the number of offers received. The procurement agency should prepare for receipt of documents, collation, and adjudication during the open period.

Some suppliers may request clarification about product description, package size, pharmacopoeial standard, labeling, or packaging requirements. If clarification is needed because of a mistake or omission in the tender package, it should be provided to all participating bidders. Similarly, if one supplier is given approval to offer a product or package that is similar to but not the same as that listed in the schedule of requirements, all bidders should be informed that such an exception is approved.

Receiving and opening tender offers

To ensure confidentiality and to avoid accusations of price fixing or undue influence on decisions, the procurement agency must adhere strictly to the closing date and time. No bids should be opened before the date and time specified. A written record should be kept of all bids received, documenting the date received and the person who received the bid. The unopened bids should be stored in a locked, secure area until the closing date. The date of bid receipt should also be entered into the procurement management information system to track the response to tenders. If due dates are approaching and suppliers—particularly those known to be reliable, low-cost sources—have not responded, the procurement agency can remind *all* suppliers of the approaching deadline by telephone, fax, or e-mail.

At the specified date and time, the bids should be formally opened, with at least one member of the procurement committee and bidder representatives (if they choose to be present) in attendance. Specifics of how the bids are opened and documented vary by country—with some procedures mandated by national regulations. Details such as the bidder's name and address, and required documentation such as bid form and bid security for each opened bid, are often read aloud. If the bid security has not been deposited, an immediate disqualification usually results.

Each opened bid should be logged in a ledger and numbered for future reference. If possible, writing the number of enclosed pages on the outside of the tender envelope may be useful to avoid confusion during adjudication. Often, a note taker documents the meeting proceedings, and at the end of the meeting, attendees sign the draft minutes, which everyone will receive for record-keeping purposes.

Collating offers for adjudication

The first step in collating offers is to determine which offers, if any, are nonresponsive to tender conditions. Suppliers that have not met the basic requirements related to bidder qualification, medicine description, strength, pack size, quality requirements, and delivery date are nonresponsive. If required information has not been provided, the bid is nonresponsive. If the tender documents require the supplier's signed acceptance of contract terms and the supplier has not signed, the bid is nonresponsive.

Information from all responsive bids should be compiled in an adjudication report to allow side-by-side comparison of the offers. Nonresponsive bids should not be entered into the collated adjudication report, but the problems should be documented in writing for review by the procurement committee.

Prices must be converted to a common currency and adjustments made for differences in trade terms (for example, adding freight costs to those bids that do not include freight expenses). If local or domestic preference is considered in the adjudication, the adjudication report should separate offers eligible for the local preference margin, so that they can be fairly compared with offers that are not eligible.

Spreadsheets are now commonly used to simplify the collation of information and the preparation of an adjudication report. In addition, specialized procurement software is available that automates all of the processes related to collecting bids, collating offers, and ranking them according to predetermined criteria (see Section 21.10). Figure 21-3 illustrates an adjudication report prepared by a specialized computer program.

Managing the adjudication process

The authority to adjudicate tenders and award contracts should be confined to the procurement committee (or government tender board). Procurement office staff should assemble information for the tender board or procurement committee and make technical recommendations, but they should not have a vote in the contract decision.

As discussed in Chapter 18, the adjudication process must be free from influence by special interests; it should be open and transparent, with written rules for the process, including evaluation, award, any special criteria, and the appeal period for rejected bidders. Results of adjudication, including the winning bidder and the contract price, should be available to all participating bidders. In countries where pharmaceutical procurement has fallen into disrepute, credibility can be rebuilt by broadening participation in the tender board or procurement committee and making sure that it has final authority for approving all pharmaceutical procurement and for enforcing transparency in the tender process.

Evaluation of offers. For restricted tenders that do not involve split contract requirements, this process can be quick. The procurement committee reviews the collated bid information and normally selects the lowest bidder for each product. Contracts are then developed. Disqualification of low bidders should be documented and become part of the tender record.

For open tenders, supplier evaluation does not begin until bids are received, and adjudication is a two-stage process: a tender evaluation committee is formed for ranking the bids according to standard evaluation criteria, and then beginning the postqualification supplier evaluation process. When the postqualification analysis has been completed, the procurement committee meets to review the recommendations of the tender evaluation committee and determine whether the lowest evaluated bid should receive the contract. If not, the next-lowest evaluated bid is considered, and so forth.

The responsible procurement committee or tender board should carefully consider each item on the tender list and make an award for each item, unless no responsive bids were received. If the primary/secondary supplier system is used, equal care is needed in selecting secondary suppliers, because they will automatically be used if the primary supplier defaults.

Written bid evaluation criteria should be applied rigorously and without exception. Tender contracts should be awarded to the lowest bidder that has the capacity to supply products that meet the standards required (considering local preference, if applicable). This award should be mandatory unless the lowest bidder has not performed in prior procurements.

In local tenders, Incoterms, such as cost, insurance, and freight (CIF) and carriage and insurance paid (CIP), are generally not applicable. Delivered price, which includes landed cost, overheads, and profit margin, is more common and is an adequate standard for comparing costs. Letters of credit are normally not used to pay local suppliers; other mechanisms, such as deferred payment, may be beneficial and should be considered if stated in the evaluation criteria and in instructions to bidders. When the health procurement agency sells its products and receives payment from health facilities, it should try to arrange supplier payment terms that are longer than those provided to health facility customers. For example, if health facilities are given thirty days to pay, then thirty-to-sixty-day payment terms to suppliers can help cash flow.

Local and foreign suppliers may offer different trade terms (CIP to purchaser's warehouse, or CIF to purchaser's main port). To make these two prices comparable, all duties, fees, handling, and transportation costs to the purchaser's warehouse must be added to the CIF price.

Delivery dates should be compared in terms of past suppliers' performance rather than promised delivery date. If the lowest acceptable bidder's expected delivery is beyond the required date, then the effect of a shortage must be considered in light of the cost of alternative treatments or of a special air shipment to cover the interim period.

Special criteria. Special criteria are sometimes applied, such as a local preference margin calculated by adding a percentage to the value of foreign bids, before they are compared with local bids. World Bank–financed international competitive bidding (ICB) procurements allow local preference, to a maximum of 15 percent. Although pricing is the accepted means of granting local preference, some countries have more explicit requirements to grant local companies preference in contract awards to foster industrial development. This approach, however, can put the procurement office at risk of having to accept lower local standards of service or product quality. In any event, all procurement agencies should use supplier performance as the basis for purchasing decisions.

Some programs try to maintain as broad a supplier base as possible to protect against loss of a primary supply source.

Figure 21-3 Sample tender adjudication report by item by supplier

Quotations from All Suppliers

Central Medical Stores

Tender Number : 42
Report ID : OR4968_PPS
Run Date : 21/11/2011 16:28:22
Page No : 1 of 5

Bid Transaction Code	: BIT-55	Bid Opening Date	: 27/01/2005	Tender Category	: Open Tender
Bid Transaction Date	: 24/01/2005	Tender Number	: 42	Tender Currency	: USD
From Item Code	: 0	To Item Code	: zzzzzzzzzzzzzzzzzzz		
From Supplier Code	: 0	To Supplier Code	: zzzzzzzzzzz		
From DMO Classification	: 0	To DMO Classification	: zzzzzzzzzzz		
From DMO Sub Classification	: 0	To DMO Sub Classification	: zzzzzzzzzzz		
From Therapeutic Class	: 0	To Therapeutic Class	: zzzzzzzzzzz		
From Therapeutic Sub Class	: 0	To Therapeutic Sub Class	: zzzzzzzzzzz		

Quotations from All Suppliers

Central Medical Stores

Tender Number : 42
Report ID : OR4968_PPS
Run Date : 21/11/2011 16:28:22
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Supplier	Brand	Supplier's	Air Shipment CIF Landed /	Air Shipment Price / Adj	Air Shipment Lead	Sea Shipment CIF Landed /	Sea Shipment Price / Adj	Sea Shipment Lead	Manufacturer	Remarks
Glaxo Wellcome Inc.	BWEBRAND	P100	180.00	1.8000	2	160.00	1.6000	1	BWEMAN	
Item Code : 01019 / Benzatropine 2mg TAB ORAL TAB							Adjudication Unit : TAB			Countries Forecast : 70,000 TAB
American Hospital Supply	AHSBRAND	P1000	42.00	0.0420	5	10.00	0.0100	14	AHSMAN	
Alcon Pharmaceuticals Ltd.	ALCBRAND	P100	3.50	0.0350	5	1.20	0.0120	10	ALCMAN	
Biomedical International Corp	BIOBRAND	TAB	0.02	0.0200	5	0.01	0.0150	7	BIOMAN	
Glaxo Wellcome Inc.	BWEBRAND	P1000	160.00	0.1600	2	120.00	0.1200	1	BWEMAN	
Item Code : 01012 / Carbamazepine 100 MG TAB ORAL TAB							Adjudication Unit : TAB			Countries Forecast : 60,000 TAB
American Hospital Supply	AHSBRAND	P500	7.00	0.0140	5	6.00	0.0120	14	AHSMAN	
Alcon Pharmaceuticals Ltd.	ALCBRAND	P1000	15.00	0.0150	5	12.50	0.0125	10	ALCMAN	
Biomedical International Corp	BIOBRAND	P1000	17.00	0.0170	5	13.00	0.0130	7	BIOMAN	
Glaxo Wellcome Inc.	BWEBRAND	P500	32.00	0.0640	2	28.00	0.0560	1	BWEMAN	

In insecure regions, maintaining a geographic and political distribution of suppliers can mitigate supply disruptions due to war, natural disasters, or international political problems.

Appeal period for rejected bidders. Some countries allow an appeal period during which rejected suppliers may request reconsideration by the tender board. The appeal process varies greatly according to national regulations; the time to resolve appeals according to law may be less than a week or many months, but ideally, the appeal period should be no more than one month, to avoid delays in procurement. Ultimately, the other bidders should be notified and given information about the winning bid.

21.7 Issuing contracts to winning bidders

When tender awards are made, contracts must be established with successful bidders (see Chapter 39).

A list of all contracts awarded, specifying for each item the supplier, price, and total value, should be made available to all responsive bidders; if necessary, the name of the successful bidder can be omitted from the public document.

If winning bidders decline to accept the contract, bid bonds or other types of security (if used) are forfeited. In the primary/secondary system, the secondary supplier is contacted immediately. In other cases, the item must be rebid; depending on the volume, local competitive bidding may be the preferred method.

21.8 Laws governing international agreements

Almost all procurement laws and regulations are based on previous laws developed in and for the country, although some countries, such as Tanzania and Uganda, have based their procurement regulations and laws on World Bank standards. With more people and goods moving from one country to another, questions about which system of law applies often arise. If, for example, the Medical Stores Department of Tanzania signs a contract to buy medicines from France, will the agreement fall under Tanzanian law or French law? The matter becomes particularly important if a disagreement arises. For example, suppose some of the goods arrive damaged, but when the contract was written, no specification of legal jurisdiction was included. Which court should adjudicate the matter?

The legal system in the country of one of the parties signing the agreement is usually chosen, or perhaps the country where the goods currently are or where payment is to be made. National procurement laws and regulations may dictate the choice of "prevailing law," but otherwise choosing the system that seems most relevant to the situation and to the risks is advisable. If, for example, goods are being imported and the concern is that the supplier may not deliver, involvement of the courts in the supplier's country may be the best way of ensuring delivery. Goods transported in boats or trains belonging to a third country are not necessarily well protected, and the laws of that country may not safeguard the goods. This fact does not alter the fact that the seller should be responsible for ensuring that the goods arrive. No guarantee exists that the courts of the country selected will agree to adjudicate any case that arises, but if the choice has been a commonsense one, it will probably be respected.

An alternative is to indicate some other body to settle disputes. In commercial contracts with some countries, the chamber of commerce may be asked to act as arbitrator. Arbitration is often a quicker and less expensive way of settling disputes than court proceedings, which may be costly and take many years. Finding a suitable arbitrator who is fair, sufficiently expert in the field concerned, and trusted by both parties is important.

One word of warning: international disputes are often not effectively settled by the courts, or even by arbitration. An unscrupulous foreign seller of a dangerous or defective product may expect to be able to escape liability because of the time and expense involved in bringing an international action. The supplier can change its name, address, domicile, and legal or corporate form and be out of reach of the courts. The law may be unclear. Even between industrialized countries with a long history of personal-injury litigation, claiming compensation for drug injury from a foreign manufacturer of a bad product remains difficult. Dealing with a firm of good reputation may be worth paying a somewhat higher price.

21.9 Monitoring performance and product quality

The procurement office is responsible for monitoring performance and compliance with contract terms by suppliers and facilities that order pharmaceuticals. The office must actively track suppliers' lead time, delivery status, compliance with contract pricing and terms, shelf life, and packaging of products. In decentralized procurement systems, central procurement authorities find it difficult to monitor local government procurement activities. Resulting problems can include high prices, poor service and product quality, irrational supplier and product selection, and poor payment practices, all of which undermine patient services. Therefore, monitoring local government and facility procurement performance becomes vitally important. Are they ordering according to schedule, in reasonable quantities, and are they paying for their purchases according to the contract? Are total purchases roughly equal to estimated needs? In some countries, governments have concluded

that recentralizing procurement is the best way to achieve desired procurement outcomes.

Maintaining an active program to ensure product quality before procurement and after receipt and distribution is crucial (see Chapters 18, 19, and 35). Reports of problems from prescribers, dispensers, consumers, and purchasing managers must be recorded in the product and supplier files and reviewed as part of the monitoring and evaluation of suppliers, and suppliers need to be made aware of any problems related to the quality of the products they supplied.

When testing is available, it is not necessary to test every drug from every supplier, but products that have been reported as suspect should always be tested. Testing should be done periodically for random samples of medicines known to be subject to degradation in questionable storage conditions, medicines that have a low therapeutic index (see Chapter 19), and pharmaceuticals received from suppliers of questionable or unknown reputation.

Chapter 39 discusses supply contracts and enforcement provisions. Enforcement is the key: there is no point in an elaborate contract unless it will be enforced when necessary. The reality is that unless substantial performance bonds are required as a condition of the contract, there may be limited recourse in the case of problems with foreign suppliers other than canceling outstanding orders and withholding payment.

21.10 The procurement information system

The most important tool in the procurement office is its management information system (MIS). The MIS can be computerized, manual, or a combination; computerized systems make it much easier to develop reports, and they speed up procurement processes such as prequalification and collation of tender offers for adjudication.

Procurement offices can probably get the greatest benefit from specialized computer software programs for procurement. Companies that sell off-the-shelf tender software include ActiveCost, Bloochip, mSupply, and Orica. The development and use of standard bidding documents can drastically decrease the time needed to prepare tender documents and contracts. The skills exist in most countries, if not in the procurement agencies themselves, to develop spreadsheet programs that can effectively accomplish most other tasks. Posting tenders and associated documents on an agency website and other Internet sites, such as dgMarket, can also help manage aspects of the tender process, such as sending out tender documents and related information, although certain tasks still require hard-copy documentation.

This section describes the information that should be tracked and used; the method of storing and retrieving the information is secondary. The information system includes several different types of records: those on products, tendering and ordering, suppliers, clients, quality assurance, accounts receivable and payable for pharmaceutical orders, and accounting records for the procurement office itself (see Chapters 41 and 49).

Product records

Product files record the standard technical specifications for a specific item and the performance of past suppliers of the product. Detailed product records are particularly important when quality is critical. A sample product card for a manual system is shown in Figure 21-4. Product records can also be maintained in a special-purpose, procurement software system or a spreadsheet. Producing a catalog of all items that can be used to compile quantification lists, tender lists, adjudication forms, and notices of awards may be useful.

Records related to tendering and ordering

A record of each year's procurement, tracking the total quantity estimated and actually purchased of each item (along with the contract supplier and price), facilitates the estimation of future prices and is essential in assembling future quantifications and checking quantity estimates from clients in decentralized ordering systems.

An ongoing record of the order status and shipments pending can be made using separate folders for orders outstanding, orders received as partial shipments, and orders completed.

Another simple manual system uses a ledger to track each order (the order number, date ordered, date received, dates additional shipments were received, and dates payments were made), organized chronologically or by purchase order number. With systems that do not use purchase order numbers, keeping track of outstanding orders may be difficult.

A computerized information system can provide standard reports on order status, organized by product, purchase order number, or supplier. Figures 21-5 and 21-6 illustrate order status reports available from a typical information system.

Records to monitor supplier and facility performance

Supplier performance monitoring has two parts. First, the system should track lead time, compliance with contract pricing terms, partial shipments, remaining shelf life, compliance with packaging and labeling instructions, and compliance with other contract terms. This record should track the number and value of tender contracts awarded chronologically and the value of total purchases from the supplier by year. Second, a file on each supplier should contain copies of all registration papers, references, special correspondence, complaints, and anecdotal information.

The facility performance monitoring system tracks total purchases compared with estimated quantities for each procurement cycle, purchases from noncontract suppliers, lead time for payment to suppliers (if that is the facilities' responsibility), compliance with deadlines for quantification, complaints about product quality and supplier service problems, and results of follow-up of complaints and requests for action.

Quality assurance records

A chronological record of all product-quality complaints, with documentation on the results of follow-up, should be separate but linked to a record that documents all quality assurance tests performed, the reason, and the results. These records should be linked to or entered into both product and supplier records.

Accounts receivable and payable

The procurement office should have a record of each order placed with contract suppliers, the dates payments were made against the outstanding amount, and the total amount still owed. A separate purchase order number for each purchase simplifies record keeping and accounting. By using individual purchase order numbers, records can be

Figure 21-4 Sample product card

Side one / product specifications

Generic name: Paracetamol		Category: Analgesic
Trade names: Calpol, Panadol, Tylenol		Code number: 02-4600
Form: Tablet	Dosage: 500 mg	Package size: 1,000 tabs
Acceptable pharmacopeial standards: IP / USP / EP / BP		
Additional technical specifications: Standard specifications (Schedule A) plus: (1) Double-scored tablet, imprinted with unique identifiers (our logo) (2) Shrink-wrapped in packaging units of 10 x 1,000		

Side two / supplier history

Purchase order number	Supplier	Quantity	Unit price	Date promised	Date delivered	Comments
085/10	Generix	5,000	20.25	01/11	02/11	
086/10	Novapharm	10,000	21.80	01/11	12/10	
003/11	Generix	5,000	20.25	04/11		Revised date 05/11
004/11	Novapharm	10,000	21.80	04/11	03/11	
046/11	Novapharm	15,000	23.00	07/11		

Figure 21-5 Sample pending purchase orders by item report

Pending Purchase Order By Item

Central Medical Stores
User ID : ORION
Run Date : 21/11/2011

Report ID : OPR012
Page No : 1 of 2

From Order Type	: PON	To Order Type	: PON1
From Order No	: 0	To Order No	: 999999999999999999999
From Order Date	: 21/11/2009	To Order Date	: 21/11/2011
From Item Code	: 0	To Item Code	: zzzzzzzzzzzzzzzzzzz
From Supplier Code	: 0	To Supplier Code	: zzzzzzzzzzz

Item Code / PO No	Date	Supplier Code and Name	UOM	Order Quantity	Delivered Quantity	Balance Quantity	Price	Discount%	Order Value	Delivered Value	Balance Value
01000		Lamivudine 10 MG TAB ORAL TAB									
PON-5	**********	AAL A.A. Laquis Ltd	TAB	9-0	5-0	4-0	10.00	4.00	86.40	48.00	38.40
PON-6	**********	AAL A.A. Laquis Ltd	TAB	9-0	0-0	9-0	10.00	4.00	86.40	.00	86.40
PON-6	**********	AAL A.A. Laquis Ltd	TAB	50000-0	0-0	50000-0	35.00	3.00	1,697,500.00	.00	1,697,500.00
						Total / Balance			1,697,672.80	48.00	1,697,624.80
01002		ACETAZOLIMIDE 250mg TAB ORAL TAB									
PON-106	**********	AHS American Hospital Supply	TAB	1100-0	0-0	1100-0	.44	0.00	484.00	.00	484.00
						Total / Balance			484.00	.00	484.00
01010		Amoxicillin									
PON-6	**********	AAL A.A. Laquis Ltd	TAB	10-0	0-0	10-0	12.00	2.00	117.60	.00	117.60
PON-6	**********	AAL A.A. Laquis Ltd	TAB	4000-0	0-0	4000-0	25.00	2.00	98,000.00	.00	98,000.00
						Total / Balance			98,117.60	.00	98,117.60
01020		Bisacodyl									
PON-107	**********	APO Apotex Inc.	TAB	30000-0	15000-0	15000-0	.00	0.00	60.00	30.00	30.00
						Total / Balance			60.00	30.00	30.00

Figure 21-6 Sample pending purchase orders by supplier report

Pending Purchase Order By Supplier

Central Medical Stores
User ID : ORION
Run Date : 21/11/2011

Report ID : OPR011
Page No : 1 of 4

From Order Type	: PON	To Order Type	: PON1
From Order Date	: 21/11/2009	To Order Date	: 21/11/2011
From Delivery Date	: 21/11/2009	To Delivery Date	: 21/11/2011
From Item Code	: 0	To Item Code	: zzzzzzzzzzzzzzzzzzz
From Supplier Code	: 0	To Supplier Code	: zzzzzzzzzzz
From Order Number	: 0	To Order Number	: 9999999999999999999
From Tender Code	:	To Tender Code	:

PO No	Date	Currency			Exchange Rate	LC No				
Item Code	Item Short Name	UOM Code	Order Qty	Price	Discount%	Order Value	Delivered Qty	Delivery Value	Balance Qty	Balance Value
Supplier Code : AAL	Name : A.A. Laquis Ltd									
PON-5	01/04/2010	USD			2.64					
01000	Lamivudine 10 MG TAB ORAL TAB	TAB	9 - 0	10.00	4.00	86.40	5 - 0	48.00	4 - 0	38.40
				Total / Balance		86.40		48.00		38.40
PON-6	01/04/2010	USD			2.64					
01000	Lamivudine 10 MG TAB ORAL TAB	TAB	50000 - 0	35.00	3.00	1,697,500.00	0 - 0	.00	50000 - 0	1,697,500.00
01000	Lamivudine 10 MG TAB ORAL TAB	TAB	9 - 0	10.00	4.00	86.40	0 - 0	.00	9 - 0	86.40
01010	Amoxicillin	TAB	4000 - 0	25.00	2.00	98,000.00	0 - 0	.00	4000 - 0	98,000.00
01010	Amoxicillin	TAB	10 - 0	12.00	2.00	117.60	0 - 0	.00	10 - 0	117.60
42017	Plaster, Dressing Strip	STRIP	10200 - 0	15.00	1.00	151,470.00	0 - 0	.00	10200 - 0	151,470.00
				Total / Balance		1,947,174.00		.00		1,947,174.00
				A.A. Laquis Ltd Total		1,947,260.40		48.00		1,947,212.40

Table 21-2 Standard procurement reports

Report name	Contents
Reorder report	Suggested order quantities, sorted by item or supplier
Purchase orders pending	Outstanding orders, by item or supplier
Physical stock status	Summary list of quantities for all items in inventory, by name or code, with nearest expiry date
Stock detail report	List of all items in stock, with quantity by batch (lot number) and expiry date
Expired stock	All expired stock and stock without expiry date
Expiry risk	Stock at risk of expiry—stock quantity, expiry date, average use, and quantity and value of stock at risk
Out of stock	All items out of stock
Stock count form	Stock count list, by name, dosage form, location, or code
Inventory adjustment	List of items for which the stock count and records differ
Inventory variance	Changes made to stock balances outside normal process
Suppliers	List of all suppliers, with contact information
Accounts payable	Aged list of debts to suppliers
Facilities	List of all client facilities, with contact information
Accounts receivable	Aged list of debts from facilities
Summary of warehouse activity	Purchases and sales, year to date and month to date
Tender request	List of items needed, with specifications
Tender offers	Bid details for each tender offer
Tender status	Tender contract status and price amendment history
Adjudication report	Bids received by item, ranked by total cost
Tender award list	List of contracts awarded
Currency exchange history	Report on exchange rates by currency
Financial transactions	Financial transactions, by date and account code
Requisition forms	Purchase requisition form and pending purchase requisitions
Stock transactions	List of all shipments to facilities, by item or facility, with total value
Purchases/receipts	List of all purchases and other receipts, by item or source, with total value
ABC analysis	ABC analysis of warehouse consumption, and analysis for each client facility
Supplier performance	Comparison of stated versus actual lead times, adherence to contracted price and delivery terms

arranged by either purchase order number or supplier. The procurement office should include the relevant purchase order number in every communication to the supplier, including the initial order, the tender contract, and any subsequent communications related to the purchase.

If the procurement office is based in a warehouse that also sells pharmaceuticals to clients, accurate records should be kept of amounts owed by clients and fees charged for procurement services. A separate transaction number assigned to each shipment or charge for services makes tracking easier.

Reporting

As discussed throughout this chapter, the procurement information system will be called upon to issue periodic reports for pharmaceutical and supplier selection, quantification, and tender collation and adjudication, as well as status reports on orders or payments. Standard reports, such as those listed in Table 21-2, are much more easily produced by a computerized information system, but even a manual system should be organized enough to produce the reports fairly regularly. ■

ASSESSMENT GUIDE

For additional indicators and procurement assessment information, see the *Methodology for Assessing Procurement Systems* (OECD/DAC 2010) and procurement system assessments from Tanzania (PPRA 2007) and Uganda (PPDA 2007). See also Country Study 36-3 on developing a procurement system assessment in India.

Quantitative indicators

- Percentage by value of ministry of health (MOH) pharmaceuticals purchased through a central procurement system
- Percentage of average international price paid for last regular procurement (indicator medicines)
- Percentage by value of MOH pharmaceutical purchases that are on the essential medicines list or national drug formulary
- Percentage by value of MOH pharmaceuticals purchased through competitive tender
- Percentage by value of pharmaceuticals purchased from local manufacturers
- Average lead time for a sample of orders (calculated separately for all suppliers, local manufacturers, foreign suppliers)
- Average time period for payment for a sample of orders (calculated separately for all suppliers, local manufacturers, foreign suppliers)

Procurement responsibility

- Is procurement managed centrally, or is authority decentralized?
- How much time is normally required to complete the following steps (and who is responsible for managing the step): selection, quantification, preparation of tender documents, tender adjudication, and contract award?
- Have the persons responsible for procurement been trained in this field?
- Is there a written procurement procedures manual? If so, do practices conform to the written procedures?
- What type of procurement method is normally used?
- Who determines the procurement method for a specific procurement?
- Are the methods based on law or written policies?
- How many different suppliers currently supply medicines to the health system?
- Are suppliers bilateral aid programs, international procurement services, multinational companies, or local import agents?
- Does a single supplier or small group seem to win most of the supply contracts for the system?
- Who is responsible for selecting potential suppliers?
- On what basis are the suppliers selected for tender participation?
- Are suppliers prequalified?
- Is a formal rating system used for evaluating suppliers' suitability?
- Are supplier selection criteria documented and closely adhered to?
- What role do local agents play in locating, selecting, and conducting business with pharmaceutical suppliers?
- Who has the authority to award contracts to suppliers?
- Are there written procedures for committee actions, and are they followed?
- Are written minutes made of procurement committee meetings?
- What kinds of influences are brought to bear on the individuals who select the suppliers and award contracts?

Tender and contract methods

- Do tenders and supply contracts specify a fixed quantity and delivery schedule or an estimated quantity, with orders placed as needed?
- If both systems are used, what is the approximate percentage by value of pharmaceuticals purchased under each system?
- What are the procedures for placing orders to suppliers?
- What is the average time required to get an order approved?
- Who approves the order?
- Is there an effective policy limiting MOH pharmaceutical procurement to drugs on the national drug formulary list or essential medicines list? If so, is it effective?
- Is there an effective policy limiting MOH pharmaceutical procurement to medicines registered with the drug regulatory authority? If so, do procedures exist for granting exemptions?
- For competitive tenders, does the schedule of requirements list medicines by generic name or brand name?
- Are any medicines or groups of medicines tendered by therapeutic group (for example, oral first-generation cephalosporin) instead of by individual medicine in the group?

- Does the tender document specify pharmacopeial standards, WHO certification, specific packaging, specific labeling on packaging, specific labeling on individual dosage form, specific labeling language, delivery or order schedule, limit on back orders or number of partial shipments, minimum shelf life, replacement of goods damaged in shipment, samples submitted with bid?
- Are domestic companies allowed a local preference margin on bids? If so, what percentage?
- Is value added required for local preference? If so, what percentage is required, and how is value added determined?
- What is the usual basis for selecting the contract supplier? Is it the lowest price with no exceptions, the lowest price from a prequalified vendor, the lowest price of products deemed to be of acceptable quality, or some other standard policy?
- If product quality is a factor in tender awards, how is quality determined?
- What circumstances prompt split tender awards, if any?
- Are secondary supplier awards routinely made in case the primary supplier fails to perform? If so, do secondary suppliers normally agree to honor original tender prices?
- What circumstances warrant switching to the secondary supplier?
- Are constraints experienced in the use of secondary suppliers?
- Are bid bonds required? If so, what percentage of procurement value is required?
- Are performance bonds required after contracts are awarded? If so, what are the usual amounts or percentage of procurement value required?
- Is a fee charged to vendors that request tender documents? If so, what is the amount?
- Does the tender contract provide for penalties if the vendor does not perform? If so, are these penalties enforced?
- Are contract terms to which suppliers are expected to adhere clearly specified?
- Do these terms provide sufficient protection from common difficulties, such as late deliveries, inadequate medicine labeling, short shelf life, and poor quality?
- Are trade terms, payment terms, delivery schedules, and payment methods clearly specified?

Payment to suppliers

- Are there problems with timely access to procurement funds or foreign exchange? If so, how do they affect the procurement timetable?
- What are the usual payment terms for international purchases and for domestic purchases?
- What are the usual real lead times for payment for credit purchases (both international and local purchases)?
- What is the total debt owed to domestic vendors and to international vendors for pharmaceuticals and supplies?

Procurement information system

- Is there a systematic method for monitoring the status of outstanding orders and for providing information to other units regarding the status of outstanding orders?
- Do suppliers frequently refuse to supply an item for which they have won the contract, or do they default on an order?
- Are there frequent problems with suppliers' performance?
- What system is used to monitor the performance of suppliers and of health units that order pharmaceuticals?
- What reports are prepared on performance, and how are these reports used?
- Are computers used in the tender management and procurement information system? If so, what kinds of software are used?
- Are the software and hardware suited to the purpose?
- Are personnel who use the computers trained in the use of the software?
- Does the computerized information system produce reliable information on consumption and performance?
- Is a reliable system in place for maintaining and supporting the hardware and software?

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★ = Key readings.

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Annex 21-1 Prequalifying new suppliers

WHO published guidelines related to pharmaceutical procurement that include a section on prequalifying suppliers (WHO/WPRO 2002). The guidelines note that the primary activities for a prequalification system include—

- Obtaining supplier information through the use of questionnaires
- Using the WHO Certification Scheme
- Seeking information from the drug regulatory authority of the exporting country
- Exchanging information with other drug regulatory authorities
- Evaluating product samples
- Monitoring and recording supplier performance

The WHO procurement guidelines also include a model questionnaire for suppliers. The World Bank (2002) also has a prequalification document for its vendors, which may be a useful resource. In addition, an example of the Organisation of Eastern Caribbean States Pharmaceutical Procurement Service's supplier prequalification form is available (OECS/PPS 2009).

Questions to ask as part of a prequalification process include the following. Annex 21-2 lists questions related to supplier performance monitoring.

Status

- Is the supplier a primary manufacturer or a distributor?
- If a manufacturer, does the supplier manufacture all products in-house?
- If the supplier does not manufacture all products in-house, who is the primary manufacturer for each product offered?

Quality control

- Does the supplier use good manufacturing practices (GMPs)?
- Does the supplier have an on-site quality control laboratory or arrangements with an immediately accessible laboratory?
- What tests—chemical, biological, stability, accelerated stability, or others—are routinely performed during and after the manufacturing process?
- Are special tests performed for stability in tropical environments?

Inspection

- What official government agencies or reputable international organizations have inspected the manufacturing facilities?
- What are the results of the most recent inspections?
- What certification documents are available from the regulatory agency concerning the supplier's status and compliance with GMPs?

Personnel and facilities

- What are the qualifications of key production and quality-control personnel?
- What is the capacity of the supplier's plant(s)?
- Does the supplier have the capacity to supply all the required quantities?
- Will the supplier have to subcontract portions of large awards?

Trade references

- What other local or foreign public procurement programs and hospitals buy from the supplier?
- How long has the supplier served the above groups?
- What is the experience of these customers with regard to the supplier's quality and service?

Financial status

- Is the supplier financially stable?
- Will the supplier remain in existence for the entire contract period?

Corporate associations

- Is the supplier a subsidiary, a parent company, or in some other way formally associated with any known supplier? If so, what is the reliability of the known supplier?
- Is the supplier producing certain products under a supervised licensing agreement with a known supplier?
- How long has the supplier been supplying the goods under consideration?

Local reputation

- How is the supplier regarded by knowledgeable physicians and pharmacists?
- How are products of the supplier regarded by knowledgeable physicians and pharmacists?
- Is any information available from public sources (such as newspapers or trade journals) concerning the supplier's performance in other countries?

Annex 21-2 Criteria for evaluating suppliers

SERVICE

Participation record

- Has the supplier attempted to alter or withdraw bids after submitting them?
- Has the supplier accepted an award of a bid and subsequently failed to deliver the product?

Response to inquiries

- Has the supplier adequately responded to all inquiries from the purchaser within a reasonable period of time?
- Did the supplier provide regular information regarding the status of outstanding orders?

Delivery time

- What was the supplier's average promised lead time? What was the actual lead time for the last procurement cycle?
- What percentage of shipments was late? How many days (weeks, months) late?
- What additional costs were incurred because of late shipments?

Adherence to delivery instructions

- Did shipments arrive under the proper shipping conditions (for example, cold storage for vaccines)?
- Did shipments arrive at the correct port?
- Did the supplier send full shipments as requested, or were there partial shipments? How many partial shipments on average?

Provision of documents

- Did the supplier provide advance copies of documents according to contract terms?
- Did shipments arrive with all required documents correctly and completely filled out and signed?
- If required documents were omitted, how did the supplier correct the problem?

Packing and labeling

- Did the supplier always ship the correct dosage form, the correct package size, the correct quantity in each package? Were short shipments frequent?
- Was labeling complete and adequate for proper use? Was it in the correct language?

Product shelf life

- Did all products shipped comply with contractual terms for remaining shelf life? If not, how many products were shipped with a shelf life less than that called for in the contract?
- Did the supplier promptly replace any items shipped that did not have an acceptable remaining shelf life or allow the return for credit or exchange of products nearing their expiration date (one standard is within three months of expiration date)?
- Did the supplier analyze samples of products approaching their expiration date to determine whether longer shelf lives can be applied to the products? Was there a charge?

Compliance with contract financial terms

- Did all invoices comply with contract pricing terms? Were any problems promptly rectified?
- Were all shipments correctly insured and shipped according to financial terms in the contract?
- Were there any problems obtaining compensation or reimbursement for lost or damaged goods?

Information available from supplier

- Did the supplier make suggestions concerning ways in which the purchaser could reduce costs (for example, by combining or splitting orders or altering delivery schedules)?
- Did the supplier provide information on purchases and payments for use in reconciling accounts?
- Did the supplier provide information on purchases broken down by products and/or therapeutic categories?

QUALITY

Pharmaceutical product

- Have complaints been received concerning product quality for this supplier? If so, what were the results of follow-up?
- Have products supplied conformed to specified pharmacopeial standards with regard to identity, purity, potency, physical appearance, dissolution, and other attributes?
- Have any products failed quality assurance testing conducted by the purchaser?
- Did the supplier provide requested batch analyses with each shipment?
- Does the supplier cooperate in making samples available and paying for quality-control tests performed by independent quality assurance agencies?
- Were there documented product problems that the supplier refused to acknowledge and rectify?
- Did the products last throughout the period of their stated shelf life?
- Was any discoloration or disintegration reported?

Packaging materials

- Were there specific examples of loss due to breakage or damage to packaging during shipments? If so, what was the extent or value?
- Did packaging meet standards appropriate to the climate of the purchasing country?
- Was external packaging sufficiently rugged to ensure arrival in the country in good condition?
- Did the external packaging protect the product from damage during transport within the country? For example, were vials sufficiently padded to withstand long trips on extremely rough roads?
- Was the immediate container able to withstand rough in-country transportation, heat, and humidity? For example, did pressure-sealed lids on tins shake loose on rocky roads?