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# Part I

## Options

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# Part I – Options

In the public sector, procurement is generally conducted on a competitive basis, although direct, sole-source contracting can be practised under special circumstances. There are several types of competitive procurement and many choices as to who will execute procurement transactions on behalf of a public sector entity. This section explains the options available and provides several tools to assist decision-makers.

## A. Procurement methods

Should an agency purchase vaccines through competitive procurement or by direct, sole-source contracting? The choice may vary with individual purchases, depending not only on the vaccine and cost/quantity factors, but also on delivery date requirements, product continuity requirements, availability of foreign currency, restrictions on the use of funds and conditions attached by donor agencies or financing organizations. The experience and skills of the procurement staff can also have an impact.

### *Competitive procurement*

Competitive procurement takes place when prospective suppliers bid against one another for an order or contract.

Competitive procurement requires that the Purchaser take initiative in contacting potential Suppliers. Competitive procurement is appropriate when several supply sources are available and reasonably large quantities and/or a large expenditure is involved. Many governments and multilateral agencies require formal competitive procedures in procurements executed with their funds. The key features of formal competitive bidding are summarized in Supplement I.A, *Ten Principles of Competitive Bidding*, located at the end of this section.

**Supplement I.A., page 23**

In addition to encouraging the lowest possible prices, competitive procurement provides a degree of protection from bias and favouritism in the award of supply contracts. Procurement of vaccine and related commodities through annual or semi-annual purchase is a common public-sector practice, which provides an opportunity for additional cost savings through lower prices for large quantities.

Competitive procurement is not appropriate when only one acceptable source of supply is available, when the volume or total value of the order is minimal, or the purchase is in response to an emergency situation. Direct contracting (sole-source) is used in these cases.

The main types of competitive procurement are as follows:

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- **International competitive bidding (ICB) (unrestricted tender)**

The objective of ICB is to provide all eligible prospective bidders with an equal opportunity to participate in the tender. It is generally initiated with a widely advertised notice of the bidding opportunity. Sealed bids are required, based on clearly stated product specifications and performance expectations. Submissions are evaluated on their technical, commercial and financial merit, with awards going to the Supplier making the most cost-effective offer. All bids are final and no negotiation is allowed, except in regard to minor contractual points, after selection of a winning bid.

ICB is the most complex of the procurement methods at the country level; however, when quantities are large, this process generally ensures the lowest price. ICB is not suited to the purchase of vaccines as these products are subject to shelf life limitations and stringent, difficult-to-control quality requirements. The public announcement of an open tender for vaccines could result in the receipt of many unacceptable offers. Under ICB rules all offers must be considered and can be eliminated only during the examination and adjudication phases of the tender. In the case of vaccines, technical evaluation would be a costly and time-consuming process. Samples of vaccine provided at the time of the tender are not relevant because vaccine, as a biological product, must be tested on a lot-by-lot basis at the time of production. In addition to expense and the impossibility of providing quality guarantees, the ICB process can require up to 17 months to complete. This is unacceptable for immunization services.

- **ICB with pre-qualification**

Pre-qualification of bidders is often employed in civil works contracts. It can also be used when there is concern that an advertised tender notice will elicit a large number of unacceptable offers and the procuring entity has only limited resources with which to perform detailed evaluations.

Pre-qualification focuses on the technical capabilities and financial stability of prospective suppliers. An invitation for pre-qualification is advertised, responses are evaluated, samples are inspected and may be tested, and a short list of qualified Suppliers is developed. Firms on the short list are invited to submit priced bids. If deemed necessary, site visits may be made at this stage in order to more fully evaluate the submissions.

Public sector purchasing entities can use a modified ICB pre-qualification process to advertise an opportunity for Producers to offer specific vaccines for licensing. Normally, the licensing of a vaccine by the NRA of the purchasing country will, in effect, pre-qualify the vaccine and the manufacturer for procurement contracts (but for that specific vaccine only). The role of the NRA in vaccine procurement is discussed further below.

- **Local competitive bidding (LCB), sometimes called National competitive bidding (NCB)**

Although not generally applicable to vaccine procurement because of the very limited number of good quality local producers, LCB is the most efficient and economical way of procuring goods which, by their nature or scope, are unlikely to attract foreign competition.

Procedures for LCB are broadly consistent with ICB, but advertising may be limited to the national press or a local official publication.

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- **Limited international bidding (LIB) (restricted tender)**

LIB is essentially ICB by direct invitation without open advertisement. It may be the appropriate method of procurement where the contract values are small, where there are only a limited number of qualified suppliers, or where there are other exceptional reasons justify departure from ICB procedures.

Under LIB procedures, the procurement entity seeks bids from a list of potential Suppliers broad enough to assure competitive prices; a total of seven to eight is often recommended.

Used in conjunction with pre-qualification and licensing of vaccines, LIB is the preferred method for procurement of vaccines when there is a range of suitable suppliers.

- **Request for quotation (RFQ), sometimes called international shopping**

The RFQ process compares quotations from several suppliers, usually at least three, to ensure competitive prices. It is an appropriate method for the procurement of vaccines provided that quotations are solicited only from suppliers of pre-qualified vaccine. This method is appropriate for other commodities when procuring ready-made, readily available goods or standard specification commodities that are small in value. Quotes can be submitted by fax, telex or email.

Although less competitive, a RFQ is sometimes used instead of the more formal sealed-bid process when the prospective supplier base is small and/or when time is limited by an urgent requirement for the commodity. Some degree of negotiation may be included in the determination of final price, terms and conditions.

### *Direct, sole-source contracting*

Sole source procurement occurs when the Purchaser does not ask for or consider offers from more than one source. Although the final price, terms and conditions are negotiated, this practice normally yields per unit prices that are higher than those obtained through competition. It is a suitable method for the procurement of vaccines only if the subject vaccine has been pre-qualified.

Sole-source procurement is used primarily for small volume purchases, proprietary products or emergency needs. Sole-source contracting may also be useful during the transition from donor-supplied products to government financing and procurement, or when brand continuation plays an important role in a programme's continued success.

When this procurement method is chosen, Purchasers should plan their negotiating strategy very carefully, using historical prices they have received and current information from sources such as the drug price bulletins issued periodically by Management Sciences for Health (MSH) or UNICEF procurement services.

Sole-source procurement is particularly appropriate when an existing contract can be expanded for additional goods of a similar nature, where no advantage would be obtained by further competition and where prices on the extended contract are reasonable.

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In practice, sole-source procurement often occurs without adequate justification when the Purchaser is passive, responding only to the initiative of a supplier. Resulting purchases are based on convenience and factors other than economic prudence and concerns for safety and efficacy.

## **B. Procurement transaction participants**

- BUYER for public sector vaccine programmes can be a government procurement entity, a qualified procurement agent, or UNICEF/WHO.
- SELLER should be a manufacturer or a manufacturer's licensed representative (agent).
- REGULATOR is the NRA in the Seller's country and in the Purchaser's country.

### *Definitions and summary of roles*

#### **• Purchaser**

Any country, organization or person that contracts with a Seller for the supply of vaccine for an agreed price.

- a) identifies the type and quantity of vaccine needed (immunization manager or programme staff)
- b) establishes specifications and draft contract requirements (NRA and procurement entity)
- c) informs prospective suppliers of opportunity to sell vaccine and how they should go about making offers (procurement entity)
- d) selects the winning bid or offer (procurement review committee made up of representatives from immunization service, procurement entity, Ministry of Health, Ministry of Finance, and others, such as NRA, as necessary)
- e) arranges for inspection and, if needed, testing (NRA)
- f) makes financial arrangements (procurement entity, Ministry of Health, Ministry of Finance)
- g) receives and stores vaccine, maintaining appropriate temperatures (Ministry of Health or immunization service)
- h) distributes vaccine, maintaining appropriate temperatures (Ministry of Health or immunization service)
- i) monitors use and reports adverse events (procurement entity, programme personnel, NRA).

#### **• Procurement agent (commercial or state)**

Organization (or individual) hired by another organization that wishes to buy vaccine but does not have the time or capability necessary to effect the transactions; the procurement agent represents the Purchaser.

- a) follows Purchaser's instructions
- b) obtains vaccine on behalf of the Purchaser
- c) charges the Purchaser a fee for services rendered

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- **UNICEF**

United Nations agency that contracts annually with WHO pre-qualified manufacturers for large quantities of vaccine on behalf of government immunization services. Also stocks non-vaccine items for sale through warehouse catalogue.

- a) estimates annual needs of all prospective “customers”
- b) purchases vaccines from producers “pre-qualified” by WHO
- c) processes orders from government organizations (“customers”) or donates vaccine to countries in greatest need
- d) requires advance payment including:
  - estimated cost of vaccine
  - administrative fees
  - estimated cost of freight
  - contingency amount
- e) directs Supplier to ship vaccine
- f) advises recipient of shipping details
- g) refunds any unused portion of advance payment

- **Manufacturer**

Producer of bulk vaccine from raw materials and, sometimes, a firm that fills vials and packages bulk vaccine.

- a) produces (or fills vials and packages) one or more vaccines
- b) develops new vaccines (optional)
- c) maintains production facilities and equipment
- d) sells vaccine
- e) ships vaccine
- f) advises recipient, agent or representative of shipping details

- **Manufacturer’s representative**

Individual who has a formal, legal relationship with a manufacturer to sell that manufacturer’s vaccine and usually receives a commission on the sale or may be salaried.

- **Independent middleman**

Individual or organization that obtains vaccine from multiple sources and re-sells it to make a profit; usually has no legal agreement with manufacturers of the vaccine; often wholesalers and discounters. The middleman may ship vaccine and may advise recipient of shipping details.

Responsible procurement entities should not purchase vaccine from independent middlemen who have no legal, verifiable relationship with the manufacturer of the vaccine. Although pre-qualified, licensed vaccine – or what is represented to be

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pre-qualified, licensed vaccine – may be offered for sale by independent middlemen, it should be considered unsafe without the manufacturer’s direct acknowledgement and assurance of identity, quality, safety, remaining shelf life and cold chain integrity. It will be necessary to carry out laboratory testing of vaccine purchased from middlemen unless the manufacturer and the quality of the vaccine can be clearly established.

This recommended source limitation seeks to assure that no counterfeit, mishandled or short-dated vaccine reaches consumers.

- **Regulator (country of *manufacture*)**

Body established and backed by national legislation to assure the quality of medicines and vaccines, i.e. NRA (see discussion in Part IV). Ideally, a specialized biologicals committee is attached to the NRA.

- a) establishes licensing criteria, including review of clinical performance
- b) monitors field performance and investigates adverse events
- c) operates a lot release system
- d) maintains appropriate laboratory capability
- e) ensures regular GMP inspections

- **Regulator (in Purchaser’s county)**

A body established and authorized by national legislation to oversee the development, production, and distribution of medicines and vaccines by manufacturers, i.e. NRA.

- a) establishes procedures for ensuring biological products intended for use in the country are of adequate quality, safety and efficacy
- b) issues, varies and revokes licenses for vaccines and other biological products on the grounds of safety, potency and efficacy
- c) monitors imports and locally produced products (lot release) and has the ability to recall, if necessary
- d) investigates adverse events (post-marketing surveillance system)
- e) collects fee from manufacturer to cover costs of licensing
- f) may inspect or arrange for inspection to monitor GMP compliance as part of pre-qualification process
- g) responsible for storage and distribution standards

### ***Purchaser’s rights and Seller’s expectations***

**Purchaser** has the right to:

- a) Decide exactly what is required and ask for it, including:
  - vaccine type and programme specifications
  - shelf life
  - quantity and delivery date
  - vial size and packaging

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- marking and packing
  - terms and conditions for the contract
  - shipping mode
  - route for shipment
  - payment mode
- b) set a maximum budget and reject offers that exceed it
  - c) decide what will comprise proof of quality (NRA)
  - d) set the rules for the purchase process
  - e) establish how and when the purchase will proceed
  - f) establish evaluation criteria and method for review and comparison of bids and priorities
  - g) seek and consider competing offers
  - h) reject offers that do not meet basic criteria
  - i) reject goods that do not meet specification or otherwise comply with the contract
  - j) insist on free replacement of defective goods

**Seller** expects that:

- a) the Purchaser has the funds needed to pay for the purchase
- b) the Purchaser will want assurances of quality
- c) the Purchaser has described exactly what he wants
- d) the Purchaser wants the most advantageous price
- e) the Purchaser understands that there is an obligation to pay extra for requested items and services that are beyond what is specifically included in the contract

### **C. Procurement entities**

Who should carry out the procurement activity? The choice of a procurement entity depends upon the existing level of procurement staffing and expertise available and conditions attached to grants or loans by donor or financing organizations. More than one procurement entity may be chosen by a public sector programme, depending on the complexity of the transactions to be managed and the entity's special expertise.

Public sector programmes generally choose among three options: procurement by in-house staff; procurement contracted out to a commercial or state procurement agent; and purchases through a United Nations agency such as UNICEF or WHO.

#### ***Procurement by in-house staff***

Staff requirements for competitive procurement operations include knowledge of international and local procurement procedures, product specifications, inspection procedures, regulatory and financial requirements, international shipping and trade documentation. Additional knowledge of international and local vaccine sources and

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price levels is desirable. Staff should have access to sufficient office space and equipment, such as typewriters, computers, copiers and communications equipment. Specialized technical assistance should include an outside assessment of staff procurement capabilities.

### *Using a procurement agent*

A public sector programme that lacks appropriate internal capabilities and experience for the proposed procurement activities may employ a commercial or state procurement agent to act on its behalf. It is important that the agent be well-qualified for the particular type of procurement to be undertaken and that programme control over procurement transactions and decisions is retained.

In practice, it is not uncommon for local middleman suppliers to label themselves as “procurement agents”. These “agents” offer vaccine from pre-arranged sources and do not initiate competitive procurement on behalf of the Purchaser. WHO recommends against the use of independent middlemen for the purchase of vaccines (see above).

A procurement agent can be local or international and is defined as one who

- a) enters into a formal contract with the Purchaser to act on his behalf
- b) solicits quotations from multiple sources for vaccine and related products that meet the required specifications
- c) involves the Purchaser and NRA in selection of the Supplier
- d) is responsible to the Purchaser for his actions
- e) charges the Purchaser an agreed fee for each procurement service based on a percentage of the cost of the goods

Unlike procurement of goods, selection of a procurement agent does not involve a competitive process with the award being made to the lowest evaluated bidder. The competence and relevant experience of the firm and the personnel to be assigned are the principal factors to consider. Financial terms must not dominate selection to the detriment of effective execution of the project.

Qualifications of the procurement agent

- a) verifiable relevant qualifications, training and experience of the personnel to be assigned to the procurement activity
- b) verifiable record of successful performance of similar services involving vaccine and cold chain requirements
- c) verifiable list of major contracts handled over the last five years
- d) current business license or registration in country of legal domicile
- e) references with contact information

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## Contracts with procurement agents

- a) Terms of reference
  - i) Precise statement of the objectives of the assignment
  - ii) Scope and timing of the required services
  - iii) Inputs to be provided by the contracting party
  - iv) Particulars of the output including documents and reports
- b) Budget for the anticipated purchases
- c) Fees and payment terms
- d) Fees paid to procurement agents are generally in accordance with the level of effort required and may range from 3% to 10%, or more, of the cost of the goods purchased.
- e) General terms and conditions of the contract, for example:
  - i) notifications
  - ii) governing language
  - iii) legal authority
  - iv) force majeure
  - v) expiration
  - vi) termination
- f) Signatures

### *Procurement through United Nations agencies (UNICEF and WHO)*

#### **UNICEF**

The United Nations Children’s Fund (UNICEF) carries out vaccine procurement on behalf of countries and public sector programmes, usually for a fee of 6% of the value of the supplies. UNICEF concentrates primarily on vaccines for national immunization services and as a procurement agent for the Vaccine Fund of the Global Alliance for Vaccines and Immunization (GAVI).<sup>2</sup> Requirements for these programmes are filled from large-quantity multi-year supply agreements that have been established with vaccine manufacturers. UNICEF may purchase and supply other vaccines on a case-by-case basis. Only manufacturers who have been assessed and prequalified by WHO for supply of specific vaccines to United Nations agencies are eligible for UNICEF vaccine supply contracts.

From the standpoint of the purchasing entity, procurement through UNICEF resembles a sole-source process. UN agencies do not respond to invitations to bid for contracts to supply goods. However, UNICEF will act as an agent for the purchase of vaccines and other commodities for which it has the necessary expertise. Additional information may be found in Part V – “The UNICEF Option”.

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<sup>2</sup> See information on GAVI in Supplement V.C.2, page 754.

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## WHO

The procurement arm of the World Health Organization (WHO) will purchase vaccines on behalf of government programmes. Typically, WHO supplies vaccines for amounts that are required in addition to the amounts a government has obtained through other methods, including self procurement, UNICEF procurement, or procurement using other purchasing agents. Governments often turn to WHO for help with vaccine procurement in the instance of stock shortfall, an outbreak, an interruption of customary supply services, or failure of their procurement system. WHO will only provide vaccines of assured quality as listed in WHO's list of pre-qualified vaccines. A special case of WHO procurement is the Revolving Fund of WHO's Regional Office for the Americas, the Pan American Health Organization (PAHO). The PAHO Revolving Fund provides procurement and other services for the countries of the Americas, generally following a similar procurement process (a detailed description of this fund is beyond the scope of this document).

As with UNICEF, procurement through WHO resembles a sole-source process. WHO will not bid for contracts to supply goods but will act as an agent for the procurement of vaccines and other commodities for which it has the necessary expertise. WHO charges a handling fee of 3% of the value of the supplies for this service.

Orders can be placed through the WHO representative or liaison in country or the regional office. Advance payment in US dollars against an estimate provided by WHO is required with the order.

While WHO has negotiated competitive prices with manufacturers for goods and products, it is important to note that WHO's procurement service does not keep vaccine on hand waiting for shipment, so its supply process takes the same amount of time as other procurement mechanisms. If an order is sizeable, the procurement specialists will conduct a competitive tender process using limited international bidding to attain the best price for products of assured quality. In the case of vaccines, WHO will solicit bids from the list of vaccines and manufacturers that it has pre-qualified for sales to UN agencies. The procurement process does not begin until a full payment has been received in advance.

WHO procurement services will not facilitate existing agreements between manufacturers and a country.

Further information can be obtained from the WHO Procurement Services in Geneva, Switzerland, or from the local or regional WHO office.

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## D. Selection tools

Several tools are available to assist in choosing the best procurement method for a specific situation. The chart titled “Comparison of purchasing methods” shows the effect on price, delivery and workload of open tenders (competitive bidding), selective tenders (limited bidding), negotiated procurement (request for quotation) and direct sole-source procurement. It also offers an opinion on the relative need for a merit rating of Suppliers under each of the procurement options and lists conditions favouring the use of each.

**Supplement I.D., page 25**

A generic outline of the individual tasks that must be accomplished during the procurement process along with an estimate of time requirements is presented for planning purposes. The “Sample procurement activity timeline” details tasks and time-spans for an average 9½-month procurement process. Public sector competitive procurement is a complicated undertaking that can require up to 17 months from the time a need is identified until the time goods are available for distribution. It is affected by the manufacturer’s “lead time”, the mode of shipment, and the degree of formality in the solicitation and adjudication process. It is also affected by the government approval process and the period allowed for prospective vendors to respond to a solicitation. The sample timeline should be revised according to individual circumstances.

**Sample I.D., page 26**

## Ten principles of competitive bidding<sup>3</sup>

### 1. Suitable package

Design tender requirements to attract the interest of as many Suppliers as possible. For vaccines, ensure that tender requirements do not exclude any manufacturers of pre-qualified vaccines.

### 2. Early warning

Allow at least 45 days for bidders to submit offers.

### 3. Non-discrimination

The tender must be open to all qualified manufacturers. When selective tendering is used in place of unrestricted advertised solicitation for the purchase of vaccine, invite only manufacturers of pre-qualified vaccines.

### . Accessibility

Ensure wide access to competition by setting reasonable costs for bid documents and bid securities. For vaccines, it is unlikely that the value of the contract will justify the purchase of bid documents or the use of bid securities.

Respond to all written questions and requests for additional information from each bidder; provide identical information to all other bidders without identifying the source of the inquiry.

### 5. Neutrality

Use generic terms in the specification rather than brand names.

Do not show preference for a specific brand or manufacturer in bid specifications; include the phrase “or equivalent” if a brand name must be used.

### 6. Formality

Require that bids be in writing, signed and received in sealed envelopes before a stated date and time.

### 7. Confidentiality

Do not open bids until the assigned date and time.

Restrict all bid information to authorized parties.

### 8. Consistency

Evaluate all bids against the same criteria.

Do not ask or permit a bidder to change the substance of the bid unless equal opportunity is given to all bidders within the competitive range.

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<sup>3</sup> Based on the essential elements of World Bank tendering.

**9. Objectivity**

Determine if bid is “substantially responsive” by checking for errors, correct signatures and adherence to basic tender requirements.

Select the most advantageous bid considering both the price and the evaluation criteria announced in the bidding documents.

**10. No negotiation before award**

Encourage the lowest responsible offer from each bidder through the process of tender competition; minor contractual adjustments may be allowed after selection of the most advantageous bid.

### Comparison of purchasing methods

Purchasing method	Brief description	Effect on price	Delivery times	Workload on the procurement unit	Need for a merit rating of suppliers	Conditions favouring use
Open tender	Bids are accepted from all interested suppliers	Very favourable	Long	Very high	Very high	<ul style="list-style-type: none"> <li>• Many reputable suppliers are available</li> <li>• May be necessary at beginning of programme to open supply channels</li> <li>• For vaccine use, open tender only for pre-qualification</li> </ul>
Selective tender	Suppliers bid against each other for the contract, but participation of suppliers is limited to those who have registered with the government or who have met established prerequisites	Favourable	Moderate	Moderate	Moderate	<ul style="list-style-type: none"> <li>• Where only a few reputable suppliers are available</li> <li>• Products where bioequivalence, sterility, precise formulation is important</li> <li>• Large volume, standard items for which all reliable suppliers are known</li> <li>• For vaccines, use only pre-qualified sources and products</li> </ul>
Negotiated procurement	The buyer approaches a small number of selected potential suppliers and bargains with them for specific price or service arrangements	Moderately favourable	Short	High initially, low later	Only initially	<ul style="list-style-type: none"> <li>• Bulk buying of single-source drugs</li> <li>• Special terms or specifications are required by the buyer</li> <li>• For vaccines, use only pre-qualified sources and products</li> </ul>
Direct procurement	Purchase is made directly from a single supplier at his quoted price	Unfavourable	Very short	Very low	No need	<ul style="list-style-type: none"> <li>• Low price, small volume items</li> <li>• Emergency items where negotiation not possible</li> <li>• Items from international non-profit groups</li> <li>• For vaccines, use only pre-qualified sources and products</li> </ul>

<sup>4</sup> Based on original work by Management Sciences for Health.

### Sample procurement activity timeline

Task Name	Duration	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10
<b>Initiate procurement</b>	<b>21d</b>										
Establish file	1d										
Approvals	20d										
<b>Develop bid documents</b>	<b>36d</b>										
Draft specs/terms	15d										
Approvals	21d										
<b>Solicit bids</b>	<b>24d</b>										
Invite tender	4d										
Receive bids	20d										
<b>Evaluate bids</b>	<b>32d</b>										
Compare offers	15d										
Selection process	7d										
Approvals	10d										
<b>Order goods</b>	<b>37d</b>										
Award notification	2d										
Financial arrangements	15d										
Sign contract	5d										
Funding process	15d										
Manufacturing lead time	30d										
Pre-ship inspection	3d										
Arrange airport cold storage	5d										
<b>Delivery</b>	<b>14d</b>										
Authorize shipment	3d										
Airport arrival	5d										
Customs clearance	5d										
Transport to MOH cold storgare	1d										