



Procuring Single-use Injection Equipment and Safety Boxes



***A Practical Guide for Pharmacists, Physicians,
Procurement Staff and Programme Managers***

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EXECUTIVE SUMMARY

Background

Ensuring sufficient and continuous access to single-use injection equipment is a key element of any strategy to achieve the safe and appropriate use of injections. Experience from immunization and general services indicates that increased access to injection equipment improves practices. Thus, in April 2002, the 12th Expert Committee on the selection and use of essential medicines recommended that "when injectable medicines are being supplied, the necessary equipment for sterile injections should be supplied." This recommendation can be achieved through the existing drug supply delivery system.

Objective

The objective of this guide is to accompany pharmacists, physicians, procurement staff and programme managers through the process of procuring single-use injection equipment and safety boxes of assured quality, on a national or international market, at reasonable prices.

Procurement procedures

International organizations have established standardized procurement procedures for medicines and medical devices. This guide describes how these procedures can be used to ensure the procurement of injection equipment and safety boxes.

Ensuring the quality of injection equipment

Institutions procuring injection equipment need to develop a list of manufacturers that are pre-qualified on the basis of certain criteria which include international quality standards. This guide provides steps and tools for procurement, including a pre-qualification procedure of injection equipment for purchase. Developing a monitoring system for supplier performance will improve and safeguard the quality of injection equipment selected and prevent or eliminate unreliable suppliers.

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Objective of the guide

The objective of this guide is to facilitate the procurement of single-use injection equipment and safety boxes of appropriate quality and to develop practical competence through a step-by-step approach, by:

- Defining the characteristics and current quality standards of injection equipment and safety boxes;
- Describing a comprehensive procurement procedure that ensures quality and responds to a variety of operational needs;
- Identifying the challenges and constraints when estimating injection equipment and safety boxes requirements for health care services.

Who should use this guide?

This procurement manual was prepared to assist pharmacists, physicians and procurement officers at the national level who wish to purchase single-use injection equipment and safety boxes on the national or international market.

This guide may also be used by:

- National programme officers and managers who have the responsibility of setting programme needs in terms of quantity and type of injection equipment;
- Wholesalers of medicines and medical devices;
- Programme officers and procurement units of international agencies (e.g., United Nations procurement agencies including WHO, UNFPA, UNAIDS and UNICEF);
- Nongovernmental organizations (NGOs) active in the health care sector;
- Bilateral donors;
- International low-cost procurement agencies.

Background

Poor injection practices spread bloodborne pathogens

An estimated 16 thousand million injections are administered worldwide each year, with more than 90% of these injections administered for curative purpose. A safe injection is one that does not harm the recipient, does not expose the health care worker to any avoidable risks and does not result in any waste that is dangerous for the community. ¹ However, unsafe injections occur worldwide with up to 70% of injections administered with syringes and needles reused in the absence of sterilization. ² Each year, unsafe injections may account for 30% of new hepatitis B virus (HBV) infections, 40% of new hepatitis C virus (HCV) infections and 5% of new human immunodeficiency virus (HIV) infections throughout the world. ²

Safe and appropriate use of injections requires a multi-disciplinary approach

To prevent injection-associated infections, safe injection practices are required and injection overuse must be reduced. Firstly, patients and health care workers need to move away from unsafe and/or unnecessary injections and toward oral medications. Secondly, single-use injection equipment must be available continuously in sufficient quantities to eliminate the reuse of syringes and needles in the absence of sterilization. Thirdly, sharps waste must be managed to eliminate the risks of reuse of dirty needles and needle-stick injuries. Guidance to multidisciplinary national safe and appropriate use of injection policies are provided in detail in the WHO injection safety planner. ³

Improving access to injection equipment to improve injection safety

Increased access to single-use injection equipment improves injection practices in immunization ⁴ and general services. ⁵ The 12th WHO Expert Committee on the selection and use of essential medicines in April 2002 recommended that “when injectable medications are being supplied, the necessary equipment for sterile injections should be supplied.” ⁶ To ensure best practices, this implies that single-use syringes and needles, appropriate diluents and safety boxes ¹ be supplied along with injectable medications. The WHO department of HIV/AIDS also stated that “by all 2005, all injectable medications and vaccines will be supplied with single-use injection equipment.” ⁷ The incremental cost of ensuring availability of injection equipment is not high. In Burkina Faso, the cost of single-use injection equipment was estimated to account for 2.2% of the essential drug expenses in primary health care facilities (WHO unpublished data, 2001). In addition, investing in single-use injection equipment and safety boxes is a cost-effective way to prevent infections with bloodborne pathogens. ⁸

For immunization services, in 2000 a joint Statement by WHO, the United Nations Children’s fund (UNICEF), the United Nations Population Fund (UNFPA) and the International Federation of Red Cross and Red Crescent (IFRC) recommended that sufficient syringes and safety boxes be “bundled” with consignments of vaccines. ⁹ Because Auto-Disable (AD) syringes offer a high level of protection against reuse and are available in sizes that allow their use for immunization, the WHO/UNICEF/UNFPA “bundling” policy called for the exclusive use of AD syringes for the administration of all vaccines by the year 2003.

This guide follows a step-by-step approach to assist stakeholders in the introduction and purchasing of single-use injection equipment and safety boxes that are needed to make injections safe in health care services.

Planning policy changes

In countries where sterilizable injection equipment is still in use, it will also ensure a smooth transition to single-use injection equipment.

Phase A: Describe current

Make an inventory of all injection equipment and safety boxes currently procured and used, including types and volumes of syringes, size of needles, purchase prices and quantities procured.

Phase B: Develop a national policy on injection equipment and safety boxes

Key policy issues include:

- Adopting of auto-disable equipment for immunization;
- Adopting single-use equipment for curative and preventive care (including syringes with a reuse-prevention feature and safety syringe);
- Securing the financial resources for injection equipment, including safety boxes;
- Adopting international quality standards for syringes and needles and for quality systems as the basis for national regulation;
- Procuring injection equipment and safety boxes in bulk, centrally, at all levels;
- Managing injection equipment and safety boxes storage, centrally, at all levels;
- Distributing effectively to ensure continuous and sufficient availability of single-use syringes, needles and safety boxes in all health care facilities;
- Coordinating with general health care services and programmes that make use of injections to ensure that an appropriate and environmentally-friendly sharps waste disposal system is in place for all levels of care.

Phase C: Develop a national plan of action to introduce the new policy on the change to new single-use injection equipment

A plan of action with timeline and budget, identifies the actions required to implement the procurement, including training of the procurement staff, and distribution of the single-use injection equipment. Implementation in a phased manner, according to the operational structure and budget resources, will facilitate transition (e.g., on a region by region and/or programme by programme basis).

Additional supporting policy components

Rational use of injectable medicines

A national strategy for the rational use of injectable medicines will limit the needs of injection equipment and safety boxes and reduce overall costs. Approaches include training of health care workers, and information, education and communication (IEC) activities. Monitoring and supervision increase effectiveness and may be used to forecast injection equipment quantities.

Sharps waste collection and management

Sharps waste management is an important part of a policy for the safe and appropriate use of injections (Appendix 1). Ensuring that safety boxes are provided by the procurement system assists broader waste management plans managed by general health services.

Managing procurement

The procurement cycle

Products that will need to be procured are (1) injection equipment (i.e., single-use syringes and needles) and (2) safety boxes.

Organization of procurement services

Procurement of injection equipment and safety boxes is based on the four strategic objectives for good pharmaceutical procurement¹⁰:

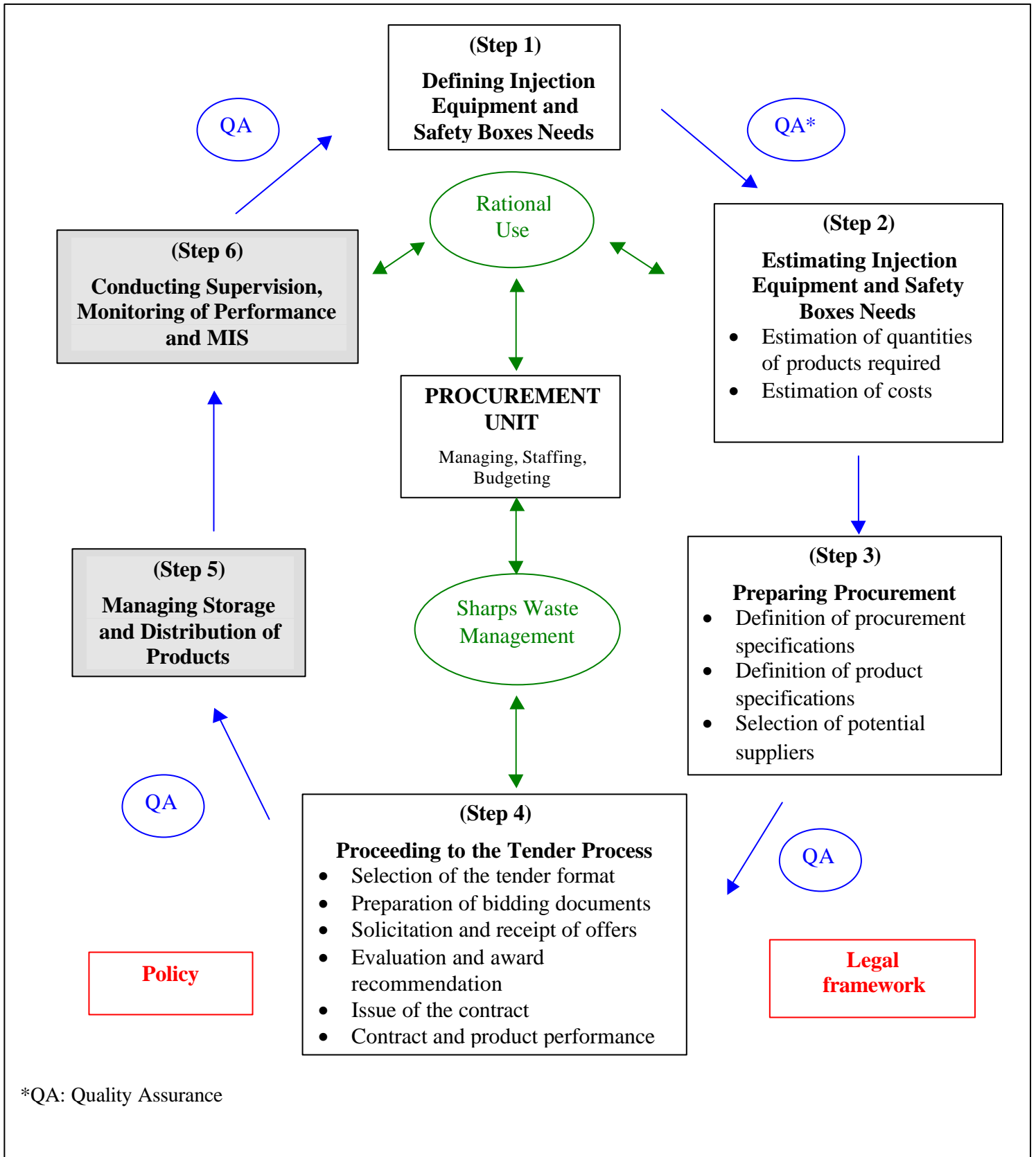
- Procure the most cost-effective safe products in appropriate quantities;
- Pre-qualify reliable suppliers of assured quality products;
- Ensure timely delivery;
- Achieve the lowest possible total cost for a good quality product and meeting the needs over the appropriate period of time.

Procurement can be thought of as a cycle (Figure 1) that includes six steps. No matter what model is used to manage the procurement and distribution system, efficient procedures in place will assist in:

1. Defining the required performance of injection equipment and safety boxes to be procured;
2. Estimating the quantity of injection equipment and safety boxes needed and their costs;
3. Preparing procurement;
4. Proceeding to the tender;
5. Managing the storage and distribution of products;
6. Conducting the supervision, the monitoring of performance of products and suppliers and the management of the information system (MIS).

Quality assurance of injection equipment and safety boxes procured is an ongoing process throughout the whole procurement cycle and is not limited to sample testing in a quality control laboratory.

Figure 1: The procurement cycle for injection equipment and safety boxes



A step-by-step approach of procurement

The different steps of the procurement process from product definition to the product and contract performance are reviewed in Table 4 and described in greater detail below:

Step 1- Defining injection equipment and safety boxes needs

The rational selection of injection equipment and safety boxes has three advantages:

- It allows cost-saving through bulk procurement;
- It standardizes quality;
- It simplifies inventory requirements and makes ordering easier.

Considerations for the selection of injection equipment and safety boxes include:

- The national injection safety policy (e.g., recommended syringe types, syringe types currently used);
- The list of injectable medications included in the national formulary or the national essential drug list and identify which injection equipment is needed to administer these medicines (e.g. needles, syringes, reconstitution syringes, IV giving sets)
- The intended area of use for the injection equipment (e.g., immunization, general curative care, specific disease or other);
- Financial resources available.

Box A: Guidance to develop a list of injection equipment and safety boxes needed in curative services:

A list of injection equipment may be based on the range of medicines used in the national formulary.

1. Identify injectable medicines in the national formulary. This list would include items such as injectable antibiotics, IV fluids, narcotics, etc.
2. Identify which injection equipment is needed to administer these medicines (e.g. needle, syringes, reconstitution syringes, IV placement unit, butterfly needles, etc.) and which safety boxes are needed to collect injection equipment (Appendix 2, Appendix 3). The sizes of injection equipment required are determined by the volume of each identified injectable medicine and the route of administration.
3. Rationalize the amount of different injection equipment and safety boxes in the list if possible. A list of injection equipment and safety boxes can be developed as proposed below according to the intended use:

Selection of needles:

- 26G needle for intradermal injection;
- 23G needle for subcutaneous injection and intramuscular for children;
- 21G needle for intramuscular injection for adults;
- 19G needle for intravenous injection and reconstitution.

Selection of syringes:

- 2 ml, 5ml, 10ml, 20ml syringe;
- Specific syringes for immunization and insulin.

Selection of safety boxes:

- 5L safety boxes for health care facilities.

Step 2 - Estimating injection equipment and safety boxes needs

Forecasting injection equipment and safety boxes requirements consists of (1) estimating the quantities of products required and (2) estimating the amount of products that can be procured with the available financial resources.

Step 2. 1. Estimation of the quantities of products required

In general services, two methods used to estimate medicines requirements can be applied to estimate injection equipment and safety boxes needs.

- The **consumption method**. This uses data on past utilization (adjusted for stock-outs and projected changes in injectable medicines utilization) to estimate future needs. This is likely to be the most reliable method providing that supply has been consistent and usage records are accurately kept. It does not require detailed morbidity data or standard treatment guidelines.
- The **morbidity method**. This uses estimates on the number of health care contacts, common disease incidences and current standard treatment guidelines (see example for a specific programme in Table 1). This method is based on rational prescribing and requires good morbidity data. It is most appropriate for calculating injection safety needs according to injectable medicines needs in new programmes and for comparing actual use with theoretical needs.

In practice, the best approach may include a combination of the consumption and morbidity methods. The consumption method may be used first to improve quantification in the short run and then the morbidity method could be applied progressively for each type of service, to allow prescribing standards to be reviewed and improved. Alternatively initial estimates might be made by the morbidity method, to establish a base from which to start, and once this is assured the consumption method can be introduced. The general approach is to calculate enough injection equipment according to each injectable medicine to be supplied for 12 months. An appropriate buffer stock at the central level will ensure that supplies can be maintained if usage increases or orders are delayed.

Table 1: Estimated quantities and costs for injection equipment and safety boxes for a curative programme “P” (use one table per injectable medicine)

		Formula	Total units needed	Unit price	Total cost
A	Number of patients for a programme “P”	#			
B	Number of injections for an injectable medicine “M” per patient for one course of treatment or for X months of need	#			
C	Number of injectable doses	A x B			
D	Number of syringes + needles *	C			
E	Number of safety boxes (+10% of extra need[†])	D x 1.11/Y [‡]			
F	Total costs	C+D+ E			

* As the estimation of injectable medicines already includes a buffer stock, a buffer stock for injection equipment is not suggested in this table. Usually buffer stocks are estimated according to national means of transport, time of delivery, and distribution system.

[†] 10% of extra need is an indicative figure that may be adapted on the basis of country experience.

[‡] Y denotes the capacity of a safety box, Y is estimated at 80 to 100 syringes per 5 L box according to the size and volume of the syringes. This estimate can be adapted according to manufacturers’ instructions and experience.

In immunization services, vaccine requirements are based on population figures (targeted population, expected coverage and number of doses required per client, with an adjustment for a wastage factor, Table 2). Injection safety requirements are calculated according to the number of children/women expected to be vaccinated, with an allowance made for syringe/safety box wastage.

Table 2 : Estimated quantities and costs for immunization injection equipment for vaccination a vaccine “V” (use one table for each vaccine)

	Formula	Total units needed	Unit price	Total cost
A	Number of children for “V” vaccinations (for Tetanus Toxoid (TT) target of women)	#		
B	Number of doses per child (per woman for TT)	#		
C	Estimated wastage factor	#		
D	Number of “V” doses	$A \times B \times C$		
E	Vaccines buffer stock *	$D \times 0.25$		
F	Total vaccine doses	$D + E$		
G	AD syringes (+10% * wastage)	$A \times B \times 1.11$		
H	AD syringes buffer stock †	$G \times 0.25$		
I	Total AD syringes	$G + H$		
J	Number of doses per vial	#		
K	Number of single-use syringes for reconstitution ‡ (+10% wastage)	$F \times 1.11 / J$		
L	Number of safety boxes § (+10% of extra need)	$(I + K) \times 1.11 / 100$		
M	Total costs	$F + I + K + L$		

Estimating the quantity of safety boxes needed will assist in safe sharps waste collection in all services. These may be estimated according to the quantities of injectable equipment ordered and the estimated capacity of the boxes. ** The appropriate use of safety boxes recommend to not overfill the boxes (1) to prevent needlesticks that occur when health workers stuff needles and syringes into full sharps containers and prick themselves with needles already inside the boxes and (2) to facilitate the complete combustion during the incineration of the safety boxes once filled with used syringes and needles.

* 10% wastage is an indicative figure that may be adapted on the basis of country experience.

† The buffer stocks for vaccines and AD syringes are set at 25%. This is calculated with the first stock of doses required to introduce the vaccination in any given geographic area. Then the country would aim to gradually reduce to 15% by the third year. For vaccine in single or two-dose vials the maximum wastage suggested is 5%.

‡ Only for lyophilized vaccines. Use zero for other vaccines.

§ The capacity of a safety box is estimated at 100 AD syringes for immunization per 5L box. This estimate can be adapted according to manufacturers’ instructions and experience. The capacity of a box depends on the design of the injection equipment. Recent developed designs of AD syringes increase the capacity of a box up to 300 pieces.

** Removing needles is not recommended according to WHO best infection control practices for injections. ¹ Estimates of syringes number are based on syringes with fixed needles.

Step 2.2. Estimation of costs

After a quantification has been completed it may be still necessary to adjust the quantities that can be procured according to the funds available. In any case, the adjustment must keep the balance between injectable medicines and single-use injection equipment ordered. Freight cost is an important element to consider both in estimating and comparing the landed cost of different solutions as injection equipment are bulky products and to include in the planning for in-country distribution. Insurance is another element to consider in the global cost.

The accurate costing of injection equipment and safety boxes requirements is needed also to avoid stock-outs or overstocks. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated quantity supply contract.

Price information on injection equipment and safety boxes can be obtained from various sources, including Internet sites and price catalogues from commercial companies, non-commercial organizations, NGOs and international procurement agencies (Appendix 4). Prices from catalogues give an indication but they may vary significantly according to quantities ordered. The cost of safety boxes is incorporated into the total required budget.

Step 3- Preparing procurement

Step 3.1. Definition of procurement specifications

The tender committee will elaborate the procurement specifications, based on the product specifications and tender requirements, e.g. transport, time of delivery, port of entrance.

Step 3.2. Definition of product specifications

Expert and users' committees define the required characteristics of the product that is needed (Appendix 2, Appendix 3).

Step 3.3. Selection of potential suppliers

Quality is the most important selection criterion when choosing injection equipment and safety boxes suppliers. Criteria used to assess potential suppliers and monitor already selected suppliers include:

- Product quality;
- Service reliability;
- On-time delivery performance;
- Financial viability.

Service reliability includes quality assurance policy and service, goods return and recall policy and freight service. In addition, the credentials of vendors who introduce themselves as representatives of manufacturers may also be checked. Pre-qualification procedures before the bidding process or post-qualification procedures after the bidding process will help to eliminate substandard suppliers.

There are two main options to select suppliers. First, the pre-qualification, also known as the procedure for assessing the acceptability, in principle, of a product and suppliers, is used for restricted tender. Second, the post-qualification procedure is used for open tender. Monitoring suppliers' performance is also an important component of supplier selection.

Pre-qualification procedure

The procedure for assessing the acceptability of injection equipment or safety boxes and suppliers is the formal procedure for the screening of potential bidders prior to invitation to bid. It is a process to ensure that invitations to bid are extended only to those who have adequate capabilities and resources. Substantial time may be required to establish an initial list of pre-qualified suppliers meeting pre-determined norms and standards. However, once this is completed it will allow the lowest acceptable bidder for each product to be deemed qualified and to expedite adjudication and contract award. International agencies (e.g., WHO, UNICEF, UNFPA) and the World Bank highly recommend and support the pre-qualification of potential suppliers according to set procedures to ensure product quality and consistent supply. WHO is currently developing procedure for the pre-qualification of single-use injection equipment named: “Procedure for assessing the acceptability, in principle, of injection equipment for purchase by United Nations agencies”.

Box B: Pre-qualification: Objectives and tools

Objectives

1. Develop a list of potential suppliers and manufacturers of injection equipment and safety boxes meeting specifications and standards by a procurement committee in collaboration with the national regulatory authority;
2. Purchase acceptable quality products while maintaining a competitive procurement process to obtain best possible prices.

Tools for the quality assessment of manufacturers/suppliers¹¹

The manufacturer has to demonstrate the production of medical equipment according to quality standards:

a. International standards:

- International standards (ISO standards) are available for injection equipment and cover both product standards and quality systems (Appendix 5). The use of international standards is recommended above the use of national standards.
- There are no ISO standards for safety boxes and some national standards are too stringent for developing countries. Thus, WHO procurement specifications and standard test procedures are use by default.²⁰

b. Control of compliance to international standards:

- Laboratory quality testing is performed to assess conformity to ISO standards and/or WHO procurement specifications;
- The manufacturer has to register its products at the national regulatory authority of the country of import.

Mechanism to assess manufacturers/suppliers

The programme/technical bodies will determine which standards and specifications to use for injection equipment and safety boxes and how compliance to these standards and specifications will be verified. The decision to purchase or to reject proposed injection equipment will be based upon (1) information provided by manufacturers or vendors and (2) an algorithm to use this information to accept or reject the product (Appendix 6, Appendix 7).

Post-qualification procedure

Post-qualification evaluates suppliers to be selected after bids have been received, according to the same criteria of quality as those requested in the pre-qualification process. The disadvantage of this procedure is that if there are numerous offers from unknown suppliers there may be long delays in awarding contracts, as it will be necessary to validate suppliers' capacity to supply assured quality products.

Monitoring supplier performance

In addition to using pre-qualification procedures, good supplier performance is ensured through a formal monitoring system that tracks:

- Product-specific performance indicators:
 - Quality of injection supply items received;
 - Remaining shelf-life;
 - Compliance with packaging;
 - Labelling instructions and other specifications.

- A file for each supplier with commercial indicators:
 - Lead times;
 - Compliance with contract terms;
 - Partial shipments;
 - Management of supply problems;
 - Number and value of tender contracts awarded and the value of total purchases from the supplier by year and performance for each tender.

A more detailed list of criteria for evaluating suppliers is given in Appendix 8.

If procurement officers already monitor supplier performance for other items, injection equipment and safety boxes can be incorporated into this monitoring system. The procurement office will keep a database of all past procurement reports and contract history, to assist in the selection of suppliers for coming tenders. This will make the procurement process more efficient, especially suppliers selection procedures and collation of tender offers for adjudication. Information collected will be kept in general procurement records (Table 3).

Table 3: Information kept in general procurement records *

Report name	Contents
Product records	Lists of specifications
Records related to tendering and ordering	Files of invitations to tender Adjudication reports Tender award lists
List of pre-qualified suppliers	Files of assessment reports per supplier
Quality assurance records	Quality assurance testing Reporting of product problems from prescribers, dispensers and consumers
Records to monitor supplier performance	Monitor performance and compliance with contractual terms by suppliers and per contract <ul style="list-style-type: none"> • Monitor suppliers' lead time • Delivery status • Compliance with commercial terms and conditions • Remaining shelf life • Compliance with packaging and labelling
	Elaborate a file on each supplier containing copies <ul style="list-style-type: none"> • All registration papers • References • Correspondence • Complaints, reporting of problems • Value of tender contracts awarded • Other information

Step 4- Proceeding to the tender

The tender process covers:

1. Selection of the tender format.
2. Preparation of bidding documents for selective tender.
3. Solicitation and receipt of offers for selective tender.
4. Evaluation and award recommendation.
5. Issue of the contract.
6. Performance of the contract and the product.

The two first actions (selection of the tender format and preparation of bidding documents for selective tender) are detailed below. The four others are generic to all procurement procedures and are outlined in Table 4.

* The list of procurement reports proposed in the table is generic and not exhaustive.

Step 4.1. Selection of the tender format

Most established procurement systems use restricted tenders with pre-qualification procedures that solicit bids only from pre-qualified suppliers. The most appropriate tender format for the procurement of injection equipment and safety boxes is the “Limited International Bidding” (LIB) combined with an pre-qualification procedure. Continuous efforts to seek out potential new suppliers maintain the competitiveness of the procurement process. Other procurement methods, including the “Request for Quotations” (RFQ) may be appropriate for emergency supply situations or when small volumes of supplies are required.¹²

Step 4.2. Preparing bidding documents for selective tender

International organizations, including United Nations agencies and the World Bank, have developed guidelines for procurement procedures that can be applied to the procurement of injection equipment.^{13,14,15} Key elements of these procedures are summarized in Table 4. Sources of templates that can be used to develop bidding documents are provided in Appendix 9.

The specific characteristics of single-use injection equipment and safety boxes will be clearly stated in the tender document.

For injectable equipment, these include:

- Type and volume of syringe (Appendix 2);
- Syringe without needle, with integrated needle or with non-integrated (attachable) needle;
- Type, size and length of needles (Appendix 2);
- Packaging;
- Remaining shelf life for single-use injection equipment after delivery (maximum life time for sterile injection equipment is five years).

For safety boxes, these include:

- Type and size of safety boxes (Appendix 3);
- Packaging.

In addition to the above, the normal tender requirements specify and include:

- Method of transport: Freight mode (Incoterms 2000);¹⁶
- Insurance for goods;
- Realistic delivery time;
- Location of the delivery: Point of receipt of goods in the recipient’s country.

Step 5 - Managing storage and distribution of products and Step 6 - Conducting supervision and monitoring of performance.

Step 5 (Managing storage and distribution of products) and Step 6 (Conducting supervision and monitoring of performance) of the procurement cycle are managed according to the same rules that apply for the procurement of pharmaceuticals and medical devices.

The focus of this guide is to describe specific features of the procurement of single-use injection equipment and safety boxes, therefore only the first four steps of the procurement cycle are discussed.

Table 4: Applying general procurement procedures to the procurement of injection equipment and safety boxes

Steps	Objectives	Tasks
<p>(Step1) Defining injection equipment and safety boxes needs</p>	<p>Define products (Appendix 2 and 3)</p>	<p>Define the type of single-use injection equipment required according to the purpose of use:</p> <ul style="list-style-type: none"> • Type of syringes • Volume of syringes • Syringes with integrated or non-integrated (attachable) needles • Diameter and length of needles • Type of safety boxes • Volume of safety boxes
<p>(Step2) Estimating injection equipment and safety boxes</p>	<p>Estimate injection equipment and safety boxes needs (Information available at national or provincial level)</p>	<p>Estimate needs in preventive and curative services according to:</p> <ul style="list-style-type: none"> • Orders of vaccines and injectable medicines • Consumption of syringes and needles, needles for reconstitution for medicines that required reconstitution, syringes and vials, including multi-dose vials • Wastage (e.g., 10% in immunization) • Buffer stock at the central level • Principle of matching quantities of injectable medicines to quantities of syringes and safety boxes
	<p>Quantify injection equipment and safety boxes: Estimate funds required</p>	<p>Calculate costs using international indicator prices or from other sources (e.g. past prices paid)</p>

Applying general procurement procedures to the procurement of injection equipment and safety boxes

Steps	Objectives	Tasks
<p>(Step3) Preparing procurement</p>	Define procurement or tender specifications	<ul style="list-style-type: none"> • Specific: attributes and features of the product needed • Non specific: Agreed transport, delivery time and location. (port of entrance)
	Specify injection equipment and safety boxes specifications (Appendix 2)	<p>Specify injection equipment characteristics:</p> <ul style="list-style-type: none"> • Type and volume of syringes • Type of needles (integrated or non-integrated) • Size and length of needles (Gauze) • Packaging (number of unit per package) • Labelling (refer to ISO standards) • Remaining shelf life after delivery (minimum of 2/3 of the life time of the product) <p>Specify safety boxes characteristics:</p> <ul style="list-style-type: none"> • Type and volume of boxes • Labelling (refer to the WHO specifications) • Packaging (unfolded)
	Prepare bidding documents (Appendix 9)	<ul style="list-style-type: none"> • Product specifications • Checklist form for vendors and product information • Tender specifications • Financial arrangements
	Select potential suppliers	Choose potential suppliers from a list of pre-qualified suppliers

Applying general procurement procedures to the procurement of injection equipment and safety boxes

	Steps	Objectives	Tasks
(Step 4) Proceeding to the tender	Selection of the tender format	Choose a tender format	Appropriate methods of procurement for injection equipment: <ul style="list-style-type: none"> • Limited International Bidding (LIB) • Request For Quotation (RFQ)
	Preparation of bidding documents for selective tender	List documentation to be presented by the bidder	Elaborate the list of documentation: <ul style="list-style-type: none"> • Eligibility documentation • Specification documentation • Pre-shipment procedures • Importation procedure
		Draft document for bid package “ <i>Invitation to Bid</i> ”	<ul style="list-style-type: none"> • Draft model of a tender documentation
		Draft selection criteria for selected tender bidders	<ul style="list-style-type: none"> • Define selection criteria • Describe evaluation methods
	Solicitation and receipt of offers for selective tender	Send invitation to bid and bidding documents	<ul style="list-style-type: none"> • Issue the bidder’s list
		Open bids on date specified on the bid document	<ul style="list-style-type: none"> • Receive and open offers • Record bid opening
		Comparison of the bids	<ul style="list-style-type: none"> • Elaborate adjudication worksheet
		Collate offers for adjudication by the tender review committee	<ul style="list-style-type: none"> • Summary cover sheet
	Evaluation and award recommendation	Select known or new pre-qualified supplier(s) according to checklist Evaluate supplier(s)	<ul style="list-style-type: none"> • Gather tender committee review panel • Choose best bid on the basis of price and other elements of the offers • Finalize award process • Notify successful bidder
		Award supplier contract(s)	<ul style="list-style-type: none"> • Transmit official award letter

Applying general procurement procedures to the procurement of injection equipment and safety boxes

Steps		Objectives	Tasks
(Step 4) Proceeding to the tender	Contract issue	Draft final purchase order	<ul style="list-style-type: none"> • Approve and sign • Submit to the supplier for signature • Advise unsuccessful bidders
		Financial arrangements	<ul style="list-style-type: none"> • Collaborate with the finance unit, • Organize the arrangement for release of funds • Notify the supplier and the purchaser of responsibilities for contract performance
	Supplier performance	Make delivery	<ul style="list-style-type: none"> • Receive and inspect goods, control batches. • Report deficiencies as necessary
		Monitor performance of supplier	<ul style="list-style-type: none"> • Assess compliance with contract terms by suppliers for this current contract
		Closeout activities	<ul style="list-style-type: none"> • Maintain warranty records
	Product performance	Monitor performance of injection equipment	<ul style="list-style-type: none"> • Detect performance problems in the field and provide feedback to the supplier and the National Regulatory Authority (NRA) monitors

Glossary and abbreviations

Auto-Disable syringes (AD): AD syringes are single-use syringes that inactivate themselves after one use. AD syringes reduce the risk of injection-associated infections because they can not be reused. AD syringes are now widely available at low cost (less than a 20% increase over the cost of a standard single-use syringes). AD syringes are the recommended equipment for administration of vaccines, both in routine immunization and mass campaigns.

Bundling: "Bundling" refers to the inclusion of the costs of AD syringes and safety sharps boxes in the costs of good quality vaccines provided by donors and lenders as described in the WHO/UNICEF/UNFPA/IFRC 1999 policy statement. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

Batch: The quantity of a product produced in one production run.

Disposal: The collection, storage, and subsequent destruction of all syringes and needles to avoid any accidents.

EO: sterilization by ethylene oxide gas

EPI: Expanded Programme on Immunization.

Expiry date: The date appearing on the packaging of the injection equipment and established by the manufacturer, beyond which the manufacturer will not guarantee the efficiency and the sterility of the injection equipment.

EXW: Ex-works- (common trade term - need to state a named place.): Ex works represents the minimum obligation of the seller. The seller pays for expenses at factory or warehouse. The buyer assumes all onward expenses (loading and transport of the goods). The seller's only responsibility is to make the goods available at the seller's premises for collection by the buyer.

FCA: Free carrier- (common trade term - need to state a named place) The seller's obligation is to pack and deliver the goods on hand of the first or only carrier at the named port of carriage (seaport or airport) into the custody of the first or only carrier and clear them for export. The risk of loss or damage to the goods is transferred from the seller. The buyer's responsibility is to pay for the onward shipment of goods to the destination.

FOB: Free on board- (common trade term - need to state the loading port) The seller is responsible for placing the goods on board the first ship or carrier at a named port of shipment in the sales agreement. The seller pays the cost of loading the goods. Once the goods are on ship's platform, the risks and responsibility pass onto the buyer, and so does the cost of onward shipping.

ILAC: International Laboratory Accreditation Cooperation. Laboratory Accreditation provides formal recognition to competent laboratories. An international guide, called ISO/IEC Guide 25, describes the basis for the accreditation of a country's testing and calibration laboratories. Adoption of this international guide has helped countries adopt a uniform approach to determining laboratory competence. To find accredited laboratories around the world, open the web page <http://www.ilac.org/>. Click "the "Directory" button will result in a world map and instructions to find members in different regions and their addresses or websites for communications.

Infection control: The activities aiming at the prevention of the spread of pathogens between patients, from health care workers to patients, and from patients to health care workers in the health care setting.

Integrated needle: The needle is fixed on the syringe and it cannot be removed.

International Organization for Standardization (ISO): The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies from some 140 countries. ISO is a nongovernmental organization established in 1947. The mission of ISO is to promote the development of standardization and related activities in the world to facilitate the international exchange of goods and services and to develop cooperation in the area of intellectual, scientific, technological and economic activity.

International procurement services: Organizations such as WHO, UNICEF, IDA, etc., and other groups that supply medicines and medical equipment on a non-profit basis.

ISO standards: Standards of general quality assurance are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics to ensure that materials, products, processes and services are fit for their purpose. The standards are not official standards and may be seen as voluntary, unless a government adopts them as part of regulatory legislation.

Gauge: Measuring system for coding thickness. For needles, the Gauge defines the external diameter of needles tube, it varies from 8 to 30 which correspond respectively to 4 and 0,3 mm. The higher the Gauge number is, the thinner the needle tube is. The gauge does not take into account the wall thickness of the needle tube, therefore the gauge do not give idea about internal diameter.

Good Manufacturing Practice (GMP): Good Manufacturing Practice is the part of quality assurance that ensures that the pharmaceutical products (medicines and medical devices) are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. The certificate is issued following inspection of the premises, manufacturing equipment, personnel, product and marketing documentation, in-house quality control, in-house process validation, etc. and is valid for a certain period of time. Hence, lack of GMP certificate or quality system certificate from a manufacturer may be a cause for concern.

Limited International Bidding (LIB): LIB is essentially international competitive bidding conducted by direct invitation to all qualified suppliers and without open advertisement. This method may be more appropriate when there is only a limited number of potential suppliers (e.g., in the case of AD syringes).

Luer conical fitting system: "Luer" fitting refers to the international standard ISO 594: Conical fittings with a 6% (Luer) taper for hypodermic syringes, needles and certain other medical equipment. This includes (1) a syringe, or certain other medical equipment such as transfusion and infusion sets, with a nozzle of specific dimensions and (2) a needle with a hub of specific dimensions compatible with each other, regardless of manufacturers.

Luer Lock conical fitting system: Luer Lock fittings refer to a screw-on conical fitting with a 6% (Luer) taper for hypodermic syringes, needles and certain other medical equipment for medical use e.g. transfusion equipment (international standards ISO 594-2)

Lead-time: The time interval needed to complete the procurement cycle. It begins at the time the need for new stock is recognized and ends when that stock is received and available for issue.

MIS: Management information system.

NGOs: Nongovernmental Organizations.

NRA: National regulatory authority.

QAS: Quality Assurance System.

Request For Quotation (RFQ): This method of procurement is used in those cases where the health sector goods are available from only one source, or for emergency supply. It is the least favoured method because in the absence of the competitive element it is more difficult to determine whether the prices quoted are economic and reasonable.

Restricted tender: Procurement procedure in which participation in bidding is limited to suppliers that meet certain prerequisites or have previously registered as suppliers.

Safety stock: The buffer or minimum stock that is kept on hand to protect against stock-outs. In theory, the safety stock is separate from the working stock, but in practice there is no separation of the two and sometimes safety stock must be issued.

Safety boxes: Safety boxes, also known as sharps containers, are puncture-proof, impermeable containers for the safe and convenient disposal of used syringes and needles and other contaminated sharps. Safety boxes must be filled only once, collected safely then destroyed immediately. When they are used consistently and correctly, safety boxes can prevent needle-stick injuries.

Safety syringes: Single-use syringes that are designed with a needlestick-prevention feature

Shelf life: The shelf life is the length of time that a product may be stored without affecting its usability, safety or potency.

SIGN: Safe Injection Global Network.

http://www.who.int/entity/injection_safety/sign/en or www.injectionsafety.org

Single-use syringes: include syringes designed for a single use, with a separate, stainless steel needle, auto-disable syringes designed for immunization, syringes with a reuse-prevention feature for general purpose and syringes with needlestick-prevention feature.

Supplier: Suppliers are primary manufacturers of health sector goods or individuals/organizations with authority to act as an agent for the primary manufacturer.

Tendering: The procedure by which competing bids are entered for a particular contract

UNFPA: United Nations Population Fund.

UNICEF: The United Nations Children's Fund.

WHO: The World Health Organization.

Working stock: Stock that is on hand in the warehouse or storeroom and is shipped to requesting operating units.

Appendices

Appendix 1: Sharps waste management

Managing sharps waste as a duty of care

Poorly managed sharps waste expose health workers and the community to injuries and infection. The efficient, safe and environmentally-friendly management of sharps waste is the only means of ensuring that single-use syringes and needles are not reused and do not lead to needle-stick injuries.¹⁷ Thus, it is important to include in the policy a statement specifying that disposal is part of the syringe life cycle and that health care services have a duty to manage sharps waste.

Integrating sharps waste management within health care waste management

The management of sharps waste must be considered within the broader context of health care waste management. Implemented as such, sharps waste management will be cheaper and more sustainable. Key elements of health care waste management are summarized in the WHO health care waste management "Aide Memoire"¹⁸ and in the WHO injection safety planner. For practical purposes, general health care services are in the best position to implement sharps waste management from a sector-wide perspective. However, to coordinate sharps waste management activities stakeholders in charge of injection equipment procurement will liaise with general health care services and purchase safety boxes as a first step of appropriate sharps collection and disposal, while new technologies are being evaluated such as used needle remover devices and needle cutters which aim to reduce the volume of sharps waste.

Information sources on health care and sharps waste management:

The WHO working group on health care waste management

<http://.www.healthcarewaste.org>

The Safe Injection Global Network (SIGN)

http://www.who.int/entity/injection_safety/sign/en or

<http://www.injectionsafety.org>

WHO's Immunization Safety Priority Project

<http://www.stage/vaccines-surveillance/ISPP>

Appendix 2: Characteristics of injection equipment

Product description:

Syringe, single-use

General characteristics	Sterile Nozzle with a Luer fitting Single-use Polypropylene (material)
Use	<ul style="list-style-type: none"> • Injection for general purpose and other uses including, reconstitution and feeding (e.g., into a naso-gastric tube) • For intradermal injection (tuberculin testing)
Type	<ul style="list-style-type: none"> • 2 pieces: one barrel and one plunger • 3 pieces: one barrel, one plunger and one elastomeric piston seal
	<ul style="list-style-type: none"> • Luer fitting • Luer Lock fitting
Need for a fixed needle	<ul style="list-style-type: none"> • Yes: with by-packed needle (see needle nomenclature) • No: without a needle
Volume	<ul style="list-style-type: none"> • 0.3, 0.5, 1, 2 ml for insulin • 0.5 ml or 1ml for tuberculin • 1, 2, 3 ml for general purpose • 5, 10, 20 ml for general purpose <ul style="list-style-type: none"> - nozzle located centrally - nozzle located eccentrically • 50 ml with Luer nozzle for mixing, • 50 ml for feeding and other uses
Specific packaging	<ul style="list-style-type: none"> • Individual sterilized blister or ribbon packs made of paper and plastic • Protective end capped syringes
Sterilization	<ul style="list-style-type: none"> • Ethylene oxide (EO) • Irradiation (R)
Shelf life remaining	Minimum of 2/3 of the life time when leaving the supplier warehouse
Requirements	<p>Conform to ISO standards:</p> <ul style="list-style-type: none"> • ISO 7886 –1: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use¹⁹ • ISO 8537: Sterile single-use syringes, with or without needle, for insulin

Auto-Disable syringes

General characteristics	Single-use Sterile Including a mechanism to prevent reuse
Material	<ul style="list-style-type: none"> • Polypropylene • Stainless steel for some mechanisms preventing reuse
Use	<ul style="list-style-type: none"> • For immunization • For curative and preventive care
Syringe size with pre-set volume and single marking	<ul style="list-style-type: none"> • 0.05 ml for BCG vaccine • 0.1 ml for BCG vaccine • 0.5, 1 ml for immunization
Syringe size with graduated scale	<ul style="list-style-type: none"> • 1, 2, 3, 5, 10 ml for preventive or curative care
Needle for immunization	<ul style="list-style-type: none"> • Diameter: e.g.: 23G , 24G, 25G for 0.5 ml and 1ml syringes e.g.: 27 G for 0.05 ml syringe • Length: e.g.: 30mm (1 1/4"), 25mm (1"), 16mm (5/8") for 0.5 ml and 1 ml syringes e.g.: 10mm (3/8"), 12mm (1/2") for 0.05 ml syringe
Needle for general purpose	<ul style="list-style-type: none"> • Diameter: for IM, IV and subcutaneous injection • Length: for IM, IV and subcutaneous injection
Types	<ul style="list-style-type: none"> • Syringes with permanently attached needle • Syringes packed with non standard Luer needle in the blister or ribbon pack • Syringes packed with a Luer needle in the blister or ribbon pack.(once the needle is fixed, the needle becomes permanently attached)
Packaging	<ul style="list-style-type: none"> • Individual sterilized blister or ribbon pack made of paper and plastic • Needle cap and cap over thumb plate (if applicable) make syringe into a sterile unit
Shelf life remaining	<ul style="list-style-type: none"> • Minimum of 2/3 of the life time when leaving the supplier warehouse
Requirements	<p>Conform to:</p> <ul style="list-style-type: none"> • WHO performance specification E8/DS.1²⁰ if AD syringes for immunization purpose • WHO specifications WHO/BCT/02.12²¹ if AD syringes for general purpose <p>In progress: ISO standard ISO 7886-3: Sterile hypodermic syringes for single use - Part 3: Auto-Disable syringes for fixed doses immunization²²</p>

Needle single-use, hypodermic

General characteristics	Single-use Sterile Luer conical fitting Stainless steel (material)																														
Purpose	<ul style="list-style-type: none"> • intramuscular • intravenous • subcutaneous • intradermal 																														
Length	<ul style="list-style-type: none"> • 10 mm (3/8") • 12 mm (1/2") • 16 mm (5/8") • 25 mm (1") • 30 mm (1 1/4") • 40 mm (1 1/2") • 50 mm (2") 																														
Diameter of the needle tube and Luer colour code of the needle hub	<table> <thead> <tr> <th>External Diameter (Gauge and mm)</th> <th>Colour code of the hub (in accordance with ISO 6009²³)</th> </tr> </thead> <tbody> <tr><td>27G : 0.4 mm</td><td>Grey</td></tr> <tr><td>26G : 0.45 mm</td><td>Brown</td></tr> <tr><td>25G : 0.5 mm</td><td>Orange</td></tr> <tr><td>24G : 0.55 mm</td><td>Purple</td></tr> <tr><td>23G : 0.6 mm</td><td>Blue</td></tr> <tr><td>22G : 0.7 mm</td><td>Black</td></tr> <tr><td>21G : 0.8mm</td><td>Deep green</td></tr> <tr><td>20G : 0.9 mm</td><td>Yellow</td></tr> <tr><td>19G : 1.1mm</td><td>Cream</td></tr> <tr><td>18G : 1.2 mm</td><td>Pink</td></tr> <tr><td>17G : 1.5 mm</td><td>Deep red</td></tr> <tr><td>16G : 1.6 mm</td><td>White</td></tr> <tr><td>15G : 1.8 mm</td><td>Blue Grey</td></tr> <tr><td>14G : 2.0mm</td><td>Pale green</td></tr> </tbody> </table>	External Diameter (Gauge and mm)	Colour code of the hub (in accordance with ISO 6009 ²³)	27G : 0.4 mm	Grey	26G : 0.45 mm	Brown	25G : 0.5 mm	Orange	24G : 0.55 mm	Purple	23G : 0.6 mm	Blue	22G : 0.7 mm	Black	21G : 0.8mm	Deep green	20G : 0.9 mm	Yellow	19G : 1.1mm	Cream	18G : 1.2 mm	Pink	17G : 1.5 mm	Deep red	16G : 1.6 mm	White	15G : 1.8 mm	Blue Grey	14G : 2.0mm	Pale green
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17G : 1.5 mm	Deep red																														
16G : 1.6 mm	White																														
15G : 1.8 mm	Blue Grey																														
14G : 2.0mm	Pale green																														
Packaging	Individually sterilized blister or ribbon packs made of paper and plastic																														
Shelf life remaining	Minimum of 2/3 of the life time when leaving the supplier warehouse																														
Requirements	Conform to ISO standards: <ul style="list-style-type: none"> • ISO 7864: Sterile hypodermic needles for single use²⁴ 																														

Proposed Nomenclature of needle size for each route

Length in mm		30 mm	16 mm	16 mm	25 mm	30 mm	40 mm	50 mm	40 mm	25 mm	40 mm	30 mm	30 mm
Outside diameter in mm		0.45 mm	0.5 mm	0.55 mm	0.6 mm	0.7 mm	0.8 mm	0.8 mm	0.9 mm	0.9 mm	1.1mm	1.1mm	1.2 mm
Outside diameter in Gauge		26G	25G	24G	23G	22G	21G	21G	20G	20G	19G	19G	18G
Length in inch		1 ¼"	5/8"	5/8"	1"	1 ¼"	1 ½"	2"	1 ½"	1"	1 ½"	1 ¼"	1 ¼"
Colour code of Luer needle hub		brown	orange	purple	blue	black	deep green	deep green	yellow	yellow	cream	cream	pink
Intradermal		Adults Children	Adults Children										
Subcutaneous		Children	Children	Adults Children	Adults								
Intravenous	Injection				Children	Adults Children							
	Tap									Adults Children	Adults Children		Adults
Intramuscular					Children	Adults Children	Adults	Adults	Adults		Adults		
Intra-arterial		Surface					Adults Children	Adults Children	Adults Children	Adults Children			
	Injection	Middle			Adults Children								
		Deep				Adults Children	Adults Children						
	Tap								Adults Children	Adults Children			
Intra-articular									Adults Children	Adults Children	Adults Children		

Appendix 3: Characteristics of safety boxes

General characteristics	Containers for the collection of used syringes and/or needles Potentially for initial distribution of syringes and needles Disposal and destruction by incineration of used syringes and needles
Material	Waterproof, puncture-proof cardboard*
Volume	<ul style="list-style-type: none">• 5 litres• 10 litres• 15 litres• 20 litres
Labelling	Pictorial instructions printed on the box to describe the use and the disposal of the box once filled Separate sheet with pictorial instructions on how to assemble the flat-packed boxes
Shelf life	Not applicable
Requirements	Conform to WHO procurement specifications E10/IC.1 for safety boxes and incineration containers ²⁵

* Other types of sharps containers exist such as plastic sharps containers for which some national standards exist. this guide only mentions the cardboard safety boxes.

Appendix 4: List of potential suppliers

International low-cost suppliers *

IDA

Procurement unit
PO Box 37098
1030 AB Amsterdam
THE NETHERLANDS
Telephone: + 31 20 40 33 051
Fax: + 31 20 40 31 854
E-mail: info@ida.nl
<http://www.ida.nl>

Médecins Sans Frontières logistique

14 rue de l'Argone
F- 33700 Mérignac
FRANCE
Telephone: + 33 556 13 73 73
Fax: + 33 556 13 73 74
E-mail: standard@bordeaux.msf.org

Transfer

Preenakker 20
B-1785 Merchtem, BELGIUM
Tel. + 32 52 26 10 21
Fax + 32 52 26 10 04
office-transfer@msf.be
www.tranfer.be

Action Medeor

Deutsches Medikamenten Hilfswerk
St. Töniser Strasse 21
D 47918 Tönisvorst
GERMANY
Telephone: + 49 21 56 97 88 0
Fax: + 49 21 56 97 88 88
E-mail: info@medeor.org
<http://www.medeor.org>

Missionpharma

Vassingerødvej 9
DK-3540 Lyngø
DENMARK
Telephone: + 45 48 16 32 00
Fax: + 45 48 16 32 48
E-mail: info@missionpharma.com
<http://www.missionpharma.com>

CHMP

4 voie militaire des gravanches
63100 Clermont Ferrand
FRANCE
Telephone: + 33 473 98 24 71
Fax : + 33 473 98 24 80
E-mail: contact@chmp.org
www.chmp.org

The Medical Export Group

Papland 16 / P.O. Box 598
NL-1200 An Gorinchem
THE NETHERLANDS
Telephone: + 31 183 356 100
Fax: + 31 183 356 115
E-mail: sales@meg.nl
www.meg.nl

* This proposed list of low-cost suppliers is indicative and not exhaustive.

UN Agencies

UNICEF Supply Division

Freeport
DK-2100 Copenhagen 0
DENMARK
Telephone: + 45 35 27 35 27
Fax: + 45 35 26 94 21
E-mail: supply@unicef.dk
www.supply.unicef.dk

UNFPA

Procurement Unit
220 East 42nd Street
New York, NY 10017
USA
Telephone: + 212 297 53 84/5392
Fax: + 212 297 49 16/5220
E-mail: saunders@unfpa.org

WHO

Procurement Services
20 avenue Appia
CH-1211 Geneva 27
SWITZERLAND
Telephone: + 41 22 791 28 01
Fax: + 41 22 791 41 96
E-mail: procurement@who.int

Manufacturers

A list of potential manufacturers of injection equipment can be obtained through the International Association of Safe Injection Technology (IASIT):

IASIT

24, chemin de Mont-Rose
CH-1294 Genthod
SWITZERLAND
Tel: +41 22 731 73 80
Fax: +41 22 731 73 82
<http://www.iasit.org>

Appendix 5: International standards and supplier information

International standards for injection equipment¹¹

The ISO standards are available on the Internet site: www.iso.ch

Product standards

Product standards listed in the Table 5 describe the current international standards governing single-use injection equipment recognized by the five founding members of the Global Harmonization Task Force (GHTF). The founding members are Australia, Canada, the European Union, Japan and the United States.

Table 5: International Standards for single-use syringes and needles

1	ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
2	ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
3	<i>ISO 7886-3 in progress</i>	<i>Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed dose immunization</i>
4	<i>ISO 7886-4 in progress</i>	<i>Sterile hypodermic syringes for single use - Part 4: Syringes for manual use - with reuse prevention feature</i>
5	ISO 8537	Sterile single-use syringes, with or without needle, for insulin
6	ISO 7864	Sterile hypodermic needles for single use

Quality standards

Quality systems are defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management. The quality standards used by the five founding members of GHTF are listed in Table 6.

Table 6: Quality standards of the five founding members of the GHTF¹¹

Founding members	Quality standards
Australia	ISO13485 or EN 46001, ISO13488 or EN46002
Canada	ISO13485, ISO13488
European Union	EN46001, EN46002, ISO13485, ISO13488
Japan	GMP (QS Standard for medical devices #1128)
United States	QS (21 CFR part 820)

Note: EN46001 and EN46002 will be phased out by the end of March 2004

Standards for safety boxes

In the absence of international standards for safety boxes, the WHO specifications E10/IC.1 for safety boxes and incineration containers and E10/IC.2 for safety boxes are used to determine procurement requirements.

Appendix 6: Checklist to collect information on quality from vendors or manufacturers

		Information item	Details					
		Item short description*						
1	<input type="checkbox"/>	Brand name				Remarks		
			Status [†] and Name	Address	Phone and Fax	Contact quality assurance Web-site, e-mail		
2	<input type="checkbox"/>	Vendor						
3	<input type="checkbox"/>	Manufacturer						
	<input type="checkbox"/>	Manufacturing Site						
4	<input type="checkbox"/>	Parent company (if any)						
5	<input type="checkbox"/>	Compliance with regulations	Regulatory authority (check all applicable)		Number (provide number)		Device name as submitted to authorities	
			<input type="checkbox"/> Australia		License number:			
			<input type="checkbox"/> Canada		License number:			
			<input type="checkbox"/> European union		CE mark number:			
			<input type="checkbox"/> Japan		License number:			
			<input type="checkbox"/> United states		510(k) number:			
		<input type="checkbox"/> Other, specify:						
6	<input type="checkbox"/>	Conformity with quality system standards	Standards used (check applicable)		Assessment body[‡] (name, country), (attached a copy of the certificate)		Last audit date	Expiration date
			<input type="checkbox"/> ISO13485 /ISO13488					
			<input type="checkbox"/> EN46001 / EN46002					
			<input type="checkbox"/> Japan QS Standard #1128					
			<input type="checkbox"/> United States QS (21 CFR part 820)					
			<input type="checkbox"/> ISO9001 /ISO9002					
		<input type="checkbox"/> Other, specify: (e.g. ISO9001:2000)						
7	<input type="checkbox"/>	Conformity with product standards	Standards used (check applicable)		Test laboratory (name, country) (attached a copy of the certificate)		Laboratory accreditation body	
			<input type="checkbox"/> ISO 7864 for needles					
			<input type="checkbox"/> ISO 7886-1 syringes for single-use					
			<input type="checkbox"/> ISO 7886-2 syringes for power-driven pumps					
			<input type="checkbox"/> ISO 8537 for insulin					
			<input type="checkbox"/> WHO performance specifications for AD syringes for immunization: E8/DS1					
<input type="checkbox"/> WHO procurement specifications for syringes with a reuse-prevention feature for general purpose								
8	<input type="checkbox"/>	Post-market surveillance reports	<input type="checkbox"/> Yes (check applicable . If yes, please provide all reports including sources. Use additional pages if necessary)					
			<input type="checkbox"/> No					
9	<input type="checkbox"/>	Other evaluation reports	<input type="checkbox"/> No ? Yes (check applicable . If yes, please provide all reports including sources. Use additional pages if necessary)					

* In addition to this checklist, the manufacturer can provide a technical description of the product.

[†] Status: please provide the status as a vendor such as wholesaler, manufacturer, distributor, etc.

[‡] e.g., Notified bodies in the European Union; Quality Systems Registrars in North America.

Instructions for completing the checklist

All potential suppliers (or original manufacturers) please fill in items 1,2,3,4,8,9. In addition,

- If a regulatory authority has cleared the device, fill in item 5.
- If a regulatory authority of the GHTF founding members has not cleared the device, fill in items 6 and 7.

Item 1: Please provide the brand name that is used on the market. If there is more than one name, please provide all names.

Item 2 and item 3: The vendor may also be the manufacturer. But if the addresses are different, please provide all information.

Item 4: If the manufacturer is a subsidiary of a parent company or is contracted from another company, please supply the necessary information. A parent company may be located locally or in another country.

Item 5: If there is more than one regulatory authority that has cleared the device, please check all applicable authorities and provide all clearance numbers with the corresponding device names as they were submitted to the regulatory authorities. The device name submitted to the regulatory authorities, which may be different from the brand name, is necessary for verification of marketing clearance by the relevant regulatory authorities.

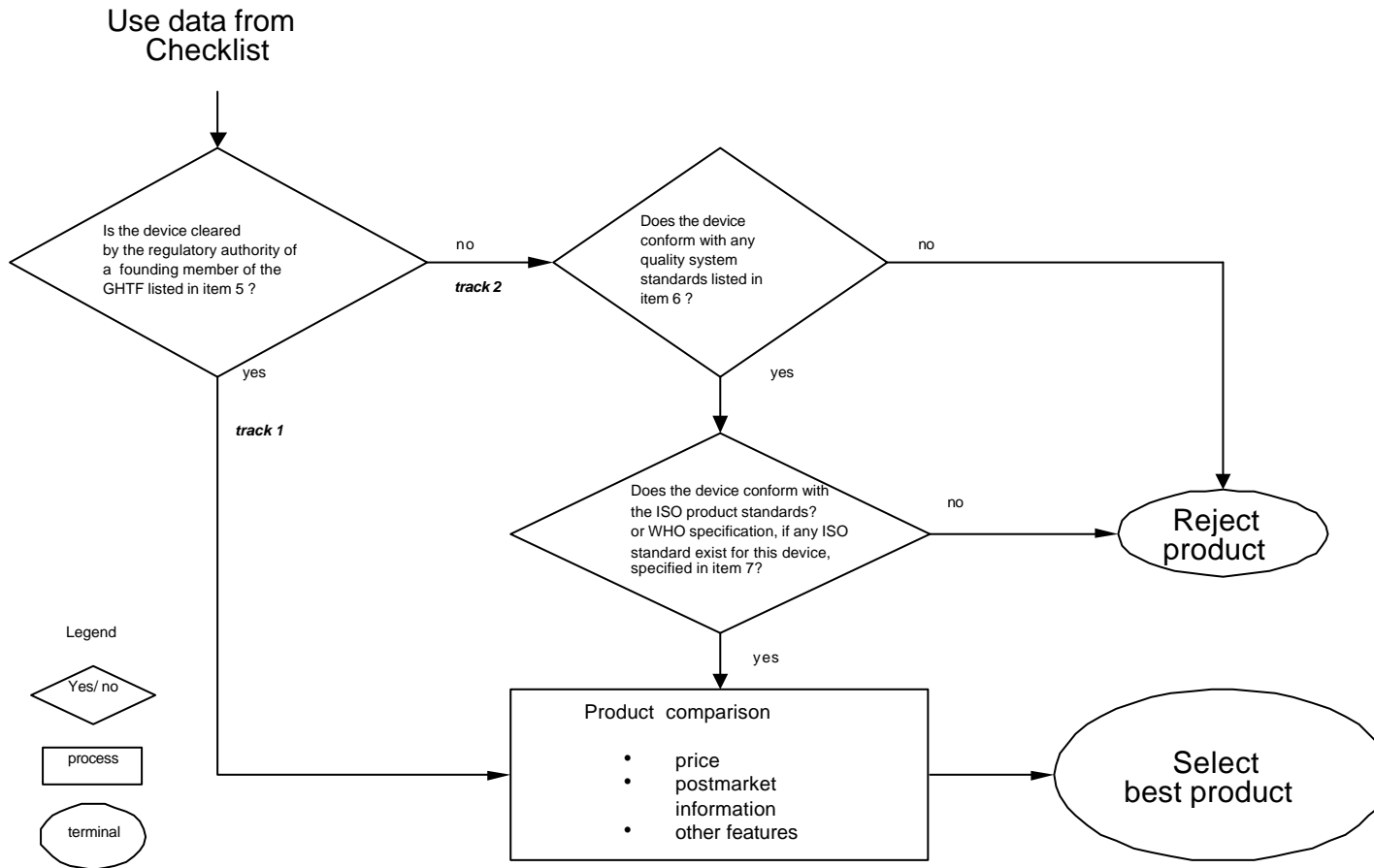
Item 6: Please confirm the applicable standard. Quality system assessment must include: (1) the proposed product is manufactured under the quality system audited; (2) appropriate international (ISO) standards for sterilization and packaging are used for Section 4.9 “process control”, (3) last audit date and expiration date of certificate. Maximum audit period must not exceed 12 months. Note that devices that are manufactured in conformity with ISO13485/88 will be given preference to those manufactured with ISO9001/02 or ISO 9001:2000.

Item 7: Please check all applicable standards with the corresponding test laboratories. Product testing must include sterility, packaging and labelling requirements. Indicate the accreditation status of the laboratories.

Item 8: Please provide all post-market surveillance reports by regulatory authorities, users or other parties and specify the sources.

Item 9: If available, provide any other third party evaluation reports.

Appendix 7: Algorithm for injection equipment selection¹¹



Please make sure the checklist (Appendix 6) is correctly completed. Follow the algorithm for product selection.

Track 1. If there are no applicable local national regulations, and if the proposed product has marketing clearance from one or more of the five GHTF listed authorities (item 5), this product can be accepted as a candidate for product selection. You may be able to verify the regulatory clearance by the Internet, if available.

Track 2. If the proposed product has not been submitted to any of the five listed authorities, then it is necessary to assure that:

1. the manufacturer has a quality system in place (any one of the systems listed on item 6 is acceptable),
2. the proposed product conforms with specified product standards (item 7) and all additional specifications. You may verify the accreditation status of the test laboratory by following the information given by the International Laboratory Accreditation Cooperation (ILAC).

If both quality system standards and product standards are satisfactory, the proposed product can be accepted as a candidate for product selection.

If the proposed product is manufactured with an acceptable quality system, but either the conformity of the proposed goods with specified product standards or any additional specifications have not been certified by an accredited laboratory of any founding member of the GHTF, an option is to submit the proposed product to WHO accredited testing laboratories. The expense for this testing will be charged to the potential supplier. If the proposed product passes the laboratory test, then it can be accepted as a candidate for product selection.

Note: The ISO9001 and ISO9002 standards are for general application for products or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a minimum set of supplementary requirements for the quality assurance of medical device manufacturing. The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

The ISO13485 and ISO13488 standards are recently specified by regulatory authorities while the ISO9001 and ISO9002 standards have been in common use worldwide. To allow a phase-in period, manufacturers registered with ISO9001, ISO9002, ISO9001:2000 should be accepted as having quality systems in place. However, preference should be given to products from manufacturers registered with ISO13485 / ISO13488 if other value indicators are equal.

Appendix 8: Criteria for evaluating suppliers

Criteria for evaluating new suppliers

Status	<ul style="list-style-type: none">• Is the supplier a primary manufacturer or a distributor?• If a distributor, who is the primary manufacturer for each product offered?
Quality control	<ul style="list-style-type: none">• Does the supplier have quality control procedures in place such as an on-site quality control laboratory, independent audit ?• Is the manufacturer in compliance with quality system standards? Has the suppliers sent the appropriate certification to quality system standards ?• Does the supplier have appropriate regulatory certificates?
Inspection	<ul style="list-style-type: none">• What official government agencies or international organizations have inspected the manufacturing facilities?• What certification documents are available from the NRA concerning the supplier's status and compliance with quality system standards?
Personnel and facilities	<ul style="list-style-type: none">• What are the qualifications of key production and quality control personnel?• What is the capacity of the supplier's plant(s)?
Trade references	<ul style="list-style-type: none">• What other local or foreign public procurement offices and hospitals buy from the supplier?• How long has the supplier served the above groups?
Corporate associations	<ul style="list-style-type: none">• Is the supplier a parent company with any known supplier?• If so, what is the reliability of the known company?• Is the supplier producing a certain product under a supervised licensing agreement with known supplier ?
Local reputation	<ul style="list-style-type: none">• How is the supplier regarded by hospital pharmacists and national regulatory authorities?

Criteria for evaluating past suppliers

Service	
Participation record	<ul style="list-style-type: none"> • Has the supplier accepted an award of a bid and subsequently failed to deliver the product?
Response to enquiries	<ul style="list-style-type: none"> • Has the supplier adequately responded to all enquiries from the purchaser within a reasonable period of time? • Did the supplier provide regular information regarding the status of outstanding orders?
Delivery time	<ul style="list-style-type: none"> • What was the supplier's average promised lead time? • What was the actual lead time for the last procurement cycle? • What percentage of shipments were late? How many days late? • What additional costs were incurred due to late shipments?
Adherence to delivery Instructions	<ul style="list-style-type: none"> • Did the shipments arrive under the proper shipping conditions? • Did the shipments arrive at the correct port? • Did the supplier send full shipments as requested or were there partial shipments?
Provision of documents	<ul style="list-style-type: none"> • Did the supplier provide advance copies of documents according to contract terms? • Did shipments arrive with all required documents correctly filled out and signed? • If required documents were omitted, how did the supplier correct the problem?
Packing and labelling	<ul style="list-style-type: none"> • Did the supplier always ship the correct package size? Correct quantity in each package? • Was labelling complete and adequate for proper use? Was it in the correct language?
Product shelf life	<ul style="list-style-type: none"> • 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?
Compliance to contract financial terms	<ul style="list-style-type: none"> • Did all invoices comply with contract pricing terms? • 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?

Quality	
Injection equipment product and safety boxes	<ul style="list-style-type: none"> • Have validated complaints been received concerning product quality for this supplier? • Did the supplier cooperate in making sample and quality control tests performed by independent agencies available?
Packing materials	<ul style="list-style-type: none"> • Were there specific examples of loss due to damage to packaging during shipments? • Did the external packaging protect the product from damage during transport within the country?

Appendix 9: Resources for standard bidding documents

Standard Bidding Document for the procurement of health sector goods and its companion Technical Note are available on the Internet at :

<http://www.worldbank.org/html/opr/procure/healthdocs.html>

Procurement under IBRD loans and IDA Credits is available on the Internet:

<http://www.worldbank.org/html/opr/procure/guidelin.html>

Management sciences for health (MSH) , Managing the tender process. Managing drug supply, second edition, chapter 16.

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<http://www.iccwbo.org/incoterms/preambles.asp>

¹⁷ “Aide-Memoire” for a national strategy for the safe and appropriate use of injection , WHO document, department of Blood Safety and Clinical Technology, 2000. Document available at http://www.who.int/injection_safety/toolbox/en/ or www.injectionsafety.org

¹⁸ Health care waste management aide memoire. Aide memoire for a national strategy for health care waste management. http://www.who.int/injection_safety/toolbox/en/ or www.injectionsafety.org

¹⁹ ISO standard: ISO 7886 –1: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use, 1993. www.iso.ch

²⁰ WHO. Equipment performance specifications and test procedures for EPI, section E8: Injection devices. WHO/EPI/LHIS/97.11 <http://www.who.int/vaccines-documents/DocsPDF/www9512/e08-9512.pdf>

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²³ ISO standard: ISO 6009: Hypodermic needles for single use – Colour coding for identification, 1988. www.iso.ch

²⁴ ISO standard: ISO 7864: Sterile hypodermic needles for single use, 1993. www.iso.ch

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