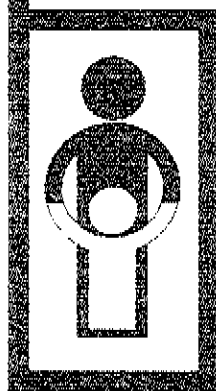


# Guidelines for the international procurement of vaccines and sera



**GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION  
VACCINE SUPPLY AND QUALITY**



*World Health Organization  
Geneva  
1998*

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# List of abbreviations

AWB	airwaybill
CIP	carriage and insurance paid
DDU	delivery, duty unpaid
EPI	Expanded Programme on Immunization
ETA	expected time of arrival
GLP	good laboratory practice
GMP	good manufacturing practice
ICB	international competitive bidding
LIB	limited international bidding
NCA	national control authority
NID	national immunization day
QC	quality control
RFQ	request for quotation

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# Guidelines for the international procurement of vaccines and sera

The purchase of vaccines and sera is complex and requires a specialized knowledge and a precise approach.

The purchasing agent must rely on information provided by the national control authority (NCA) and the EPI manager.

1. Vaccines are different from drugs and purchasing cannot follow the same procedure for both. Health specialists are not always aware of the need to apply different purchasing approaches.
2. There are many companies producing vaccines but only a few which meet internationally-recognized standards of safety and efficacy. Making awards based only on price is dangerous. Quality is the first consideration.
3. The safety and efficacy of the vaccines cannot be determined through laboratory testing.
4. Vaccines are heat sensitive. Cold-room capacity must be available at the time the vaccines are delivered.

*Vaccines are market products subject to usual business practices  
BUT they require extra consideration.*

It is recommended that governments purchase their vaccines and sera through a well-established procurement entity which follows standard drug-procurement procedures and takes account of the extra considerations related specifically to vaccines.

This document intends to address the extra considerations that may not be covered by standard drug-procurement procedures.

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## 1. What is special for vaccine?

**National impact:** Vaccination programmes are designed to reach all infants in a country. Vaccination therefore has a national impact on public health.

**Biological product:** Vaccine production is a biological process; it uses living organisms as raw material. Production and quality control require full compliance with good manufacturing practices (GMPs) and good laboratory practices (GLPs). The quality of the finished product cannot be determined only by laboratory testing.

**Captive consumer:** Vaccination is generally mandatory; the consumer has little choice. Vaccination is preventative and administered to healthy persons to prevent illness. The patient cannot judge the quality of the treatment.

**Semi-captive market:** The vaccine market is limited to a few suppliers. At the present time, there are no more than 20 manufacturers exporting vaccines.

**Difficult handling:** Vaccines are heat-sensitive and should be handled through a cold chain. They have a limited shelf-life (two years maximum).

**Credibility/quality:** Public acceptance of vaccination is dependent on high quality vaccine. Children immunized with low quality vaccines may die from the diseases which the vaccines are meant to prevent. This destroys public confidence in vaccination and puts even more lives at risk.

**Low cost:** Traditional vaccines cost only a few pennies per dose and have often been provided free of charge. Because of this perceived low value, vaccines are sometimes not given the priority they deserve.

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## 2. What is imperative for vaccine?

- Quality
- Reliability
- Availability

## 3. What should be taken into consideration for vaccine?

Basic data:

Forecast

- Which vaccine
- When required
- What quantity

Receiving issues

- Cold storage availability at time of delivery
- Customs and clearance procedures

Budget

- Total cost
- When the funds will be released

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## 4. Procurement cycle

### 4.1 Pre-qualifying sources for each vaccine

To ensure quality, as well as reliability and availability, it is imperative to purchase only from suitable sources. If vaccines and suppliers are pre-qualified it will ensure that critical criteria are met and eliminate unsuitable bidders, and/or bids of inferior products.

Sources can be pre-qualified as follows:

- **Registration in country by National Control Authority (NCA):** See "Regulation and licensing of biological products", *WHO Technical Report Series* No 858, 1995
- **International competitive bidding (ICB) procedure:** This should be used as a first step for pre-qualifying suppliers if appropriate or if requested by the government. The procedure is that an invitation to bid for pre-qualification is publicly advertised, and responses are reviewed for technical acceptability by the NCA. The NCA will review each vaccine bid on its merits and undertake an appropriate review of the vaccine and the producer.

In addition to the usual commercial information requested for pre-qualification, the following conditions are critical in selecting vaccine suppliers to ensure that they meet NCA or WHO minimum requirements. The supplier must be a manufacturer (or importer of bulk product for filling, labelling and repackaging) and must provide the following documentation:

- Certificate of registration /licensing in country of origin
- Documentation on quality control (QC) and sampling procedures
- Copy of most recent GMP certification.
- Production and quality control summary protocols.
- Certificate of analysis from NCA in country of origin.
- Statement of licensing status in other countries.

For WHO pre-qualifying sources, see updated list available from WHO/GPV/VSQ<sup>1</sup>.

### 4.2 Bid preparation

The limited international bidding (LIB) documents should be prepared following standard procedures for drugs, including the minimum requirements for vaccines (NCA or WHO standards). See WHO standards, as published in the *WHO Technical Report* series.

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<sup>1</sup> Available on the Internet at <<[www.who.int/gpv-supqual/unprequalprod.htm](http://www.who.int/gpv-supqual/unprequalprod.htm)>>.

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### 4.3 Bidding

Competitive bidding is the preferred method, using the LIB procedure which limits participation to pre-qualified sources (taking into account the suppliers' performance). By issuing invitations and bidding documents to pre-qualified sources only, bidding should cover a full year's supply with staggered delivery, for instance every quarter.

Request for quotation (RFQ) and direct, sole-source procurement could be used as alternative methods, depending on the circumstances (such as ordering small quantities or ordering for emergency needs) and/or government decisions. Purchases should always be from pre-qualified sources.

### 4.4 Evaluation/adjudication

The offers accepted for adjudication must meet the following conditions:

- Minimum product requirements
- Registration and certification requirements
- Packing and shipping requirements
- Delivery-schedule requirements
- Shelf-life requirements.

Other criteria: Financial, commercial and contractual factors should be evaluated.

### 4.5 Contract

In addition to the standard government terms and conditions for drug contracts, the following points should be covered in vaccine contracts in order to assure quality, reliability, and availability:

- (a) **Packaging and shipping of vaccines:** Refer to the WHO/EPI document: *Guidelines on international packaging and shipping of vaccines for the EPI* (WHO/EPI/CCIS/81.04 Rev.5)
- (b) **Delivery terms:** As per *Incoterms*<sup>2</sup>:
  - usually airfreight is used for international delivery and should be CIP (carriage and insurance paid);
  - for national suppliers, delivery should be DDU (delivery, duty unpaid);
  - the trans-shipment point should be clearly indicated.

Any other Incoterms should be used only if there is a clear understanding of their implications. See *Incoterms* 1990 (No 460).

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<sup>2</sup> A copy of Incoterms may be obtained through the WHO Distribution and Sales Department.

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- (c) **Delivery date:** This should be clearly specified at delivery point. Partial delivery is either not accepted or is subject to prior approval.
- (d) **Marking:** In addition to standard address information, marking on packages should include:
- Batch no;
  - Expiry date;
  - Cautionary wording "Vaccine for human use - to be kept refrigerated (0°C to 8°C)."
- (e) **Delivery information:** Prior to shipment, the manufacturer must telex or fax the following information to the consignee:
- Number of vials and doses per vial
  - Type of vaccine
  - Number of cartons
  - Gross weight
  - Value of shipment
  - Flight number and estimated time of arrival (ETA) at final destination
  - Airwaybill (AWB) number

The fax must also include a request that the consignee arranges immediate collection and/or advise the manufacture immediately if the shipment does not arrive as scheduled.

- (f) **Shipping instructions:** In addition to standard and customary international shipping documents, the following documents and monitors must be included with each lot (batch):
- Certification for the release of vaccine by the manufacturer's NCA;
  - Manufacturer's batch information including protocols, certificate of analysis, test summary sheets, approval and release records signed by the authorized manufacturer;
  - Certificate of origin.
  - Vaccine cold chain monitor cards: Refer to the WHO/EPI document: *Vaccine cold chain monitor* (EPI/CCIS/85.01/Rev.5).
  - Individual vaccine vial monitors: Refer to the WHO/ UNICEF specification E6/ IN 5 included in the WHO/EPI document: *Equipment performance specifications and test procedures: E6: Temperature monitoring devices* (WHO/EPI/LHIS/97.09).

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## 5. Responsibility of the procurement entity

Although the procurement entity may not necessarily be in a position to take decisions on all the above considerations, it is responsible for ensuring that such considerations are properly addressed

The vaccine procurement entity and the authorities usually involved in the drug procurement process, should liaise closely with the NCA, the ministry of finance and EPI management regarding:

- (a) **Vaccination demand (forecasting):** This should:
- be established preferably on a five-year plan by vaccine;
  - take into account calculated discard rates, based on an accurate reporting system;
  - integrate not only routine but also special needs like NIDs or specific campaign(s).
- (b) **Specifications:** These must refer to NCA or WHO documentation.
- (c) **Certification, quality assurance:** Pre-qualified sources should be reviewed regularly, with periodic re-confirmation from the NCA or WHO, alternatively issuing an ICB as a requisite to pre-qualification.
- (d) **Suppliers' performance:** Review of a supplier's performance should be based on:
- visual inspection of the product, packing, labelling, marking;
  - examination of quality assurance documents;
  - delivery.
- (e) Arrangements to collect vaccine at the airport.
- (f) **Cold chain:** Capacity and ability to maintain appropriate storage conditions, mainly at the national store level.
- (g) **Monitoring:** A monitoring system of the distribution will facilitate stock control, ease tracking if a recall is ever required or when there are questions after an adverse event.

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## 6. References

The following additional references are available:

- WHO minimum requirements: see WHO standards, as published in the WHO Technical Report Series.
- WHO certification scheme on the quality of products, *WHO Technical Report Series*, No 790
- Good manufacturing practices for pharmaceutical products, *WHO Technical Report Series*, No 823
- Good manufacturing practices for biological products, *WHO Technical Report Series*, No 822
- Guidelines for national authorities on quality assurance for biological products, *WHO Technical Report Series*, No 822
- Procedure for evaluating the acceptability in principle of vaccines proposed to UN Agencies for use in immunization programmes (unpublished document: WHO/VSQ/97.06);
- National control authority: Guidelines for assessment of vaccine quality in non-producing countries (unpublished document: WHO/VSQ/95.01)
- Injection containers for injectables and accessories, Part 2: Closures for injection vials, ISO 2859
- Regulation and licensing of biological products in country with newly developing regulatory authorities, *WHO Technical Report Series*, No 85/1995

**The Global Programme for Vaccines and Immunization**, established by the World Health Organization in 1994, defines its goal as "a world in which all people at risk are protected against vaccine-preventable diseases". The Programme comprises three units:

**Expanded Programme on Immunization  
Vaccine Research and Development  
Vaccine Supply and Quality**

**The Expanded Programme on Immunization** focuses on the prevention of selected childhood diseases and, through support to national immunization programmes, aims to achieve 90% immunization coverage of children born each year. Its goals are to eradicate poliomyelitis from the world by the year 2000, reduce measles deaths and incidence, eliminate neonatal tetanus as a public health problem and introduce hepatitis B vaccine in all countries.

**Vaccine Research and Development** supports and promotes research and development associated with the introduction of new vaccines into the Expanded Programme on Immunization. This includes research and development of new vaccines, improvement of immunization procedures and support to epidemiological studies.

**Vaccine Supply and Quality** ensures adequate quantities of high quality, affordable vaccines for all the world's children, supports the efforts of governments to become self-reliant as regards their vaccine needs, and assists in the rapid introduction of new vaccines.

**The Global Programme for Vaccines and Immunization** produces a range of documents, audiovisual materials and software packages to disseminate information on its activities, programme policies, guidelines and recommendations. It also provides materials for group and/or individual training on topics ranging from repair of health centre equipment to curricula guidelines for medical schools, nursing colleges and training of vaccine quality control personnel.

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