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Procurement of vaccine for public-sector programmes

World Health Organization
Department of Immunization, Vaccines and Biologicals

**The Department of Immunization, Vaccines and Biologicals
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Ordering code: WHO/V&B/03.16

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Contents

<i>Acknowledgements</i>	<i>v</i>
<i>Preface</i>	<i>vii</i>
Introduction	1
Overview	6
Part I – Options	11
A. Procurement methods	12
B. Procurement transaction participants	15
C. Procurement entities	18
D. Selection tools	21
Part II – Procedures	27
Introduction	28
A. Planning and forecasting	29
B. Pre-qualification	35
C. Preparation for procurement	47
D. Preparation of bid documents for selective tender	57
E. Preparation for bid evaluation	93
F. Solicitation and receipt of offers – selective tender	97
G. Evaluation and comparison of bids	105
H. The selection process	115
I. The aware process	123
J. The contract	135
K. Financial arrangements	139
L. Contract performance	147
M. Shipment	153
N. Customs clearance and delivery	157
O. Closeout activities	161
Part III – Specifications	165
Introduction	167
A. General requirements and standards	168
B. BCG vaccine	258
C. DTP vaccine (diphtheria–tetanus–pertussis vaccines)	290
D. Measles vaccine	349
E. Oral polio vaccine (OPV)	415
F. Hepatitis B vaccine	527
G. Yellow fever vaccine	573
H. Tetanus toxoid vaccine	620
I. <i>Haemophilus influenzae</i> type b (Hib) vaccine	628

Part IV - Quality assurance	669
A. Role of the World Health Organization	670
B. Information for procurement personnel	671
C. Donations and special offers of vaccine	675
D. Pre-shipment compliance programmes	676
Part V - The UNICEF option	745
Introduction	746
A. UNICEF Procurement Services	746
B. Vaccine Independence Initiative (VII)	748
C. Contracts for procurement of vaccines and vaccine related goods	749
D. UNICEF vaccine quality programme	750
Part VI - General information	819
A. Price and cost data	821
B. Vaccine sources and supply survey	832
C. Payment options	835
D. International commerce	842
E. International shipping documents	849
F. Cold chain issues and products	876
G. Vaccine temperature monitoring products	925
H. Vaccine vial monitors	931
I. Injection equipment	949
Part VII - Procurement under World Bank projects	971
A. What the “Bank” is	972
B. What the “Bank” does	972
C. General conditions	972
D. How Bank projects are developed	973
E. How Bank loans are agreed	973
F. How Bank projects are implemented	974
G. How Bank projects are monitored	974
H. What the Bank usually monitors in the area of procurement	974
I. Why the Bank is so concerned about procurement methods and procedures	975
J. General timeframes associated with World Bank projects	975
K. Guiding documents	975
L. Special issues of vaccine procurement under World Bank projects	978
Acronyms and abbreviations	1147
Glossary	1149
General index	1165
Index of forms, samples and supplements	1171
Index of WHO documents	1175
Other WHO documents of interest	1177

Acknowledgements

This manual as the previous version 1999, is the result of a joint effort between the United States Agency for International Development (USAID), through the Basic Support for Institutionalizing Child Survival (BASICS) contract (HRN-C-00-93-00031-00), the Program for Appropriate Technology in Health (PATH), United Nations Children's Fund (UNICEF) and the World Health Organization (WHO), Immunization, Vaccines and Biologicals Department and Access to Technology (IVB/ATT) unit.

Precepts for procurement of vaccines for public sector programmes

The historical role of vaccines in disease prevention is unprecedented in the reduction of devastating epidemics and suffering throughout the world. The substantial investments in research and development of vaccine-based disease prevention have gone hand-in-hand with investments in public health infrastructure to procure, store and deliver these life-saving medicines. The success of global immunization efforts has depended on leadership and cooperation among many different organizations, including private industry, inspection and testing laboratories, public health ministries, health care providers, bilateral and international donor institutions and nongovernmental organizations.

It is appropriate for a document which details the complex procedures and safeguards in managing vaccines procurement, quality assurance and distribution, that the community of organizations involved in these processes reflect on some key precepts for continued success in global immunization efforts. Four fundamental principles can guide and encourage ongoing immunization programmes and the development of new vaccines for new and re-emergent diseases.

1. Strong global leadership for immunization activities which incorporates efficient managerial capacities will provide the fundamental basis for success. This leadership must consist of the top level executives of all the relevant partners in global programmes. Public and private cooperation among health care providers, academia, technical laboratories, public health and finance ministries, the pharmaceutical industry, donor institutions and private sector charitable organizations is essential. It is important for these partners to set up the working mechanisms to provide the strategic planning and review of issues and lessons learned in successful immunization efforts.

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2. Governments, private-sector charitable organizations and foundations and donor organizations must be committed to sustained and increased financial resources for vaccines procurement and immunization programmes. The benefits of immunization in disease prevention must be clearly articulated and quantified in these organizations so that the cost-effectiveness is understood by finance ministries and other health care payers. This is particularly relevant to the development of new vaccines for such worldwide health problems as tuberculosis, malaria and HIV.
 3. The community of partners in global immunization activities must recognize the work of appropriate pricing and tendering in the development, quality assurance and delivery of vaccines. The costs of innovative research, vaccines approval, inspecting and testing procedures, administrative infrastructure in procuring vaccines and adequate storage and distribution require education and training of those involved in the procurement process. Governments and donor organizations have an important role to play in helping countries develop this essential infrastructure.
 4. Both public- and private-sector entities should work towards promoting a general environment which preserves the incentives to invest in research and development of vaccines for the diseases most prevalent in developing countries. These organizations will need to enforce product quality and safety through the elimination of corruption which contributes to the high and growing problem of substandard and counterfeit pharmaceuticals. Governments, donor organizations and private industry can play a vital role in strengthening local drug regulatory agencies, customs, storage, distribution systems and patent and judicial offices.

There is every reason to believe that ongoing immunization efforts can be strengthened and that new resources and commitment by global leaders can continue to reduce disease and death throughout the world. The leveraging of knowledge and financial resources through the global partnership of public and private institutions can be assured of success through agreement on common precepts and the will to continue working together on preventing the most destructive infections affecting people throughout the world.

Preface

Since *Procurement of vaccines for public-sector programmes – A reference manual* was published in 1999, many changes have taken place that impact on the procedures and advice it offered country vaccine purchasers. This second edition, incorporates new documents, updates relevant information and harmonizes the advice it contains with current resources and practices.

Over the past several years, worldwide attention to the vaccine needs of children in developing countries has brought about new funding and strategic partnerships between donors, governments and industry. The Global Alliance for Vaccines and Immunization (GAVI) has become a focal point for strengthening immunization services in the poorest countries and developing global strategies for affordable access to new and underused vaccines. The marketplace has continued to consolidate, new and combination vaccines have become available, and many countries are upgrading their regulatory systems for vaccines and biologicals, with the help of WHO's Global Training Network. Health sector reforms have had an impact on traditional EPI programmes through integration of services and decentralization of responsibility. Both UNICEF and WHO have undergone significant reorganization and there are new ways of doing business at UNICEF. The World Bank has increased its involvement in health sector projects and has recently issued a special subset of standard bidding documents that is much more appropriate for vaccines than ever before. New vaccine-related products have been developed and WHO has published new policies and documents – notably on injection safety (including waste disposal) and vaccine stability. Communications and information technology has changed radically since 1999, with internet/web access available to more and more users. And, finally, the International Chamber of Commerce has issued a new set of INCOTERMS (2000).

Introduction

The user of this guide to the procurement of vaccines may wonder why it has been necessary to create such a substantial document. A wealth of text has been written about the theory and practice of procurement in general, but very little is available to explain, in detail, how to go about doing this work. In addition, the purchase of safe, effective vaccines is a process that requires special expertise and knowledge. Thus, the authors have attempted to deliver, in one comprehensive document, a step-by-step model for vaccine procurement, critical background information and basic reference materials of importance to procurement personnel in developing and transitional country programmes.

Many government ministries and agencies that, in the past, received vaccines through international donor agencies or a central authority are now assuming responsibility for the financing and procurement of vaccines for their national immunization services. Personnel charged with the task of procurement often have very little experience and are in need of practical advice with regard to purchasing vaccines on the international market. The guidance offered should be considered in the context of the legislation in the purchasing country with particular reference to legal and economic systems and administrative structures.

This manual is mainly directed to the purchase of vaccines by countries that have established, through appropriate legislation, a national regulatory authority (NRA) with competency for vaccines. Advice also is provided to countries that have not yet established such a regulatory authority on what steps they should take to acquire the necessary vaccines.

Vaccine marketplace issues

In comparison with the number of drugs available in the marketplace and the range contained in essential drug lists, the number of vaccines that are likely to be purchased is limited. WHO has provided to member governments a number of recommendations for vaccines to be included in national immunization services, and those to be used for special purposes, such as outbreak response and prevention. Most countries have been using six different vaccines in their immunization programme: OPV (oral polio vaccine) measles, BCG (tuberculosis) and DTP (diphtheria–tetanus–pertussis) and many are now adding HepB (hepatitis B), *Haemophilus influenzae* type b (Hib), and YF (yellow fever), where local disease epidemiology warrants. The number of vaccines and vaccine manufacturers is still very limited compared to the number of essential drugs and pharmaceutical manufacturers.

Vaccine manufacture involves high technology, rigid production protocols, process controls and strict quality control. Vaccines have a very limited shelf life, and large production volumes are needed for the manufacturer to recover costs. Many international vaccine manufacturing companies have undergone mergers and consolidations in the past few years; this trend has important implications for vaccine procurement.

Vaccine quality and safety issues

Vaccine quality and safety is not assured by all suppliers. In principle, while the vaccine manufacturer is responsible for the quality of the product produced, vaccine purchasers depend on the regulatory oversight of a NRA to ensure that the vaccines being manufactured and used within their borders are consistently safe, potent, and effective, i.e. of assured quality. There are very few vaccine manufacturers in the world, of which even fewer (perhaps 30) are implementing effective quality assurance systems which are functioning under effective regulatory oversight.

Vaccine production is a biological process, using living organisms as raw material. Thus, the character of each batch is subject to variation and the quality of the finished product cannot be determined solely by laboratory testing. Quality assurance requires full compliance with good manufacturing practice (GMP). It is essential that quality is ensured from the first steps in the production process to the final packing of the product.

Vaccines are heat sensitive and must be stored and transported in a “cold chain”. Certain vaccines are damaged by freezing and light as well. Most vaccines lose their potency if they are transported and stored in conditions where temperature is not strictly controlled. Vaccines of uncertain and inconsistent quality, including those that have not been properly stored and handled, are dangerous and may not protect the recipient from the disease. Furthermore, there is also potential for side effects related to the use of improperly manufactured and improperly handled vaccines.

Even under the most favourable conditions, vaccines have a very limited shelf life (generally a maximum of three years).

Vaccine quality is not only important in and of itself; the credibility of an immunization service is highly dependent on it. Children immunized with vaccines of poor quality may die from the disease that the vaccine should have prevented. Such deaths have the potential to destroy public confidence in an immunization programme and thus place even more lives at risk.

Vaccines have a national impact on public health. Immunization services are designed to reach all children and all women of childbearing age in a country. Vaccination is generally mandatory, so the “consumer” has no choice. Vaccination is also preventive and therefore administered to a healthy person with the expectation of preventing illness. The consumer cannot judge the quality of the protection provided. It is therefore the responsibility of the immunization service to ensure that the vaccine purchased is in compliance with internationally and nationally accepted standard requirements and that the quality and efficacy of the vaccine is maintained throughout its receipt, transport, storage and use.

The need for competent procurement

The above factors show that effective vaccine procurement requires specialized knowledge and a careful approach. Vaccines should always be purchased by a competent procurement entity following established procedures. Ideally, countries should be able to buy safe, effective vaccines at reasonable prices; if not, they should have a plan in place to upgrade their staff skills. In the absence of vaccine procurement expertise, a country may need to use a purchasing agent. Options here include:

- purchasing vaccines using a commercial agent, with instructions from the NRA and national immunization service staff
- purchasing vaccines using the guidance of competent procurement staff of another country
- purchasing through the United Nations Children’s Fund (UNICEF) or World Health Organization (WHO)

A competent regulatory authority

It is essential that any country in which vaccines are manufactured have a regulatory authority with expertise in vaccines and biologicals. It is equally important for non-producing countries to have a regulatory authority to manage vaccine imports, whether the vaccines are purchased by a government procurement entity or by international agents.

In order to ensure the quality of the product purchased, it is important that no government undertake the procurement of vaccines unless they have established, through appropriate legislation, a NRA with competency for vaccines. Such an authority, which is often an autonomous part of a national drug regulation body, must be properly staffed and have the authority to license vaccines for use in the country, to establish procedures for lot release and to create a post-marketing surveillance structure.

The following summary of the functions of such a regulatory body provides a general context for the links between the regulation of vaccines and the purchase of the product. More information on the functions and responsibilities of a NRA can be obtained from WHO publications (see Part IV – Quality Assurance).

Critical regulatory functions

Vaccine source	Licensing	Surveillance	Lot release	Laboratory access	GMP inspection	Clinical evaluation
UN agency	✓	✓				
Procure	✓	✓	✓	✓		
Produce	✓	✓	✓	✓	✓	✓

The terms of reference of the regulatory authority established by government legislation should provide the authority to:

- define the criteria for ensuring the effective licensing of vaccines to be used in the country
- issue, vary or withdraw licenses for the importation and use of vaccines on the basis of safety, potency and efficacy
- continually oversee the quality of the vaccines by releasing each lot intended for use in the country, using the manufacturer's Summary Lot Production Protocol as the minimum basis for review
- monitor the impact of vaccines in use through a surveillance system that provides for the possibility of taking regulatory action if problems are detected

The procurement entity should work closely with the NRA for vaccines, since the main responsibility for specifications and for quality management rests with this body. The importance of the regulatory authority will become even more evident as the user of this manual makes use of the procedures described.

Different countries use different terminology to describe the regulatory authority. Throughout this manual the term "national regulatory authority" has been used generically as has the abbreviation "NRA". Whatever the term used, the functions are the same and should be assured by appropriate legislation.

Where there is no functional regulatory authority for biologics

Ideally, every country should have a biologicals committee within its national pharmaceutical regulatory authority. If it does not, it should have, at a minimum, a system in place for registering vaccine imports, reporting adverse events and recalling vaccines if required by the manufacturer. Surrogate regulatory controls may need to be considered. These include:

- purchasing vaccines following the advice of WHO as to acceptability of the vaccine in principle;
- purchasing vaccines using the guidance and oversight of a NRA of another country found to meet international regulatory oversight standards (see section IV); or
- purchasing vaccines through UNICEF or WHO.

The responsibilities of the national immunization manager

In addition to the programmatic responsibilities of managing the implementation of the immunization service, the immunization service manager must ensure that the specifications of the vaccines will meet the needs of the programme. While the technical specification of the vaccine is the responsibility of the regulatory authority, the programme manager must specify physical characteristics, such as vial size (i.e. number of doses per vial most suited to the programme strategy), the packaging and the information contained in the package insert and on the vial label, including the language used in the insert and label. It is therefore essential that full consultation on the programme needs take place before the tender for a new supply of vaccine is launched.

If immunization service management needs support

Purchased vaccines must meet programme needs, with detailed specifications that match training materials, cold chain performance and other programme realities. A country should be able to determine its own needs; however, if it cannot, it should have a plan in place to upgrade its staff. In the absence of this expertise, surrogate expertise must be sought, such as:

- purchase following WHO advice as to the acceptability (in principle) of the vaccine
- purchase using the guidance of competent immunization staff of another country
- purchase through UNICEF or WHO

These options will help to ensure the provision of products that are suitable for most programmes.

Conclusion

Vaccine procurement clearly requires specialized approaches, using different procedures from those established for the purchase of pharmaceuticals and other commodities or equipment. The risks related to the use of a vaccine and the limited number of companies currently producing vaccines of assured quality demand special attention. The supply of good quality vaccine depends on careful procedures, a national authority overseeing the quality of vaccines to be purchased and an immunization manager to ensure that vaccines meet programme needs. The procurement entity should maintain strong links with the NRA and the immunization service manager.

It must be clearly understood that in order to ensure the purchase of potent, safe and effective vaccine, no public sector purchasing entity should consider purchasing vaccines on its own unless the Purchaser's country has established, through appropriate legislation, a regulatory authority that has competency for vaccines and carries out the essential functions necessary for the country based on vaccine source. See Part IV.

The various appendices in Part VI of the manual contain additional information on vaccine procurement from the regulatory authorities of major producing countries, from major producers of vaccines and from the Department of Vaccines and Biologicals (V&B) at WHO headquarters in Geneva.

Overview

About this manual

Procurement of vaccines for public sector programmes – A reference manual is designed to be an easy-to-use guide and compendium of information on how to purchase vaccines for public sector immunization services. It will be most effective when used in conjunction with the support of specialized technical assistance. Much of the information in the manual can be applied to the purchase of other products, but the focus throughout is specific to vaccines.

The procedures selected and described in the manual are based on those widely used in public sector international tendering, with a number of variations that are tailored to the special requirements of vaccines. World Bank requirements have strongly influenced these procedures because governments are increasingly purchasing critical medical supplies with the financial assistance of the International Bank for Reconstruction and Development (IBRD) loans and the International Development Association (IDA) credits. These World Bank programmes require strict adherence to the Bank's procurement guidelines.

Architecture and contents

Procurement of vaccines for public sector programmes – A reference manual is divided into seven parts. Parts I, II and III contain basic introductory and operations material, and vaccine specifications. Parts IV, V, VI and VII contain a compendium of frequently needed reference material and relevant information, and are followed by an acronyms list, a glossary and indices. Supplementary material, forms and samples appear between sections of text within the seven Parts of this Manual.

A summary table of contents appears before Part I (page 8). A separate table of contents appears at the beginning of each of the seven sections, outlining the contents of that section in more detail. Pages are numbered continuously.

Advice to new vaccine buyers on how to use this manual

Make yourself familiar with the architecture and basic features of the manual.

1. Review the main table of contents.
2. Locate the beginning of each part and review its detailed table of contents.
3. Notice that supplementary material is located between sections of text.
4. Pick a reference box in the main text (Part II contains many) and locate the additional material it mentions.

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5. Locate the glossary and take notice of the words that have been included.
 6. Locate the index and take notice of the phrases that have been included.
 7. Look at several of the flow charts in Part II located at the beginning of each section. Take note of the column headings – Funder/Supplier, Procurement team, Ministry/senior programme management, Resources – and the activities listed under each.

Read parts I, IV and V.

Use part II as an operations model.

Use parts III, VI and VII for reference.

Rely on page numbers to find the beginning of specific parts or documents.

Part I – Options

Several methods of procurement are available to public sector entities, as well as choices as to who will actually execute procurement transactions. Part I explains these variables.

Part II – Procedures

Part II, the main focus of this reference manual, contains a step-by-step guide for international competitive procurement of vaccines through Limited International Bidding.¹ In order to meet the needs of those seeking only a brief overview of international procurement as well as those requiring in-depth information, the material is presented on three increasingly detailed levels:

- At the most basic level, the face page for each section A through O shows a flow chart summary of steps within each task, roughly divided into two main columns according to who is normally expected to execute the step, i.e. the procurement team or ministry/senior programme management/immunization service staff. In addition, a column at the right indicates resources the procurement team may need to call upon and a column at the left shows points of contact with the funder and the Supplier.
- The main content of each section A through O provides the next level of detail. Task steps indicated by the flow chart are expanded and presented in outline form along with supporting directions, justifications and considerations.
- The third level of information is contained in forms, samples and supplements. Forms are blank documents to be copied and used as is or modified for specific applications. Samples are completed forms. In most cases, the samples are actual examples useful for guidance in filling out forms; they are not intended as a case study with a single vaccine procurement process. Supplements contain additional information on particular topics.

Forms, samples and supplements are labelled with the corresponding part, section and paragraph numbers of the text that they augment.

¹ Preferred method for vaccine procurement

**Summary of table of contents
Procurement of vaccines for public-sector programmes***

**Acknowledgements
Preface
Table of contents
Introduction
Overview**

Part I	Part II	Part III	Part IV	Part V	Part VI	Part VII
Options Page 11 Volume 1	Procedures Page 27 Volume 1	Specifications Page 165 Volume 1	Quality Assurance Page 669 Volume 2	UNICEF Page 745 Volume 2	General information Page 819 Volume 2	World Bank Page 971 Volume 2
Methods Participants Procurement entities Selection tools	Step-by-step A-O with supplementary information and implementation tools	General requirements BCG DTP Measles OPV HepB Yellow fever TT	Role of WHO Information for procurement personnel Donations and special offers Pre-shipment compliance Collection of WHO documents	Procurement services VII Purchase agreement Minimum requirements QA programme VVM Pricing	Price data Sources Payment options Letter of credit INCOTERMS Shipping documents Transportation and storage Related products	What the Bank is What the Bank does General loan conditions Developing bank projects Linking loans to projects Project implementation Project monitoring Procurement monitoring Procurement concerns General timeframes Procurement guidelines Vaccine procurement Special clauses

**Acronyms
Glossary
Index**

*Approximately 1000 pages contained in 2 volumes.

Boxes located to the right of main text alert the reader to the existence of related Forms, Samples or Supplements and provide a key to locating it, usually at the end of the Section, but sometimes in an entirely different Part of the manual.

Example:

The box to the right of this sentence indicates that there is a related *supplement* at the end of Part II, section D, paragraph 9c boxes to the right of main text also are used to indicate the location of related *text*.

Supplement II.D.9.c., page 72

Example:

The box to the right of this sentence indicates that there is related information in the text of Part VI, section C.

Part VI.C., page 819

Part III – Specifications

Part III contains reference information and sample “procurement requirements” for standard vaccines. It also contains a general section relevant to all vaccines.

The purchasing entity will find this Part useful in developing product specifications for bidding documents.

Part IV – Quality assurance

Part IV provides information on techniques that can be used by a procurement entity to help ensure that the products it buys are safe and effective. Part IV includes information about sampling and testing vaccines prior to purchase, prior to shipment and upon delivery. It also includes information about national regulatory controls on vaccines and manufacturers.

The purchasing entity will find this section useful in developing specifications and contracts, as well as understanding basic quality assurance issues associated with vaccines.

Part V – The UNICEF option

Part V explains vaccine procurement through UNICEF. It includes a description of UNICEF vaccine procurement services and the related quality assurance programme.

Part VI – General information

Part VI contains a collection of information on sources, prices and payment options, as well as model instructions on packing, shipping and storage of vaccines. It also provides information on vaccine-related products, such as syringes and temperature markers.

The purchasing entity will find this Part useful for planning and executing procurement activities.

Part VII – World Bank

Part VII discusses the World Bank bidding procedures and contains *Standard bidding documents for procurement of health sector goods*. It also contains a user's guide to the technical note issued by the Bank in conjunction with its bidding documents for health sector goods.