Executive Summary

Antiretroviral therapy (ART) has radically changed the outlook for people who can pay for it or use it in well-resourced health care systems. Living longer, healthier lives, they can become productive and able to care for themselves. ART is not a cure, but it diminishes the viral load and thus reduces damage to the immune system. It also reduces the statistical risk of passing on the virus through whatever route—blood, breast milk, and sexual or other bodily fluids.

Despite some dramatic reductions in the last three years, the costs associated with antiretroviral drugs (ARVs) and other medicines for HIV-related problems are still very high and may remain so. Skilled negotiation and lobbying on behalf of—and by—people with HIV has already had some effect in reducing prices. But even when full advantage is taken of the lowest possible prices on the global market, the annual total cost of ART is still more than the national budget for health care in some countries.

Much higher costs will be incurred in countries that cannot get low-cost supplies for patent or other market reasons. Costs will also be higher if drug resistance develops and more expensive alternative medicines have to be used. So for many countries, assistance from the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other key donors will be essential to make the public health promises of ART a reality, at least for the foreseeable future.
Planners and decision makers must have a clear understanding of the importance of treatment in tackling HIV and ensure that specific services and facilities required for treatment be included in the scaling up effort:

- HIV counseling, testing, and follow-up services for adherence to treatment and psychosocial support.
- Capacity for appropriate management of HIV and opportunistic infections.
- Laboratory services for monitoring treatment.
- Continuous supply of ARVs, other medicines for HIV-related illness, and supplies for laboratory tests and preventive precautions.
- Reliable regulatory mechanisms that ensure the quality of treatment while protecting the individual’s right to treatment.

Procurement is only one link in this large network of factors affecting the HIV epidemic. Yet it is clearly vital. Successful treatment depends on continuous, reliable supplies of the necessary medicines and related commodities. Without sustained access to ARVs, the challenge of treatment cannot be met—and the ravages of the epidemic will continue.

**Estimating resource requirements**

Estimating the financial and resource requirements of an ART program is a key step in assessing its feasibility and sustainability. Resources for direct treatment are not the only obstacle to introducing and scaling up ART. The lack of physical and human health infrastructure and the inadequacy of systems to distribute essential medicines affect the availability of drugs and financial feasibility. In all cases, the finances for such a program would have to include expenditure on both capacity building (if it is not adequate) and the purchase of drugs and related medical supplies and services—but in varying proportions, depending on skill sets, income levels, epidemic proportions, and local needs in each situation.

**Dealing with patents**

Many HIV/AIDS medicines and laboratory products are relatively new and are still protected by patents granted to the originators, usually within countries where the originator has, or expects to have, a significant market. But the patent situation varies widely across countries, affected by such international agreements as the Agreement on Trade-Related
Aspects of Intellectual Property Rights (TRIPS)—so it is important that staff responsible for project implementation assimilate the information in this Guide. Early clarification of the intellectual property rights situation (and of registration requirements and import regulations) will prevent frustration, wasted time and money, and possible litigation.

As a consequence of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by members of the World Trade Organization in November 2001, least developed countries are authorized to forgo the enforcement of patents on pharmaceutical products at least until January 1, 2016. When a least developed country’s government and its procurement authority take advantage of this maximum flexibility, HIV/AIDS medicines may be imported (or locally produced) without concern about whether patents on those medicines have been granted within the country.

In addition, several least developed and developing countries are eligible to receive patented ARVs under access programs that have been set up by originator companies, at prices that sometimes may be lower than those of the generic versions.

Developing countries that are not considered “least developed,” have the option to override existing patents by issuing a compulsory licensing or government use authorization. A patent is a government grant that permits its holder to exclude third parties from the market for a product, such as an HIV/AIDS–related medicine. A “compulsory license” is an authorization by the government to itself or to a third party to use the patent without the permission of the patent holder. When the government is authorizing its own use, this is also called a “government use” authorization or license, which is a form of compulsory license.

Important HIV/AIDS medicines or supplies are covered by one or more patents in many countries. If the procurement authority wishes to procure a bioequivalent medicine (a generic version) from a party other than the patent holder or its authorized distributor, including by importing the medicine, it may need to authorize procurement under a compulsory license. The TRIPS Agreement, in Article 31, authorizes every government to grant compulsory licenses.

Managing the supply cycle for better outcomes

The medicines supply cycle comprises all elements required for the establishment and continuity of supplies for health delivery, including medicines and related commodities. It includes four key stages, with a
central requirement for good management support, an understanding of the policy and legal frameworks for the supply cycle, and an appreciation that medicines are special commodities that have constraints concerning quality assurance, storage, and use.

Two key elements of the cycle are selection and procurement. But to get good results, it is clear that these must not happen in isolation. All elements of the cycle must function well, and the broader context must be understood so that a holistic and realistic approach can be taken to achieve the best possible results in each setting.

In many countries, a national drug policy will set out approaches to achieving these priorities within the national context. Such policy is also likely to include setting requirements for registration of drugs and limiting who may prescribe, dispense, or sell them. National HIV/AIDS treatment policies must also be consulted, since these set out guidelines for approving HIV treatment regimens and deciding who is entitled to prescribe them.

Some key policy or legal issues that affect procurement include:

- Intellectual property (patent) legislation of medicines—the national patent situation will directly affect what products can be procured from which suppliers and the scope for negotiation of prices.
- Health rights and access to HIV-related treatment when limited supplies, particularly of ARVs, are available, eligibility criteria will be applied to the selection of which members of the population qualify for treatment. This process will affect product selection and quantification and may change as scaling up proceeds.
- Security issues—ARVs for HIV treatment are high in value and thus vulnerable to theft and diversion to illegal markets, or to individuals who are not priority recipients of HIV treatment programs. Planning the supply cycle will have to incorporate effective security measures and a legal framework that allows for sanctions against theft or diversion.

**Deciding who does what**

An assessment should be made at an early stage to find out who is already carrying out the tasks related to the supply cycle and to test whether the Bank needs to fund the setting up of new systems and personnel, the use of existing systems, or a combination of both. A preliminary mapping exercise could be used to identify different systems and personnel rele-
vant to the HIV procurements. The strengths and weaknesses of each one should be examined, estimating their willingness and capacity. Bear in mind that a period of rapid growth will be a feature of most HIV treatment programs during scaling up. This rapid growth may strain the capacities and funding of all those who have a part in treatment delivery. It may thus have unforeseen effects on their ability to provide cooperation as programs develop.

When it is clear who can do what for Bank-funded HIV procurement in a specific country, a further assessment of the proposed procurement systems should be carried out. An assessment of the initial situation should also lead to the setting up of monitoring and evaluation criteria and tools for the ongoing performance monitoring of procurement. Performance indicators and monitoring procedures, responsibilities, and financing will be expected.

Selecting drugs for HIV-related treatment

Public health criteria for selecting ARVs and drugs for opportunistic infections focus on drugs of the greatest importance to satisfy the health needs of the majority of the population of HIV-positive people:

- The selection of drugs should be carried out by a multidisciplinary group, including representatives of the national AIDS committee or council and the national drug formulary committee, together with an HIV specialist doctor, an HIV specialist nurse, a pharmacist with knowledge of available HIV-related medicines, and a procurement specialist. Additional members may be co-opted on an ad hoc basis.

- Drugs should be identified in any printed material by their generic name or international nonproprietary name. But abbreviated chemical names and brand names will also be used when appropriate.

- Drug selection should be based on predetermined criteria, as recommended by the WHO or any existing guidelines of the national drug or AIDS programs.

Deciding on quantities

It is important to realize that in situations where the HIV/AIDS epidemic or responses to it are expanding, careful judgment will be necessary to
arrive at the correct quantities of each commodity needed for procurement and to decide how much to buy. Underestimates will deprive people of necessary treatments or tests. Overestimates may waste resources if limited-shelf-life products expire unused, especially as treatment protocols and diagnostic preferences change.

Three methods can be used for quantification:

- The usage (consumption) method that relies on past use (consumption) records to estimate future need.
- The adjusted usage (adjusted consumption) method that uses data from other facilities, regions, or countries, adjusted or extrapolated to the specific situation on the basis of population coverage or service level.
- The patient morbidity–standard treatment method that estimates the need for specific drugs, based on the expected number of attendances, the prevalence or incidence of diseases, and standard treatment guidelines for the health problems that are to be treated.

Assessing capacity

In many countries the implementing agencies might lack the capacity to forecast, procure, store, and distribute ARVs and other related medical supplies of the HIV/AIDS care package. It is therefore essential to examine the procurement capacity of the central medical stores for this category of specialized drugs and supplies before deciding on the project’s procurement strategy and plan.

If the central medical store is totally deficient and poorly managed, a third alternative must be sought (such as employing a specialized procurement agency or UN agency). This agency can be required, as part of its contractual obligations, to include a training, capacity-building, and technology transfer component intended to strengthen the capacity of the central medical store.

Using commodities that support the HIV/AIDS program

The HIV/AIDS commodities package is more complex than other products and supplies managed in the public sector:
A functioning lab infrastructure is essential to support service delivery (equipment, supplies, and human resources).

The supply chain must be agile and responsive in changing situations, delivering products before they expire or are diverted.

Service delivery and provider, client, and community education are in the early stages of development, unlike more established health programs.

A set of comprehensive, interdependent services needs to be provided.

Decentralizing interventions to the community adds to the complexity of planning, coordination, distribution, and management, because the technical skills for managing these products may be lacking or insufficient.

The HIV/AIDS care package comprises three main product categories: multisource or generic products, limited-source products, and single-source products. Each category corresponds to a distinct procurement strategy:

- Multisource products are pharmaceutically equivalent products that may or may not be therapeutically equivalent, available from different manufacturers. They are well established, normally off patent, and not restricted by continuing intellectual property agreements or other exclusive market arrangements. They are generally available from a wide range of producers, have published pharmacopoeial quality standards, and have available reference standards for quality-control testing.

- Limited-source products are pharmaceutically equivalent products available from a limited number of manufacturers. Newer, they are products usually protected by patents or market-exclusivity arrangements in some countries. Pharmacopoeial quality standards and publicly available reference standards for quality control testing may not yet be available.

- Single-source products are generally under patent with no licensing agreements that allow other firms to manufacture the drugs. Single-source availability may be due to patents, marketing exclusivity, technical challenges of production, or a lack of economic incentives for production by other manufacturers. Pharmacopoeial quality standards
Choosing procurement methods

The market situation of each product, the nature of the medicines and medical supplies, and the critical dates for delivery—are all major factors determining the choice of procurement method. Choices are restricted by the characteristics of medicines and supplies of the HIV/AIDS care package. As already noted, the majority of antiretrovirals and some other HIV-related drugs are either single-source or limited-source products. Other drugs and commodities for opportunistic infections or for basic or palliative care may be multisource but effectively restricted to limited sources in many settings. So, international (or national) competitive bidding without prequalification typically cannot be the preferred method of procurement. Instead, limited international bidding, direct contracting, or shopping may be the most appropriate. The key is to understand what situations are suitable for each of them.

Pricing

The price of medications can be a significant barrier to HIV/AIDS treatment, especially for ART, a chronic treatment that requires the daily intake of a combination of pharmaceutical compounds. The coverage of health insurance in developing countries is often limited. And when drugs are purchased out-of-pocket, the price of ARVs can make a vital difference for poor people’s ability to afford treatment. Even the lowest available prices are unaffordable for most patients in the developing world, where about 3 billion people live on less than US$2 a day. Many HIV-infected patients rely on the subsidized or free provision of antiretroviral treatment by the public sector. For resource-constrained governments in poor countries, the purchase price for the pharmaceutical compounds directly affects the number of patients that can be treated. And lower prices leave more room for investments in the complementary health infrastructure needed to make ART effective.
Assessing the economic impact of antiretroviral therapy

A primary challenge facing policymakers is estimating the benefits of ART. In the short term, simple models of resource estimation can be used to determine the immediate budgetary implications of ART. Given the resources required for administering ART, it is essential to ensure effectiveness and safety.

Treatments must be proven to work not only in “ideal” clinical trials, with closely monitored patients in a hospital setting, but also in a context that is likely if the program is scaled up. A realistic study should consider compliance and adherence to treatment under alternative strategies, such as directly observed therapy (DOT) strategies, to account for the potential misuse of drugs.

Economic constraints—the fact that other health considerations need to be addressed—call for a critical appraisal of the pros and cons of all technically feasible interventions, and put a premium on rational resource allocation so that health needs can be addressed holistically.
Preface

This Guide sets out principles and advice for the procurement of HIV/AIDS medicines and related supplies for programs scaling up antiretroviral therapy (ART) and associated health services, such as basic and palliative care, disease prevention, treatment of opportunistic infections, and laboratory tests. ART includes the treatment of infected adults and children and the prevention of mother-to-child transmission. A wide range of other commodities—particularly condoms and support for basic living and care—are also essential to support the treatment and prevention of HIV.

The primary audience for this guide is World Bank staff and those responsible for procuring HIV/AIDS medicines and related supplies in Bank-funded programs and projects—which could include either procurement agency staff or technical agency staff. Policymakers and Bank partners will also benefit from the information and advice in the guide.

The added value of this Guide

Although there already are guidance documents covering the procurement of health goods, this guide specializes in procurement for HIV-related programs for these reasons:

- It focuses on resource-poor settings with little experience of treatment programs that include antiretrovirals (ARVs).
It discusses newer and more expensive drugs and tests required for ART, which because of cost or scale have not yet become part of essential medicines policy in many countries.

It draws attention to some of the unpredictable factors associated with the scaling up of ART such as rapid growth in demand, the appearance of new medicines and tests, and sudden changes in markets.

It provides practical advice on intellectual property rights, a complex but important subject, and it lays out in simple terms the array of options available to national governments.

It provides references to valuable materials and offers links to readily available instructions and documentation.

**Key resources used in the development of this Guide**

The authors of this guide gratefully acknowledge the assistance and cooperation of a number of organizations experienced in responding to the HIV epidemic and in managing and procuring medicines and other health goods. Many of their resources are available on their Web sites, and readers of the guide are recommended to those sites for further information. We particularly acknowledge the following organizations and groups:

- World Health Organization departments:
  - Essential Medicines (WHO/EDM) www.who.int/medicines/default.shtml
  - Regional Office for Africa (AFRO) www.afro.who.int/
  - Blood Safety and Clinical Technology
- The International Dispensary Association (IDA) www.ida.nl/engels/ida.html
- Organization of Eastern Caribbean States (OECS) Pharmaceutical Procurement Service at www.oecs.org/units_pps.htm
- Management Sciences for Health www.msh.org/projects/rpmplus/1.0.htm
- Médicins Sans Frontières www.accessmed-msf.org
- UNICEF www.unicef.org
- UNFPA www.unfpa.org
- John Snow Incorporated www.jsi.com
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## Abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ART</td>
<td>Antiretroviral therapy</td>
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<td>ARVs</td>
<td>Antiretrovirals</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>DOTS</td>
<td>Directly Observed Therapy Short-course program</td>
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<td>EU</td>
<td>European Union</td>
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<td>HAART</td>
<td>highly active antiretroviral therapy</td>
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<td>IDA</td>
<td>International Dispensary Association</td>
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<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturers Associations</td>
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<td>MAP</td>
<td>Multi-country HIV/AIDS Program</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>PLWHA</td>
<td>People living with HIV/AIDS</td>
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<tr>
<td>PMTCT</td>
<td>Prevention of mother-to-child transmission</td>
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<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>UNDP</td>
<td>United Nations Development Programme</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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All dollars are U.S. dollars unless otherwise stated.