



Chapter 22

Procurement of HIV/AIDS Medicines and Supplies

(Executive Summary of Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies)

1. Introduction⁵¹

Antiretroviral therapy (ART) has radically changed the outlook for people who have access to it. Living longer, healthier lives, they can become productive and able to care for them selves. 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, especially by the Clinton Foundation, has already had a dramatic 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 antiretroviral therapy 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 for AIDS, TB and Malaria, and other key donors will be essential to make the public health promises of antiretroviral therapy a reality, at least in 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, supplies for laboratory tests and preventive precautions.
- Reliable regulatory mechanisms to ensure the quality of treatment, while protecting the individual's right to treatment.

Experience has shown that the cost of the ARV drugs is only part of the antiretroviral therapy and that other costs, such as additional drugs, biological monitoring, personnel, equipment, testing, etc. are usually as expensive if not more expensive than the ARVs. Ensuring that the comprehensive support package is funded is essential to the success of antiretroviral therapy.

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 antiretrovirals, the challenge of treatment cannot be met—and the ravages of the epidemic will continue.

⁵¹ This chapter is a summary of *Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies* published by the World Bank and available on the World Bank Procurement website at: <http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,pagePK:84271~theSitePK:84266,00.html>

2. Estimating resource requirements

Estimating the financial and resource requirements of an antiretroviral treatment 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 an antiretroviral program. 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.

3. Dealing with patents

Many HIV/AIDS medicines and laboratory products are relatively new, 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). That makes it important for staff responsible for project implementation to 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 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 these medicines have been granted within the country.

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.

4. 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 for 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 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 what scope there will be for negotiation on prices. Refer to Figure 2.3 of the *Battling HIV/AIDS: A Decision Maker’s Guide to the Procurement of Medicines and Related Supplies* in references (CD-ROM)
- Health rights and access to HIV-related treatment—when limited supplies, particularly of ARVs, are available, eligibility criteria will be applied to selection of which members of the population qualify for treatment. This will affect product selection and quantification and may change as scaling up proceeds.
- Security issues—antiretroviral medicines 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. So, planning the supply cycle will have to incorporate effective security measures and a legal framework that allows for sanctions against theft or diversion.

5. 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 funding is needed for the setting up of new systems and personnel, the use of existing ones, or a combination of both. A preliminary mapping exercise could be used to identify different systems and personnel relevant to the HIV procurements. The strengths and weaknesses of each one should be examined, estimating their willingness and capacity. A period of rapid growth will be a feature of most HIV treatment programs during scaling up. This 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 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 finance will be expected.

6. How drugs should be selected for HIV-related treatment

Public health criteria for selecting antiretroviral drugs 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 added 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 World Health Organization (WHO) or any existing guidelines of the national drug or AIDS programs.

7. 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 deciding 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.

8. Assessing capacity

In many countries the implementing agencies might lack the capacity to forecast, procure, store, and distribute antiretroviral medicines 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 deficient and poorly managed, a third alternative must be sought (such as employing a specialized procurement agency or a 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.

9. 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 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 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 and publicly available reference standards for quality-control testing might not be publicly available.

10. Choosing procurement methods

The market situation of each product, the nature of the medicines and medical supplies, and the critical dates for delivery—all are 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. Refer to Figure 5.2 of the *Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies* in references (CD-ROM)

11. Pricing

The price of medications can be a significant barrier to HIV/AIDS treatment, especially for antiretroviral therapy, 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 antiretrovirals 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 \$2 a day. Many HIV-infected patients rely

Box 22.1: Clinton Foundation Agreements for Lower-Priced Drugs and Diagnostics

In April 2004, the Global Fund, UNICEF and the World Bank joined the Clinton Foundation HIV/AIDS Initiative (CHAI) in announcing agreements that will make it possible for developing countries to purchase WHO-approved high-quality AIDS medicines and diagnostics at the lowest available prices, in many cases for more than 50% less expensive than is currently available. These prices have been negotiated by CHAI with five manufacturers of ARVs and five manufacturers of HIV/AIDS diagnostic tests and are available in 16 countries in the Caribbean and Africa where the Clinton Foundation has existing partnerships. The April agreements will pave the way for all World Bank and Global Fund recipients to access the reduced pricing. While all suppliers may not be able to service every country, due to limited distribution networks, drug registrations and other factors, there will be suppliers in every country that joins the program. Countries interested in accessing the program should contact the Clinton HIV/AIDS Initiative before contacting suppliers directly. Contact information for the Clinton HIV/AIDS Initiative is as follows:

Clinton HIV/AIDS Initiative
225 Water Street
Quincy, MA 02169 USA

Tel: +1 617 774 0110
Fax: +1 617 774 0220
Email: procurement@hivaidsinitiative.org
Website: www.clintonpresidentialcenter.com/AIDS_overview.html

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 complementary health infrastructure needed to make antiretroviral treatment effective.

12. Assessing the economic impact of antiretroviral therapy

A primary challenge facing policymakers is estimating the benefits of antiretroviral therapy. In the short term simple models of resource estimation can be used to determine the immediate budgetary implications of antiretroviral therapy. Given the enormous resources required for administering antiretroviral therapy, 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 likely if the program is scaled up. A realistic study should consider compliance and adherence to treatment under alternative strategies, such as DOT (directly observed therapy) 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.

13. Lessons learned and recommendations for MAP projects.

- Antiretroviral therapy requires a complete package of support including funding and making available in a timely fashion ARVs and other drugs, testing equipment, monitoring, personnel, logistics, etc.
- Donors must be willing to finance local costs and operating expenses in order to scale up and maintain antiretroviral therapy for large numbers of people.
- Since the procurement of ARVs is both complicated and infrequent, many countries would benefit from contracting this capacity from specialized agencies and agents.
- An early clarification of Intellectual Property Rights situation (and of registration requirements and import regulations) will prevent frustration, wasted time and money, and possible litigation.
- 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 funding is needed for the setting up of new systems and personnel, the use of existing ones, or a combination of both.

