

Chapter VII

Drug Procurement

OVERVIEW

A central component of expanded HIV and AIDS care and treatment is the production, procurement and supply of medicines, in particular antiretrovirals. To support the operational plan, the drug procurement system must achieve the following general objectives:

- Medicines must be of the highest quality and appropriate for the treatment regimens outlined in the plan.
- The supply of medicines must be secure and sustainable at a volume large enough to meet the significant demand envisioned.
- Medicines must be purchased at the lowest possible price.
- The sustainable supply should be ensured through local production of antiretrovirals and sustainable financing.

The framework for the procurement of ARVs has been designed to meet these objectives. This framework is also guided by principles of good procurement practices, sound financial management and accountability and compliance with good quality standards.

BACKGROUND AND RATIONALE

Historically the cost of ARVs has restricted access to ARV therapy to a limited number of patients with AIDS. Though the introduction of equivalent generic products has substantially lowered the market price for these medicines, they are still prohibitively expensive for the vast majority of people who need them. The current market for ARVs in developing countries is small and fragmented. As a result, the production system for these medicines is sub-scale and high cost. Producers have not had the demand or predictability that they need to organize efficient production systems.

The South African pharmaceutical market is characterised by high import penetration, with a significant volume of products coming in as finished products, with limited local

generic production.

The current tender process for pharmaceuticals allows for split contracts among suppliers of critical items that address prevalent conditions and priority programmes. This approach enhances continuity and sustainability of supplies.

Medicines that are procured in the country including antiretrovirals should be registered by the Medicines Control Council and must meet standards of quality, efficacy and safety.

This plan takes into consideration the declarations of the SADC Health Ministers agreed to at two meetings held in Pretoria on the 17th June 2000 and in Durban on the 8th July 2000. These related to legislative and regional legal regimes that will ensure the availability of technologies and drugs at affordable prices for treatment, including bulk purchasing of drugs and manufacturing of generic medicines in the region. The first meeting developed principles that would be used in any negotiations with the companies and these are:

- The prime focus of the negotiations must remain on Sub-Saharan Africa where the magnitude of the problem is greatest.
- WHO should become the convening agency for these negotiations in the light of its broad health mandate and the greater opportunity for representivity that it can provide through the World Health Assembly.
- The negotiations should address the overall provision of care for HIV and AIDS-related conditions and must include a consideration of all the elements related thereto viz. health infrastructure, diagnostic kits, pharmaceuticals and the technology that would ensure that these can be safely and effectively administered.
- All proposals should be centred around the principle of sustainability and on this basis, seek to make drugs both affordable and accessible.
- Health ministries should define all research priorities based on local conditions and national objectives.
- Those options open to Member States under TRIPS (parallel importation and compulsory licensing), should not be compromised.
- Member States should not be required to assume the responsibility of ensuring that these products do not leave their markets.

In particular, at the second meeting held in Durban, Ministers reaffirmed that HIV and AIDS is a serious developmental issue and that therapy for HIV and AIDS-related conditions should be delivered through sustainable health systems. Ministers further

directed that a minimum package of services that can be used by SADC countries when negotiating as individual countries or as a collective with pharmaceutical companies should be developed. The package would not focus only on the provision of antiretroviral drugs, but would address issues of HIV and AIDS-related infections in a holistic way, therefore including aspects such as laboratory support, treatment of opportunistic infections, infrastructure, capacity building and monitoring of drugs, especially antiretroviral drugs.

APPROACH

The national procurement of ARVs will operate on several principles. Firstly, the supply of ARVs must be of high quality and suppliers must have the technical know-how to produce specific treatment regimens and a long-term commitment to deliver high quality pharmaceuticals consistently. Manufacturers of the medicines must conform to national and international quality standards and be able to produce adequate quantities of medicines into the future. The procurement of ARVs must also be flexible; as new and better medicines are introduced, or as the treatment regimen of a particular patient is changed over time, adjustments must be made.

Secondly, there must be a competitive market for the production of ARVs. Engaging with a number of competing manufacturers will further drive price reductions. As more suppliers qualify for tenders, it is envisaged that additional competition will create downward price pressure. A number of viable and competing manufacturers will also guarantee security of supply should any supplier fail for any reason.

Thirdly, ARVs must be affordable and legislative provisions exist to ensure access to affordable medicines. One method of promoting low cost medicines is to maximize the volume of demand by aggregating orders within the country and possibly with other countries in the procurement of ARVs. An additional way to promote efficient production is to commit to long-term supply agreements. Both methods enable investments in large-scale production facilities and significant reductions in cost by manufacturers. On the basis of cost analyses, a maximum forward price can be set along a diminishing cost curve. This will further reduce prices with increased total purchasing volume.

Fourthly, the supply of ARVs must be uninterrupted to meet the treatment needs of patients. There is always a risk of failure in the supply chain of pharmaceuticals. It is intended that the procurement plan coordinates a sustainable supply through the participation of viable suppliers, and local production of finished products and active pharmaceutical ingredients.

To achieve these goals, the following processes are planned.

Appointment of Negotiating Team

The Minister of Health will appoint a negotiating team to implement the procurement strategy recommended in this plan.

The negotiating team appointed by the Minister should be composed of people with the following skills and expertise:

- Knowledge of the tendering process
- Knowledge of procurement and Treasury regulations
- Knowledge of Competition Commission rules and regulations
- Knowledge of the cost and pricing structure and pricing models of the pharmaceutical industry
- Knowledge of the strategic and policy positions of the South African government regarding the pharmaceutical sector
- Knowledge of trade and legal issues

Procurement Mechanisms

There are at least three options by which procurement processes could be put into operation, namely:

- A regular government tender using local suppliers.
- A public-private partnership/initiative.
- International tendering as stipulated in section 1(4) and Regulation 3 of the Medicines and Related Substances Act 101 of 1965.

The Task Team recommends that the regular national government tender procurement pre-qualification procedures be used. In the case of ARV procurement, a substantive

contractual agreement for sustainable supply of medicines would require a longer-term agreement than the standard two-year tender agreement as well as more flexible terms to allow for changes in drug regimens within an existing procurement agreement. This would also enable the department to negotiate diminishing cost curves as volumes increase.

If the usual tender process is unsuitable, ARVs could be purchased through a public private partnership (PPP) with specified suppliers, in accordance with Treasury regulations, led by the Department of Health. The PPP could be established to administer the tendering process for ARVs and to coordinate a sustainable and competitive long-term market for ARV production. While this mechanism allows greater flexibility in the tender process, the establishment of the PPP may involve delays.

International tendering may be considered in accordance with Section 1(4) and Regulation 3 of the Medicines and Related Substances Act 101 of 1965 as amended if such medicine;

- is essential for national health as approved by the Minister,
- can be obtained at a lower price outside the Republic and
- is registered by the Medicine Control Council (MCC)

International tendering or procurement however implies that continuous quality monitoring capacity must be strengthened to ensure that imports are not sub-standard and the possibility of counterfeiting is guarded against.

Pooled Procurement

Coordinating procurement with other countries provides manufacturers the volume required to achieve maximum economies of scale. This would allow for dramatically lower prices, enabling the government to realize one of the core goals of ARV procurement. Enhancing the total size of the ARV market also provides greater opportunity for competition, economic sustainability, and secure supply by multiple manufacturers. Pooled procurement could also be considered within the framework of the SADC Ministers' statement entrenching cooperation in strengthening local production and access to affordable medicines. Though this type of buying group has advantages, it requires careful management of country specific contracts.

Security of Supply and Local Production

To secure the long-term sustainable supply of ARVs, local production should be enabled through transfer of technology and production of active pharmaceutical ingredients (APIs) in South Africa. Local production policy should be aimed at establishing local production capacity that builds on existing realities of our investment drive and development initiatives. The strengthening of the industrial pharmaceutical and technological base in South Africa will respond to the NEPAD initiative and ensures that South Africa assumes an international market role.

Tender Process

The tender process consists of four stages. It is expected that the tender process will take about twelve weeks. A lead-time of two to four weeks may be required after the first orders are placed.

1. Supplier pre-qualification

All suppliers with MCC-approved drugs will be invited to participate in the pre-qualification process. All suppliers will be required to meet national and international standards in order to be qualified to tender to supply South Africa with ARVs. Pre-qualification is open to any manufacturer of ARVs, including companies producing generic, branded, and/or patented medicines. The criteria will include:

- MCC product registration and licensing of suppliers and distributors
- Pre-qualification standards (WHO or MCC approval)
- Financial viability
- Manufacturing quality, capacity and scale
- Cost transparency
- Agreement to price ceilings
- Commitment to establishing integrated production in South Africa
- Compliance with local regulations e.g. Black Economic Empowerment (BEE), Preferential Procurement Act etc.

2. Request for proposal and tendering (RFP)

Consistent with the notion of a partnership, a request for proposals will be developed to ensure procurement needs are met with the least cost and disruption to production. The RFP will establish:

- Product specifications
- Unique identification
- Volume of ARV supply for tender
- Duration of supply
- Substitution of medicines to alternative regimens
- Forward price setting according to a diminishing scale curve
- Annual review of costs of production and future prices
- Currency denomination
- Bid bonds
- Contingencies and risks assumed by each party
- Minimum inventories
- Distribution

3. Contracting

The final stage of the procurement transaction is negotiation, agreement on final terms and completion of the purchase contract.

4. Monitoring and evaluation

Contracts completed under the procurement process must be actively managed, monitored and evaluated for compliance with agreed to performance criteria and cost effectiveness.

Under this process it is envisioned that dedicated amounts of demand, e.g. 100,000 patient-dose-years, will be offered for tender to supply ARVs over a fixed period extending up to five years. To ensure adequate ongoing supply of ARVs by multiple manufacturers the total volume of any tender may be apportioned amongst bidders. During the fixed tender term, one drug regimen may be substituted for another regimen set at a different forward price curve depending on the clinical needs of the population.

SPECIAL CONSIDERATIONS

Regulatory Considerations

For both imported and locally produced medicines, it is important to have a robust regulatory and legal framework for the manufacture, sale, distribution and use of medicines, including ARVs, to underpin the long-term security of supply.

Regulatory Context for Supply

Like all medicines, ARVs must meet the normal standards for drug regulation and approval. All suppliers must include the following criteria for tendering:

1. Establish a legal presence in South Africa, i.e. appoint and designate a natural person who resides in the Republic to be responsible under local law
2. Use premises licensed for warehousing and distribution by the Director-General: Health
3. Gain approval as a pharmacy with the Pharmacy Council. From May 2004 the Medicines Control Council (MCC) will be responsible for licensing manufacturers, wholesalers, distributors, importers, and exporters.
4. Register the product with the MCC.

Accelerated Registration Processes

It is important to reduce administrative delays in the registration and approval of any new medicines that may improve health outcomes and mitigate drug resistance. All medicines procured must be registered by the MCC. Registration with the MCC is a thorough and occasionally time-consuming process. Fast track procedures are in place for expediting MCC approval.

Intellectual Property Considerations

All ARVs on the market are still under patent protection. The maintenance of intellectual property rights is essential to foster innovation and industrial development, however, the costs of patented medicines may prevent equitable access to essential medicines. The introduction of ARVs to the care and treatment of HIV and AIDS must comply with South African medicines law, patent law, and international obligations under the Trade Related Intellectual Property Rights (TRIPS) agreement. There are several ways in which access within existing laws can be facilitated.

Voluntary licenses

In cases where medicines can be obtained at a lower price, generic manufacturers can apply for voluntary licenses from patent holders. The disadvantage with voluntary licenses is that they are granted by the patent holders, who may or may not cooperate. Secondly, prices generally do not fall substantially where there is only one generic on the market. Prices come down with more competition. Thirdly, voluntary licenses may have strings attached e.g. royalties or restrictions with regard to whom products can be sold to.

So far, only one generic company has been granted a voluntary licence by two patent holders. This option may not be very useful as it is weighted heavily on the goodwill of the patent holder who may also have an interest in a viable market share. There are two further options to ensure a sustainable and affordable supply of necessary medicines as outlined in 2 and 3 below.

Compulsory licenses

The Patent Act provides for granting of a compulsory license by the Patent Commissioner, where demand for a patented ARV is not being met to an adequate extent and on reasonable terms. International legal norms provide further guidance regarding the granting of compulsory licenses. In cases of national emergency or where a product is for public non-commercial use, TRIPS allows the use of a patented product without the authorization of the patent holder. The detailed operation of this provision in the case of HIV, TB, and malaria has been reaffirmed and elaborated by the World Trade Organisation (WTO) Council for TRIPS. Most recently, the WHO has declared access to antiretroviral treatment by HIV and AIDS sufferers a global health emergency. A legislative amendment to the Patent Act to introduce compulsory licensing in the case of national emergency and public non-commercial use would be one way to further reinforce the comprehensive legal environment to enable broad access to affordable medicines and to facilitate secure and sustainable local supply.

The underpinning principle in the granting of compulsory licenses is that the patent holder is abusing his/her patent rights by maintaining an unaffordable price. This therefore implies that there must be negotiation with the patent holders to lower prices to an affordable level. The advantage with this option is that it opens the market to any generic

manufacturer. The disadvantages are that it may take a few months (three to four) to set it up and the patent holders may appeal to the Patent Commissioner on the basis of their not abusing their patent rights e.g. by granting voluntary licenses or bringing their prices down through the preferential price framework. This may therefore lead to protracted negotiations, appeals and delays.

Parallel importation

To enable the supply of more affordable medicines and to protect the health of the public, the Minister of Health may grant a permit that allows parallel importation of medicines. In this case, the Minister may determine that patent rights relating to a medicine patented in South Africa do not apply and the medicine can be imported. This provision is applicable and better invoked where the patent holder is abusing his/her patent rights by maintaining unaffordable prices. If parallel importation is invoked, it must be clearly demonstrated that there is no other option to access affordable medicines. Though this provision is at the behest of the Minister of Health, it may have wider trade related implications. It may also have a negative impact on the prevailing South African manufacturing capacity. The Doha and Cancun discussions however lessen this risk. The Department has all along been stating that this would be a last resort, after having exhausted all other negotiations to make medicine affordable. If this provision is invoked, communication in this regard is necessary. Secondly, parallel importation would be open to other players, beyond government in line with administrative justice and fairness. This implies that the monitoring arm of the Medicine Regulatory Authority must be vigilant and ensure that sub-optimal products are not imported into the country.

Regulation 7 of the Medicines and Related Substances Act stipulates that the permit granted by the Minister under this provision will be valid for two years and proof of registration of the product in the country of origin by a regulatory authority recognized by the MCC must be furnished. The person seeking a permit must also furnish documentary proof of the lowest price at which the medicine is currently sold in South Africa as well as the price at which it will be sold in South Africa. To ensure safety and efficacy, all parallel imported drugs must be registered with the MCC.

The principles outlined above, which aim at making medicine more affordable, will be extended to all essential medicines, in the spirit of the minimum package as stated by the SADC Ministers.

ADMINISTRATIVE STRUCTURE

Interdepartmental Leadership

An interdepartmental group will be established to oversee the implementation of the ARV procurement system. The Pharmaceutical Policy and Planning Cluster within the Department of Health will manage day-to-day operations in coordination with the Negotiating Committee. The Cluster will be responsible for managing tenders, aggregating provincial orders, placing order directly with suppliers, and ensuring that appropriate payment systems are in place.

Quality Assurance

Quality assurance (QA) for all companies registered by the MCC is administered by the MCC. The MCC inspects premises, determines Good Manufacturing Practice (GMP) standards, and recalls defective products. For purchased medicines, random product sampling is required. At present there is a need to strengthen the QA laboratory facilities at two centres, based in Cape Town and Johannesburg.

PROGRAMME ASSESSMENT

The effective management of the ARV procurement process requires routine, detailed analysis of the procurement portfolio and processes themselves. This review should include:

- Monitoring and evaluation data
- Review of market dynamics for ARVs
- Procurement patterns and irregularities
- Total volumes of procurement
- Analysis of prices paid
- Analysis of any hidden costs
- Management costs, times and other metrics
- Contractual performance

- Management of supplier relationships/ performance