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PSM in the Kyrgyz Republic

A rapid assessment of procurement & supply management activities financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria

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Acronyms

ART	Antiretroviral Treatment
ARV	Antiretroviral
BIPAI	Baylor International Pediatric AIDS Initiative
CCM	Country Coordination Mechanism
CHAI	Clinton Foundation HIV/AIDS Initiative
CIS	Commonwealth of Independent States
CSW	Commercial Sex Worker
DOI	Drugs for Opportunistic Infections
EML	Essential Medicines List
GMP	Good Manufacturing Practice
GPRM	Global Price Reporting Mechanism
HAI	Health Action International
ICB	International Competitive Bidding
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDU	Injecting Drug User
INCB	International Narcotics Control Board
LFA	Local Funding Agent
MIS	Management Information System
MOH	Ministry of Health
MSM	Men having Sex with Men
NDRA	National Drug Regulatory Authority
NGO	Non Governmental Organization
OSI	Open Society Institute
PA	Procurement Agent
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
PIU	Project Implementation Unit
PLWHA	People Living with HIV/Aids
PO	Purchase Order
PR	Principal Recipient
PRM	Price Reporting Mechanism
PSM	Procurement and Supply Management
QA	Quality Assurance
QC	Quality Control
SIZO	Detention Center (Russian abbreviation)
SR	Sub Recipient
ST	Substitution Therapy
TB	Tuberculosis
TRIPS	Trade-related Intellectual Property Rights
UN	United Nations
UNODC	United Nations Office on Drugs and Crime
UNDP	United Nations Development Program
VCT	Voluntary Counseling & Testing
VL	Viral Load
WHO	World Health Organization
WTO	World Trade Organization

Below is an overview of the organizations involved in the Global Fund project:

	Function	**Organization**
PR*	Principal Recipient	Republican Aids Center
PIU*	Project Implementation Unit	Republican Aids Center
LFA	Local Funding Agent	PriceWaterhouseCoopers

* The PR is the Republican Aids Center and has created a separate unit for the implementation of the Global Fund grant: PIU. In the report, the terms PR and PIU are used for the Republican Aids Center in the role as PR whereas the Republican Aids Center as such is mentioned while referring to the, mainly technical, activities as Aids Center.

Introduction

The Open Society Institute (OSI) has provided a grant to us to conduct an assessment of purchasing practices of Global Fund recipients in the Kyrgyz Republic and Azerbaijan. This report focuses on the former country with an end to:

- ✓ Assessing all influencing factors on procurement of antiretroviral (ARV) medicines and substitution therapy (ST) medicines under Global Fund grants in Kyrgyz Republic (e.g. patents, product registration, quality control (QC) and quality assurance (QA) procedures and requirements, tender processes, coordination with governmental procurement, forecasting and quantification, etc.);
- ✓ Collecting data on prices paid for ARVs and ST by Global Fund principal recipient (PR) in Kyrgyz Republic;
- ✓ Assess the experiences of PR with the Global Fund Price Reporting Mechanism Tool (PRM);
- ✓ Actively collaborate with civil society organizations in country for the purpose of advocating for better and more effective practices.

For OSI the main goal of the research is to obtain a clear picture of the general access to ST and ARV medicines, and to identify the major influencing price factors of these pharmaceuticals. Furthermore OSI strives to making these products more affordable and accessible for all people in need of ARV and substitution treatment in the Kyrgyz Republic. The information gathered during this assessment can be shared with relevant governmental institutions in order to enable them to make the necessary changes in their policies. Civil society members as well should have access to this report with the main objective to inform them about potential ways of adequate advocacy in the sphere of access to essential medicines.

Information about practical issues related to procurement and supply management (PSM) in Kyrgyz Republic is extremely limited. As is the case in most Commonwealth of Independent States (CIS) countries, numerous laws, orders and regulations are in place to regulate and control the procurement of pharmaceuticals. In practice, however, the number and stringency of rules and regulations issued by the government has made it rather challenging to purchase and provide pharmaceutical products to those in need.

PSM is a complex area, covering a broad spectrum of specialties, including but not limited to product selection; forecasting of needs; procurement policies procedures and systems; quality assurance; international and national laws; inventory management; distribution; rational use of medicines; supply chain management; management of information technology; training of staff; and contracting. Successful implementation of any PSM operation – small or large – usually depends on successful implementation of all of these interrelated PSM activities and requires specialists with varying professional backgrounds. For a better understanding of procurement of ARVs and methadone and their prices, a general understanding of this entire PSM chain is indispensable, rather than just the purchasing element. During the assessment all steps of the chain have been taken into consideration See for more information section 4 below.

This report describes the main results and findings of the assessment. The most important information related to prices of ARVs and methadone has been included in a comprehensive overview (see annex I). More background on the influencing factors is described in section 5. We have included general recommendations for each step of the chain, which will contribute to removing some of the bottlenecks in the Kyrgyz Republic PSM system.

Finally we note that despite the fact that many of the persons were very open during the interviews, it has been challenging to obtain accurate PSM-related information in Kyrgyz Republic. Quantitative information provided by interviewees tends to vary considerably and in some cases, basic information on prices paid for pharmaceuticals appears to be unavailable. Information on the ARV treatment costs per patient per year is available, however this information does not give a clear picture on the costs of the separate products as there are many different regimens in use for the current cohort.

We clearly indicated in the text where crucial information - mainly related to price information and procurement systems - is missing. Despite these challenges, we are confident that the information collected and assessed by us forms a reliable basis of this report. The functioning of the complete PSM chain became sufficiently clear during the meetings as all partners we met were able and willing to explain us the operating procedures.

1 The Fight against HIV/AIDS in the Kyrgyz Republic

The Kyrgyz Republic is a low income country in the Central Asia and belongs to the CIS. The total population is estimated at 5.2 million. According to figures from the World Health Organization (WHO) HIV prevalence among adults is 0.14%. The epidemic is concentrated among Injection Drug Users (IDUs), commercial sex workers (CSW), prisoners, mobile populations and men who have sex with men (MSM). The total number of IDUs is estimated at 25,000 (data from 2006, United Nations Office on Drugs and Crime - UNODC). According to the most recent sentinel surveillance - conducted every year covering all major risk groups - the prevalence among IDUs is 7.7%. There is a strong concentration of the epidemic in and, in the southern part of Kyrgyz Republic around the city of Osh and near the border with Uzbekistan. The fight against HIV/Aids however, is still mainly centralized in and coordinated from Bishkek. More decentralized projects are being planned for in the future.

In Kyrgyz Republic 1,686 cases are officially reported as HIV positive including around 97 children (data June 2008). However, according to UNAIDS the actual number may be up to 10 times higher; the Republican Aids Center estimates that the total number may be up to 4,200 cases. It should be noted that no wide spread voluntary counseling and testing (VCT) takes place. Testing is common among pregnant women (whether forced or not) and blood donors. However, it is not (yet) common among the most at risk to test. Lack of confidentiality is mentioned as one of the main reasons for the relatively small number of persons who are tested on a voluntary basis. The lack of general information about HIV/Aids is another limiting factor.

At present treatment for both ARV and ST is only be provided by governmental entities. There are however no restrictions to entities to provide ARV treatment as long as the treatment is prescribed by a special team of medical doctors which has been established particularly for this task. At present, Global Fund is the only source of funding for the supply of ARVs and methadone. For more information on this issue please see sections 3 and 10.4.

Out of the registered cases around 500 persons need ARV treatment (ART). ART started mid 2005 and at present approximately 100 patients are on ART (information received from the Project Implementation Unit (PIU) during the interview), including approximately 30 children. A very limited number of patients are on second-line treatment. It is estimated to scale up to 150 patients by the end of 2008. The mortality rate is relatively high which is caused by the fact that, due to stigmatization, discrimination and lack of information, patients come to the treatment centers at a very late stage of the disease - if they come at all. In theory, purely based on availability of medication (and/or the necessary funds to procure medication), there is almost universal access to treatment but in practice not all People Living with HIV/Aids (PLWHA) in need of ART receive ART.

In 2007 Kyrgyz Republic was alarmed with the outbreak of HIV in one oblast (Osh). HIV was detected among approximately 100 children in three hospitals mainly caused by parenteral transmission. Over 30 of these children started treatment.

Many of the PLWHA needing ART suffer from other illnesses and/or opportunistic infections such as Hepatitis B, Hepatitis C and tuberculosis (TB), which complicates and delays enrolment. In general, anti TB medication is available for free for all Kyrgyz citizens. The detection of TB in PLWHA however remains challenging mainly due to the lack of experienced medical staff. The TB registry is not linked to the HIV/Aids register. For a limited number of patients medication for Hepatitis C is currently available through governmental programs thanks to humanitarian aid from donors. No procurement is foreseen under the Global Fund project.

Drugs for other regular opportunistic infections (DOI) are available through governmental programs or – on payment - in the regular private pharmacies, where mainly (expensive) branded products are marketed. Supply of DOI has not been included for Round 2 but is foreseen in Round 7.

Reagents for tests for patient monitoring such as Viral Load (VL) and CD4 cell count are included in the Global Fund project. Serious problems occurred in the course of the project with the supply of these tests; stock outs have been reported during long periods of the project. The necessary equipment is available in the capital of Bishkek.

In general there is a very open approach to ST of all parties involved at all levels. However, there are also strong forces from government officials and other individuals against the distribution of methadone. The existing programs demonstrate several weaknesses but the overall achievements are noticeable, especially given the background of Kyrgyz Republic being a former Soviet state.

The first ST project started in 2002, with support of the Soros Foundation and United Nations Development Program (UNDP). At present the program is fully supported by the Global Fund. Approximately 550 patients are on methadone treatment and for the end of 2008 a total number of 1.200 patients is foreseen. Currently there are nine treatment centers in the whole country and plans for expansion are being developed. A pilot project for methadone distribution in 3 prisons including 1 detention center (SIZO in Russian abbreviation) will start in August 2008. 150 prisoners are already on the waiting list.

The challenges for this pilot project are immense: the prison population is mobile due to continuous relocation of prisoners within the prison system which increases the risk of treatment interruption. Furthermore the referral of these patients is complicated.

One of the weaknesses observed in the fight against HIV/Aids is the absence of integrated care. Cases of co-infection in combination with drug use are common. These persons have to go to at least three different health centers for their daily care and treatment; almost a mission impossible for persons in these conditions.

2 The Global Fund project

The first Global Fund grant for HIV/Aids in the Kyrgyz Republic, Round 2, is currently in its final year. Ending date of this grant is 28 February 2009. The total grant amount is USD 17,073,306.

Round 2 aims to contain the spread of HIV in the Kyrgyz Republic at the initial stage of the epidemic through targeted interventions among the vulnerable groups and organization of support to people living with HIV and Aids patients.

The main objectives are:

1. Strengthening political and legal support to Aids prevention programs based on multi-sectoral approach;
2. Reducing vulnerability of young people;
3. Containing HIV infection among vulnerable populations;
4. Ensuring safety of donors blood;
5. Provision of medical and social support to people living with HIV/Aids and affected by them.

The grant agreement for Round 7 was signed in May 2008 and the grant start date is foreseen in January 2009. The approved grant amount for Phase I is USD 11,845,090. This Round aims to increase the effectiveness of national measures in the area of HIV by expanding the services available to key population groups, as well as comprehensive development of the capacity of implementing organizations and vulnerable communities. The PSM plan for this Round has not yet been approved by the Global Fund; it is currently under development the PIU foresees to submit the final version to the Global Fund shortly before the starting date of Round 7.

Specific proposal objectives are:

1. Increasing the life expectancy and quality of life of people living with HIV;
2. Restricting the spread of HIV in key population groups (IDUs, CSWs, MSM, prison inmates, mobile population groups);
3. Reducing the risk of HIV spread in the general population.

This project correlates with the implementation of the state program to prevent the HIV/Aids epidemic and its social and economic consequences in the Kyrgyz Republic (2006-2010). In this state program no budget is foreseen for the procurement of ARVs and methadone. There is budget available for the salaries of the staff at the central and regional Republican Aids Center and the Narcology Centers. Furthermore the state finances several rehabilitation centers and supports detoxification services for IDUs. Salaries of the staff from the Republican Narcology Centre involved in the ST project are covered by the Global Fund project.

The PR is the Republican Aids Centre of the MOH of the Kyrgyz Republic who established the PIU. It acts as the Principal Recipients (PR) operational unit and is directly responsible for the implementation and operational management of the grants. For all disbursements and payments, the bank accounts of UNDP in Kyrgyz Republic are used. As of the start of the grant, an agreement was made between the government, the Republican Aids Centre and UNDP. The role of UNDP is to support the PIU in its responsibilities to meet the conditions and deadlines set by the Global Fund for proper program implementation and to ensure further grant disbursement. The terms of the agreement include that UNDP support is provided only on request from the PIU and that the PIU has overall responsibility for management and implementation as well as achievements of results. UNDP co-manages all funds of the PIU and distributes them only on request by the PIU.

Following the initial PR assessments by the Local Funding Agent (LFA), PriceWaterhouseCoopers, at the start of the grant, some of the recommendations of Global Fund included: outsource health product procurement to an international procurement agency acceptable to the Global Fund and register ARV drugs for inclusion in the Essential Medicines List (EML), implement measures to enhance the health

product receipt, storage and distribution by installing a computerized stock control system, and implement measures to enhance health product forecasting, including the installation of a standardized information system to monitor the distribution and stock levels at regional centers.

According to the grant performance report dated April 2008 on performance until 2007, the program showed very satisfactory results. The Portfolio Cluster rated the programs performance as "A" (expected or exceeding expectations). Although the programmatic achievements have "A" rating, the Portfolio Cluster concurred with the LFA overall rating "B1" (adequate) mid 2007. One of the reasons was the poor drug management system, as a result of which the PIU disposed and burnt expired ARV drugs for USD 16,000, which corresponds to 5% of the total value of pharmaceuticals procured until present.

In the course of the project several changes of staff took place, at all (implementing) partners involved on the ground such as MOH (and PIU) and the Republican Aids Centre. On top, in 2007 the composition of the Country Coordination Mechanism (CCM) modified as well. According to many interviewees this is considered to be downturn rather than progress; in the new composition the MOH has considerably more power and control than in the former CCM. Since the MOH is also PR, this can lead to conflicts of interest and less control and monitoring on the performance of the PR.

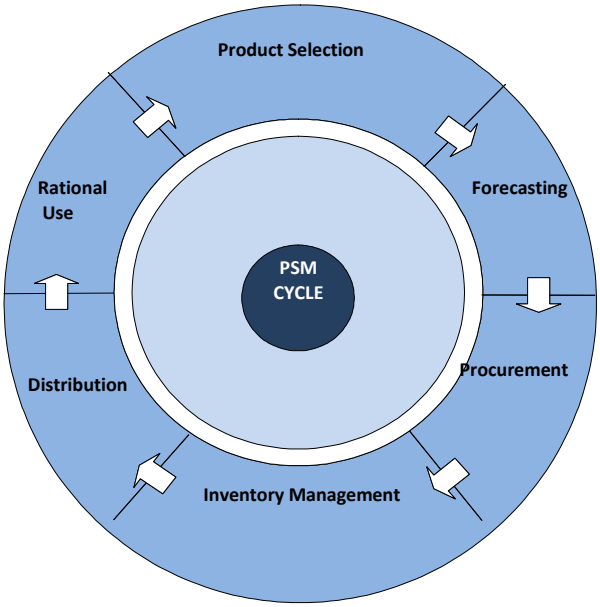
Furthermore the role of the LFA does not seem to be entirely clear for the various partners involved. Many interviewees complained on the lack of availability and visible performance of the LFA. The LFA was not available for an interview during our visit in Kyrgyz Republic.

The PIU is responsible for all procurement under both grants. The total expenditures for pharmaceuticals under Round 2 are USD 287,833 till present. For more information see section 6 below. The following categories of health products are/will be procured under the current grant by the PR:

- ✓ ARV
- ✓ Drugs for Opportunistic Infections (for Round 7 only)
- ✓ Reagents for Viral Load
- ✓ Reagents for CD4
- ✓ Rapid tests
- ✓ Condoms
- ✓ Syringes
- ✓ Methadone

3 Global Fund-financed procurement and supply management

PSM is often equaled to purchasing. However, PSM covers a much broader spectrum of specialties, including but not limited to product selection; forecasting of needs; procurement policies procedures and systems; quality assurance; international and national laws; inventory management; distribution; rational use of medicines; supply chain management; management of information technology; and contracting. Successful implementation of any health project depends to a large extent on successful implementation of all of these PSM activities. The PSM chain is as strong as its weakest link. The following sections describe the various particles in the chain in relation to the Global Fund project in the Kyrgyz Republic.



3.1 Product selection

The rationale for selecting a limited number of drugs is that for a certain project (or essential drugs in general) it may lead to better supply, more rational use, and lower costs. Because it has a considerable impact on the quality of care and the cost of treatment, the selection of drugs is one of the most cost-effective areas for intervention.

The most recent version of the Kyrgyz EML dates from March 2007. All ARVs procured under the Global Fund grant as well as methadone appear on this list. Methadone is also mentioned in the List of Narcotic Drugs and belongs to category 1 ”Narcotic substances posing particular hazard because of particular harmful consequences which may bring to abusing them and posing interest in terms of using for medical goals”. The EML is available in hard and soft copy and is updated every year.

At present new general treatment guidelines for treatment for HIV/Aids are being printed (June 2008). The new guidelines are based on the general treatment guidelines from the WHO European region. Several changes have been made to adopt this protocol to the specific situation of Kyrgyz Republic.

Despite the various efforts of many partners involved in the program, it resulted to be impossible to obtain a copy of the general treatment guidelines from WHO. This can be caused by the fact that the new printed version is not yet available but it is more likely that the former guidelines were not widely spread since most of the interviewees were even not aware of a revision of the current guidelines. It leads

anyway to the assumption that these documents are not widely spread and not consistently used among health care providers.

The lists of ARVs procured in the past could not be analyzed against the general treatment guidelines as no copy of these guidelines could be obtained. Since the Kyrgyz guidelines are based on the WHO European region guidelines the latter was used for a quick scan on conformity: the first purchase did not contain Abacavir and Lopinavir+Ritonavir the WHO guidelines indicates this product for first and second-line treatment.

Recently general treatment guidelines for ST have been developed and approved by the government. Kyrgyz Republic is one of the first countries in the region in possession of general treatment guidelines for ST.

Registration requirements also affect the product selection. As this is issue is even more related to Quality Control and Quality Assurance (QA/QC), it will be discussed in more detail in the section 4.4 below.

In many countries the issue of the Trade-related Intellectual Property Rights (TRIPS - often referred at as patents) influences the selection of products in the sense of selection of generic of branded product. Kyrgyz Republic is member of the World Trade Organization (WTO) and is therefore obliged to include medicines in their regime for product and process patents. “Kyrgyz Patent” is the responsible entity for patents in Kyrgyz Republic. According to information received by their employees during a phone conversation no information is available at Kyrgyz Patent on patents of pharmaceuticals neither is it available on their website. The issue has been raised during the different interviews but has never been reported as problematic. One of the main reasons is most probably the lack of information on this highly complicated issue.

The situation for methadone is different as it concerns only one product, namely methadone powder for oral solution. The Republic Narcology Centre has the necessary equipment for the distillation of water for the preparation of the solution.

Recommendations

- ✓ Follow up on approval and implementation of general treatment guidelines (Republican Aids Center, civil society);
- ✓ Improve data collection needed for proper product selection (Republican Aids Center, PIU);
- ✓ Wide and proper distribution of EML and general treatment guidelines (both for HIV/Aids and ST) (Republican Aids Center);
- ✓ Investigate the situation on TRIPS for ARV (PIU, civil society).

3.2 Forecasting

The drug list is the central component of any forecasting process. It is not possible to calculate quantities required until it has been decided which products are selected for the treatment of patients (see previous section). Forecasting involves estimating the quantities of specific drugs needed for appropriate treatment of patients. Most forecasting exercises also include the financial requirements to procure the drugs.

The Republican Aids Centre is responsible for forecasting of ARVs. In the past national consultants with international training and/or experience were hired under the Global Fund grant byt the PIU for additional technical assistance.

Forecasting has been done on a yearly basis but recently, as a result of the outbreak in Osh, an additional forecasting exercise took place for a new – additional – order for this particular cohort. Unicef is one of the leading organizations and they are supported by specialists from Baylor International Pediatric Aids Initiative (BIPAI). Their experts assisted Kyrgyz Republic in defining the treatment regimens for the children eligible for treatment. During the summer of 2008, an expert will come to Kyrgyz Republic to conduct training on forecasting and procurement focused on pediatrics. General training on forecasting is foreseen for the end of 2008 by WHO in collaboration with Unicef.

Forecasting is based on the number of patients on treatment and the enrolment plan. A security stock is taken into consideration as well, although the exact information on the calculation methods for this security stock is not clear. It is said that this stock would cover the needs for 4 to 6 months for the current cohort.

As for every project starting ART, forecasting is a challenge: no historical data are available and there is a lack of experienced staff. In the Kyrgyz Republic there is an additional complicating factor, namely the fluctuating number of patients. The main raisons for this fluctuation are the following:

- ✓ Many patients come to the Republican Aids Centre in an advanced stage of the disease. As a consequence the mortality rate of patients on ART is relatively high.
- ✓ Many patients are IDUs and CSWs who often do not have permanent homes. Discipline and regularity is also very challenging for this group of people; two essential characteristics for adherence.
- ✓ Many patients are prisoners and during detention transfers from one prison to another are not uncommon. As a consequence, patients are sometimes obliged to interrupt their treatment even though ARVs should theoretically be available for all in need in all prison settings.

For the first purchases also some second-line ARVs and pediatrics were included, for which forecasting is even more complicated. During the course of the project it appeared however that no patients required (yet) second-line treatment neither were children eligible for treatment (this was before the outbreak in Osh). This resulted in expiries on the shelf. See for more information section 4.5 below.

Forecasting for methadone is done by the Republican Narcology Centre on a yearly basis. For the calculations of needs the following data are used:

- ✓ existing number of patients (the same remarks as for ART are relevant)
- ✓ planning for scaling up
- ✓ number of distribution points
- ✓ remaining stock levels
- ✓ a small security stock

The forecasting made by Republican Narcology Centre is reviewed by the Drug Control Agency. The Drug Control Agency is responsible for the request for annual quota at the International Narcotics Control Board (INCB).

Recommendations

- ✓ Regular coordination meetings with partners involved (PIU, civil society, donors);
- ✓ Follow up on development and implementation of general treatment guidelines (Republican Aids Center, civil society);
- ✓ Improve data collection needed for proper forecasting (Republican Aids Center, PIU);
- ✓ Gradually switch to a more frequent forecasting and adjust purchases accordingly (Republican Aids Center, PIU);
- ✓ Active involvement of the PIU in forecasting (Republican Aids Center, PIU).

3.3 Purchasing

The pharmaceutical procurement system is a major determinant of drug availability and total health costs. In most HIV/Aids projects – and health projects in general, drug procurement represent the single largest health expenditure after personnel costs. An effective procurement process should:

- ✓ procure the right drugs in the right quantities;
- ✓ obtain the lowest possible purchase price;
- ✓ ensure that all drugs procured meet recognizes standards of quality;
- ✓ arrange timely delivery to avoid shortages and stock-outs;

- ✓ ensure supplier reliability with respect to service and quality;
- ✓ set the purchasing schedule, formulas for order quantities, and safety stock levels to achieve the lowest total cost at each level of the system;
- ✓ achieve these objectives in the most efficient manner possible.

Good procurement management demands medical, pharmaceutical, managerial, economic and often the ability to work within a politically demanding environment.

As per the grant agreement between the Global Fund and the PR, the PR – in this case the PIU which is the same organization as the Republican Aids Centre - is responsible for the procurement of all health products. All funds of the Global Fund project pass through the Kyrgyz UNDP account (see above in section 3) and in this case UNDP acts as a supervision entity. The PIU considers the approved PSM plan as the procurement guidelines to comply with. A PSM plan describes how the PSM chain is organized but does not mention detailed information on the implementation of the procurement policies opted for.

Officially the role of the UNDP is to support and monitor whether the procurement processes are properly followed by the PIU. UNDP also reviews all the supporting documents for the bidding and selection procedures prior to paying suppliers. According to UNDP, the documents used for the selection of suppliers by the PIU in the past, did not always fully comply with UNDPs standards. UNDP is not involved directly in procurement. As an example, UNDP is not member of the tender evaluation committee. For the services provided, UNDP receives a maximum of 1.5% of the total amount, depending on the volume and the type of services provided.

Apart from the support available from UNDP, the PIU also contracted the private company Avanco Ltd. for technical assistance for the development of bid documents and for contracting. Unfortunately no additional information - on reliability, reputability, track record, etc. - could be found on this company, nor in country nor on the internet.

The suppliers are selected once a year by means of an open international tender (International Competitive Bidding – ICB). Bids are evaluated by a tender committee. The suppliers tend to be local representatives of different manufacturers meaning that the PIU deals with one local agent only for the supply of different products from different manufacturers. Lead times are around 60 to 90 days, counting from the moment of placing the purchase order (PO) till the moment of arrival at the final destination (warehouses from the Republican Aids Centre). All ARVs are exempted from VAT and other import duties and are delivered at the central warehouse of Republican Aids Centre in Bishkek. The remaining shelf lives of all pharmaceuticals procured are, according to the requirements, not less than one year at the moment of arrival at the Aids Centre.

The first purchase of ARVs dates from 2004 and included only products from MacLeods Pharmaceuticals Ltd., an Indian manufacturer. All ARVs of this purchase are registered in Kyrgyz Republic but not pre-qualified by WHO and not mentioned on the “List of ARV Pharmaceutical Products classified according to the Global Fund Quality Assurance Policy for single and limited source pharmaceutical products” (see the section 4.4 for more information). At the time of this purchase it was still allowed to procure locally registered pharmaceuticals according to the QA/QC guidelines of Global Fund. Apparently the PIU has not followed Global Funds initial recommendation to outsource procurement to an international procurement agent (PA) acceptable to the Global Fund.

Later purchases only included WHO pre-qualified ARVs according the verbal information received. However, no supporting documents are available. For the last purchase Pharmacentre was selected as supplier, a local representative of several manufacturers such as Aurobindo, Glaxo Smith Kline and Abbott. Not all ARVs from the recent purchases are registered in Kyrgyz Republic at present which is contradictory to national legislation and Global Fund requirements. For more information on this issue see section 4.4 below.

Currently the PIU is processing an additional – emergency - order for the cohort in Osh. This order includes pediatric ARVs.

Methadone is purchased once a year through Unihelp, a local company in medical supplies and equipment. The methadone purchased powder for suspension, from manufacturer Zentiva is not registered in Kyrgyz Republic. Lead times are 60 to 90 days. Methadone is also exempted from VAT and other import duties.

An often heard comment from partners and stakeholders concerns the transparency of the ARV and methadone procurement. No public information is available on the procurement process, the prices paid, contract with suppliers and delivery times. Indeed very few information on procurement is available despite the fact that Global Fund requires open, competitive and transparent procedures for all procurement. This makes the PIU extremely susceptible to criticism and speculations.

There is no structured and permanent involvement of civil society in the procurement process notwithstanding the countless and continuous efforts from civil society members to participate and contribute to this important and extensive process. For the procurement of both masculine and female condoms civil society was partly involved, namely for the development of the technical specifications.

The LFA is responsible for general monitoring of the procurement by the PIU. The LFA is not participating in the different procurement processes. Indeed, this is not the role of the LFA: .

More information on prices for both ARVs and methadone can be found in Annex I.

Recommendations

- ✓ Share public information on procurement regularly with stakeholders (PIU);
- ✓ Involvement of (PSM-trained) civil society members in the procurement process (PIU, civil society);
- ✓ Training of PIU staff on pharmaceutical procurement (PIU, LFA, Global Fund);
- ✓ Ensure full compliance with Global Fund requirements (PIU, LFA, Global Fund);
- ✓ Ensure full compliance with national legislation (on registration) (PIU, LFA, Global Fund);
- ✓ Consider revision of shelf life condition from 1 year to a remaining shelf life of a certain percentage (e.g. 75%) (PIU).

3.4 Quality Assurance & quality control

The purpose of quality assurance in public drug supply systems is to make certain that each drug reaching a patient is safe, effective, and of standard quality. A comprehensive quality assurance program includes both technical and managerial activities, spanning the entire supply process from drug selection to patient use.

In all interviews and discussions in Kyrgyz Republic the only reference made to quality of ARVs is the WHO pre-qualification. It might not be generally known that the Global Fund uses other QA policies and accepts, in particular cases, also ARVs that are not WHO pre-qualified. In short, the QA/QC policy contains the following options for procurement of ARVs and other single or limited source pharmaceutical products:

- ✓ **Option A** - WHO pre-qualified products;
- ✓ **Option B** - Product authorized for use by a stringent regulatory authority from one of the countries participating in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) (www.picscheme.org) and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (www.ich.org).
- ✓ **Option Ci** – Product manufactured by manufacturer who submitted an application for approval of such product to the WHO Prequalification Program or a stringent regulatory authority. Such product is manufactured at a site that is compliant with the standards of Good Manufacturing Practice (GMP), as certified (after inspection) by the WHO or a stringent regulatory authority.
- ✓ **Option Cii** - Product is manufactured at a GMP-compliant manufacturing site, as certified (after inspection) by the WHO or a stringent regulatory authority.

For the procurement of products falling under option Ci or Cii, the PR has to comply with strict requirements from the Global Fund as per the QA guidelines. The PR should obtain approval from the Global Fund for purchasing of these products prior to placement of the order.

It should be noted that methadone is not included in the WHO pre-qualification program; only ARVs, anti-TB medicines and anti-malarials are part of this program. It is also not part of the Global Fund guidelines as mentioned above.

According to the Kyrgyz legislation all pharmaceuticals imported have to be registered. The marketing of pharmaceutical products requires prior evaluation, approval, and licensing by a National Drug Regulatory Authority (NDRA). The criteria for approval and licensing include efficacy, safety, and quality. Registration falls under the responsibility of the Department of Drug Provision and Medical Equipment under MOH. Besides the quality control done during the registration process, all batches of all products imported are tested in the laboratories in Bishkek and/or Osh. After this quality control, batches are released from customs. There is no customs warehouse on the airport and at the borders but the purchasing party can obtain authorization for provisional storages until official release.

Regulations for registration and registration fees vary according to the type of product, branded or generic, and the location of the manufacturer. The prices range from USD 1,000 to USD 2,500 per product. Registration takes up to 6 months and is valid for 5 years.

In theory this quality assurance system should be adequate for the Kyrgyz Republic. However in practice it has been proven that several non registered pharmaceuticals entered the country, including some products procured under the Global Fund grant. Many interviewees confirmed that on the market many illegal pharmaceuticals can be found.

For this assessment only ARVs and methadone have been taken into consideration. From these categories, several non registered products have been imported in the past. For more detailed information see section 4.3 below.

In the tender documents used by the PIU quality requirements for ARVs contain WHO pre-qualification and registration. Both the Drug Provision and Medical Equipment under MOH and the PIU confirmed all ARVs procured are registered or in the process of registration. In case a product is not registered at the moment of contracting, the supplier is supposed to have the product registered before its arrival in Kyrgyz Republic. In theory there is sufficient time to complete this process. According to legislation a non-registered product arriving in country is either sent back to the manufacturer or destroyed in country at the costs of the manufacturer.

In many countries waivers allow purchasers of critical products, such as ARV and methadone, to import these without registration certificates. There seem to be some cases in which the MOH decided to import unregistered products for emergency cases but it is not clear whether this has been the case for ARVs. Apparently there has been a meeting between the Global Fund Portfolio Manager and the Department of Drug Provision about the option of obtaining a waiver for pharmaceuticals procured under the Global Fund grant. According to the Department of Drug Provision all international donors should comply with local legislation. It is not clear whether the Global Fund came to an agreement with the Department of Drug Provision.

In general the registration requirements can create severe obstacles for procurement for Global Fund programs. The PR is required to follow local legislation and the general Global Fund guidelines regarding QA/QC. This can cause problems in case a certain product is only registered by one or two manufacturers (local legislation) not compliant with Global Fund guidelines. This is the case for some ARVs in Kyrgyz Republic. Also, some of the ARVs included in the EML and in the WHO European Region general treatment guidelines are not registered at all. In short, if the registration law is applied strictly, the complete range of necessary ARVs according to the treatment guidelines cannot be procured.

For methadone only one supplier registered its product. This supplier was contracted for the first purchase but in the meantime the project switched to another supplier, Zentiva; a Czech company with a manufacturing plant in the Slovak Republic. Its methadone is not (yet) registered in Kyrgyz Republic.

For more information Annex I.

Recommendations

- ✓ Ensure a waiver is obtained for methadone and WHO pre-qualified (but not-registered) ARVs (PIU);
- ✓ Review registration law to enable an accelerated and simplified registration for WHO pre-qualified pharmaceuticals (MOH, civil society);
- ✓ Improve quality assurance systems to avoid import of illegal and poor quality pharmaceuticals (MOH).

3.5 Inventory management

Inventory management is at the heart of the drug supply system; without a healthy inventory management system, the drug supply system as a whole will not be viable. For the storage of ARVs there is one main warehouse, in Bishkek, and 3 regional warehouses: in Bishkek, Osh and Jalalabad. The major stock is stored in Bishkek from where the other warehouses are being supplied. During this assessment no proper attention could be paid to several important inventory management issues such as batch tracking systems and storage conditions in all warehouses. Especially ARVs and reagents are extremely sensitive products requiring adequate storage conditions, e.g., dry, clean and temperature controlled (in general between 5 and 25 °C) areas. Also proper safety procedures should be in place since these products are expensive and therefore susceptible to theft.

Apparently several products expired on the shelf. It is however not clear when this happened and which products it concerned as the information received is contradictory. Some second-line products were included in the first purchase but since no patients were in need of second-line treatment these products expired. The PIU mentioned that they procured stocks for 60 patients but only 43 patients were on ART which lead to expired drugs worth about USD 5,000 in the beginning of 2006. The grant performance report from Global Fund mentions a poor drug management system in the period covering 1 December 2006 – 30 June which has lead to the disposal and burning of expired ARV drugs for USD 16,000.

Although the situation regarding expiries in the past remains unclear, it is sure that the program has been faced with expiries. Different reasons - not all directly related with inventory management - can be given for this situation:

- ✓ Inadequate forecasting;
- ✓ Weak planning;
- ✓ Lack of experience;
- ✓ Delay in scaling up of ART;
- ✓ Fewer patients in need of second-line treatment than foreseen.

Until 2007 no stocks outs of ARVs were reported. As a consequence of the outbreak in Osh in 2007, the number of children in need of ART increased drastically (from an exceptional case to over 30) and the available stocks were not sufficient to cover these needs. A lot of critics were spread regarding this stock out however; it is normal and reasonable that in the case of Kyrgyz Republic with its relatively small number of patients on ART, no sufficient stocks were available immediately after the outbreak for the high number of children in need of ARVs. Needs for outbreaks of this size in the context as described, can never be fully covered. Indeed, in a normal situation most of the ARVs would expire on the shelf if such quantities should be kept as security stocks.

For the short term, the PIU and the Republican Aids Centre managed to obtain pediatric ARVs from the Global Fund project in neighboring country Uzbekistan. In the meantime a new order has been prepared

and is currently in the process of placement at the supplier. Unicef assisted the program on forecasting of this particular order.

The regional Aids Centers report on their stocks to the Republican Aids Centre on a monthly basis. Since the Republican Aids Center and PIU are one and the same organization, control and monitoring of these reports might be hindered.

Currently there is no Management Information System (MIS) available for stock management despite the recommendation of Global Fund at the start of the grant. Since there are relatively small numbers of treatment sites, warehouses and patients, an excel-based system can perfectly serve. However, given the planned expansion of treatment sites, scale up and the consequential increase changes in treatment regimens (e.g., more and more second-line), a MIS is definitely required in the near future. According to the PIU a pilot project, 'Electronic following HIV', is developed and will start at the end of 2008 / beginning of 2009 in Bishkek.

Methadone powder for suspension is stored in a safe and secured place at central level. At this level the syrups are prepared and distributed to the distribution points (see section 4.6 below). Methadone in syrup form is perishable during 7 to 10 days.

Stock records are kept both at the central level and regional level. The Republican Narcology Centre reports to the Drug Control Agency on quarterly basis. Reporting from the Republican Narcology Centre to the PIU on general issues and activities is done on a monthly basis, reporting on patient numbers happens every week.

In the course of the project no expiries neither stock outs have been reported. There has been however a period of limited access of methadone for patients during an overall crisis of around 8 months in 2005 when the Drug Control Agency discovered the violation of rules for implementation in one of the projects. Give the high risk of stock out caused by this crises, no new patients were accepted by the project and the existing cohort was strongly encouraged to reduce their doses or to go through rehabilitation.

Recommendations

- ✓ Start preparations for implementation of MIS on national level (PIU, Republican Aids Center);
- ✓ Develop procedures for emergency orders (needed in case of outbreaks or other unforeseen situations) (PIU);
- ✓ Assess drug management systems and storage conditions in regional warehouses (PIU, Republican Aids Center).

3.6 Distribution

The primary management goal is to maintain a steady supply of drugs and supplies to facilities where they are needed while ensuring that resources are being used in the most effective way. Effective drug distribution relies on good system design and good management.

Presently there are 10 treatment centers for ARV; 7 regional centers, 1 prison and 2 detention centers. These centers receive fresh stocks once every quarter, based on requisitions prepared by these centers. The PIU is responsible for transport from the warehouses to the treatment centers. The Republican Aids Centre manages the stocks for the patients in prison.

There are 8 distribution points for methadone. This number will increase in the future starting in August 2008 with the pilot project for methadone distribution in one of the prisons. Besides expansion through this pilot project, distribution in regular centers will start in other oblasts as well. Distribution takes place according to the guidelines from the Drug Control Agency.

All distribution points receive methadone syrup every week, based on requisitions. The syrup is prepared in Bishkek and Osh Narcological Dispensaries.

3.7 Ensuring rational use

The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. The steps of product selection, forecasting, procurement, and distribution are necessary precursors to the rational use of drugs.

In general the quality of medical services provided to PLWHA leaves room for improvement. The low service level has different reasons and causes.

ARVs are available for free. However, not all other pharmaceuticals and health products needed for an appropriate treatment are available in the health facilities. In case the products can be found in the regular – private – pharmacies, these are available at cost. Many problems have been reported for DOIs and reagents for VL.

Unfortunately there is no sufficient medication available for the treatment of Hepatitis C which is a common disease among PLWHA. ART demonstrated to be complicated for PLWHA with Hepatitis C.

Furthermore the staff in the health facilities lacks the necessary experience related to HIV/Aids. Several interviewees also reported cases of low commitment of staff towards patients. Some physicians are even unwilling to treat PLWHAs. There are a very limited number of well trained medical doctors for prescription of ARV. In Osh oblast, where approximately 100 children were infected in 2007, there is only one qualified doctor.

Adherence is causing major problems in Kyrgyz Republic. As already mentioned in section 4.2 above, the number of patients on ART is fluctuating which is caused partly by large number of patients belonging to a mobile population. However there are some additional reasons and causes:

- ✓ Lack of proper counseling;
- ✓ Lack of information (on side effects, adherence, etc);
- ✓ Lack of additional support to patients (social, psychological, financial);
- ✓ Lack of skills of medical staff to deal with this extremely complicated group of patients.

In general there is a strong preference for branded products among the prescribing medical staff and the general population. The first group might have financial reasons to prescribe a certain product instead of the cheaper but comparable product the latter simply does not believe that cheaper generics can be of good quality. Recently a survey took place on quality of both generics and branded products conducted by WHO. At the moment of the assessment the outcome was not publicly available. Government programs officially promote the use of generic drugs. The future activities of Health Action International (HAI), a Dutch Non Governmental Organization (NGO) recently established in the Kyrgyz Republic will be focused on rational use and the promotion of generic drugs. A certain part of the ARVs procured are generics.

Recommendations

- ✓ Improve information and support for patients (Republican Aids Center, civil society);
- ✓ Train medical staff at all levels on general aspects of HIV/Aids (Republican Aids Center);
- ✓ Train medical staff on prescription and care of HIV/Aids patients (Republican Aids Center);
- ✓ Improve general awareness on HIV/Aids (Republican Aids Center, civil center);
- ✓ Improve quality and access to VCT (Republican Aids Center).

4 Factors influencing commodity pricing

This chapter outlines the main factors influencing the prices of key health commodities as required and purchased by the PR.

4.1 General treatment guidelines

For product selection the general treatment guidelines and EML serve as the main base. The general treatment guidelines indicate the number and type of products to be used. Obviously prices for treatment will be significantly lower in case 3 ARVs are prescribed for first line treatment instead of 8 ARVs. Prices for second–line and pediatric ARVs tend to be higher than for first line ARVs. In the case of Kyrgyz Republic, mainly first line ARVs have been procured given the low number of patients in need of second line and/or pediatric treatment.

Furthermore, the availability of the recommended product itself, its dosage and form can cause serious consequences for prices since some ARVs are not available in generic form. In general, supply of generics will decrease the total costs considerably. Except for the first purchase, containing only generic ARVs - none of them WHO prequalified -, it is not known in detail to which extent the PIU is purchasing generics. According to the information received, as of April 2006 the PIU is purchasing only WHO prequalified pharmaceuticals. This does not automatically mean that generics are procured. Apparently the PIU is procuring products from Aurobindo (generic), Abbott Laboratories (branded) and Glaxo Smith Kline (branded).

4.2 Registration

Probably registration is the main factor influencing the prices of ARVs. In fact, registration determines the manufacturer(s) for the selected products. The purchasing entity fully depends on the registered products. In this case a country can end up paying a high price for a particular product since there may be only one manufacturer who registered a particular product. Indeed, the same product with the same quality standard can be available on the world market for a lower price.

Not all necessary ARVs are registered from a source which is acceptable by Global Fund and there are even some of the necessary ARVs not registered at all (see section 4.4). This is worrisome both for prices and continuous supply; at present no uninterrupted supply can be guaranteed and interruption can have major consequences for the patients and the continuation of the project in its entirety.

Prices depend on two main factors. Firstly, which manufacturer has been and will be ready and eager to register its products? And, more importantly, which prices will these manufacturers charge now and in the future (the registration fee needs to be earned back and there might be a monopoly position for the manufacturer who registered its products)? Secondly the Global Fund quality requirements play a crucial role (see below).

4.3 Global Fund quality assurance requirements

The QA policy of the Global Fund also influences pricing as only a limited number of pharmaceuticals may be procured with Global Fund funds. Please see the section 4.4 for more information.

4.4 Local and regional determinants

In general the ARV market is not very transparent. This is demonstrated by the large number of attempts to make accurate price overviews throughout the world and the overall conclusion by all the organizations involved in the development of such overviews: there are many variables which makes it extremely challenging to develop accurate and useful overviews.

One of the variables is the price policy applied by the different manufacturers and suppliers. Although there is no clarity about the policies in use, it is generally known that prices charged for low income

countries are different than prices charged for lower-middle income countries. The region also has an influence on the prices; for sub-Saharan countries prices are generally lower than the prices charged for CIS countries.

4.5 Purchasing volumes

It is common practice among suppliers to charge different prices for different quantities: in general prices decrease as quantities increase. This is definitely not in the favor of the project in Kyrgyz Republic given the rather low number of patients on ART. It can be assumed that projects from this size, with no foreseen significant scale up pay relatively higher prices than large scale projects.

Pooled procurement is often mentioned as an option for several small projects to achieve better prices by economies of scale. Pooled procurement is purchasing done by one procurement office on behalf of a group of facilities, health systems or countries. This type of purchasing requires considerable efforts from the participating countries in terms of harmonization of legislation regarding registration and QA/QC, patents, treatment guidelines, etc. If it does not function well all group members suffer. Although the prices may be theoretically better the system may not provide the medicines needed in time to provide continuous care to patients.

4.6 Planning

Suppliers tend to charge favorable prices for projects which are able to share reliable information on future needs. It makes their planning easier and therefore they can afford to offer lower prices. In the case of Kyrgyz Republic the procurement planning has been challenging and so far no projections on future needs have been developed.

Besides the unknown future needs, no detailed planning has been developed for future procurement. In principle one order per year is foreseen but so far contracts for one supply only have been signed instead of – probably more favorable – long(er) term agreements.

4.7 Branded versus generic products

The choice for the branded or generic version of ARVs is influenced to a large extent by the QA/QC guidelines from Global Fund and on registration requirements by the NDRA.

Currently Abbott Laboratories, Glaxo Smith Kline and Aurobindo are the main suppliers. Only the latter supplies generics. Since no detailed information is available on which products have been procured from which supplier, it cannot be verified whether the branded products procured are also available and eligible for procurement in generic version.

4.8 Selection procedures

According to the PSM Plan 2004-2006 all purchases above USD 5,000 an open tender should be undertaken. The fact that the PIU did not follow the recommendation of Global Fund to outsource procurement to an international procurement agency acceptable to the Global Fund for the first purchase and the fact that UNDP has observed in some cases non-compliance with procurement standards after review of the documents may lead to the assumption that a non transparent supplier selection process can influence the pricing of products.

5 Global Fund Price Reporting Mechanism

One of the requirements from Global Fund for disbursement of funds is reporting price information of the most important product categories, including ARVs. PRM is a web based tool in which price information must be uploaded, using information contained in invoices, including additional information about the products procured such as dosage, pack size, delivery conditions (Incoterms), registration status, supplier, manufacturer, country of manufacturing, etc. Updated information on received invoices should be reported in PRM by PRs prior to submitting quarterly (or semi-annual) programmatic reports to the Global Fund. The PRM information of all countries is publicly available on the Global Fund website.

WHO also has a web based price monitoring tool, the Global Price Reporting Mechanism (GPRM), that screens and shares prices for ARVs. Currently, the GPRM contains prices of ARVs purchased and supplied by various procuring agencies for different countries, based on information by Unicef, IDA HIV/Aids Group and the Global Fund.

For Kyrgyz Republic, information on only one purchase is available in PRM, namely the first purchase dating from November 2004. According to the PIU one order per year is placed which leads to the assumption that in total four orders have been placed so far.

5.1 First purchase

Information from this purchase, dating from November 2004, is available in PRM. After analysis of the information of the PRM the following inaccuracies and errors were found:

- ✓ Condoms are reported within the category of products of ARVs.
- ✓ Dosages of Nevirapine oral liquid, Lamivudine oral liquid and Zidovudine oral liquid are not properly entered (5 ml should probably be 50mg/5ml or 10mg/ml).
- ✓ There are two different entries for one product (Didanosine 200 mg) with different unit prices.
- ✓ Payment terms are not specified.

No further explanation about this entry in PRM could be given by the current PR procurement staff. The reason expressed was that other staff was responsible for procurement and PRM at the moment of data entry.

Furthermore it is noted that these ARVs, manufactured by MacLeods Pharmaceuticals Ltd. of India, are not WHO prequalified and do also not appear on the “List of ARV Pharmaceutical Products classified according to the Global Fund Quality Assurance Policy for single and limited source pharmaceutical products” even if at that time it was still allowed to procure locally registered pharmaceuticals according to the QA/QC guidelines of Global Fund (e.g., Global Fund policies were complied with).

5.2 Subsequent purchases

Probably three additional purchases have been made. As mentioned above, no details on these purchases were shared by the interviewees. According to the information received from the PIU, as of April 2006 only WHO prequalified ARVs have been procured from 3 manufacturers: Glaxo Smith Kline, Abbott Laboratories and Aurobindo. No supporting documents are available.

The PIU has attempted to enter information relating to later purchases three times, but has not succeeded due to technical problems with the tool. After consultation with Global Fund it has been agreed that the information could be sent to the LFA with a copy to the Portfolio Manager. This information never has, however, been uploaded in the PRM reports on the Global Fund website and the Global Fund should therefore be requested to provide clarity on this issue.

Although detailed information on later purchases has not been obtained, one product list was received during the interview. It contains the planned purchase for Year 4 of the Global Fund project (1 March 2007 – 29 February 2008) but it is not clear if these products have been procured according to the list.

The PIU also confirmed that a new attempt will be made for data entry of the last purchase, which arrived recently in Kyrgyz Republic. If data cannot be entered on the website, the information will be sent again to the LFA and Global Fund Portfolio Manager directly.

5.3 Conclusions

The PIU has reported problems in the use of PRM mainly caused by technical problems making it impossible to save the information entered on the website. Last year, three attempts were made to enter data but without success.

The PIU has not reported any problems in gathering the required information for necessary for data entry in the PRM as all this information is said to be available in one file specifically created for PRM. The PIU has not received any feedback from Global Fund and LFA about the contents and quality of the entry (or entries).

PRM is a quite unique tool able to provide useful information not only for PRs but also for many other stakeholders on pricing of ARVs and other important health products. In general, there is not a lot of information on global pricing of ARVs and the market is not entirely transparent to the average purchaser of ARVs, which justifies the necessity of a tool such as the PRM. However a number of relevant questions remain unaddressed about the accuracy of the data reported. Apparently, PRM is considered to be primarily a requirement that needs to be complied with by PRs without a proper monitoring on the quality of the data reported. This leads to a considerable risk of misinterpretation of data, especially by non-professionals.

The case of Kyrgyz Republic shows that missing reports in PRM can also be misinterpreted; The PR appears to not comply with the reporting requirement whereas the information has been provided to the Global Fund. The Fund, however, never bothered to enter the data into the PRM.

It should be noted as well that the accuracy of data in the PRM can be verified only in part: information on supplier, manufacturers, countries of origin, etc. is available among experts and on the internet. However, part of the data can only be verified with the necessary supporting documents which are not publicly available. Verification of these data should be the role of the LFA.

The LFA, responsible for monitoring the PRs compliance with the PRM requirement, should have specific PSM expertise available to perform this task. It is however not clear to what extent the LFA is monitoring the PRs compliance with the PRM requirement. The PR stated that the LFA has asked several times for reporting but as a consequence of the technical problems of the tool, the lack of reports could be justified.

5.4 Recommendations

- ✓ Improve PRM tool by making it more user friendly (e.g. by simplifying the tool: request only crucial price influencing information) (Global Fund);
- ✓ Reconsider whether the tool should remain a web-based one given the often limited access in receiving countries (Global Fund);
- ✓ Improve monitoring on quality of data entered into PRM (Global Fund and LFA);
- ✓ Provide feedback to PR on entries (Global Fund and LFA);
- ✓ Ensure that all data is reported by PRs (Global Fund and LFA);
- ✓ Ensure that all data reported is made available publicly, especially data about subsequent purchases that have been reported directly to LFA and/or Global Fund (Global Fund and LFA);
- ✓ Improve harmonization with WHO GPRM in order to avoid duplications and/or inaccuracies (Global Fund and WHO).

6 Civil society and procurement & supply management

There is a large number of well organized NGOs active in the fight against HIV/Aids and specifically in the area of harm reduction. The NGOs usually consist of a network of smaller organizations and initiatives, and focus on different vulnerable and most at risk groups such as MSM, CSW and IDU. The majority are based in the capital. Several NGOs receive grants from the Global Fund, directly or through Sub Recipients (SRs).

The Public Health Program of the Soros Foundation Kyrgyzstan provides organizational support to several NGOs mentioned above being SR for the implementation of the grant, mainly focusing on support for IDUs, CSW, MSM and PLWHA, and prevention activities. Public Health program of the Soros Foundation is strengthening the cooperation between the NGOs and different stakeholders in the fight against HIV/Aids in Kyrgyz Republic, such as MOH, PIU/Republican Aids Center, CCM, Republican Narcology Centre, and the Ministry of Justice. Furthermore the Public Health Program Coordinator of the Soros Foundation is in the advisory board of the team which is monitoring the activities of the implementing agencies of the grant.

Civil society has been of major importance to this assessment. Members of NGOs are fully aware of the situation in country related to treatment and access to medicines. During the interviews, however, it has also become clear that some important challenges remain unaddressed in relation to the collaboration amongst three of the main associations active in HIV prevention and harm reduction. This may lead to a decrease of the impact of the activities and a loss of credibility.

The knowledge of procurement and especially the concept of PSM is not widely understood by members of civil society in the Kyrgyz Republic. Access to the appropriate levels of expertise in the field of PSM is imperative if civil society is to make a meaningful contribution to national debates around PSM under Global Fund –financed and other health care interventions.

Recommendations

- ✓ Improve knowledge on PSM related issue to be able to monitor and advocate more effectively;
- ✓ Increase civil society involvement in PSM of the Global Fund grant;
- ✓ Monitor all PSM issues encountered in great detail (e.g., quality, availability, expiries, etc);
- ✓ Make use of the available PSM information (e.g., on the website of Global Fund, Médecins sans Frontières, etc);
- ✓ Harmonize activities of the different NGOs;
- ✓ Appoint one individual or one NGO as PSM Focal Person for all issues related to PSM;
- ✓ Improve relationships with implementing partners.

7 Summary and conclusions

There is a common misconception about procurement that often permeates an entire implementation approach. Namely, that procurement is the same as purchasing and that procurement and supply management, or PSM, is a sort of procurement-plus. Consequently, this misunderstanding almost inevitably results in a fragmented approach that fails to meet the needs of any treatment and care intervention.

Though much more complex than purchasing, say, office furniture and vehicles, purchasing pharmaceuticals is probably the most straightforward particle of the PSM chain. The real challenge in PSM consists of getting the right products at the right prices in the right quantities to the right end-users at the right time of the right quality, and, of course, at the right cost.

In other words, PSM consists of the coordination of all the activities in the chain such as appropriate product selection and choice of manufacturer, accurately forecasting the needs of a diverse and geographically disparate community, ensuring distribution is safe and efficient and that the stock levels are maintained exactly to avoid stock outs, along with data collection and constant assessments of all the above, as well as monitoring and distributing all relevant information to all the appropriate parts of the chain. Successful PSM is the management of all these things and still being able to deal with ancillary issues from patent issues to managing the training of sub-recipients in appropriate use of drugs. Indeed, PSM is an ongoing synergistic process.

In the Kyrgyz Republic it appears to be extremely difficult to obtain clear, reliable and unambiguous information on issues related to HIV/Aids. This seems to be a common experience among persons and organizations, both national and international, active in this area. Some information such as prices paid for pharmaceuticals cannot even be located, even if invoices have in fact been paid for. In many cases the documents posted on the websites of relevant organizations cannot be opened and data provided by individuals is often inconsistent and, therefore, probably unreliable.

The lack of basic information puts severe limitations on the ability to fight HIV/Aids of government officials, physicians, health workers and end-users alike. For example, the unavailability of elementary documents such as general treatment guidelines and an essential medicines list (EML) among all organizations involved in the fight against HIV/Aids make it virtually impossible to implement a basic treatment and care intervention successfully.

Furthermore, there appears to be a lack of information related to purchasing; although some basic data is available, key details are ambiguous or even absent altogether. A number of relevant questions remain unanswered:

- ✓ How many purchases have been made in the course of the project and what was their value?
- ✓ Who are the suppliers and manufacturers of each of the ARVs procured and what were the prices paid per product?
- ✓ Why has the requirement of Global Fund to outsource procurement to a PA not been followed?
- ✓ Are waivers a requirement for the importation of products not registered in-country and, if so, have they been issued by the relevant authorities?
- ✓ What are the procurement guidelines (UNDP, PSM plan, and Global Fund procurement guidelines)?

The high turnover of staff at all departments within the MOH appears to have contributed to the fact that these important questions remain unaddressed. Though not un-common in the Kyrgyz Republic, frequent changes of government officials contribute to an instable and general inefficient project implementation environment.

The legislation in Kyrgyz Republic stipulates that all pharmaceuticals entering the country must be registered. Certain ARVs are however only registered by one or two manufacturers that do not comply with the Global Fund's QA/QC policies. Also, some of the ARVs included in the EML and in the WHO

European Region general treatment guidelines are not registered at all by manufacturers. In case the registration law is applied strictly, and if waivers are or cannot be issued, various key ARVs as listed in the general treatment guidelines cannot be procured.

There is a strong feeling among partners and stakeholders that the roles and responsibilities of the local Global Fund entities (e.g., PR, CCM) are not properly identified. For example, the MOH has considerably more control over the current than in the former CCM. And because the MOH is also PR, this can lead to conflicts of interest and insufficient control and monitoring of the PR's performance. Furthermore, the role of the LFA does not appear to be entirely transparent. Many interviewees noted with regret that the LFA is insufficiently visible.

One particularly weak link in the PSM chain is rational use. Severe problems related to enrolment and adherence have been observed, mainly caused by:

- ✓ Lack of basic information on the epidemic among the general population, including most at risk groups;
- ✓ Poor health services due to lack of motivation, information, skills and experience of medical staff;
- ✓ Large number of patients belonging to mobile population;
- ✓ Lack of additional support to patients, such as social, psychological and financial support;
- ✓ Complications in treatment due to other severe (opportunistic) infections such as TB and hepatitis C.

Civil society is very active and eager to participate in the fight against HIV/Aids. However, the limited level of knowledge of issues related to PSM and the unavailability of crucial data make it challenging to make a constructive contribution to the effectiveness of the PSM operations and monitor the performance of implementing partners. Furthermore, the impact seems to be limited due to distrust and ongoing conflicts among the three of the main associations active in HIV prevention and harm reduction.

Out of the estimated four purchases for ARVs, only one, the first one, has been added to the PRM at the Global Fund website. The PRM information of at least one of the later purchases has been sent directly to the Global Fund Portfolio Manager since the PIU experienced technical problems with the use of this web-based tool. At the time of writing, this information has not been uploaded in the PRM database and is therefore not publicly available. It therefore appears as if the PR is not complying with the reporting requirement whereas the information has indeed been provided to the Global Fund. There may be special arrangements between the PR, LFA and Global Fund related to the PRM requirement but no details were provided to us.

8 Summary of PSM recommendations

8.1 Product selection

- ✓ Follow up on approval and implementation of general treatment guidelines (Republican Aids Center, civil society);
- ✓ Improve data collection needed for proper product selection (Republican Aids Center, PIU);
- ✓ Wide and proper distribution of EML and general treatment guidelines (both for HIV/Aids and ST) (Republican Aids Center);
- ✓ Investigate the situation on TRIPS for ARV (PIU, civil society);

8.2 Forecasting

- ✓ Regular coordination meetings with partners involved (PIU, civil society, donors);
- ✓ Gradually switch to a more frequent forecasting and adjust purchases accordingly (Republican Aids Center, PIU);
- ✓ Active involvement of the PIU in forecasting (Republican Aids Center, PIU);

8.3 Procurement

- ✓ Share public information on procurement regularly with stakeholders (PIU);
- ✓ Involvement of (PSM-trained) civil society members in the procurement process (PIU, civil society);
- ✓ Training of PIU staff on pharmaceutical procurement (PIU, LFA, Global Fund);
- ✓ Ensure full compliance with Global Fund requirements (PIU, LFA, Global Fund);
- ✓ Ensure full compliance with national legislation (on registration) (PIU, LFA, Global Fund);

8.4 Quality assurance and quality control

- ✓ Ensure a waiver is obtained for methadone and WHO pre-qualified (but not-registered) ARVs (PIU);
- ✓ Review registration law to enable an accelerated and simplified registration for WHO pre-qualified pharmaceuticals (MOH, civil society);

8.5 Inventory management

- ✓ Start preparations for implementation of MIS on national level (PIU, Republican Aids Center);
- ✓ Develop procedures for emergency orders (needed in case of outbreaks or other unforeseen situations) (PIU);
- ✓ Assess drug management systems and storage conditions in regional warehouses (PIU, Republican Aids Center);

8.6 Ensuring rational use

- ✓ Improve information and support for patients (Republican Aids Center, civil society);
- ✓ Train medical staff at all levels on general aspects of HIV/Aids (Republican Aids Center);
- ✓ Train medical staff on prescription and care of HIV/Aids patients (Republican Aids Center);
- ✓ Improve quality and access to VCT (Republican Aids Center).

9 Other considerations

In addition to the recommendations above, we have also come up with a number of overarching recommendations, which are all (in-)directly related to PSM

9.1 Transparency

At present there is considerable criticism of the procurement activities of the PIU. Whilst products do arrive at the treatment centers, it remains unclear for partners and stakeholders which products are procured, when these are procured, from whom these are procured and how these are procured. It might be that (part of) the critics are based on speculations and guessing rather than on facts and figures but that does not change the fact that there are widespread discussions and common rumors on procurement and the PIU in general.

This can be avoided by making the procurement activities of the PIU more transparent. More transparency could be created by presenting the obtained results of the project to CCM and other partners and stakeholders after submission of the quarterly (or semi-annual) report to Global Fund. Apart from information sharing this may lead to a sense of joint ownership of the project.

Furthermore, the involvement of civil society members in PSM activities can, if properly organized and supported by both the PIU and the civil society members, contribute to more openness. The Global Fund implementing partners should examine options for involvement of civil society in order to find the best strategy for this particular project. Among the options are:

- ✓ Establishment of committees for product selection and quantification, and selection of the supplier (evaluation of the bids)
- ✓ Organization of monthly meetings on PSM
- ✓ Comprehensive trainings on the PSM

In general the involvement of civil society members in the procurement process of the PIU will likely lead to a better understanding of the challenging PSM operation. The general misunderstanding that procurement is 'just buying products' will probably disappear quickly.

9.2 Roles and responsibilities

Among all partners and stakeholders several misunderstandings and general uncertainty exist about the roles and responsibilities and more specifically the separation of roles and responsibilities between the different local Global Fund entities. It is recommended to clarify these issues by indicating clearly the roles and responsibilities of each entity. The most appropriate partner for this case would be the Global Fund Portfolio Manager given his impartiality. Indeed this is also an opportunity to clarify other issues related to the project in general.

9.3 Improve general awareness on HIV/Aids

Persons and organizations involved in the fight against HIV/Aids – ranging from local health care providers to vulnerable groups - need to be informed properly and regularly in order to implement the appropriate and necessary activities. It will also help to understand the epidemic better, strengthen commitment, and increase the sense of ownership of the problem and the project.

9.4 Sustainability of the HIV/Aids program

The government budget for the fight against HIV/Aids is very limited. It seems that the MOH relies to a large extent on the existence and continuation of Global Fund grants. It is recommended to start the

development of an appropriate phase out strategy in the near future. Lessons learned from post-Global Fund countries show lengthy and complicated transition periods. Furthermore the Global Fund grants have ceiling amounts and serve as an additional fund to national budgets.

9.5 Strengthening of the PSM capacity of the PIU

A common misunderstanding among staff of health projects is that a purchasing officer is the appropriate person to lead the PSM operation whereas in fact, indeed, procurement is part of PSM but for a proper execution of this complex operation it would be extremely useful and efficient to have a dedicated person available at PR level with a helicopter view on PSM rather than purely a procurement expert.

At present the different steps of the chain are divided among different organizations and departments, in other words, the chain is cut many times and every cut causes a certain delay and reasonable risk of proper continuation of the activities.

The PIU focused on procurement rather than on PSM. It is strongly recommended to strengthen the PSM capacity, including the purchasing component.

9.6 Cooperation with the Clinton Foundation HIV/Aids Initiative (CHAI) for the Osh cohort

CHAIs mission is to work with governments and other partners to increase the availability of high-quality HIV/Aids care and treatment for people in need. Since a few years CHAI focuses on programs for pediatrics. Their support can be particularly useful for the cohort in Osh.

9.7 Implementation of integrated care

No systematic collaborative activities between the different programs of MOH are in place at the moment. Among PLWHA a considerable number is IDU. Around 550 IDUs are currently on ST. A large number of PLWHA also suffer from opportunistic infection such as TB. PLWHA on treatment of both ARVs and methadone and/or TB end up at visiting two to three different centers for their treatment and care which is a close to impossible task for the patients. The different centers do not dispose of or do not share the relevant clinical data on patients. A system of integrated care would be a benefit for both patients and health care workers. This definitely also will lead to better adherence of the different treatments and to a decrease in costs.

10 Documents and websites reviewed

Most data used in this report was gathered through stakeholder interviews. Nevertheless, a number of key documents and websites have been reviewed:

- ✓ PSM Plan 2004-2006
- ✓ Original Country Proposal Round 2
- ✓ Original Country Proposal Round 7
- ✓ Grant Agreement Round 2
- ✓ Amended Grant Agreement Phase II Round 2
- ✓ Grant Performance Report Round 2
- ✓ Grant Score Card Round 2
- ✓ Treatment Protocol WHO European Region
- ✓ National Essential Medicines List
- ✓ Main findings of the research on 'Community involvement for improved procurement, supply and pricing of Antiretroviral and Opioid Substitution medicines' executed by civil society in Kyrgyz Republic
- ✓ Website Kyrgyz Patent
- ✓ Website Drug Control Agency
- ✓ Updated list of registered products dated 20 February 2008
- ✓ General treatment guidelines for ST
- ✓ PRM at Global Fund website
- ✓ GPRM at WHO website

11 List of interviewees

For this assessment the following persons have been interviewed:

- ✓ Ruslan Tokubaev, Director - Republican Centre of Addictions, MOH
- ✓ Rustam A. Kurmanov, General Director - Department of Drug Provision and Medical Equipment, MOH
- ✓ Dr Anara A. Salamatova, National Programme Officer - UNAIDS
- ✓ Talgat K. Subanbaev, Program Manager - Project Implementation Unit GFATM
- ✓ Raimberdi Yrysov, Assistant to the Procurement Manager - Project Implementation Unit GFATM
- ✓ Erkin Tostokov, doctor-pediatrician - Republican Aids Center
- ✓ Saliya Karymbaeva, Country Programme Coordinator for STIs/HIV/AIDS - WHO
- ✓ Kuban Mambetkulov, Procurement Officer - UNDP
- ✓ Beishekeev Nurlan Asanakunovich, Head of Department of Legal Circulation of Drugs and Drug Abuse Prevention - Drug Control Agency of Kyrgyz Republic
- ✓ Muratalina Asel Melisovna, Senior Inspector - Drug Control Agency of Kyrgyz Republic
- ✓ Abdylgaziev Azizbek Duishekeevich, Main Inspector - Drug Control Agency of Kyrgyz Republic
- ✓ Larisa Bashmakova, National Expert on HIV/AIDS
- ✓ Aisuluu Bolotbaeva, Public Health Programs' Coordinator - Soros Foundation Kyrgyzstan
- ✓ Madina Tokombaeva, Director - NGO “Ranar”
- ✓ Irene Ermolaeva, Director - NGO “Asteria”
- ✓ Naila Tashbulatova, Country Coordinator - Health Action International – Kyrgyzstan office)
- ✓ Batma Estebesova, Director - Harm Reduction Association “Partner’s Network”
- ✓ Gulnara Kurmanova, Director - Association of AIDS Service Organizations
- ✓ Marat Djamankulov, Head Department of the Reforming Criminal Execution System - Ministry of Justice
- ✓ Alimjan Koshmuratov, Head of Department - MOH