Strengthening pharmaceutical systems through transparency and accountability: the MeTA Kyrgyzstan framework

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List of Abbreviations

ADP	Additional Drug Package Program (under MHIF)
DRA	Department on Drug Supply and Medical Equipment (Drug Regulatory Authority)
EDL	Essential Drug List
KGS	Kyrgyz Soms (currency; 100.00 KGS = 1.69652 GBP)
MHIF	Kyrgyz Mandatory Health Insurance Fund
MOH	Ministry of Health
SGP	State Guarantee Program

Executive summary

Following initial expression of interest from the Ministry of Health (MOH) and the Mandatory Health Insurance Fund (MHIF), a scoping visit to explore potential for a MeTA pilot in Kyrgyzstan was carried out from July 2–6, 2007, by Brenda Waning (Boston University) and Cheryl Cashin (University of California at Berkeley), accompanied by Peter Stephens (IMS), and Aziz Jafarov (USAID/ZdravPlus Program). The scoping mission was conducted on behalf of MeTA, with the support of the DFID Kyrgyzstan country office, in coordination with the MOH and MHIF (Mandatory Health Insurance Fund). While widespread interest was expressed from stakeholders in the pharmaceutical sector, there was no official decision by the previous MOH to approve Kyrgyzstan as a pilot MeTA country.

Since that time, a new Minister of Health has been appointed. A next visit to the Kyrgyz Republic was carried out from February 25-29, 2008, with the support of the DFID Kyrgyzstan country office, in coordination with the Ministry of Health (MOH) and the Mandatory Health Insurance Fund. The purpose of the mission was to continue discussions about the feasibility of Kyrgyzstan serving as a pilot country and to meet with the new MOH to ascertain his level of interest in supporting MeTA in country. The visit provided an opportunity to further discuss with stakeholders the potential of Kyrgyzstan participating in MeTA as a pilot country.

The current Minister of Health (MOH) granted official approval for Kyrgyzstan to participate in MeTA as a pilot country; he expressed particular concern about high medicine prices and affordability of medicines. He noted that despite removal of Value Added Tax on medicines, prices did not change and competition decreased. He also expressed concern about limited physical access to medicines in rural areas.

The National MeTA Secretariat was hired in November 2008, who, in their turn, initiated establishment of National MeTA Council composed of representatives from government, private and civil sectors. (see Appendix 1).

From January – February 2009 National MeTA Secretariat and MeTA Council developed a draft National Plan of Action for 2009-2010 representing set of priority activities identified jointly with stakeholders represented in the Council that will be executed within existing means. This work plan is focused on three principal issues which they decided are of imperative importance in drug provision sphere in the Kyrgyz Republic and include the following:

1) **strengthening the pharmaceutical system** to improving access to essential medicines through transparency and accountability by
    a. **developing transparency instruments** in regulatory practice and
    b. ensuring easy **access to information** on drugs circulating in pharmaceutical market of the Kyrgyz Republic;
2) assessing of situation concerning
    a. **quality** of drugs currently available in the market;
    b. **access** to state privileges to certain groups of populations, and
    c. existing legislation base concerning transparency and accountability in pharmaceutical market, and
3) designing and carrying out a **campaign** on rising awareness on drug related health issues among the population with focus on substandard quality and counterfeit medicines to be avoided.

Obviously, there are many more issues to be resolved with regards to ensuring better access to essential medicines, like high prices and affordability of drugs and treatment, lack of accessibility and availability to medicines, especially in rural areas, rational drug use and use of generics, adverse reaction monitoring, public procurement system and improvement of supply chain, corruption and ethical issues,

and appropriate and patient-friendly practice in pharmacies and so on, but those three have been identified as the priorities to start with having considered them as the base to further build a transparent and accountable drug supply system layered onto regulatory analyses and survey findings with the aim of improving access, quality and rational use, especially for low income people. It aims to do this by working with all stakeholders – public, private and non-governmental – to encourage wider disclosure of information relevant to pricing, quality and availability of essential medicines, and to place particular emphasis on engagement with civil society and the private sector.

Introduction

Pharmaceuticals play a crucial role in saving lives, restoring health and preventing diseases. By complementing other types of healthcare services they can reduce morbidity and mortality rates and enhance quality of life. Therefore, access to pharmaceuticals is increasingly being viewed as a fundamental human right.

The ability of pharmaceuticals to save lives, reduce suffering and improve health depends on their being of good quality, safe, available, affordable and properly used.
Yet in many countries these conditions are far from being met. Lack of access to good quality essential medicines is a major problem worldwide. A number of factors contribute to these challenges including poverty, corruption, market failures, government failures and the existence of unreliable and weak pharmaceutical regulatory and supply systems. The latter often results, at least in part, from a **lack of transparency** in the pharmaceutical systems. Transparent and institutionally strong pharmaceutical systems can contribute towards improving access of the population to good quality pharmaceuticals. [1]

[1] Technical guideline: Improving Transparency in Pharmaceutical Systems

History and situational analyses

Considerable social-economical changes, taking place since 1990, substantially influenced healthcare system in Kyrgyzstan, as well as pharmaceutical sector. After the Kyrgyz Republic stepped into market economy with the goal to improve drug provision for the population, the pharmaceutical sector has been fully privatized. In 1998 there was approved the first National Drug Policy aimed at improving of health through better access to safe, effective and quality drugs, which are at the same time affordable, and controlling of rational drug use. The current national drug policy, which is consistent with tasks put in the National Health Care Reform Program "Manas Taalimi", was adopted in 2007.

Citation from the National Drug Policy: The Department on Medicine Supply and Medical Equipment under the Ministry of Health of the Kyrgyz Republic (DRA) oversees dynamics over price changes with the purpose to work out flexible price regulating policy through improvement of taxation mechanism.

It has been implemented indirect regulation of prices, and drug out-of-pocket expenditures of the population have been decreasing. The basic prices for medicines reimbursed within the Additional Drug Package Program (MHIF) and State Benefit Program on providing the citizens of the Kyrgyz Republic with healthcare services, are reviewed on regular basis.

With the purpose to effective and safe use of medicines, as well as to ensure transparency, the medical and pharmaceutical workers and population are provided with reliable and objective information on medicines.

It is anticipated to develop a data base accessible to population which includes the following information:

- on rejected and falsified drugs;
- on monitoring results concerning to side effects of the medicines;
- on medicines with instruction on how to use them;
- on nonprescription / over-the-counter drugs;
- on normative documents regulating pharmaceutical business.

In 2007 Kyrgyzstan imported drugs with a value of 1 595 357 884 KGS (about 40m USD). Imports in 2006 were 45% higher than in 2005. There are currently 3548 registered medicines in Kyrgyzstan (Pharmacopoeia committee 2008).

In connection with growth of drugs import, issues related to quality control of drugs have become of vital importance in Kyrgyzstan. Unfortunately, in spite of measures undertaken by the drug inspection unit of the DRA, the existence in the pharmaceutical market of falsified and smuggled medicines remains very critical. It is estimated that about **30% of all medicines** currently available in the country are **smuggled**.

Citation for National DRA report of 2008: It was withdrawn 1231 drugs in a value of 251280 KGS ($US 7170), including those destroyed in a value of 206809 KGS ($US 5908), as the result of 109 spot checks of markets in Bishkek conducted jointly with other authorities (customs, Ministry of Internal Affairs etc.).

Following the Code of the Kyrgyz Republic on Administrative Responsibility 24 administrative sanctions were imposed in a value of 73500 KGS ($US 2100), including 11 for carrying the pharmaceutical business without pharmaceutical education and 13 for absence of resolving documents.

The South DRA Affiliate jointly with the customs "South", Police Departments of Osh, Batken and Jalalabat oblasts inspected 164 juridical and physical persons running the pharmaceutical business, and conducted 21 spot checks to eliminate street traders, that led to liquidation of medicines in a value of 54112 KGS ($US 1546).

According to a WHO survey on quality of drugs in the pharmaceutical sector conducted in 2007, about 70% of drugs are of "unknown" quality (manufactured in CIS countries and in Asia) and there is a wider range of products available in the retail pharmacies than listed in the official wholesale network, which means that there is still an illegal market present in the country.[2]

The WHO survey states *"The quality control system currently existing in Kyrgyzstan cannot guarantee the quality of medicines. There were NO rejections based on quality control (QC) results in the registration process between 2007 and March 2008.* [3] *However, all batches of imported medicines were laboratory tested. A total 5730 tests were performed during 2007. There were 36 rejections during the period of 2007-March 2008. 34 of those were due to medicines, which belong to quality level 3 ("unknown quality"- manufactured in CIS countries and/or in Asia). 12 of these rejections (33.3%) were due to medicines of the same manufacturer from one of CAR countries. However, no measures have been considered by DRA regarding withdraw of license of this manufacturer. In general, during period of 2005-March 2008 no license was rejected or withdrawn based on quality testing."* [4]

On the base of the WHO review and recommendations the DRA developed a Plan of Corrective Measures to be implemented within several years with regards to regulation of registration and certification of the medicines, licensing of pharmaceutical business, inspections, as well as performance of DRA itself, including personnel policy. To realize the Plan of Corrective Measures the large scope of work on reviewing and changing of legal basis regulating the pharmaceutical sector needs to be performed. According to the WHO recommendations it is necessary to develop a DRA website (technically independent of Ministry of Health) to ensure transparency and accessibility of information on medicines and keep the information related to regulating of drugs updated.

There is also no system for supervising and monitoring of drug procurement by hospitals and there is no mechanism which allows tracking each medicine in the reimbursement system.

[2] Quality of medicines within the public sector drug procurement system in the Republic of Kyrgyzstan, WHO, 2008

[3] Quality of medicines within the public sector drug procurement system in the Republic of Kyrgyzstan, WHO, 2008

[4] Quality of medicines within the public sector drug procurement system in the Republic of Kyrgyzstan, WHO, 2008

The elements of quality assurance system (registration, licensing, inspection and quality control) are not adequately coordinated and transparent, to promote and guarantee quality of pharmaceuticals presented by the market.

Since 1990 the pharmaceutical sector has been fully privatized, which was confirmed in 2000 by changes in the medicines legislation. On 01.01.2007 2382 pharmaceutical entities are operating in the market: 888 pharmacies, 823 pharmaceutical points, 11 hospital pharmacies, 300 pharmaceutical kiosks, 49 optical shops and medical equipment, 259 wholesale storehouses, and 53 local manufacturers.

The Ministry of Health has developed a significant legislative and regulative base that emphasizes the use of generics. An essential drugs list was developed in 1996 and revised again in 1998, 2000, 2003 and 2006. An essential drugs formulary has been developed and distributed to health facilities.

Legislation forms the foundation of pharmaceutical systems. It provides the pharmaceutical systems the power and authority to carry out its mandates. Legislation should define clearly the scope of the pharmaceutical systems; areas and activities to be carried out; the roles, responsibilities and rights of all those governed by the legislation. It should establish the administrative structure and set standards to be used in operating the pharmaceutical systems.

But nowadays the situation in pharmaceutical market has been changed and current legislation in Kyrgyzstan requires analyses to be conducted to match those changes and make them consistent with current environment. The principal law regulating the pharmaceutical sector in Kyrgyzstan is the “Drug Law” adopted by Parliament in 2003. This law regulates the development, manufacturing, registration and quality control of drugs, and defines rights and responsibilities of subjects operating in pharmaceutical market with regards to activities they conduct. The “Licensing Law” of 1997 regulates state licensing of pharmaceutical business, but it is no longer consistent with contemporary requirements and further development of pharmaceutical market. Consequently, the medicines legislation needs to be reviewed to insert adequate and appropriate changes regarding regulations in the pharmaceutical market.

In fact, a review of the legislation may be more difficult due to the liberalization being introduced by the government to promote entrepreneur activities and to reduce state intervention of business.

MeTA in the Kyrgyz Republic will have a focus on reviewing the regulatory base in the pharmaceutical sector and working out recommendations with the purpose to optimize and eliminate contradictions in existing legislation related to pharmaceuticals, and to promote and introduce transparency principles in healthcare system in general. The expected results include absence of conflicts regarding to regulation of medicines and better access to information necessary for all stakeholders. Legislation shall be developed in consultation with stakeholders, printed and made widely and easily accessible to all stakeholders and interested parties. Involvement of stakeholders and interested parties in the formulation of the legislation and regulations will enable them to know their rights and obligations and demand for justice when provisions of the legislation and regulations are not properly implemented. It will in turn facilitate implementation of the provisions of the legislation and the regulations since they have been formulated with the full participation of the stakeholders.

In accordance with the strategy on improvement the country investing environment and supporting of entrepreneurship to eliminate business barriers announced by the President of the Kyrgyz Republic and currently being implemented, all the ministries and authorities since January 2009 have been performing analysis of influence of current legislation on business development. In the light of this strategy the goal was set up to study and eliminate contradictions in the legislation which interfere with the business performances. The Ministry of Health as a pilot organ was the first who conducted such analysis. The DRA also conducted the analyses in pharmaceutical sector about what is the regulative influence of authorizing documents, including certificate on state registration, license, compliance certificate, attestative pharmacist's certificate and the attestative pharmaceutical premise compliance certificate.

Drug regulatory structures in the Kyrgyz Republic are designed in such a way that there is a central coordinating drug regulatory body (Department on Drug Supply and Medical Equipment) with overall responsibility and accountability for all aspects of drug regulation for the entire country.

While drug laws provide the basis for drug regulation, the regulatory authority does not provide for public, transparent standard procedures for registration, guidelines and checklists for inspection. The absence of regulatory tools leads to variations in the implementation of the law, or even to questions about the transparency of law enforcement.

Thus, these tools should then be made publicly available to all the parties involved in order to bring transparency to the drug regulatory process.

Thus, there is interest in establishing a centralized web portal/posting of medicines information, including registered medicines, medicines policies, quality certificates awarded, prices, price comparison across brand and generic versions of medicines within a therapeutic category, etc. This mechanism for disclosing pharmaceutical market information and making it accessible to all stakeholders would provide a valuable tool for improving procurement by public hospitals, reducing search costs for individuals buying drugs through private pharmacies, and monitoring the market effects of government regulations and interventions.[5]

Effective drug regulation is required to ensure the safety, efficacy and quality of drugs, as well as the accuracy and appropriateness of the drug information available to the public. Several areas in drug regulation currently receive relatively little attention in the implementation process. Counterfeit products and products of dubious quality and faulty information (especially efficacy claims) are often found, especially in remote areas. That is why problems related to the safety and quality of drugs still exist in the country. Monitoring of the accuracy and appropriateness of information is generally inadequate, and the effectiveness of existing systems of regulation is unknown.

Drug information should be distributed as widely as drug products themselves. Promoting rational use of medicines by prescribers and consumers can generate health gains and financial savings. Drug information received by both the consumers and the providers of medicines would have a significant influence on rational drug use.

[5] Medicines Transparency Alliance: Kyrgyzstan mission report, March 2008

Consequently, the regulatory process should be routinely and systematically monitored in order to identify problems in the process and determine whether the activities actually carried out are consistent with the intended course of action.

The Kyrgyz MeTA Strategic Plan

The overall goal is to strengthen pharmaceutical system through transparency and accountability.

During first one and half year it focuses on key government structures at the national level to create within the current health system transparency and accountability to work, with active participation of civil and private sectors with the end in view that it shall result into improved decision making processes and reforms in the pharmaceutical sector.

The key activities that are indicated here are those that would primarily respond to the key national challenges and the areas which would need adequate and sustainable support.

Key strategies and activities

I. Developing **transparency** instruments in regulatory practice and ensuring easy **access to information** on drugs circulating in pharmaceutical market of the Kyrgyz Republic.
II. Research and assessment of the **quality** of drugs currently available in the market; **access** to state privileges to certain groups of populations, and existing **legislation** concerning transparency and accountability in pharmaceutical market.
III. Raising **awareness** among the population on health issues and increase responsibility of their own health protection

Developing transparency instruments and access to information

I. Developing transparency instruments in regulatory practice and ensuring easy access to information on drugs circulating in pharmaceutical market of the Kyrgyz Republic.

This would include improvement of transparency within regulatory functions of Drug Regulation Department through creation of website and development of drug information system allowing regular updates and maintenance of data related to various aspects of pharmaceutical marketing; collection and analysis of reliable data; and development of transparent and feed back mechanism along the registration, selection and procurement systems.

Development and maintenance of Kyrgyz DRA website, includes the following objectives:

1) Develop basic reference normative indicators on the base of unified codifying system that will allow sorting out, tracking and analyzing data coming from various sources.
2) Develop information systems to systematize and optimize decision making process and state regulatory activity on the base of integrated and comprehensive drug related information including:
    - Registration of drugs,
    - Licensing of pharmaceutical activities,

- Certification of imported drugs ,
- State inspections,
- Automating of drug accountability procedures,
- Monitoring and assessment of drug consumption,
- Monitoring of drug supply and procurement at hospital level,
- Price monitoring,
- Analysis of information for decision making process.

3) Create websites within DRA easy accessible to the stakeholders and general public.

4) Create a website for the MeTA project in the Kyrgyz Republic to share knowledge and information effectively with the purpose to strengthen understanding of MeTA principles and approaches among stakeholders and external audience. The MeTA website is currently being developed. It shall serve also as the main information system for the activities of MeTA in Kyrgyzstan, and would be a source for data, research and assessments carried out in the Kyrgyz Republic.

Research and assessment

II. **Research and assessment**.

The research priorities identified are:

1. Drug Quality Survey.

Drug quality ID will be assessed by testing purchased samples of pharmaceuticals using mini-lab kits. The survey will be aimed at determining quality of generic drugs, and consequently the reasonableness of substitution of brand products by generics. An additional list of medicines for testing could be defined during the survey, based on "suspicious" results of analyses of prices (when retail price appeared to be cheaper then the wholesale price).

It is proposed to buy 2 mini-labs and cover two regions of the country (GPHF-Minilab®) and train people to carry out the tests on regular basis. It is anticipated to have an external consultant to conduct training on GPHF-Minilab®) test.
The survey will cover 2 regions of the country and be implemented in parallel with another survey to be conducted by HPAP/DFID/WHO aimed on investigation of factors influencing use of generics.

The policy of using generics has been implemented at all levels of healthcare system in the frame of the Rational Drug Use Conception adopted in Kyrgyzstan in 1996. It is encouraged to practice the generic and therapeutic substitution while prescribing and dispensing of the drugs to population (citation form NDP, paragraph on rational Drug Use 2).

The practice to prescribe the drugs using generic names was also introduced within the MHIF reimbursement system "Provision with drugs of ensured citizens on outpatient level" and "Beneficial drug provision through the State Guarantee Program".

Introducing the generic strategy contributes a lot to the reforms aimed at improvement of drug procurement, extension of drug assortment, decreasing of medical treatment expenditures and increasing access to essential medicines.

On the whole, the drug market in Kyrgyzstan is represented mostly by generic medicines. At the same time price difference between generic/generic and brand/generic in

most cases is rather high. All this causes distrust to the quality of cheaper drugs among health providers and patients and undermines the policy of using the generic drugs.

The conduction of such a survey was preliminary discussed with HPAP/DFID/WHO (Mellita Jakab) in the context of MeTA National Work Plan. Subsequently HPAP/DFID/WHO suggested carrying out the drug quality survey independently. This was discussed with MHIF (the principal customer) and the Kyrgyz MeTA Secretariat. It was also discussed a question on conduction of parallel drug quality studies by MeTA project in the same oblasts. It is anticipated that in this case both surveys could be able to give more reliable estimate of the situation in this sphere.

The expected results include working out of recommendations to submit for consideration and insertion into regulatory tools related to registration and certification of drugs and requirements to drug quality. Pharmacies, participating in the reimbursement scheme, should be advised to choose medicines of proven quality in their procurement. This should be promoted through information on survey findings available through MeTA or/and DRA websites.

Usage of mini-labs will allow assessing drug quality and revealing falsified drugs. The findings of the survey will also serve as a base for public campaign against falsified drugs.

2. Survey on accessibility of State Guarantees Programs.

This survey will focus on assessment of drug affordability through the State Guarantees Program, its impact on health statistics and individual expenditures and health of particular group of patients such as with psychic disorders and asthma.

Since 2006 the basic psychotropic drugs were included in the List of drugs of the State Guarantee program. Following the budget assessment for psychiatry sphere carried out in 2007-2008 it was concluded that this step was exceptionally effective. But, it also revealed that while some regions effectively master the drug package to benefit the patients, other regions for unexplained reasons do not use the funds available at primary healthcare level. In Chu region, for example, the rate of suicides is highest in the country.[6] But, suicide rate directly relating to quality of psychic health means that need in mental health services, including demand for psychotropic medicines, is very high particularly in Chu region. Though, surprisingly, disbursement of funds there is low.

Thus, investigation of factors laid upon such a situation requires purposeful analyses with regards to assessment of prevalence of mental disorders, reasons of avoidance to prescribe psychic drugs which could be caused probably by bias to mental disorders and necessary clinical skills. Lack of professional cadres to promote protection of mental health, absence of indicators and negligence of medical statistics with this regard, as well as weak accountability concerning treatment of such disorders, could also lead to low motivation in using of psychotropic drug package.

So, study of reasons of low disbursements of funds in some selected regions is required and this would lead to better access to psychotropic drugs among patients with mental disorders.

[6] Suicidal and homicidal trends in the Kyrgyz Republic, “Reforms” series, 2000, Bishkek

Nowadays diseases of respiratory tracts are on the first place on morbidity lists and the second on mortality lists. One of the serious diseases is bronchial asthma. About 10,000 patients suffer from asthma and every year this number has been increasing.

It is worth to note, that the Kyrgyz-Finn Lung Health Program (2003 -2009) does its best with this regards. Currently they are introducing training for pharmacists where they receive updated information on appropriate medicines to treat asthma and privileges provided through the State Benefit Program. In addition it revised and updated some clinical protocols which are now in the process of approval at the national level. On the base of the protocols a number of drugs for asthma were included into EDL, and SGP, and Additional Package Program under MHIF.

But, still the situation with treatment of asthma is complicated. One of the reasons is inappropriate treatment caused by low access to inhalation drugs for asthma due to lack of transparency in privileged drug provision system, particularly in rural areas. Consequently prescription of such asthma drugs did not become regular and mandatory, creating inequality between patients residing in cities and rural areas.

The survey shall focus on the ways to improve transparency and fair access to asthma drugs in the Kyrgyz Republic.

a. Regulatory analysis with regard to transparency and accountability.

In order to understand the pharmaceutical market structure as it relates to issues around medicine price, availability and quality, it is necessary to analyze the regulatory framework, both within and beyond the health sector, under which the pharmaceutical market is operating. An analysis is needed to determine whether the current regulatory framework is appropriate or can be improved to obtain better market outcomes. For example, it was noted that the procurement of drugs in public hospitals is largely governed in the country by the regulations of the State Agency for Procurement, which are at least perceived to limit the use of quality criteria in the hospital drug tender process. Strengthening the role of the Ministry of Health in establishing tender criteria, including pre-qualification of products and/or suppliers, may emerge as an appropriate intervention based on the regulatory analysis.

Thus, the survey will have a focus on conduction of analyses of regulatory base in pharmaceutical sector and working out recommendations with the purpose to optimize and eliminate contradictions in existing legislation related to pharmaceuticals and promote and introduce transparency principles in healthcare system in general. The expected results include absence of conflicts regarding to regulation of medicines and better access to information necessary for all stakeholders.

This might entail developing an appropriate policy or regulatory response in order to improve market or health systems efficiencies, strengthen health sector governance or facilitate responsible business practices.

Further measures could include not only quality testing but also contacting other medicines agencies and effort to retrieve as much information about these manufacturers/medicines as possible.

Raising awareness

III. Raising awareness among the population on health issues and increase responsibility of their own health protection.

The objective of this activity is to launch a campaign to raise awareness about the dangers of counterfeit and substandard medicines.

There are legitimate health concerns pertaining to quality, safety and efficacy of medicines as there are problems concerning products with wrong information on the label with regard to the content, date of manufacture, place of manufacture, date of expiry (known as false labelling), products which on the contrary to the label contain no active ingredient or a wrong active ingredient or an insufficient amount of active ingredient (known as spurious drugs) and low-quality drugs caused by poor manufacturing practices, poor transportation techniques or poor storage facilities (substandard drugs).

In February 2009 one of the parliamentarians (member of "Ak-Jol" fraction) requested Mr. Kurmanov (DRA) to make a statement on TV letting people know that pharmaceuticals without appropriate labels and inserts on proper usage are substandard. According to his appeal, it is necessary to tell people not to buy counterfeits; he said in particular "Nowadays there is a flux of medicines coming to the country from which many are of bad quality. We have to stop this flow to store the gene pool of our nation". [7]

Concerns about the quality of available drugs are pervasive. The use of toxic, substandard and counterfeit drugs is not only a waste of money, but may also threaten the health and lives of those who take them. Unlicensed manufacturers, importers, wholesalers, retailers and even persons engaged in the pharmaceutical business pose difficult challenges to drug regulation.

The campaign will focus on a number of basic issues such as:

- Education for consumers about counterfeit and substandard medicines.
- Education about health rights and the need to combat discrimination against the rights of patients, including access to health care and treatment
- Ensuring availability and accessibility of independent, objective sources of advice and information for people and those responsible for their health and care.
- Development and support of mechanisms for regulating pharmaceutical quality, promotion and prescribing.
- Mechanisms for regulating media reporting and advertising of health-related products.
- Development of local and national consumer representation to ensure that measures are taken to protect health rights prevent harm and ensure consumer-friendly policy-making.

[7] http://www.akipress.org

Working plan of MeTA project for 2009 -2010

IMPLEMENTATION 2009 -2010						
GOAL I: Develop transparency instruments in regulatory practice and Ensure easy access to information on drugs in pharmaceutical market of the Kyrgyz Republic to enable transparent and accountable practice.						
Objective	**Specific objective**	**Activity**	**Expected results**	**Time line**	**Expected outcomes**	**Responsibility of**
A. Kyrgyz DRA should develop up-to date drug information system and a web site which should be regularly updated with all regulatory information to enable a transparent regulatory practice.	1. Develop integral and comprehensive drug information system, and work out coordinated and integrated national strategy on development and maintenance such a drug information system that allow regular update and maintenance of relevant drug related data and keep it open to public. 2. Develop basic reference normative indicators on the base of unified codifying system that will allow sorting out, tracking and	1. Workshop to define basic topics/ drug related issues to be transparent for public 2. Organize Tender among providers to develop a WEB-site with a purpose to make transparent all issues related to drug provision, and development of user friendly soft ware to get easier access to information. 3. Development and presenting the web-site to all stakeholders 4. Training for DRA staff to increase its	1. Give patients, healthcare professionals and consumers quick and easy access to the most up-to-date and accurate information on medicines. 2. Ensure reliability and relevancy of drug information system on the whole as well as for every particular component; 3. Effective decision making process and	May 2009– March 2010	Strengthened transparency and accountability within the current medicines regulatory and control activities through publicly available websites allowing easy update, development and make further changes with regards to content, design and structure of the website, if necessary	**MeTA Secretariat/Council, and Working/expert group** **Department on Drug Supply and Medical Equipment (DRA) Financing by WB**

	analyzing data coming from various sources. 3. Development of information systems to systematize and optimize decision making process and state regulatory activity on the base of integrated and comprehensive drug related information including: - Registration of drugs, - Licensing of pharmaceutical activities, - Certification of imported drugs , - State inspections, - Automating of drug accountability procedures, - Monitoring and assessment of drug consumption, - Monitoring of drug supply and procurement at hospital level, - Price monitoring, -Analysis of information for decision making process.	capacity so that to improve efficiency and efficacy of the Web-site. 5. Determine the ways how to deliver and disseminate selected information from the Web-site among those from remote areas with no access to Internet (bulletin, press-release, hot-lines etc.).	monitoring of progress (at all steps) ensured by development and introduction of M&E system on drug quality and accessibility with the purpose to improve access to essential drugs, particularly for vulnerable group of population 4. Facilitated communication, dialogue and engagement process used and adapted by stakeholders at international and international level			

B. Development and maintenance of Kyrgyz MeTA project website	Create websites MeTA project in the Kyrgyz Republic to share knowledge and information effectively with the purpose to strengthen transparency and accountability.	1. RT: Define basic topics/ drug related issues to be transparent for public 2. Organize Tender among providers to develop a WEB-site with a purpose to make transparent all issues related to drug provision, and development of user friendly soft ware to get easier access to information. 3. RT: Development and presenting the web-site to all stakeholders	The MeTA website promotes understanding of MeTA principles and approaches among stakeholders and external audience. It also serves as the main information system for the activities of MeTA in Kyrgyzstan, and a data source, researches and assessments carried out in the Kyrgyz Republic.	April – June 2009	Trough MeTA website understanding of MeTA principles and approaches with the purpose to strengthen transparency and accountability in Kyrgyzstan leads to effective decision making in drug procurement sector and better access to medicines, particularly, for poor people	**MeTA Secretariat/Council, and Working/expert group** **Financing by WB**
GOAL II: Research and Assessment to Analyze current situation related to drug provision and availability and develop strategy on improvement of pharmaceutical market and increasing access to medicines						
Objective	**Specific objective**	**Activity**	**Expected results**	**Time line**	**Expected outcomes**	**Responsibility of**
A. Drug Quality Survey	Conduct Drug Quality Survey in two aspects: quality of generics and quality of other drugs	1. Workshop/s to Define a design of the study with international technical assistance.	There are developed concrete recommendations on what kind of changes/amendmen	June – October 2009	Necessary changes are introduced into normative documents related to registration,	**MeTA Secretariat/Council, DRA**

		2. Train local researchers 3. Review WHO studies related to drug quality with the purpose to review and take into account their recommendations.	ts related to drug quality.		certification, licensing and quality control requirements with the purpose to ensure drug quality in pharmaceutical market.	
B. Survey on accessibility of State Guarantees Programs.	1. Carry out a Survey on accessibility to State Guarantees Program and assessment of rationality of drug prescriptions, including prescription of generics. 2. Study impact of SGP on health statistics and individual expenditures assess effectiveness of ADP on health of the population	1. Train Local researchers so that they are capable to conduct further studies and/or monitoring. 2. Get baseline data. 3. RT/ Workshop/s: Discuss the survey findings with stakeholders with the purpose to improve drug provision for certain group of patients with: - psychic diseases - asthma	1. Certain number of local researchers and monitors are trained. 2. There is set of basic indicators related to drug affordability through SGP. 3. Main factors influencing usage of generics and effectiveness of health related programs on to population are determined.	April –June 2009	The strategy to improve drug provision among certain groups of patients (with asthma, mental problems) is developed and necessary changes are inserted into normative documents	**MeTA Secretariat/Council** **NGO "Mental health and Society"** **NGO "Lung Health"**
C. Assessment of legislation with regard to transparency and accountability	Collect of baseline data to analyze regulations related to pharmaceutical market in the light of	1. Revision/In-depth analysis of current legislation regulating pharmaceutical sector. 2. RT/ Workshop/s	1. Disclosure of information on registration, certification, licensing,	July-August 2009	The legislation is adapted so that to provide transparency in pharmaceutical	**MeTA Secretariat/Council, and Working/expert group**

	transparency aspects and Review and develop strategy on improvement of legislative base with regards to pharmaceutical market of the Kyrgyz Republic and.	with relevant stakeholders to discuss finding of the revision and define regulating issues to be changed/adapted/added to ensure transparency in pharmaceutical sector.	procurement, and defining drug quality. 2. Information on registration, certification, licensing, procurement, and defining drug quality is available to the public. 3. Develop recommendation concerning pricing policy.		sector, including all regulating procedures, pricing, quality etc.	
Goal III: Raise awareness among the population on health issues and increase responsibility their own health protection						
A. Raising public awareness about counterfeit drugs.	Conduct a Public campaign on rising of public awareness about counterfeit drugs.	1. Workshop/s to define basic topics/ drug related issues to be high lightened during the campaign 2. Development of educational programs for TV, radio and articles for newspapers, IEC and promotional materials (leaflets, posters, brochures etc.) 3. Testing and finalizing of educational programs	Through educational programs for TV, radio and articles for newspapers, IEC and promotional materials (leaflets, posters, brochures etc.) population received information against counterfeit drugs.	April – December 2009-2010	Population at large is aware about counterfeit drugs and avoids using of them for treatment and prophylaxis purposes.	**MeTA Secretariat/ Council, HAI/CSO**

		for TV, radio and articles for newspapers, IEC and promotional materials (leaflets, posters, brochures etc.) 4. Carrying out the campaign on raising of public awareness about counterfeit drugs				
B. Raising public awareness on drug related issues, including use of generics and forming a responsible attitude to self-treatment and use of alternative treatment. Promote the patient rights to access information	Conduct a Public campaign to raise public awareness on drug related issues and consumers' rights.	1. Conduct a Campaign on raising awareness on patients' rights and usage of generics among population through village health committees. 2. Assess availability of privileges to patients and observance of patients' rights while providing medical service in pilot regions 3. Carry out seminar/s for representatives of civil society on monitoring and evaluation of patients/clients rights. 4.Establish a kind of Watching Committee consisted of CSO in	Village Health Committees have information on patients rights and basic information on generic use, and disseminate this information among population Watching Committee monitor provision of patients.	January – February 2010	Patients rights are observed while providing health services, and patients can demand it from the medical staff Increased awareness/ knowledge of the population about medicines, prices, benefits, and rights.	**MeTA Secretariat/ Council, CSO**

		hospitals to promote transparency in the sphere of patients/clients rights				

Organizational arrangements

The MeTA Council Kyrgyzstan was established in November 2008. The Council is composed of representatives from the government, the academe, professional associations and non-government organizations (see the List attached).

The Council serves as the policy-making body and shall lead in the implementation of the National Plan of Actions for MeTA. It will regularly convene to assess progress and plan future responses, and work to respond to weaknesses.

MeTA Secretariat

The MeTA secretariat will manage the day-to-day operations of MeTA, including funds flow and contracting. The administrative body will also manage the implementation of MeTA work plans and report to the MeTA Council on progress and implementation issues. The Kyrgyz MeTA secretariat will also function as a service and central source of information for all stakeholders.

Two part-time co-coordinators have been appointed in Kyrgyzstan: Djanyl Jusupova, Chairman of the Pharmacopoeial Committee and Mariam Djankorozova from the Mandatory Health Insurance Fund. Given these two professionals are currently employed in high level positions demanding of their time, they will need to be released from some current responsibilities in order to assume the roles of co-coordinator. Each of the 2 co-coordinators will spend 50% of their time working as MeTA co-coordinator and 50% of time working in their regular jobs, with decreased duties. Two full time, bi-lingual (English/Russian) technical staff members to assist in project implementation, managing partner relations, and assisting with international communications have been hired.

MeTA Council

The MeTA Council functions as an Executive Board, providing the governance and oversight function for the project. The MeTA Council is a high level multi-stakeholder group that will ensure that the main directions and priorities of the project are consistent with the broader health reform objectives and process in Kyrgyzstan, monitor the progress and outcomes of the project, and ensure that the policies and procedures of MeTA activities are established and followed. In Kyrgyzstan, preliminary discussions suggest the following organizations should be represented on the MeTA /Council:

Government:	Drug Department
	Mandatory Health Insurance Fund
	Center for Health Systems Development
Private Sector:	Pharmaceutical Manufacturers' Association
	Pharmacists' Association
Civil Society:	Asthma Association
	Diabetes Association
	Maksat
	Mental Health Association
	Rational Drug Use

Village Health Committees

International Organizations: World Health Organization

MeTA Forum

All stakeholders will be invited every year for a MeTA Kyrgyzstan Forum. This will be a conference where all results from research and activities will be presented, and where all stakeholders are invited to participate.

Implementing partners

Small groups of experts and stakeholders will be formed as needed to work on specific MeTA activities. Local experts will be contracted to carry out specific technical work according to terms of reference developed by the expert groups. The expert groups will report to the MeTA country co-coordinators.

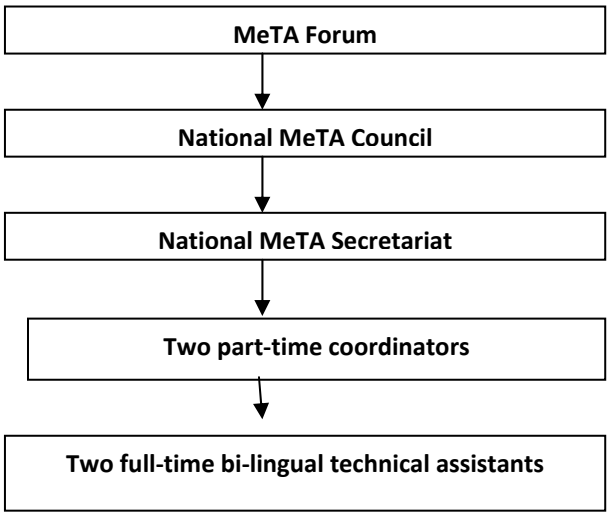
Funds Flow and Budget

The NGO "Association of Family Group Practitioners" will handle the funds for the initial year for MeTA project in Kyrgyzstan.

In terms of budget, the first phase of MeTA is expected to be 1 year with a budget of 100,000 GBP for in-country activities.

It is anticipated that International technical assistance with regards to designing of the Drug Quality Survey and using of mini-lab kits will be made available by the global MeTA secretariat. Access to the academic expertise will be sourced from the Access to Medicines Research Network. This external assistance will be additional available resources and will not be funded out of pilot country budgets.

The MeTA Kyrgyzstan Organogramme



Budget

MeTA Kyrgyzstan budget 1 April 2009 - 31 March 2010

Exchange date 12/03/2009 1gbp=$1,38 version 18 March 2009

Description	units	USD/month	frequency	per month (£)	12months/(£)	%	comments
Salaries and office expenses							
Co-coordinators (50% LOE each):	2	$ 700	12	£ 1.014	£ 12.174	12,2%	
Full time bilingual technical staff (+19%)	2	$ 990	12	£ 1.435	£ 17.217	17,2%	
Communication	1	$ 250	12	£ 181	£ 2.174	2,2%	
Translations	1	$ 150	12	£ 109	£ 1.304	1,3%	
Other costs	1	$ 50	12	£ 36	£ 435	0,4%	
Rent	1	$ 150	12	£ 109	£ 1.304	1,3%	
Office supply (printing paper, stationary, coffee, sugar, toilet paper etc.)	1	$ 50	12	£ 36	£ 435	0,4%	
Subtotal				**£ 2.920**	**£ 35.043**	35,0%	
MeTA council meetings							
Printing	16	$ 5	4	£ 58	£ 232	0,2%	
Transportation of 2 members	2	$ 150	4	£ 217	£ 870	0,9%	
Per diems	2	$ 15	4	£ 22	£ 87	0,1%	
Accommodation	2	$ 55	4	£ 80	£ 319	0,3%	
Coffee-break	16	$ 10	4	£ 116	£ 464	0,5%	
Subtotal				**£ 493**	**£ 1.971**	2,0%	
Annual Forum					**£ 5.000**	5,0%	
Drug Department website							**World bank**
website of DLO and hosting with support	1	$ 6.000	1				
software for DLO	1	$ 25.000	1				
Technical maintenance (installing optical cables, working stations) and training of the staff	1	$ 25.000	1				
MeTA website	1	$ 4.000					
Subtotal		**$ 60.000**					
Drug Quality Survey							
Minilabs	2	$ 4.450	1	£ 6.449	£ 6.449	6,4%	
Training for 8 participants:						0,0%	
Per diem	8	$ 7	3	£ 41	£ 122	0,1%	
Accommodation	4	$ 55	3	£ 159	£ 478	0,5%	
Transportation of participants	4	$ 150	1	£ 435	£ 435	0,4%	
Stationary and printing	8	$ 10	1	£ 58	£ 58	0,1%	
Rent	1	$ 150	3	£ 109	£ 326	0,3%	
Lunch+coffee-break	12	$ 35	3	£ 304	£ 913	0,9%	
Field work during training	1	$ 700	1	£ 507	£ 507	0,5%	
Fee for field work	4	$ 25	10	£ 72	£ 725	0,7%	
Per diem	4	$ 7	10	£ 20	£ 203	0,2%	
Accommodation	4	$ 35	10	£ 101	£ 1.014	1,0%	
Transportation of participants	4	$ 150	1	£ 435	£ 435	0,4%	
Stationary and printing	5	$ 10	1	£ 36	£ 36	0,0%	
Control drug purchase	1	$ 6.000	1	£ 4.348	£ 4.348	4,3%	
External consultant	1	$ 10.000	1				MeTA Intl Secr
Subtotal				**£ 13.075**	**£ 16.049**	16,0%	
Survey on State Guarantee Benefit Program: access to psychic drugs							
Travel	7	$ 50	6	£ 254	£ 1.522	1,5%	
Accommodation	7	$ 20	6	£ 101	£ 609	0,6%	
Per diem	9	$ 7	7	£ 46	£ 320	0,3%	
Short-term consultant fee	4	$ 555	2	£ 1.609	£ 3.217	3,2%	
communication and hiring costs of experts	1	$ 450	1	£ 326	£ 326	0,3%	
stationary	1	$ 500	1	£ 362	£ 362	0,4%	
Subtotal					**£ 6.356**	6,4%	
Survey on State Guarantee Benefit Program: access to antiasthmatic drugs							
Travel	1	$ 450	1	£ 326	£ 326	0,3%	
Accommodation	7	$ 20	12	£ 101	£ 1.217	1,2%	
Per diem	12	$ 7	7	£ 61	£ 426	0,4%	
Short-term consultant fee	4	$ 1.210	1	£ 3.507	£ 3.507	3,5%	
education materials for patients and doctors	1	$ 3.000	1	£ 2.174	£ 2.174	2,2%	
communication and hiring costs of experts	1	$ 450	1	£ 326	£ 326	0,3%	
stationary	1	$ 450	1	£ 326	£ 326	0,3%	
Subtotal					**£ 8.303**	8,3%	
Campaign on rising public awareness							
Public Service Announcements TV/Radio/newspapers etc.					£ 2.000	2,0%	
Media Production (video materials)					£ 4.000	4,0%	
RT to discuss the materials					£ 400	0,4%	
Development of educational programmes, newsletters, press-releases					£ 600	0,6%	
Video cassettes/DVDs/CDs					£ 100	0,1%	
IEC Materials: calendars, booklets, billboards etc.					£ 2.000	2,0%	
MeTA website	1	$ 4.000			£ 2.900	2,9%	if not spent on MeTA Website then added to Public service announcements
Subtotal					**£ 12.000**	12,0%	
Study on drug legislation							
Local expert for revision	3	$ 700	3	£ 1.522	£ 4.565	4,6%	
communications and hiring costs of experts	3	$ 60	3	£ 130	£ 391	0,4%	
Stationary	3	$ 20	3	£ 43	£ 130	0,1%	
Subtotal					**£ 5.087**	5,1%	
Subtotal					**£ 89.809**	89,8%	
Contingency 5%					**£ 4.087**	4,1%	
Total					**£ 93.896**	93,9%	
Programme Support Costs 6,5%					**£ 6.103**	6,1%	
Grand total					**£ 100.000**	100%	