Disclosure Status of Pharmaceutical Sector Data

Part of Component 1 of the MeTA Baseline Assessments

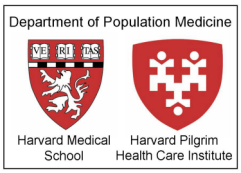
Kyrgyz Republic

July 2010

The Medicines Transparency Alliance Kyrgyzstan

Data Collection Tool developed by:

WHO Harvard Collaborating Center in Pharmaceutical Policy
On behalf of
The Medicines Transparency Alliance



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Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws/policies and associated regulations exist and have been published:

The Law called «The law of the Kyrgyz Republic On medicines", approved on 30.04.2003 says that only registered medicines could be produced, sold and used in the territory of the country.

The Order of the Ministry of Health N 215 of September 8, 1998, defines the instructions and lists the documents and information to be submitted to the DRA for state registration of a medicine.

Those instructions are:

- on registration and re-registration order of local medicines and substances
- on registration and re-registration order of imported medicines and substances
- on examination, approbation and registration of medicines (substances) produced by manufacturers of CIS and Baltic countries

The Order of the Ministry of Health N 215 (September 8, 1998) defines the registration order, structure and requirements for registration dossiers and other issues concerning registration procedures.

The following additional Orders of the Ministry of Health have been issued since the Drug law was enacted:

- Order of the MOH of 07.10.03 № 431 «On approval of the regulations for simplified state registration of medicines";
- Order of the MOH of 25.08.04 № 390 "On approval of temporary instructions on state registration of medicines used for treatment of animals"
- Order of the MOH of 09.12.04 № 546 «On insertion of changes and amendments into Orders of the MOH of 08.09.1998 № 215 and of 07.10.2003г № 431

There is a so called 'Council of Quality' which is in charge of decision making in DRA with regards to registration.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The Law and all the orders are posted on the "TOKTOM (TOKTOM.KG)" National Electronic Reference System that is accessible only through paid subscription. (It is quite an awkward system, not 'user friendly.')

The "TOKTOM.KG" site has been developed and supported by a Private Company TOKTOM. And there is no possibility making them to provide the services for free.

The information on medicines registration fees is posted on the DRA website www.pharm.med.kg.

The DRA issues every year a reference book on normative acts which includes also the Drug Law.

The State Drug Register is available through the DRA website. *(The DRA website is not always working, and the Drug Register link does not work sometimes.)*

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The data could be used by anybody interested.

The number of registered products is publicly available. List of registered products therapeutic class, and registration data exists and publicly available.

The "State Drug Register" is available through DRA website, but it is outdated. The updated Register in printed version is available only by request.

Barriers: The updated policies and information are not always available through the website.

Wider use: The renovated DRA website (within META KG), supported financially by WHO, when it is completed should be updated in a regular and timely manner by authorized DRA staff.

- Explicit policies guiding registration along with decision making criteria (initial and renewal, patented and generic products) –**AVAILABLE. The users are private companies**.
- Information on registration fees, steps in registration process, regulations for general and/or restricted registration, for expedited review - **AVAILABLE. The users are private companies**
- Policies and processes for de-registration of registered products - **AVAILABLE. The users are private companies**
- Information on decision makers and potential conflicts of interest –**NOT AVAILABLE**
- Dossiers submitted for medicines registration with dates and disposition – There is a dossier, but there is no information about the stage of the registration process. The length is 6 months.

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Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Regulations concerning GMP criteria and certification processes for domestic and foreign manufacturers – DO NOT EXIST

There is a national regulation regarding local production criteria:

The drug production in the country falls under the Law of the Kyrgyz Republic «On licensing» of 03.03.97(Art.9, part 4).

The drug production is also regulated by the Drug Law № 91 of 30.04.2003 (Art.I, Art. 1, 5, 6; Chapter. III, Art.10; Chapter. VIII, Art 30,31, 32,34.).

The Order of the MOH № 74 of 14.03.01 approved the «Temporary instruction concerning to basic requirements which are in compliance with elements of good manufacturing practice»

The Order of the MOH N 75 of March 14,2001 approved the "Temporary instruction on inspection order at drug production facilities"

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures concerning GMP criteria and certification processes for domestic and foreign manufacturers – DO NOT EXIST

The Instruction on basic requirements to local pharmaceutical production is available at TOKTOM (TOKTOM.KG), and once was also issued in printed version with the WB support.

DRA conducts assessment of compliance with the appropriate requirements at the local production facilities while licensing. The assessment of compliance is standardized through *The Order of the MOH № 74* of 14.03.01 approving the Temporary instruction concerning to basic requirements which are in compliance with elements of good manufacturing practice»

The further inspections are conducted by the DRA pharmaceutical inspection and by the Certification Unit under DRA. There is no separate unit for inspection of the local manufacturers.

The inspections are conducted on the planned basis (once per year) after receiving approval from the Ministry of Economical Regulation and from Prosecutor General's Office.

The results of inspections, the inspection reports are discussed by the managers of the DRA (including Director General, heads of units) at the meetings of the Licensing Committee. The minutes are not publicly available.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The results and data on inspections of manufacturers are not discussed openly.

List of domestic manufacturers exists in the DRA, but not publicly available. (See Pharmascan Survey)

The access to those data is restricted.

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Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Explicit criteria for supplier pre-qualification – **do not exist**

Once (in 2007), there was a published (TOKTOM (TOKTOM.KG)) list of pre-qualified suppliers approved by the Ministry of Health, but the criteria for selection were unclear.

Procedures for pre-qualifying suppliers – **do not exist**

The drug procurement tenders conducted are based on info submitted by the pharmaceutical suppliers with regards to registration status (approved by DRA), quality certificates and other requested info.

The guiding principle for the tenders is in most cases the price: the lesser the better. The quality of drugs may not be ensured.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The tender procedures are published and available to those interested by request. They are also posted on the State Procurement Agency website.

The agency should conduct the auditing among all the public health facilities as they have to procure the drugs and follow the certain procedures. The Agency focus only on the compliance with approved tender requirements. No evidence is publicly available.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Barriers:

List of pre-qualified suppliers for public, non-profit, or private sector tenders – **does not exist**
Once (in 2007) (TOKTOM (TOKTOM.KG)) a list was published of pre-qualified suppliers approved by the Ministry of Health. Tt was unclear what criteria were used for selection.

List of suppliers who failed to meet pre-qualification standards in the past – **does not exist**

Proportion of medicines by volume and value procured from prequalified suppliers in public sector and non-profit medicines supply systems – **data do not exist**

The audit results are confidential as well as the data provided for the tender by the suppliers.
As a matter of fact, some of the META council members (CSO after consultation with their lawyer) do not consider it an important development of the List of pre-qualified suppliers as they think it will limit the freedom of the market.

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Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

The laws/policies, associated regulations exist and published:

The **Order of the Ministry of Health N 215 (September 8, 1998)** defines clearly the order and stages of the registration process, structure and requirements to the registration dossiers, including list of documents necessary to be submitted.

The Order describes:

Content of the registration dossier;

List of the documents to be attached to the application for registration of new medicines;

List of the documents to be attached to the application for registration of generics and licensed in the country medicines.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The DRA say they ensure drug quality through the registration process as there are:

- Regulations and procedures for assuring quality of domestic and imported products during registration or procurement processes -EXIST
- Product quality assurance documents (both domestically produced and imported products) – SUBMITTED BY THE SUPPLIERS WITH THE DOSSIERS
- No part of the dossier is accessible to the public. Even requested the DRA does not provide any information from the dossier justifying this by saying "it is the private business information'.

Bioavailability studies (generic products) - SUBMITTED BY THE SUPPLIERS WITH THE DOSSIERS

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Reports of violations of quality standards – DO NOT EXIST

List of products that failed quality assurance procedures during registration or procurement processes and dates of failure and steps taken to address problems – DATA ARE NOT AVAILABLE

Information on number of tests performed by the Lab in a year is presented in a DRA Annual internal report (not publicly available). For the year 2009 the number of tests performed by DRA's Lab accounted for 3,993 tests. Only one sample was found unsatisfactory.

BARRIERS:

- There are no data about medicines which failed the quality standards check at the moment of registration or purchase, no dates when the checks were carried out, and no information on the measures taken

WIDER USE:

To place on DRA website information on the progress and results of registration for every medical product submitted to DRA for registration; also how the decision on registration is made and who makes the decision; reports on infringements of the quality standards

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Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

The laws/policies, associated regulations exist and are published:

No legal provisions for routine quality testing of drugs on the market exist.

As to government official position, it is stipulated in the "Drug Law" through Article 47 which is saying about "prohibition of selling of substandard and falsified drugs in the Kyrgyz Republic".

The "Drug Law" of the Kyrgyz Republic, approved on 30.04.2003 N 91 (Chapter III «State system on control of quality, efficacy and safety of medicines», Article 10 «State system on control of quality, efficacy and safety of medicines»

The Government Decree of January 12 2007, N 11, "On State Drug Policy of the Kyrgyz Republic for 2007-2010" about pharmacovigilance.

The Orders of the Ministry of Health №174 of 13.05.03г. "On National Drug Committee of the Ministry of Health of the Kyrgyz Republic", and "On Drug Committee of the health facility" were developed with the purpose to improve the quality of medical services provided to the population, introduction of RDU concept based on WHO recommendations, as well as to increase rational distribution and use of the medicines and medical supplies.

This Order introduces also the following:

- Provision on National Drug Committee under the Ministry of Health,
- Standards on Drug Committee at the health facility.
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One of the tasks of the NDC is to control and analyze information about adverse events/side effects.

The Government Decree of January 12, 2007, On State Drug Policy of the Kyrgyz Republic for 2007-2010, stipulates the order of pharmacovigilance

Order of the Ministry of Health №535 of December 25 2003 года «On improving the work at the health facility with regards to control and registration of the side effects».

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The procedures are not published. Analysis data are not publicly available.

- Routine and ad hoc reports of products tested by quality testing laboratories – no public data
  3, 993 tests for 2009
- Reports of adverse events identified in post-marketing surveillance studies - no public data
- Number of samples from the market that were sent to quality control laboratories by government inspectors for routine testing in last year - no public data
- List of products that failed quality testing, date of testing, and steps taken to resolve problem - no public data

The procedures have not been published. The data are not accessible. Only DRA staff can access the data.

In reality the pharmacovigilance system is very weak now due to unclear policy and lack of experienced staff despite of the Law and Decrees, and Orders of the Ministry of Health.

There is no appropriate monitoring and reporting system with regards to pharmacovigilance.

Pharmacists are not involved into the pharmacovigilance system

The DRA's Information Center is formally responsible for implementing the mandated procedures.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The data are not publicly available, if any.

The data on adverse events are collected by a DRA department: "Information Dpt". They also prepare the regular reports once per year and send them to UPSALA. Last year, there were 13 adverse events registered by the DRA Information Dpt. The Dpt does not submit the reports to the MoH as the MoH does not request them.

Among those 13 – National Hospital (1), National Infection Hospital (6), City Clinical hospital (1), City TB Hospital (1), City Children TB Hospital (2), Issik-Kul Area Hospital (1), Hospital for government (1).

BARRIERS: no relevant government website devoted to this issue.

WIDER USE:

It is necessary to develop an independent system of routine quality testing and monitoring of adverse reactions, obliging the private pharmaceutical companies to make annual contributions to support such a system.

2. Medicine Availability

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Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

1. Policies and procedures for creating and updating guidelines – the MOH Orders exist (see below)

2. Procedures for selecting national STG committee members
– all out-off-staff MOH specialists are the national STG committee members; the list is prepared by DRA (Mrs Zigelskaya- Dpt on pharmaceutical management)

3. Processes to declare and document conflict of interest of STG committee members
– **do not exist**

4. List of members of national STG committee with qualifications and affiliations
- an updated list does not exist

5. Existing STGs for key adult and paediatric illnesses, including organization that created STG and year last updated – The MOH Coordination Committee on Development and Implementation of Clinical Protocols approves STGs developed by numerous specific working groups. But, there is no consolidated info on how many STGs have been approved in total. The website of the National Centre for Health Development does not contain any STGs developed, but, Mrs Aida Zurdinova (Head of Pharmacology Department at the Kyrgyz Slavonic University) said that there are at least 6 STGs developed and approved: On Bronchial asthma in children, On Non-Q wave Miocardial infarction, On ulcer, On hypertension, On diabetes II type, and Hypertensive disorders in pregnancy. The last developed STG is on Viral Hepatitis which was submitted to the Committee.

The Order of the Ministry of Health of June 12, 2006 года N 310:
“On Council of Experts on evaluation of the clinical guides/clinical protocols of the Ministry of Health”

There is an APPRAISAL OF GUIDELINES RESEARCH & EVALUATION
AGREE INSTRUMENT (AGREE)to be used in the country accordance with The AGREE Collaboration of September 2001

PROVISION on the Expert Council exists

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Policies and procedures for creating and updating guidelines – the MOH Orders exist.

Enforcing and encouraging guideline use is made through contracts concluded between health public facilities and ‘Mandatory Health Insurance Fund’ which reimburses some public expenditure within a certain number of drugs. The contracts are concluded mostly with public health facilities and very few with private facilities.

Processes for disseminating guidelines – are sent to the health facilities
The professionals can use them.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

BARRIERS: No data on how successful / unsuccessful clinical protocols are implemented on the ground. MHIF conducts similar studies, but the data are not available These data are not available as, in fact, nobody formally requested the MHIF to make it publicly available. If requested they might be placed on the MHIF website.

WIDER USE:

Carry out regular monitoring of the implementation of clinical protocols, and make the data available through a free independent government or public resources.

It is necessary to improve MHIF IT system to make MHIF web-site navigation easier, so that MHIF staff is able to put some information from the internal data base on the MHIF website. It is also necessary to develop a list of materials and documents which can be publicly available and which can not to be.

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Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

The laws/policies, associated regulations exist and are published:

Government Resolution, January 12, 2007 N 11 , 'STATE DRUG POLICY of the Kyrgyz Republic for 2007-2010 '

1. Selection of medicines

Selection of medicines for inclusion in the list of essential medicines is based on the recommendations of the World Health Organization for the selection of essential medicines in the light of evidence of efficiency and safety of medicines.

The list of essential medicines is reviewed by the National Drug Committee of the Ministry of Health of the Kyrgyz Republic every 2 years, but the review process is not transparent and public. The MoH specialists, approved by an MoH order, discuss and review an outdated EML.

The first EML was developed and approved in 1996. The previous EMLs are not available at the DRA website, so is the information on which medicines were added or removed for each of the previous review. But, one could get this information from the DRA by request.

The list of essential medicines is a priority in relation to other lists that govern the selection of drugs while public tenders and procurement processes. In general STG and EML are related, but sometimes the medicines in STGs are not in current EML if an STG is approved before the EML is updated.

Clinical protocols also should include drugs from the list of essential medicines for priority diseases in accordance with the principles of evidence-based medicine.

May 14, 2009 N 253

ORDER OF THE MINISTRY OF HEALTH OF THE KYRGYZ REPUBLIC "On the implementation of resolutions of the Government of the Kyrgyz Republic of March 20, 2009 N 187 "On Approval of the List of essential medicines of the Kyrgyz Republic " , March 20, 2009 N 187

RESOLUTION OF THE GOVERNMENT OF THE KYRGYZ REPUBLIC "On approval of the Essential Drug List of Kyrgyz Republic"

EDL is available through DRA web site. The previous versions are not publicly available. But, could be received by request.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Hospitals should be guided by the ORDER OF THE MINISTRY OF HEALTH OF THE KYRGYZ REPUBLIC “On the implementation of resolutions of the Government Kyrgyz Republic of March 20, 2009 N 187 "On Approval of the List of essential medicines of the Kyrgyz Republic " , March 20, 2009 N 187 in their procurement preferences.

EML is available through DRA website. Valid EML is sent to each health organization.

In the provision on drug procurement within SGP certain criteria are stipulated with regards to hospital drug procurement: the hospitals should be guided by EML – MOH Order N 431b.

According to this MOH Order the hospitals are allowed to buy up to 20% of medicines beyond EML, but in reality no monitoring has been conducted in the hospitals to check whether they follow the 20% rule.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Hospitals should be guided by the ORDER OF THE MINISTRY OF HEALTH OF THE KYRGYZ REPUBLIC “On the implementation of resolutions of the Government Kyrgyz Republic of March 20, 2009 N 187 "On Approval of the List of essential medicines of the Kyrgyz Republic " , March 20, 2009 N 187 in their procurement preferences.

The Order was sent to all public health facilities.

BARRIERS: No data on whether the EML drugs are used/prescribed on the ground and whether they are in stock. In addition, no data on what drugs from EML are registered, which are not, which EML drugs expiring or have expired the date of registration. It is possible for unregistered drugs to be included into EML.

WIDER USE:

DRA should carry out regular monitoring of the use and availability of the EML drugs, including the prices of these drugs in different regions, and publish the data on a free independent state or public resources. To place on an accessible resource the information about which EML drugs have been registered, which are not, which EML drugs expiring or have expired the date of registration.

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Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- Laws and regulations governing IP, pharmaceutical patents, and market exclusivity - Patent Law of the Kyrgyz Republic of Jan. 14, 1998 N 8.
- Documentation of the status of relevant IP and trade agreements – **no data available**
- List of registered medicines – exists, renewed once per 2 years
- Their patent status, and the date of patent expiry (individually and by therapeutic class) – **no data available**

The laws/policies, associated regulations available through TOKTOM (TOKTOM.KG):

Kyrgyz Republic is a member of WIPO.

Legal protection of property, as well as the associated relations are governed by:

Patent Law of the Kyrgyz Republic of Jan. 14, 1998 N 8, as well as by the

Law on Trademarks, Service Marks and Appellations of Origin of January 14, 1998 N 7, and

The Law on Trade Names "from December 23, 1999, N 145, and

“KR Drug Law" of 30.04.03, Nr 91 (Chapter I, Article 4, Chap. VIII, item 30)

Order of the MOH N 215 of 08.09.1998 "Instruction on the procedure for registration and re-registration of the drugs and substances" (registered in the MOJ, on16.09.1998, № 18) according to which the applicant must provide a registration dossier, information on the patentability and the presence of security instrument (drug, trademark - if applicable).

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The laws/policies, associated regulations exist and available through TOKTOM (TOKTOM.KG).

DRA regulates it to some extent through dossiers submitted by the companies (MOH Order N 215).

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The laws/policies, associated regulations exist and available through TOKTOM (TOKTOM.KG).

BARRIERS: there is no a government website, which would contain all the necessary information. State organizations / agencies / authorities may have their own websites, which do not operate regularly, are not updated in a timely manner, or which do not contain the necessary information (examples: the website of Ministry of Health, DRA and others).

WIDER USE:

Create a free government website (easy to navigate, updated in a timely manner, independent, having feedback from the grassroots) and alert the general public about the existence of such resource.

***2.4** Error! Reference source not found.*

Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Government budget documents – no data available

Policies and regulations governing the disclosure of drug procurement or utilization data in the public and non-profit sectors – do not exist

Ministry of Health, Central Medical Stores, regional, or institutional medicines procurement or utilization reports – no data available

Non-profit sector medicines procurement or utilization reports – no data available

Type, volume, and value of medicines procured in the public and non-profit sectors (by region, by facility level, by innovator vs. generic, by therapeutic category) - no data available

Government budgets for health care and pharmaceuticals for last fiscal year - available on the website of the Ministry of Finance for the 2010 with prognosis for 2011.
The budget 2009 for health care and pharmaceuticals might be on the ministry of health website, which is now under construction.

At the level of health facilities the VEN \ ABC analysis in procurement was introduced: MOH Order?

Data on the level of coverage by this analysis and its effectiveness do not exist.

The laws/policies, associated regulations exist and published:

Centralized public procurement (MOH and Health Insurance Fund) are made in accordance with the procedures of the World Bank on the basis of specific needs:

- The diabetic medicines (insulin and hypoglycemic agent tablets);
- Vaccines, immunoglobulins for dangerous infections;
- Vaccines included in the National Calendar
- Rabies vaccine and immunoglobulin
- Clotting factors for hemophiliacs children under 16 years

Semi-annual reports on the volume purchased and consumed drugs and medical products are submitted to the DRA and MHIF by July 15 and January 15 annually. All public hospitals submit the written reports to DRA on how many and which drugs have been consumed, but nobody analyze the reports and huge heaps of the reports have been stored in the DRA archives.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Data on centralized procurement are in the accounting records, but not published anywhere. Access to data is restricted to personnel of MOH and MHIF

- Data on procurement in hospitals are not published and are not processed and analyzed by DRA due to weak IT system. Employees of hospitals and DRA might have access to the data.
- Policies and regulations governing the disclosure of drug procurement or utilization data in the public and non-profit sectors – do not exist
- Ministry of Health, Central Medical Stores, regional, or institutional medicines procurement or utilization reports – no data available
- Non-profit sector medicines procurement or utilization reports – no data available
- Type, volume, and value of medicines procured in the public and non-profit sectors (by region, by facility level, by innovator vs. generic, by therapeutic category) - no data available

Government budgets for health care and pharmaceuticals for last fiscal year - available on the website of the Ministry of Finance for the 2010 with prognosis for 2011.

- The budget 2009 for health care and pharmaceuticals might be on the ministry of health website, which is now under construction.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

There are data in the primary accounting documents about the drug procurement process in the MOH, hospitals and MHIF for internal use only.

BARRIERS: lack of technical capacity to summarize the procurement information available and lack of the drug codifiers.

Hospitals are reluctant to publish these data. Absence of adequate IT systems is a main obstacle to disclosure these data as preparing the reports is time and efforts consuming.

WIDER USE: Creation of drug information systems and development of a normative act with regards to mandatory publication of information about public drug procurement.

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Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

DRA has the Drug Imports Unit which registers the data on imported drugs. The DRA has data on type, value and volume. Though the DRA IT system is not appropriately designed to make selecting and sorting for any analysis.

Amount of imported drugs is registered at customs when importing using customs codes.

The National Statistics Committee gathers aggregate data on sales based on data provided by the pharmaceutical suppliers (including all range of pharmaceutical products) in accordance with established procedures. They can not define separately the sales volume of medicines.

Policies and regulations governing the disclosure of drug supply data in the private sector – do not exist

Procedures and practices concerning release of private sector data on drug importation, manufacturing, and sales – do not exist

Data on type, volume and value of products imported, manufactured, or sold (by region; by therapeutic category, by level of the supply system) – do not exist

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The DRA staff might have access to the data on imported drugs – no data available. They can not distinguish drugs imported for the use in public vs. private sector. But, there are specific medicines (like insulin or some vaccines) used only in public sector.

The Customs has the aggregated data on the imported products – no data available.

Customs records the data on the drug supply in aggregated form - CFEA codes are used (Customs foreign-economic activity) - Data not available

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

BARRIERS:

- Technical barrier to access the import data on medicines: no information systems and related drug codes to process the data on imported drugs at the DRA.
- There is no a government website, which would contain all the necessary information. State organizations / agencies / authorities may have their own websites, which do not operate regularly, are not updated in a timely manner, or do not contain the necessary information (examples: the website of Ministry of Health, DRA and others).

WIDER USE:

- Create a free government website (easy to navigate, updated in a timely manner, independent, having feedback from the grassroots) and alert the general public about the existence of such resource.
- Establish information systems and related drug codifiers for data processing

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Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- Stock records for key medicines from public and non-profit health facilities (by region, by facility type, by therapeutic category) – no information
- Documented follow-up on reports of pharmacy stock-outs in public health facilities, including time to resolution – no bookkeeping
- IMS data or other surveys of availability of medicines in private importers, wholesalers, or private retail pharmacies – do not exist

Availability of medicines is ensured only for a certain number of medicines reimbursed within State Guarantees program and Additional Package Program of the Mandatory Health Insurance, like:

ORDER OF THE MINISTRY OF HEALTH OF THE KYRGYZ REPUBLIC of December 6, 2007, N431b:

On the implementation of resolutions of the Government of the Kyrgyz Republic of 24 August, 2007, N363 "On the State Guarantees Program to ensure provision of the citizens of the Kyrgyz Republic with the health services "

The order to implement resolutions of the Government of the Kyrgyz Republic, August 24, 2007

N363 "On the State Guarantees Program for the citizens of the Kyrgyz Republic " approved:

1.1. Types and amounts of health services provided to citizens of the Kyrgyz Republic on free and concessional terms within the State Guarantees Program.

1.5. The order on drug provision within the State Guarantees Program for the citizens of the Kyrgyz Republic.

April 30, 2001 N 133

ORDER OF THE MINISTRY OF HEALTH OF THE KYRGYZ REPUBLIC

"On provision of medicines within the Additional Drug Package Program of the Mandatory Health Insurance at the primary level "

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The provision on the procedures is available through TOKTOM, and delivered to the doctors, patients at FGP; these provisions were described in pamphlets and posters; information about ADP MHIF and SGP have to be displayed on stands in the FGPs.

Prescription of the ADP drugs is based on a limited list of medicines (75 INN), reimbursed within ADP and SGP, which is published in the reference book of the same name and is supposed to be in doctors' hands. According to MHIF all the pharmacies contracted by MHIF under ADP Program have the List with relevant codes available. But, the List is not anywhere available for public/patients. The last update was in July 2006, and now (according to MHIF) it is in the process of updating. 12% of medicines (8 INN) from the List are not in the current EML.

The info about benefits provided within SGP and ADP is posted at the TOKTOM (TOKTOM.KG), and available at primary health care facilities.

There is no government body to enforce.

Data about accessibility to SGP and ADP is not publicly available if any.

Some booklets were issued for the population with the SGP and ADP info to raise awareness, but still most of the population as well as health professionals are not much aware about the benefits and guarantees.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The provision on the procedures is available through TOKTOM, delivered to doctors and patients at FGP, and described in pamphlets and posters; information about ADP MHIF and SGP have to be displayed on stands in the FGPs.

Prescription of the ADP drugs is based on a limited list of medicines (75 INN), reimbursed within ADP and SGP, which is published in the reference book of the same name and is supposed to be in doctors' hands.

The info about benefits provided within SGP and ADP is posted at the TOKTOM (TOKTOM.KG), and available at primary health care facilities.

The data about accessibility within ADP and SGP are gathered, processed, and kept at the MHIF. These data are not currently used to inform the public procurement process. According to MHIF they are going to make these data available for the hospitals in near future.

The data are regularly updated on a monthly basis through processing the information submitted by the primary health facilities and drug stores. The data could be used by MHIF experts (to control RDU), by the doctors (for internal management) and by other health specialists to analyse the situation in general.

BARRIERS: Checking compliance of the provisions with medicines of insured persons within the ADP MHIF was not done.

WIDER USE:

- Develop a monitoring system with a purpose to monitor/assess stock-out / availability of key essential medicines (by region, by product, by innovator vs. generic, by therapeutic class, if available) in public sector or non-profit health facilities
- Conduct a survey to assess compliance of the provisions with medicines of insured persons within the ADP MHIF at the primary health care level.
- Assess the budget to cover the needs of the target groups within ADP MHIF and SGP (insured population and patients with certain diseases)

The info about benefits provided within SGP and APP is posted at the TOKTOM (TOKTOM.KG), and available at primary health care facilities.

Some booklets were issued for the population with the SGP and APP info to raise awareness, but still most of the population as well as health professionals are not much aware about the benefits and guarantees.

2.7 Error! Reference source not found.

Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Exist and available through TOKTOM (TOKTOM.KG).

August 21, 2008, N 434

ORDER OF THE MINISTRY OF HEALTH OF THE KYRGYZ REPUBLIC :

'On approval of Instruction on the procedure of inspection in pharmaceutical organizations by the DRA'

Presidential Decree of July 2, 2007, N 330 "On measures to improve the arrangements for inspections of businesses"

'Law on the procedure for conducting inspections of businesses entities' of May 25, 2007, N 72;

Resolution of the Government of the Kyrgyz Republic of Nov. 6, 2007, N 533 "On procedure of inspections of businesses and identifying the list of authorized bodies having the right to conduct inspections of businesses"

Order of the Ministry of Health of the Kyrgyz Republic "On Approval of Instruction on the procedure of inspection of pharmaceutical organizations by DRA of August 21, 2008 N 434. The order stipulates to the basic principles, procedure for verification and order for processing audit results.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures available through TOKTOM (TOKTOM.KG).

- Characteristics, training, and case load of drug regulatory agency auditors – no data available
- Number and percent of facilities audited in last year (by region, by type of facility) – no data available The medicines outlets used to be audited by DRA inspectors who had a standardized checklist approved by a relevant MOH Order. But, now all inspections and audits of business enterprises, including pharmacies, are prohibited within Improvement of Business Environment National Strategy unless the permissions of the Prosecutors Office and Ministry of Economics Regulation received.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The inspections data theoretically exist (as the DRA has the inspection department), but the data are only available for internal use. Given the fact that so far the media has never announced to the general public about the facts of violations, we can assume that the inspections did not reveal anything.

BARRIERS:

- Current regulation on inspection in pharmaceutical outlets does not allow the government to reveal any violations. Now all inspections and audits of business enterprises, including pharmacies, are prohibited within Improvement of Business Environment National Strategy.
- no data available on characteristics, training, and case load of drug regulatory agency auditors as not required
- no data available on number and percent of facilities audited in last year (by region, by type of facility)
- no data available on number, type, and resolution of violations reported during audits and undertaken measures
- no relevant government website

WIDER USE:

- Update / improve the existing legislation regarding inspections in pharmacies so that to

ensure adequate quality of drugs in retail market.

- Reports on inspections, including number of inspectors and their characteristics, should be placed at DRA website.

3. Medicine Prices

3.1 Error! Reference source not found.

Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

There is no price regulation in the country.

- Laws and regulations governing ex-manufacture and end-user pricing of medicines in the public, non-profit, and private sectors - **do not exist**
- Insurance program policies and procedures for medicines reimbursement – ADP MHIF and SGP
- Ex-manufacture price from manufacturers or importers/wholesalers[1] (both innovator and available generic versions) – **no data**
- Insurance system reimbursement data – **no data available**

Indirect price regulation exists through such insurance programs as ADP and SGP.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

All pharmacies in Kyrgyzstan are private. Drug pricing is not regulated - the price is determined by the pharmaceutical suppliers based on the market prices.

Information on retail drug prices or prices in health care facilities are not available for public access.

In the current system of drug cost reimbursement for insured persons (ADP) and patients with certain diseases, MHIF reimburses the drug cost based on fixed price.

According to MHIF all the pharmacies contracted by MHIF under ADP Program have the List with relevant codes available. But, the List is not anywhere available for public/patients. The last update was in July 2006, and now (according to MHIF) it is in the process of updating. 12% of medicines (8 NN) from the List are not in the current EML.

Wholesale prices are available through websites of some local large distributors.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

[1] Disclosing ex-manufacturer prices by manufacturers or importers/wholesalers may be a sensitive issue in some circumstances. Aggregation of individual products into an average price per essential medicine, or the use of an intermediate agency (IMS, University, or consultant) might help obtain such data. Even if data cannot be disclosed, the arguments and potential process for disclosure could be discussed.

In fact, there is no public (i.e. available to the public) resource on the prices of medicines.

There are data on wholesale prices (of major wholesalers), but no data on retail prices in pharmacies, where the packages are often without price tags. It means that there is no resource publicly available on average retail prices for customers. Every pharmacy establishes their own prices. But, the retail prices in the country differ sometimes significantly between the pharmacies.

No data on producer/ex-manufacturer prices, i.e. prices, which are declared to the Customs. Private wholesalers carefully conceal this information for obvious reasons: they are interested in reducing taxes on imported goods. Nevertheless, information on producer prices can be found out from the manufacturers themselves thanks to the Internet and other communication channels. But no one in the country has ever conducted such surveys.

BARRIERS:

- No data on private sector retail prices for list of key essential medicines (by region, by innovator vs. generic versions)
- No data on prices charged to patients in public sector or non-profit health facilities for list of key essential medicines (by region, by level of facility, by innovator vs. generic versions), including visit fees or dispensing fees if applicable
- No data on affordability of medicines to treat key acute and chronic health problems in public, private, and non-profit sectors, with prices expressed in relation to a standard metric such as the wages of the lowest paid government worker
- No data on the amount charged and reimbursed to patients by insurance programs for list of key essential medicines (by insurance program type, by innovator vs. generic versions). The last MHIF Price List was approved in 2006. The Price List (according to MHIF) is available in health facilities and contracted pharmacies. Now (according to MHIF) the Price List is going to be updated in near future.
- No relevant government website

WIDER USE:

- Conduct price research to get missing data.
- It is advisable to carry out a study similar to that one that took place recently in Russia, based on which it was found out that the retail markup on drugs may be more than 1000%. *As a result, the Government of Russia has taken steps to establish the limit of wholesale and retail margins on medicines.*
- Create a free government web site (easy to navigate, updated in a timely manner, independent, having feedback from the population), which would provide regular information on wholesale and retail prices, availability of medicines, refunds and so on and inform the general public about the existence of such a resource.

***3.2** Error! Reference source not found.*

Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

2005 - study conducted by WHO / HAI

- Laws and regulations governing the disclosure of public sector medicines procurement prices – do not exist
- Notifications about explicit procedures to be followed in handling bids in the public procurement process – the current regulation is based on the principle "the cheaper the better".
- Audits for compliance with public medicines procurement regulations – no data available
- Ministry of Health medicines procurement records – no data available

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Data on prices in the tenders are closed and not publicly published anywhere. Data on individuals who make the decisions within the tenders are not published anywhere.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The data are not publicly available. Most interested parties can search and find information about who won the tender and at what amount. These data can be found in the monthly publication, which is published by the Public Procurement Agency (now renamed) and sent to state institutions.

BARRIERS:

- No data on public sector procurement prices for list of key essential medicines (by region, by level of care, by administrative unit, by product, by therapeutic class, if available)
- There is no a government website, which would contain all the necessary information. State organizations / agencies / authorities may have their own websites, which do not operate regularly, are not updated in a timely manner, or do not contain the information that promised through the content (examples: the website of Ministry of Health, DRA and others).

WIDER USE:

- Conduct a research project to get missing data The price survey (using HAI methodology) has been conducted within META in Kyrgyzstan, and would be finalized by the middle of September.
- Develop laws and regulations on mandatory disclosure of information in public sector medicines procurement prices, audits for compliance with public medicines procurement regulations, Ministry of Health medicines procurement records
- Create a free government web site (easy to navigate, updated in a timely manner, independent, having feedback from the population), which would provide regular information on prices, availability of medicines, refunds and so on and inform the general public about the existence of such a resource.

***3.3** Error! Reference source not found.*

Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

There are no rules or regulations, regulating/determining the price components of the drugs, in public or private sector.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- There are no rules or regulations, regulating/determining the price components of the drugs, in public or private sector.
- The WHO-HAI survey on price components - available at HAI. Was not widely discussed. Not many people in the country know about this study.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

BARRIERS:

- Lack of any laws / regulations, rules or instructions, establishing / determining the price components of the drugs, in public or private sector.

WIDER USE:

1. Develop a survey focused on:
   - Price components of the drugs, in public or private sector for list of key essential medicines (by region, by level of care, by administrative unit, by product, by therapeutic class
2. make the survey publicly available

3. Develop a draft law regulating markups for the key drugs.

4. Medicine Promotion

4.1 Error! Reference source not found.

Sources:	

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

The laws/policies, associated regulations exist and are published:

Law "On Advertising" from 24.12.98 N 155

Law On medicines of 30.04.03 N 91 (Chapter III, Articles 10, 12; gl.IV, Art. 17, 18, ch. XVIII, Articles 48, 49):

"Advertising of medicines should contribute to the pharmaceutical market with high quality, effective and safe drugs, and to facilitate their effective application…"

"Advertising should not undermine the reputation of manufacturers of medicines, consumer confidence in the drug effect ..."

Control on drug advertising is carried out by the DRA..The Drug Law stipulates necessity for any drug advertisements to be approved by an Authorized body, which is DRA.

In case of violation the DRA may prohibit the further promotion of medicines or warn advertisers about the need to change the approach to their advertising of a health product.

No code of conduct for health care professionals on how to respond to pharmaceutical promotion exists. But, there are MOH orders prohibiting pharmaceuticals promotion in the health facilities.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

DRA monitors advertising in the mass media. Info might be available in DRA, if any.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

No data available.

Monitoring data are not publicly available and for internal use only.

BARRIERS:

- No data of manufacturers and distributors that subscribe to internationally or nationally recognized codes of conduct
- No national committee to monitor adherence to industry codes of conduct
- No Reports of numbers and types of complaints submitted to the national monitoring committee regarding promotional practices, numbers of violations, and resolution of the complaints

WIDER USE:

- Develop procedures for handling complaints, and for identifying, sanctioning, and publicizing violations of codes
- Publish or place on the DRA website a list of manufacturers and distributors that subscribe to internationally or nationally recognized codes of conduct

- Publish or place on the DRA website a List of individuals with their affiliations who are on the national committee to monitor adherence to industry codes of conduct
- Publish or place on the DRA website Reports of numbers and types of complaints submitted to the national monitoring committee regarding promotional practices, numbers of violations, and resolution of the complaints.