



Pharmaceutical Sector Scan

Part of Component 1 of the MeTA Baseline
Assessments
Part III - Data Sources and Comments

KYRGYZSTAN

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

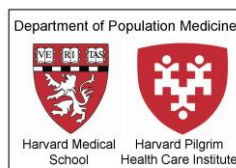


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1. Country Profile: Demographic and Socioeconomic Indicators

Possible sources: MOH, Ministry of Planning, National Bureau of Statistics, WHOSIS¹, WHO Global InfoBase², World Bank Annual Development Report³, WHO National Macroeconomics Report⁴

Document source of each item and year collected:

Item Number	Source, Location, & Year	Comments
Population, mortality, fertility		
1.1 →	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004-2008
1.2	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.3	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.4	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.5	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.6	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.7	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
Economic status		
1.8	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.9	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004
1.10	WORLD BANK	Research data of the world bank
1.11	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004- 2008
Education and literacy		
1.12	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004-2008
1.13	NATIONAL STATISTICAL COMMITTEE FOR 2008	According to census there is no separate data by gender. There is only data on primary education without separation by gender (6.3%)
1.14	NATIONAL STATISTICAL COMMITTEE FOR 2008	According to census there is no separate data by gender. There is only data on primary education without separation by gender (6.3%)

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2. Country Profile: Mortality and Causes of Death

Possible sources: MOH, Ministry of Planning, National Bureau of Statistics, WHOSIS¹, WHO Global InfoBase², World Bank Annual Development Report³, WHO National Macroeconomics Report⁴, WHO National Health Accounts⁵

Document source of each item and year collected:

Item Number	Source, Location, & Year	Comments
<i>Life expectancy and mortality</i>		
2.1.	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004-2008 http://www.stat.kg/
2.2.	NATIONAL STATISTICAL COMMITTEE FOR 2008	Statistical Yearbook of KR for 2004-2008 http://www.stat.kg/
2.3.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.4.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.5.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.6.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.7.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.8.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.9.	NATIONAL STATISTICAL COMMITTEE FOR 2008	Deaths not only from cancer, but from malignant neoplasms are reflected.
2.10.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
2.11.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
<i>Causes of death among children <5 years</i>		
2.12.	RMIC, MOH, 2008	
2.13.	RMIC, MOH, 2008	
2.14.	RMIC, MOH, 2008	
2.15.	RMIC, MOH, 2008	
2.16.	RMIC, MOH, 2008	
2.17.	RMIC, MOH, 2008	
2.18.	RMIC, MOH, 2008	

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3. Country Profile: Health Care Expenditures

Possible sources: MOH, Ministry of Finances, Ministry of Planning, National Bureau of Statistics, WHOSIS¹, WHO Global InfoBase², World Bank Annual Development Report³, WHO National Macroeconomics Report⁴, WHO National Health Accounts⁵, WHO Global Burden of Disease and Risk Factors Data Base⁶, Demographic and Health Surveys⁷, World Bank Health and Nutrition Data Base⁸

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Overall health expenditures		
3.1. ➡	Health Policy Analysis Center, 2008	Review of the total expenditures for healthcare for 2008
3.2.	Health Policy Analysis Center, 2008	Review of the total expenditures for healthcare for 2008
3.3. ➡	MOH, 2008	
Health expenditures by source		
3.4. ➡	Health Policy Analysis Center, 2008	Review of the total expenditures for healthcare for 2008
3.5. ➡	MOH, 2008	Report on midterm revision of the National Health Reforms Program “Manas Taalimi” 7 May, 2008
3.6.	NATIONAL STATISTICAL COMMITTEE for 2008	
3.7. ➡	Health Policy Analysis Center, 2008	National Health Accounts of KR, 2008 <i>Table 2</i>
3.8.	Health Policy Analysis Center, 2008	National Health Accounts of KR, 2008 <i>Table 2</i>
3.9. ➡	Health Policy Analysis Center, 2008	National Health Accounts of KR, 2008 <i>Table 2</i>
3.10.	MOH of Kyrgyz Republic, 2008	Report on financial monitoring of the realization of the National Health Reforms Program “Manas Taalimi”, 2008
3.11. ➡	MHIF report, 2009	

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4. Country Profile: Health Personnel, Infrastructure, and Primary Health Care

Possible sources: MOH, Ministry of Finances, Ministry of Labor, Ministry of Planning, National Bureau of Statistics, WHOSIS¹, WHO Global InfoBase², World Bank Annual Development Report³, WHO National Health Accounts⁵, WHO Global Burden of Disease and Risk Factors Data Base⁶, Demographic and Health Surveys⁷, World Bank Health and Nutrition Data Base⁸

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Personnel		
4.1. ↗	NATIONAL STATISTICAL COMMITTEE, 2008	http://www.stat.kg/
4.2.	NATIONAL STATISTICAL COMMITTEE, 2008	http://www.stat.kg/
4.3. ↗	Pharmaceutical Employees Attestation Committee at the DRA, 2010	On the base of Decree of MOH from 28 March 2008, N 118 "On Approval of Provision on attestation and registration of medical and pharmaceutical personnel in the Kyrgyz Republic" there is an Employees Attestation Committee working at the DRA. On 01.06.2010 there were 3,341 pharmacists or 6.3 per 10,000 inhabitants
4.4.	DRA report, 2009	On 01.01.10. 484 permissions for the health workers from the villages for the medicine trade were given.
4.5.	MOH report, 2009	
Facilities		
4.6.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
4.7.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
4.8. ↗	DRA	
Primary Health Care		
4.9.	NATIONAL STATISTICAL COMMITTEE FOR 2008	
4.10.	REPUBLICAN IMMUNE PROPHYLAXYS CENTER	There is no at birth vaccine in the National Immunization Calendar.
4.11.	RMIC, MOH, 2008	

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5. Medicines Policy and Regulatory Framework

Possible sources: National legislative proceedings, MOH, Medicines Regulatory Agency, WHO Level I Survey 2003⁹ and 2007, WHO Evaluation of Pharmaceutical Regulations¹⁰, WHO Good Governance for Medicines Project¹¹

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Policy framework		
5.1.	KG Government	National Health Reforms Program “Manas Taalimi” 2006-2010
a.		
5.2. →	KG Government	National Health Reforms Program “Manas Taalimi” 2006-2010 Realization Plan
a.	KR Government Decree from 12 January 2007, N 11 “On National Drug Policy of the KR for 2007-2010”	
b.		
5.3. →	State Drug Policy Realization Action Plan for 2007-2010, approved by the KR Government Decree from 12 January 2007, N11 “On National Drug Policy of the KR for 2007-2010”	
a.		
Regulatory framework		
5.4. →	KR Government Decree from 26 September 1997, N 556 “On Establishing of the Department on Drug Provision and Medical Equipment under the MOH KR”	
5.5. →	1. Drug Law of the KR from 30.04.03 № 91; 2. Law of 22.05.04 N 67 “On basics of Technical Regulations in the Kyrgyz Republic”; 3. KR Government Decree of 26.06.97 № 556 “On Establishing of the Department on Drug Provision and Medical Equipment under the MOH KR”; 4. KR Government Decree № 639 of 30.12.05 “On Obligatory Assurance of Product Compliance”; 5. KR Government Decree № 8 of 11.01.06 “On Order of importing of products subjects to Obligatory Assurance of Product Compliance in the form of obligatory certification, and	

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Item Number(s)	Source, Location, & Year	Comments
	on acceptance of the results of obligatory assurance of product compliance received beyond Kyrgyz boundaries”; 6. MOH Order № 215 “On approval of number of instruction” from 08.09.98; 7. MOH № 431 Order “On Approval of simplified procedure of state registration of medicines” from 07.10.03.	

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Item Number(s)	Source, Location, & Year	Comments
5.6.	http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/ «Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce»	DRA didn't join «Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce». Drugs certification requirements are regulated by the National legislation on technical control.
5.7. →	KR Government Decree from 26.09.97 № 556 “On Establishing of the Department on Drug Provision and Medical Equipment under the MOH KR”	
		The State Executive Organ in Pharmaceutical Sector is the Department on Drug Provision and Medical Equipment of the Kyrgyz Republic
a.	KR MOH Order from 12 February 2010, № 72 “On Approval of organizational structure and personnel of the Department on Drug Provision and Medical Equipment under the MOH KR”	Currently the DRA staff is composed of 59 people.
5.8. →	1. KR GD № 639 from 30.12.05 “On Obligatory Assurance of Product Compliance” 2. DRA Drug Certification Unit Report 3. Drug Law 4. KR Government Decree of 18 September 2009 N 591 “On approval of instructions on submission and registration of inspections of subjects of business”	According to the statement 7 of the KR Government Decree № 639 from 30.12.05, “On Obligatory Assurance of Product Compliance”: Accredited certification authorities should submit on monthly basis to an authorized body on technical regulation the data on Register of certified products and information on violations of obligatory safety requirements from any applicants” . According to statement 22 of the ‘Instructions on submission and registration of inspections of subjects of business’: Power authorities and government controlling bodies should report quarterly by 10 th of the month following the quarter to the Registering Unit of the Prosecutors Office about audits conducted in accordance with the Annex N 7 of the Instructions
5.9. →	DRA order from 16 April 2010 «Code of conduct for the staff and out-of-staff experts of DRA»	Current codex was developed in compliance with WHO recommendations.

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Item Number(s)	Source, Location, & Year	Comments
5.10. ➡	1. Eurasian Economic Community, Integration Committee 2. Interstate Committee On Standardization, Registration And Quality Control Of The Drugs And Medical Equipment For CIS Countries 3. WHO 4. WTO 5. Economic Cooperation Organization	
5.11. ➡ a.	www.pharm.med.kg	Information on the web site is out-dated and limited, there is a need to change the design and the content

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6. Medicines Market at Retail Price

In this section, “medicines market” refers to public, private, and not-for-profit markets.

Possible sources: National legislative proceedings, MOH, Medicines Regulatory Agency, Ministry of Trade, National Bureau of Statistics, Manufacturer associations, Importer or wholesaler records, WHO Level I Survey 2003⁹ and 2007, IMS country reports¹², WHO World Medicines Situation¹³

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
6.1. ↗	DRA report for 1 st quarter, 2010	On 01.04.2010 there were 5,544 pharmaceutical products registered. 4,016 – drugs; biologically active supplements – 261.
6.2. ↘	State Register on drugs permitted in medical practice in KR on 01.06.2010	There is no indication on the patent status for the registered drugs permitted in medical practice in the State Register
6.3.	DRA report, 2009	<p>For the year 2009 the wholesalers imported the pharmaceutical products in the amount of 4 021, 226, 544.50 soms; and animal drugs for 72 891, 263.30 soms.</p> <p>The local production for 2009 constituted 210 million soms. The DRA coordinates humanitarian assistance supplies delivered for charitable foundations and NGOs: for the year 2009 it was given 52 permissions for importing of humanitarian aid in the amount of 483 645, 039.12 soms. The import data differ between the DRA and Customs Inspection.</p> <p>The MOH received the humanitarian aid in the amount of 17994,751.2 soms</p> <p>Thus, the value of the pharmaceutical market for the year 2009 (without wholesale and retail mark-ups) amounted to 4732,866,344,8 soms</p>
6.4. ↘	Health Policy Analysis Center. Policy Research Paper №67 “Study of factors influencing use of generics”	Research showed that value of the generics amounted to 59,47%
6.5. ↘	KR NSC Decree from 12.06.2002 № 5 “Form № 1-P (DRA) Report of the local pharmaceutical manufacturers”. Data is analyzed by DRA	The volume of pharmaceutical production manufactured by the local manufacturers in 2009 amounted to 210 mln soms. Local pharmaceutical production constituted 4.37% of the whole pharmaceutical market

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Item Number(s)	Source, Location, & Year	Comments
6.6. ➡		List of top 20 medicines is not defined
6.7.	DRA reports, 2005, 2006, 2007, 2008, 2009	Market volume of the years 2005 – 2 310,3 mln. som 2006 – 2 774,4 mln. som 2007 – 3 602,5 mln. som 2008 – 3,694 mln. som 2009 – 4 797,7 mln. som The average market growth for the last 5 five years is 26,25 %
6.8.	Data are not consolidated	

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7. Medicines Financing: Government Expenditures and Health Insurance

Possible sources: MOH, National or Social Health Insurance, WHO National Health Accounts⁵, WHO Level I Survey 2003⁹ and 2007, WHO World Medicines Situation¹³

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Medicines expenditures		
7.1. ↗	MOH of KR	Financial monitoring report, 2008
7.2. ↗		Financial monitoring report, 2008
7.3. ↗		Financial monitoring report, 2008
7.4. ↗		Financial monitoring report, 2008
7.5. ↗		Financial monitoring report, 2008
Health insurance		
7.6. ↗	MHIF, 1999	Law of the KR “On health insurance of the citizens of the Kyrgyz Republic” of 18.10.1999
7.7. ↗	1. State Benefits program 2. Additional Drug Package Program on drugs provision for citizens on outpatient level	
7.8. ↗	Social program on help for the low-income citizens of Bishkek	
7.9. ↗	Social program on help for the low-income citizens of Bishkek	
7.10. ↗	MHIF	
7.11. ↗	MHIF: Additional Drug Package list	

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8. Medicines Financing: Public Programs Providing Free Medicines

Possible sources: MOH, National or Social Health Insurance, WHO National Health Accounts⁵, WHO Level I Survey 2003⁹ and 2007, WHO World Medicines Situation¹³

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
8.1. ↘	KR GOVERNMENT, 2007	KR Government Decree of 24 August 2007 N363 “On State Benefits Program for provision of citizens of the Kyrgyz Republic with health services”
8.2. ↘ a. ↘	KR GOVERNMENT, 2007	Currently there are several preferential drug provision programs for people both on in-patient and out-patient levels, but only in public healthcare.
b. ↘	MHIF, ADP MHIF, 2007	Since children of this age are being insured by MHIF, they obtain drugs preferentially through ADP MHIF
c. ↘	MHIF, ADP MHIF, 2007	Pregnant women insured by MHIF obtain preferential drugs through ADP MHIF
d. ↘	MHIF, ADP MHIF, 2007	Retirees are being insured and obtain preferential drugs through ADP MHIF
8.3. ↘ a. ↘	KR GOVERNMENT, 2007	Free drugs provision is being performed by the government healthcare programs and specified drugs names
b.	KR GOVERNMENT, 2007	National Malaria Strategy for 2006-2010
c.	KR GOVERNMENT, 2007	National Tuberculosis strategy for 2006-2010
d.	KR GOVERNMENT, 2007	Part of National HIV/AIDS Strategy for 2006-2010
e.	KR GOVERNMENT, 2007	National Malaria Strategy for 2006-2010
8.4. ↘ a. ↘		
b. ↘		

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9. Medicines Financing: Patient Fees and Copayments

Possible sources: MOH, National or Social Health Insurance, WHO National Health Accounts⁵, WHO Level I Survey 2003⁹ and 2007, WHO World Medicines Situation¹³

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
9.1. ↗	KR GOVERNMENT: KR Government Decree of 24 August 2007, № 363 “On State Benefits Program for provision of citizens of the Kyrgyz Republic with health services”	
9.2. ↗		
9.3. ↗		
9.4. ↗	MOH of KR (Order №349, 2000)	Includes list of drugs that are provided free for the patients on the primary level in case of emergency conditions
9.5. ↗		
9.6. ↗	KR GOVERNMENT, 2007: KR Government Decree of 24 August 2007 № 363 “On State Benefits Program for provision of citizens of the Kyrgyz Republic with health services” – Provisions on co-payment	
a.		Co-payment level is being differentiated by the regions depending on healthcare level and rights for preferences
9.7. ↗		
a.		

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10. Medicines Trade: Intellectual Property Laws

Possible sources: Ministry of Trade, National Patent Office, WTO¹⁴

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
10.1.	Law of the KR of 17 November 1998, N 146 “On ratification of the Protocol on accession of the Kyrgyz Republic to Marrakech Agreement about establishing of the World Trade Organization”	1. Marrakesh Agreement includes an "Agreement on intellectual property aspects related to trade" (hereinafter referred to as "TRIPS Agreement"), which applies to drugs. Manufacture of patented drugs and their sale are made in accordance with the patent laws of the Kyrgyz Republic, as well as the Law of the Kyrgyz Republic "On Trademarks, Service Marks and Appellations of Origin”.

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11. Medicines Trade: Registration

Possible sources: MOH, Medicines Regulatory Agency, WHO Level I Survey 2003⁹ and 2007, WHO Evaluation of Pharmaceutical Regulations¹⁰

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
11.1. →	1. Drug Law of the KR of April 30, 2003, N 91 2. MOH order of 8 September, 1998, N 215 “On approval of number of instructions”	
11.2. →	1. MOH order of September 8, 1998, N 215 “On approval of number of instructions” 2. MOH of February 12, 2010, № 72 “On Approval of organizational structure and personnel of the Department on Drug Provision and Medical Equipment under the MOH KR”	DRA structure includes registration department, committee of pharmacopoeia, pharmacological committee, medical equipment committee.
11.3. →	1. Article 9. “Conflict of interest” of the Law of the KR “On state services”. 2. Government Decree of October 3, 2001, N 602 “On Approval of Rules on eliminating of conflict of interests in the sphere of state regulation in business”	There is no normative act where the conflict between people responsible for the drugs registration is declared
11.4.	MOH order from September 8, 1998, N 215 “On approval of number of instructions”	According to the article 1 of the MOH Order of September 8, 1998, N 215 “On approval of number of instructions”: the medicines are registered under the name of manufacturing company, but the application procedure requires indicating the INN of the drug.
11.5. →	1. Drug Law of the KR 2. Order of the State Agency for Antimonopoly Policy and Promotion of Competition under the Kyrgyz Republic of April 14, 2010, № 117 “On approval of tariffs for expertise provided by the Department on Drug Provision and Medical Equipment under the MOH KR”	
11.6.	Order of the State Agency for Antimonopoly Policy and Promotion of Competition under the Kyrgyz	A new drug examination provided by the DRA costs 1,500\$

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Item Number(s)	Source, Location, & Year	Comments
	Republic of April 14, 2010, № 117 “On approval of tariffs for expertise provided by the Department on Drug Provision and Medical Equipment under the MOH KR”	

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Item Number(s)	Source, Location, & Year	Comments
11.7.	Order of the State Agency for Antimonopoly Policy and Promotion of Competition under the Kyrgyz Republic of April 14, 2010, № 117 “On approval of tariffs for expertise provided by the Department on Drug Provision and Medical Equipment under the MOH KR”	Through the simplified registration process examination of a reproduced medicine costs US \$1,000
11.8. →	1. Civil Code 2. Contract between the DRA and a patentee.	According to the terms of the agreement/contract: Any disputes between the Parties regarding this Agreement must be solved, if possible, amicably. In the event of such dispute can not be resolved within thirty days after reception by one of the Parties of the written notice / claim from the other Party, the matter shall be referred to the Arbitration Court at the Chamber of Commerce in Bishkek
11.9. →	1. MOH order from September 8, 1998, N 215 “On approval of number of instructions”	<p>According to the MOH Order from September 8, 1998, N 215 “On approval of number of instructions”:</p> <p>2.2. Depending on nature of the drug the developer submits the documents and samples in accordance with the following applications: 1, 2, 7, 8, 9, and 10.</p> <p>2.3. Registration Department according to the applications sends to the Pharmacological Dpt, Pharmacopoeia Committee and the Central QC laboratory the samples of active substance and products in the suggested dosage forms (out of 5 pilot lots) in the quantity required for the three complete tests in accordance with the requirements provided by the normative documents and taking into account the tests of microbiological purity.</p> <p>A. The order “On Examination, Clinical Trials and Registration of a New Drug”</p> <p>2. The Central QC Lab conducts laboratory tests of the samples according to the draft NDs submitted.</p> <p>Conclusion on the results of quality control is sent to the Pharmacopoeia Committee.</p>
11.10. →	See the Attachments	
11.11. →		Information on products submitted for registration and at what stage of the

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Item Number(s)	Source, Location, & Year	Comments
		review, is available to legal and physical persons in case of receiving a written request. This information is not posted. on the website
11.12.	1. Drug Law of the KR	According to the article 35 of the Drug Law of the KR: The state registration is performed by the state authorized body of the Kyrgyz Republic within the period not more than 6 months from the date of receiving an Application and the documents for registration procedure.
11.13.	MOH order of October 7, 2003, No 431 “ On approval of simplified drug registration procedure”	State registration procedure on simplified scheme should not be longer than 1.5 month

12. Medicines Trade: Manufacturing

Possible sources: MOH, Medicines Regulatory Agency, Ministry of Labor, Ministry of Trade, National Manufacturer Associations, Pharmacist Associations, International Manufacturer Associations¹⁵, WHO Level I Survey 2003⁹ and 2007

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Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
All manufacturers		
12.1. ➡		There are no pharmaceutical manufacturers satisfying GMP standards in the Kyrgyz Republic
12.2. ➡		Granting, suspension, withdrawal of certification documents. The procedure is done on the base of “KMC ГОСТ Р ИСО/МЭК 65” and Government Decree of 30.12.2005, № 639 ‘Obligatory Assurance of Product Compliance’
Domestic manufacturers		
12.3. ➡	1. Law of the KR “On Licensing” 2. MOH Order of 14.03.2001, № 74 “On approval of the temporary instruction regarding to basic requirements to the manufacturing process” 3. KR Government Decree of May 31, 2001, N 260 “O licensing of selected types of business” 4. Drug Law of the KR	
12.4.	See the Attachments	
12.5.	DRA, 2010	With the aim to find new active substances 3 local companies conduct R&D
a.	Kyrgyz State Medical Academy, data of the PAK “FARM-UNION”, 2010	
b.	DRA, 2010	Kyrgyz pharmaceutical manufacturers do not produce primary pharmaceutical substances
c.	DRA, 2010	33 manufacturers have registered their drugs and stated technological procedures.
d.	DRA, 2010	‘Ashian-medical ltd’. does the prepackaging of the drugs produced by the Kvality Pharmaceuticals Pvt. Ltd
12.6.		
12.7.	DRA report, 2009	The volume of the pharmaceutical products manufactured by the local manufacturers in 2009 was 210 mln. soms. Local drugs value constituted

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Item Number(s)	Source, Location, & Year	Comments
		4.37% of the whole market.
Multinational manufacturers		
12.8. ⇨	1. Law of the KR “On Licensing” 2. MOH order of 14.03.2001, № 74 “On approval of the temporary instruction regarding to basic requirements to the manufacturing process” 3. KR Government Decree of May 31, 2001, N 260 “O licensing of selected types of business” 4. Drug Law of the KR	There are standards for the multinational manufacturers specified by the national legislation
12.9. ⇨	1. Law of the KR “On Licensing” 2. KR Government Decree of May 31, 2001, N 260 “O licensing of selected types of business” 3. MOH order from 08.11.2007, № 393 “On approval of specific requirements to pharmaceutical outlets for running of pharmaceutical business in the Kyrgyz Republic” 4. Drug Law of the KR	
12.10.		
12.11.		

13. Medicines Trade: Quality Assurance

Possible sources: MOH, Medicines Regulatory Agency, WHO Level I Survey 2003⁹ and 2007, WHO Evaluation of Pharmaceutical Regulations¹⁰, Pharmaceutical Security Institute¹⁶

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Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
13.1. →	<p>1. Law of the KR "On order of conduct of inspections in subjects of business"</p> <p>2. Kyrgyz Parliament Decree from June 20, 2008, N 553-IV "On approval of list of the entitled bodies having the right to conduct the inspection of subjects of business";</p> <p>3. KR President Decree from July 2, 2007, N 330 "On measures to improve the inspection order of the subjects of business";</p> <p>4. KR President Decree of May 14, 2009, N 237 "On implementation of unified order of inspection of the subjects of business";</p> <p>5. KR Government Decree of November 6, 2007, N 533 "Order of conduct of inspections in subjects of business and defining the list of the authorized bodies having the right to conduct the inspection of subjects of business";</p> <p>6. KR Government Decree of September 18, 2009, N 591 "On approval of the rules on submission and registration of acts and assigning inspections for the subject of business"</p> <p>7. Law of the KR "On Basics of Technical Regulation in the Kyrgyz Republic"</p> <p>8. List of the authorized bodies performing the state surveillance over enforcement of the obligatory requirements to the products and sphere of their competencies, as approved by the government decree of June 30, 200, N 473</p>	<p>Order of conduct of inspections of businesses engaged in pharmaceutical sector is governed by several laws and regulations that limit the ability to conduct inspections and identify gaps in the work of entrepreneurs.</p> <p>Based on the Action Plan for the planned inspections of businesses involved in pharmaceutical sector, approved by the Office of Entrepreneurship of the Ministry of Economic Management, the DRA during 5 months in 2010 inspected 50 entities. All charges have been recorded in the General Prosecutors Office.</p> <p>In order to implement paragraph 2 of the Decree of the Provisional Government of the Kyrgyz Republic № 35 dated 05.13.2010 "On Limitation of the audits conducted by law enforcement, tax and other authorized bodies entitled to conduct inspections of businesses," the DRA reduced the number of inspections of pharmaceutical organizations by 70%.</p> <p>The DRA is a specially authorized state body of executive power, exercising state supervision over the implementation of mandatory requirements for pharmaceutical products according to their area of competence.</p>
13.2. →	<p>1. Drug Law of the KR</p> <p>2. Bishkek municipal</p>	<p>Drug Law, art. 10 specifies that the authorized state body carries out the state quality control of drugs through the imposition of the ban on the</p>

Pharmaceutical Sector Scan – Data Sources and Comments

Item Number(s)	Source, Location, & Year	Comments
	<p>administration decree № 98 “On illegal trade of poor quality drugs in Bishkek” dated 28.05.04 .</p> <p>3. Osh Bishkek’s municipal administration decree № 1479 “On illegal trade of poor quality drugs in Bishkek” dated 31.10.05 .</p> <p>4. The cooperation agreement in struggle against the falsified medical products, signed on November, 14th, 2008 in the city of Kishinev, approved by the Governmental Order KR N 246, from April, 23, 2009</p> <p>5. MOH Order from 16 July 2009, No 539 “ On realization of the Government Decree N 246 of April 23, 2009, "On approval of the Cooperation Agreement in struggle against the falsified medical products, signed on November, 14th, 2008 in the city of Kishinev”</p>	<p>dispensing of the counterfeit, substandard and smuggled drugs into the territory of the Kyrgyz Republic.</p> <p>The Department is currently introducing new forms of combat against proliferation of smuggling drugs, as accordance with Bishkek municipal administration Decree № 98 “On illegal trade of poor quality drugs in Bishkek” dated 28.05.04 and Osh Bishkek’s municipal administration decree № 1479 “On illegal trade of poor quality drugs in Bishkek” dated 31.10.05 it is prohibited trade of pharmaceuticals in the markets and public places, and heads of the markets could be brought to book.</p>
13.3. ➡	See point 13.3	
13.4. ➡	<p>1. DRA QC Lab report, 2009</p> <p>2. Southern DRA branch report, Osh city, 2009</p> <p>3. DRA Certification Unit report, 2009</p>	In 2009, the accredited QC labs conducted 10,529 certification tests of medicines and medical equipment. In addition, Central QC Lab of the DRA conducted 1,642 tests of the drugs submitted for registration, and 57 – for re-examination.
13.5. ➡	DRA Certification Unit, report, 2009	18 drugs were found defective in 2009
13.6. ➡		The annual number of qualitative analyses is not being reported. Protocols of the drugs tests are kept within the date of expiration (about 5 years).
13.7. ➡		

14. Medicines Trade: Price Control and Transparency

Possible sources: MOH, Medicines Regulatory Agency, Wholesalers, Retailers, Health Insurance Agencies, IMS¹², WHO Level I Survey 2003⁹ and 2007, WHO Evaluation of Pharmaceutical Regulations¹⁰, WHO/HAI Surveys¹⁷

Pharmaceutical Sector Scan – Data Sources and Comments

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Legal or regulatory provisions for medicines price control		
14.1. ⇒	GD KR of April 22, 2009, N 242 “ On state price regulation of selected types of the socially important food products”	Drugs are not included into the list of regulated products.
a.		There is no regulation on maximum price markup for the drugs.
b.		There is no regulation on maximum price markup for the drugs.
c.		There is no regulation on maximum price markup for the drugs.
d.	1. Tax Code 2. Drug Law (contains definition on what is the ‘medicine’).	1. According to article 242. “Products and services in health care system” of the Tax Code from October 17, 2008, N 230 “drug supply is a supply exempted from VAT”. 2. Imported drugs are assessed the customs duty 0.15%
e.	1. Tax code 2. Drug Law (contains definition on what is the ‘medicine’).	Article 257. Clearing of the VAT of the imported goods 1. The following goods imported on to the territory of the Kyrgyz Republic are released from the VAT: 1. Medicines 2. Imported drugs are assessed the customs duty 0.15%
f.	1. Tax code 2. Drug Law (contains definition on what is the ‘medicine’). 3. Customs Code of the KR. 4. Law of the KR “On Customs Tariffs”	1. According to article 242. “Products and services in health care system” of the Tax Code from October 17, 2008, N 230 “drug supply is a supply exempted from VAT”. 2. Imported drugs are assessed the customs duty 0.15% There is 1% tax of the sales. There is 10% tax from the profit.
14.2.		
Medicines price transparency		
14.3. ⇒	www.antimonopolia.kg	The drug prices are posted on www.antimonopolia.kg
14.4. ⇒	1. KR Government Decree from January 12, 2007, N 11 “On State Drug Policy for 2007-2010” 2. The law «About protection of the	Point 3.3.4. of the Plan of Measures on realization of the State Drug Policy stipulates the regular publications of drug price monitoring results

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Item Number(s)	Source, Location, & Year	Comments
	rights of consumers»	
14.5. →		

Pharmaceutical Sector Scan – Data Sources and Comments

15. Medicines Trade: Price Comparison in the Private-for-Profit Sector

Possible sources: MOH, Medicines Regulatory Agency, Wholesalers, Retailers, Health Insurance Agencies, IMS¹², WHO Level I Survey 2003⁹ and 2007, WHO Evaluation of Pharmaceutical Regulations¹⁰, WHO/HAI Surveys¹⁷

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Medicines price comparison in the private for-profit sector (i.e. retail pharmacies)		
15.1. a.	1. Retail prices of the original drugs of Neman-Pharm Ltd., Bimedpharm Ltd. 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
b.	1. Retail prices of the original drugs of Neman-Pharm Ltd., Bimedpharm Ltd. 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
15.2.	DRA Import Unit , 2009	The average selling price of the manufacturer (CIF) was calculated on the basis of invoices of importers and price-lists of the pharmaceutical companies in Bishkek.
15.3.	Wholesale price Lists, 2010	The average wholesale price was calculated on the base of prices of the pharmaceutical companies.
15.4.	PAK 'FarmUnion', 2010	3-6% of the wholesale price
15.5.	1. Tax code 2. Drug Law (contains definition on what is the 'medicine'). 3. Customs Code of the KR. 4. Law of the KR "On Customs Tariffs"	Import drugs are assessed the customs duty 0.15% There is 1% tax of the sales. There is 10% tax from the profit.

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16. Medicines Trade: Consumer Prices of Medicines on HAI Global Core List

Possible sources: WHO/HAI Survey¹⁷

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Medicine, Strength, Formulation		

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16.1.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.2.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.” Semiannual health facilities reports on procured drugs for 2009	
16.3.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.4.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.5.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.6.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.7.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.8.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.9.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.10.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.11.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.12.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	

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16.13.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	
16.14.	Retail networks “Neman-Pharm Ltd.”, and “Bi-med Ltd.”, 2010 Semiannual health facilities reports on procured drugs for 2009	

17. Medicines Trade: Promotion and Advertising - Legal and Regulatory Provisions

Possible sources: MOH, Medicines Regulatory Agency, National Manufacturer Associations, Consumer Associations, NGOs, Public Procurement Agencies, International Manufacturer Associations¹⁵, WHO/HAI¹⁷

Pharmaceutical Sector Scan – Data Sources and Comments

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
17.1. →	<p>1. KR Law “On advertising”</p> <p>2. Drug Law, Article 49. Advertising of medicines;</p> <p>3. MOH Order from 3.02.2004 №42 “On approval of drug advertising rules in the Kyrgyz Republic”</p> <p>4. KR Government Decree from 12 January 2007 N 11 “On State Drug Policy for 2007-2010”</p>	<p>According to the MOH Order from 3.02.2004, №42 “On approval of drug advertising rules in the Kyrgyz Republic”: advertising of the medical products is executed on the basis of permission given by the authorized controlling body, after examination of the advertising materials by the Expert Commission on Examination Of Advertising Materials.</p>
17.2. →	<p>1. KR Law “On advertising”</p> <p>2. Drug Law, Article 49. Advertising of medicines;</p> <p>3. MOH order from 3.02.2004 №42 “On approval of drug advertising rules in the Kyrgyz Republic”</p> <p>4. KR Government Decree from 12 January 2007 N 11 “On State Drug Policy for 2007-2010”</p>	
17.3. →	<p>1. Drug Law</p> <p>2. MOH Order from May 18, 2005, N 196 “On measures on suppression of the facts of illegal trade of poor-quality medical products and medical items on the territories of the health organizations of the Kyrgyz Republic”</p> <p>3. MOH Order from 14. 01.2010 № 15 ‘On works with medical representatives’</p>	<p>According to the article 12. Drug marketing and promotion:</p> <p>Promotion of medicines on the market should be exact, impartial and objective, correspond to the legal requirements, and also to high ethical standards.</p> <p>The heads of the health and medical educational institutions, scientific research institutes and the national centers, and also private clinics, should not participate in unethical marketing of medicines. For infringement of the rules and orders of drug regulations the administrative and criminal punishment in an administrative and criminal order is envisaged.</p>
17.4. →	<p>MOH Order from 3.02.2004 № 42 “On approval of the drug advertising rules in the Kyrgyz Republic”</p>	<p>According to the MOH Order from 3.02.2004, №42 “On approval of drug advertising rules in the Kyrgyz Republic”: the advertising of the medical products is executed on the basis of permission given by the authorized controlling body, after examination of the advertising materials by the Expert Commission on Examination Of Advertising Materials</p>
17.5. →	<p>MOH Order from 3.02.2004, № 42 “On approval of drug advertising rules in the Kyrgyz Republic”</p>	<p>The Expert Commission on Examination Of Advertising Materials is developed and</p>

Pharmaceutical Sector Scan – Data Sources and Comments

		functions in the DRA
a.	MOH Order from 3.02.2004, № 42 “On approval of drug advertising rules in the Kyrgyz Republic”	
b.	MOH Order from 3.02.2004, № 42 “On approval of drug advertising rules in the Kyrgyz Republic”	
c.		There is no normative act.
17.6. ➡	Law of the KR from 24 May 2004, N 69 “On Public Procurement”	Standard tender documents for public procurement have been developed.
17.7. ➡		Complaint reports for promotion practice are not available, because a complaint tracking system is not developed.
17.8. ➡	DRA Drug Information Center data, 2009-2010.	For the period of 2009-2010 there were no cases of violations and sanctions concerning drugs advertisements.

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18. Medicines Trade: Promotion and Advertising - Code of Conduct and Spending

Possible sources: MOH, Medicines Regulatory Agency, National Manufacturer Associations, consumer Associations, NGOs, Public Procurement Agencies, International Manufacturer Associations¹⁵, WHO/HAI¹⁷

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Code of conduct		
18.1. →	Code of professional ethics of the medical worker. Approved by the MOH order, on January 16, 2004 N 2-4	The current Code does not restrict any gifts from pharmaceutical companies to the medical workers.
18.2. →	The moral - ethical Code of the pharmacists. Approved by the 1 st Congress of the pharmaceutical workers, 2003	... the pharmacist should adhere to principles of an ethical competition, ethical marketing and advertising...
a.		
b.	The moral - ethical Code of the pharmacists. Approved by the 1 st Congress of the pharmaceutical workers, 2003	
c.		A procedure of complaints and sanctions is not stipulated in the Code. The Procedure is regulated by the law of the KR from May 4, 2007, N 67 'On order of the civil complaints consideration"
d.	Tax Code of the KR	The list of complaints and sanctions for the last 2 years is not available. These data are not published.
Promotion and Advertising Spending		
18.3. →		Some pharmaceutical companies have been surveyed to clarify the issue: the contracted media companies submit to the customers the invoice for media services provided, which includes 12% of VAT and 2% sales tax.

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19. Medicines Supply System: Selection

Possible sources: MOH, Health Insurance Agencies, WHO Level I Survey 2003⁹ and 2007

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
19.1. ➡	Health Development Center with Evidence Based Medicine Department, and the MOH Expert Committee on consideration of clinical guidance and protocols, 2010	There is a strategy for development of evidence based medicine in the Kyrgyz Republic. Clinical guidelines/protocols are developed in accordance with approved at the MoH plans and schedules. If new evidences are found, then the reviewing of existing clinical protocols is carried out in accordance with an international methodology, adapted to local conditions. In 2007, there have been trained 880 specialized doctors, 1,332 family doctors, and 1,332 paramedics on clinical protocols on the base of the Kyrgyz State Institute for Retraining
a.		Clinical protocols and guidance are approved by the orders of MOH
b.	MOH order from March 10, 2010, N 126 'On approval of clinical protocols'	The following clinical protocols were approved by the order: " Community-acquired pneumonia in adults" for primary healthcare level, " Community-acquired pneumonia in adults" for the secondary level, "Tobacco dependence".
19.2. ➡	Government Decree from March 20, 2009, N 187 "On approval of the EDL"	
a.		350 INN were included into EDL of the KR.
b.		For the last 20 years the ELD was revised 6 times (1996, 1998, 2001, 2004, 2006, 2009)
c.	Government Decree from March 20, 2009, N 187 "On approval of the EDL"	
d.		Information on revision of an EDL with the questionnaire form used is posted on the MOH website; in addition it is distributed among healthcare organizations. In 2008, 1,500 doctors were questioned within the EDL revision survey.
e.	KR Government Decree from June 24, 1996, N 288 "Human Health protection issues and health reforms in the Kyrgyz Republic"	6.3.2. Selection of the essential drugs Selection of drugs for the List has been produced, mainly, on international

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Item Number(s)	Source, Location, & Year	Comments
		<p>generic names and is based mainly on the following criteria: efficacy and safety proved by reliable and adequate data sources, obtained through clinical trials, and with information on use in various health conditions; cost efficiency, cheapness, accessibility, and presence in formulation only one pharmaceutical substance</p> <p>Further actions require the following: - Drug Committee, which was established under the Ministry of Health of 41 representatives of different medical specialties, will be periodically (every two years) review and update the EDL to meet changing priorities of the health services and epidemiological conditions, as well as advances in pharmacology and pharmacy .</p>
f.		<p>The list of the EDL Examination Drug Committee members is approved by the MOH Order. The list is available through official request.</p>
g.		<p>All members of the Drug Committee are supposed to declare any conflict of interests. But such procedures is not clearly defined .</p>
19.3. ➡		<p>Drug selection for EDL is executed on the base of WHO recommendations.</p>
19.4. ➡		<p>Currently a new National Drug Formulary is being prepared for publishing</p>
a.		<p>The National Drug Formulary contains EDL with INN, trade names of originators and generics.</p>
b.		<p>EDL is being revised every 2 years. The last revision was done in 2009.</p>

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20. Medicines Supply System: Procurement in the Public Sector

Possible sources: MOH, Government Procurement Agency, Public Hospitals and Dispensaries, WHO Level I Survey 2003⁹ and 2007, WHO/HAI Surveys¹⁷, IMS¹²

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
20.1. →	Law of the KR “On public procurement” MOH Procurement Department , 2010	For each tender a new tender committee is created.
20.2.	MOH Order from November 17, 1999, N 333 “Regulation on provision of ensured citizens through Basic Mandatory Health Insurance Program in health organizations working in Mandatory Health Insurance system with medicines and medical items”	
20.3. →	Law of the KR “On public procurement”	The criteria for pre-qualification of drug suppliers have not been developed.
a.		
b.		
c.		
20.4.		Last year procurement data was not available. The data is kept in the MOH.
a.		
b.		
c.		
20.5. →		Information on all executed tenders have been published in Public procurement bulletin of the KR and posted on the Procurement Agency website.
20.6. →		Tender results have been published in Public procurement bulletin of the KR and posted on the Agency website.
20.7. →		Electronic system is not developed yet.
20.8. →		Procurement quality review results are available only for tender participants.
20.9.		There is no such data.
a.		
b.		

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21. Medicines Supply System: Procurement Price of Medicines (HAI Global List)

→ Possible source: WHO/HAI Surveys¹⁷

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Medicine, Strength, Formulation		

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21.1. Salbutamol 0.1mg/dose Inhaler	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.2. Glibenclamide 5 mg Cap/tab	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.3. Atenolol 50 mg Cap/tab	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.4. Captopril 25 mg Cap/tab	1. Semiannual health facilities reports on	It was calculated the ratio of local prices of originator

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	procured drugs for 2009 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International 3. Management Sciences for Health (MSH)	and generic drugs to the International Reference Price. Then, the average MPR was calculated.
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Pharmaceutical Sector Scan – Data Sources and Comments

21.5. Simvastatin 20 mg Cap/tab	<ol style="list-style-type: none"> 1. Semiannual health facilities reports on procured drugs for 2009 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International 3. Management Sciences for Health (MSH) 	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.6. Amitriptyline 25 mg Cap/tab	<ol style="list-style-type: none"> 1. Semiannual health facilities reports on procured drugs for 2009 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International 3. Management Sciences for Health (MSH) 	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.7. Ciprofloxacin 500 mg Cap/tab	<ol style="list-style-type: none"> 1. Semiannual health facilities reports on procured drugs for 2009 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International 3. Management Sciences for Health (MSH) 	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.8. Co-trimoxazole 8 + 40 mg/ml Susp.	<ol style="list-style-type: none"> 1. Semiannual health facilities reports on 	It was calculated the ratio of local prices of originator

Pharmaceutical Sector Scan – Data Sources and Comments

	procured drugs for 2009 2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International 3. Management Sciences for Health (MSH)	and generic drugs to the International Reference Price. Then, the average MPR was calculated.
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Pharmaceutical Sector Scan – Data Sources and Comments

21.9. Amoxicillin 500 mg Cap/tab	<p>11. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.10. Ceftriaxone 1 g/ vial Injection	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.11. Diazepam 5 mg Cap/tab	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.
21.12. Diclofenac 50 mg Cap/tab	1. Semiannual health facilities reports on	It was calculated the ratio of local prices of originator

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	<p>procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	<p>and generic drugs to the International Reference Price. Then, the average MPR was calculated.</p>
21.13. Paracetamol 24 mg/ml Susp.	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	<p>It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.</p>
21.14. Omeprazole 20 mg Cap/tab	<p>1. Semiannual health facilities reports on procured drugs for 2009</p> <p>2. Medicine prices: new measurement approach, 2004 edition, World Health Organization, Health Action International</p> <p>3. Management Sciences for Health (MSH)</p>	<p>It was calculated the ratio of local prices of originator and generic drugs to the International Reference Price. Then, the average MPR was calculated.</p>

22. Medicines Supply System: Distribution

Possible sources: MOH, Ministry of Trade, Pharmacists Associations, WHO Level I Survey 2003⁹ and 2007, WHO mapping medicines supply and distribution project (ongoing), MeTA mapping

Pharmaceutical Sector Scan – Data Sources and Comments

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
All Distributors		
22.1. ➡	DRA, 2010	It is developed the draft Kyrgyz Republic GD "On Approval of Technical Regulations on Safety of Drugs for Medical Use", which included guidelines on good distribution practice
22.2. ➡		
Central Medical Store		
22.3.	DRA, 2010	The DRA, DGSEN have warehouses for storage of medical equipment and drugs
22.4.	RMIC, 2010	There is a software on contraceptives. The data on contraceptives is submitted to and generalized in the RMIC quarterly. As to other groups of medicines - no software has been developed yet.
22.5. ➡	DRA, 2010	Drugs remains information is submitted to the DRA on monthly basis.
22.6.	DRA, 2010	In 2009 and for the first 5 months of 2010 there were no supply disruptions with diabetic drugs, contraceptives and serums.
22.7.		Data are missing
22.8. ➡	DRA, 2010	Shelf life of drugs is regulated by the Drug Law and tracked by the pharmaceutical companies on the basis of internal documents
Wholesale market characteristics		
22.9. ➡	1. Law of the KR "On Licensing" 2. MOH order from November 8, 2007, N 393 "On approval of specific requirements to pharmaceutical outlets to conduct the pharmaceutical business in the Kyrgyz Republic". 3. GD KR of May 31, 2001, N 260 "On licensing of selected types of business" 4. Drug Law of the KR	
22.10. ➡	Pharmaceutical Organizations Handbook, edition № 6, 2009	
22.11. ➡	«Pharm-Union», Association of pharmacists of Kyrgyzstan.	
22.12.	«Pharm-Union»	Large wholesale suppliers are united in Pharmaceutical Association of

Pharmaceutical Sector Scan – Data Sources and Comments

Item Number(s)	Source, Location, & Year	Comments
		Kyrgyzstan “Pharm-Union”, 50 members.
22.13.	Licensing Unit of the DRA	16 out of 40 manufacturers having drugs manufacture license are involved in the integrated wholesale activity.

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23. Medicines Access

Possible sources: MOH, Medicines Regulatory Agency, WHO Level II Survey, WHO Medicines Survey (ongoing), INRUD Indicators¹⁸, World Health Survey¹⁹, International Household Survey Network

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Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
Geographic access		
23.1. →		
23.2. →		
Affordability of medicines		
23.3. →	WHO/HAI Drug prices: new pricing methodology, Geneva, World Health Organization, 2003	The minimum paid employee had to pay 2.5 daily wage to the private pharmacies for the treatment with cotrimaxozol suspension of the child with acute respiratory illness
23.4. →	WHO/HAI. Drugs prices: new pricing methodic, Geneva, World Health Organization, 2003	The minimum paid employee had to pay in private pharmacies 1.5 daily wage for the standard treatment with atenolol of the hypertension
23.5. →	NATIONAL STATISTICS COMMITTEE, Retail Pharmacy Network.	Only data on civil servant average wage is available.
23.6. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	The doctors prescribed 79% of EDL.
Availability of medicines		
23.7. →	DRA data for 2009 based on the HF annual reports on procured medicines, as well as on analysis of the data on imported drugs for the year of 2010r	407 medicines and INNs were included in the EDL, from those 132 names weren't imported in 2010 (32%)
23.8. →	Policy Research Paper №46 "Health, healthcare referral, patient cash expenses "from-pocket" in Kyrgyzstan", 2007	92% of patients have told they bought the drugs prescribed.
Equity in access		
23.9. →		no data
23.10. →		no data
23.11. →		no data

Pharmaceutical Sector Scan – Data Sources and Comments

24. Medicines Use: National Structures

Possible sources: MOH, Professional organizations, NGOs, WHO Level II Survey, WHO Level I Survey 2003⁹ and 2007, INRUD indicators¹⁸

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
24.1. →	1. GD Kyrgyz Republic of January 12, 2007, N 11 "On National Drug Policy for 2007-2010" 2. KR Government Decree from 16 February 2006, N 100 "On National Health Reforms Program 'Manas Taalimi' for 2006-2010".	
24.2. →	DRA Drugs Information Center.	
24.3. →		There is a National Antimicrobial Resistance Strategy project.
24.4. →	NGO "Prophylaxis", MOH	
24.5.	1. MOH Order from 15.04.2003 "On research and methodological Center on Rational and Safe Use of Medicines 2. DRA 3. National Drug Committee	
INRUD facility indicators		
24.6. →		Clinical protocols are introduced in all health institutions of the KR
24.7. →		EDL is used in all health institutions of the KR

Pharmaceutical Sector Scan – Data Sources and Comments

25. Medicines Use: Prescribing

Possible sources: MOH, Professional organizations, NGOs, WHO Level I Survey 2003⁹ and 2007, WHO Level II Survey, INRUD indicators¹⁸, WHO Level II survey

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
25.1. →	1. Drug Law of the KR 2. MOH Order from 30 January 2006, N 48 "On drug prescribing and dispensing rules" 3. MOH Order from 30 April 2001, N 133 "On provision of ensured citizens with medicines within Additional Drug Package Program of the mandatory health insurance on primary healthcare level"	
25.2. →	1. Drug Law of the KR 2. MOH Order from 30 January 2006, N 48 "On drug prescribing and dispensing rules"	
25.3. →	1. MOH Order from 30 April 2001, N 133 "On provision of ensured citizens with medicines within Additional Drug Package Program of the mandatory health insurance on primary healthcare level"	
25.4.	1. MOH Order from 30 April 2001, N 133 "On provision of ensured citizens with medicines within Additional Drug Package Program of the mandatory health insurance on primary healthcare level"	
a.		
b.		
c.		
25.5.		
a.		
b.		
c.		
INRUD prescribing indicators		
25.6. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	On average, the doctors prescribed 2 medicines at one visit.
25.7. →		

Pharmaceutical Sector Scan – Data Sources and Comments

Item Number(s)	Source, Location, & Year	Comments
25.8. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	Antimicrobial drugs prescription level is 35,7%.
25.9. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	Injection prescription level in the country is 17 %
25.10. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	EDL drugs prescription level is 79%
25.11.		
Disease-specific prescribing indicators		
25.12.		
25.13.		

Pharmaceutical Sector Scan – Data Sources and Comments

26. Medicines Use: Dispensing

Possible sources: MOH, Professional organizations, NGOs, WHO Level II Survey, WHO Level I Survey 2003⁹ and 2007, INRUD indicators¹⁸, WHO Level II survey

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
26.1. →	1. Drug Law of the KR 2. MOH Order from 30 January 2006, N 48 "On drug prescribing and dispensing rules" 3. MOH Order from 30 April 2001, N 133 "On provision of ensured citizens with medicines within Additional Drug Package Program of the mandatory health insurance on primary healthcare level"	
26.2. →	MOH Order from 30 January 2006, N 48 "On drug prescribing and dispensing rules"	
26.3. →	'The moral – ethical Code of the pharmacists'. Approved by the 1 st Congress of the pharmaceutical workers, 2003	
26.4. a.	MOH Order from 20 June 2006, N 332 "On preferential drug provision on outpatient level with State Benefits Program"	42.1. If the doctor prescribed a generic name drug and generic code is indicated, the pharmacist must inform the patient of all available options in the drugstore of the generic substitution with an indication of price parameters. In this case, it may be dispensed any drug given in the Handbook of Drugs within a package of generic names of drugs, taking into account the wishes of the patient;
b.	GD Kyrgyz Republic of January 12, 2007, N 11 "On National Drug Policy for 2007-2010"	
26.5. →	MOH Order from 30 January 2006 N 48 "On drug prescribing and dispensing rules"	Antibiotics are not included in the list of medicines and medical products which are allowed to be dispensed from pharmaceutical organizations without a prescription
26.6. →	MOH Order from 30 January 2006, N 48 "On drug prescribing and dispensing rules"	The list of medicines and medical products which are allowed to be dispensed from pharmaceutical organizations without a prescription includes a number of injectable

Pharmaceutical Sector Scan – Data Sources and Comments

Item Number(s)	Source, Location, & Year	Comments
		medicines.
26.7. →	MOH Order from 30 January 2006, N 48 “On drug prescribing and dispensing rules”	
INRUD dispensing indicators		
26.8.		
26.9. →		
26.10. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	94,3 % of drugs had been appropriately labeled while dispensing from the pharmacy.
26.11. →	Monitoring report of Family Doctors Performance and State Drug Policy implementation (April-June 2003)	71 % of questioned clients knew about proper intake of the drug and its dosage.

Pharmaceutical Sector Scan – Data Sources and Comments

27. Medicines Use: Pharmaco-vigilance

Possible sources: MOH, Medicines Regulatory Agency, WHO Level I Survey 2003⁹ and 2007, WHO Evaluation of Pharmaceutical Regulations¹⁰, Uppsala WHO Collaborating Center²¹

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
27.1.	1. Drug Law of the KR 2. MOH Order № 535 from 25.12.02, 'On Improvement of HF's Performance with Regards to Control and Registration of the ADRs when Using Drugs'	According to article. 29: The health organization involved into use of medicines should report on ADRs and the characteristics of the interaction of drugs with other drugs to the public health authority of the Kyrgyz Republic.
27.2.	DRA report, 2009	"Yellow cards" were distributed among health institutions of the KR
27.3.	DRA report, 2009	In 2009, 13 ADRs were reported to the DRA Information Center

Possible National Sources of Key Data

1. Government Procurement Agency
2. Manufacturer Associations
3. Medicines Regulatory Agency
4. Ministry of Finances
5. Ministry of Health
6. Ministry of Labor
7. Ministry of Planning
8. Ministry of Trade
9. Mission Hospitals
10. National Bureau of Statistics
11. National or Social Health Insurance Agency
12. Non-Governmental Organizations
13. Private Health Insurers
14. Professional Organizations: physicians, pharmacists, nurses
15. Public Hospitals and Dispensaries

ACHRONYMS

NSC	National Statistic Committee of the Kyrgyz Republic
SCI	State Customs Inspection
RMIC	Republican Medical Information Center of the Kyrgyz Republic
FAP	Rural Obstetrician Point
DRA	Department on Drug Provision and Medical Equipment in the Kyrgyz Republic
MOH	Ministry of Health of the Kyrgyz Republic
MHIF	Mandatory Health Insurance Fund in the Kyrgyz Republic
DGSEN	Department of State Sanitarian and Epidemiological Control in the Kyrgyz Republic
HF	Health Facility
GPC	General Practice Center
FMC	Family Medicine Center
FGP	Family Group Practitioners
ADR	Adverse Drug Reaction
RDU	Rational Drug Use
KR	Kyrgyz Republic
GD	Government Decree

Possible International Sources of Key Data

¹ WHO Statistical Information System (WHOSIS)

<http://www.who.int/whosis/en/index.html>

Provides recent and comprehensive health data on all of the 193 WHO Member States. The data, selected on the basis of quality and availability, relevance to global health, and comparability across member nations, cover over 50 core health indicators, which are organized into six major areas: mortality and burden of disease, health service coverage, risk factors, health system inputs, differentials in health outcome and coverage, as well as basic socio-demographic statistics. These are published in the World Health Statistics that is released in May of each year.

Data exist for all seven MeTA pilot countries.

² WHO Global InfoBase

<http://www.who.int/infobase/report.aspx>

The WHO Global InfoBase is a data warehouse that collects stores and displays information on chronic diseases and their risk factors for all WHO member states.

Data exist for all MeTA pilot countries.

³ World Bank Development Report

http://siteresources.worldbank.org/INTWDR2009/Resources/4231006-1225840759068/WDR09_22_SWDIweb.pdf

The World Bank development report 2009 provides recent values for most country profile indicators.

⁴ National Macroeconomics and Health Report

<http://www.who.int/macrohealth/en/>

National Macroeconomic and Health Reports provide data on health status, health systems, health care financing, and an analysis of costs of health care and investment plan.

A 2005 Report of the Ghana Macroeconomics and Health Initiative exists.

⁵ WHO National Health Accounts

<http://www.who.int/nha/en/>

National Health Accounts (NHA) provides evidence to monitor trends in health spending for all sectors, public and private, different health care activities, providers, diseases, population groups and regions in a country, intended to help in developing national strategies for effective health financing and in raising additional funds for health. Information can be used to make financial projections of a country's health system requirements and compare their own experiences with the past or with those of other countries.

Data until 2005 (last revision in 2007) exist for all MeTA pilot countries. However some data may be much older. That is why it is important to document the date of data collection for each data point included in the sector scan.

⁶ WHO Global Burden of Disease and Risk Factors database

<http://www.who.int/healthinfo/bod/en/index.html>

Statistical estimates of mortality and burden of disease (DALYs) by cause for the world, regions and WHO Member States. Estimates of Healthy Life Expectancy (HALE) and Life Expectancy for WHO Member States; latest documentation, methods, results and projections for the Global Burden of Disease; manuals, resources and software for carrying out national burden of disease studies.

⁷ Demographic and Health Surveys (DHS)

<http://www.measuredhs.com/aboutsurveys/start.cfm>

DHS supports a range of data collection options tailored to fit specific monitoring and evaluation needs of host countries.

Demographic and Health Surveys (DHS)

Provide data for a wide range of monitoring and impact evaluation indicators in the areas of population, health, and nutrition.

AIDS Indicator Surveys (AIS)

Provide countries with a standardized tool to obtain indicators for the effective monitoring of national HIV/AIDS programs.

Service Provision Assessment (SPA) Surveys

Provides information about the characteristics of health and family planning services available in a country.

Key Indicators Survey (KIS)

Provides monitoring and evaluation data for population and health activities in small areas—regions, districts, catchment areas—that may be targeted by an individual project, although they can be used in nationally representative surveys as well.

Other Quantitative Surveys

Includes biomarker collection, geographic data collection, and benchmarking surveys.

Qualitative Research

Provides informed answers to questions that lie outside the purview of standard quantitative approaches.

Data for many of these surveys exist for MeTA countries. Details can be found at:

<http://www.measuredhs.com/aboutsurveys/search/>.

⁸ World Bank Health and Nutrition Data Base (HNPStats)

<http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTDATASTATISTICSHNP/EXTHNPSTATS/0,,menuPK:3237172~pagePK:64168427~piPK:64168435~theSitePK:3237118,00.html>

The World Bank's comprehensive database of Health, Nutrition and Population (HNP) statistics makes a variety of national and international data sources available in one location, compiles World Bank data on health, nutrition and population, adopts an analysis-friendly format that enables flexible access and custom-tailored reports, and provides links to a large number of websites of international agencies and country statistical offices.

Data exist for all MeTA pilot countries.

⁹ WHO Level I Pharmaceutical Assessment

http://www.who.int/medicines/areas/technical_cooperation/supply_management/AssessMoni/en/index.html

To monitor the progress and consequently improve the global medicines situation, WHO/TCM has developed a system of indicators that measures key aspects of a country's pharmaceutical situation. A standard methodology allows over time progress monitoring as well as comparisons across facilities, districts and countries. The process of pharmaceutical monitoring and assessment uses a hierarchical approach with three groups of indicators: Level I, Level II and Level III. Standardized key informant questionnaires (Level I) assess the structures and processes related to medicines in a country legislation and regulations; quality control of medicines; essential medicines lists; supply systems; financing; production; rational use; and protection of intellectual property rights. Level II facility and household surveys medicines assess, product quality, and rational use (see MeTA Assessment Component E). Level III tools measure specific components of the pharmaceutical sector, health system, or national medicines policy in more depth. Examples include the WHO/HAI medicines price surveys (see MeTA Assessment Component E).

Level I data from 1999 and 2003 exist for all seven MeTA pilot countries.

All Level I data revised in 2007 are available upon request

¹⁰ **WHO Multi-Country Study on Effective Drug Regulation**

<http://www.who.int/medicinedocs/en/d/Js2300e/#Js2300e.17>.

The aim of this 10-country study was to assess drug regulation performance in selected countries using a standardized study guide, and to document the results so that other countries may learn from them.

The standardized study guide assesses drug regulation in general and specific drug regulatory functions (licensing, inspection and surveillance, product assessment and registration, adverse drug reaction monitoring, clinical trials, control of drug promotion and advertising, drug quality control laboratory).

Uganda is a MeTA pilot country included in the 2002 report

Data until 2005 (last revision in 2007) exist for all MeTA pilot countries. However some data may be much older. That is why it is important to document the date of data collection for each data point included in the sector scan.

¹¹ **WHO Ethical Infrastructure for Good Governance**

<http://www.who.int/medicines/areas/policy/goodgovernance/home/en/>

Guided by WHO's Medicines Strategy 2004-2007 and launched in late 2004, the Good Governance for Medicines programme's goal is to raise awareness of abuse in the public pharmaceutical sector and to promote good governance. Participating countries complete a standardized Good Governance Assessment Tool on the level of transparency and vulnerability to corruption in the public pharmaceutical sector. The Assessment Tool evaluates medicines registration, control of medicines promotion, inspections of establishments, selection of essential medicines, procurement, and distribution.

Data exist for the following MeTA pilot countries: Ghana, Jordan, Philippines, Zambia

¹² **IMS Pharmaceutical Market Assessment Data**

<http://www.imshealth.com/portal/site/imshealth>

IMS agreed to share data on request

Data exist in Peru and the Philippines, and possible other MeTA pilot countries.

¹³ **WHO World Medicines Situation (WMS)**

<http://www.who.int/medicinedocs/index.fcgi?sid=zNnGhaRZ9ee80ca600000000476162bf&a=d&c=medicinedocs&d=Js6160e>

The statistical Annex to the 2004 WMS contains country-level data on production, trade, sales, expenditures (1995 and 2000), and data from the 1999 world drug survey.

Data exist for all MeTA pilot countries

Data will be updated in 2009

¹⁴ **World Trade Organization**

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

¹⁵ **International Manufacturer Associations**

<http://www.ifpma.org/aboutus>

¹⁶ **Pharmaceutical Security Institute**

<http://www.psi-inc.org/index.cfm>

¹⁷ **WHO/HAI Medicine Price Surveys**

<http://www.haiweb.org/medicineprices/>

In May 2003 Health Action International (HAI) and the World Health Organization (Department of Medicine Policy and Standards) published a working draft of a manual to collect and analyse the prices people pay for a selection of important medicines across sectors and regions in a country, as well as medicine availability, treatment affordability and all price components in the supply chain (taxes, mark-ups etc.). The results of over 50 surveys are currently available in the web-based database, along with survey reports and other information.

WHO/HAI surveys were conducted in the following MeTA pilot countries: Ghana (May 2002, October 2004), Jordan (May 2004), Kyrgyzstan (February 2005), Peru (May 2002, September 2005), Philippines (June 2002, February 2005), and Uganda (April 2004).

Reports for the pricing surveys conducted in African countries can be found at:

http://www.afro.who.int/edp/publications/afro_essential_medicine_price_indicator_2007.pdf

In addition to price surveys, WHO/HAI provides information about promotion of medicines at:

<http://www.drugpromo.info>

¹⁸ **INRUD**

The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test, and disseminate effective strategies to improve the way drugs are prescribed, dispensed, and used, with a particular emphasis on resource poor countries.

<http://www.inrud.org/>

¹⁹ **WHO World Health Survey (WHS)**

<http://www.who.int/healthinfo/survey/en/>

The WHS was conducted in 70 countries in 2002. In 52 countries, household expenditures for health care including medicines, and individual respondents' need for and access to care were assessed.

Surveys with household expenditures information exist for the following MeTA pilot countries: Ghana, Philippines and Zambia (Zambia data to be verified).

²⁰ **International Household Survey Network (IHSN)**

<http://surveynetwork.org/home/>

The IHSN is a partnership of international organizations seeking to improve the availability, quality and use of survey data in developing countries. This informal network was established as a recommendation of the Marrakech Action Plan for Statistics. The Central Survey Catalogue allows searching for surveys conducted in countries by type of survey and country.

Income and expenditure surveys are available in all MeTA pilot countries except Ghana.

²¹ **Uppsala WHO Collaborating Centre**

<http://www.who-umc.org>