



Disclosure Status of Pharmaceutical Sector Data
Part of Component 1 of the MeTA Baseline Assessments

GHANA
May 2010

The Medicines Transparency Alliance Ghana

Data Collection Tool developed by:

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

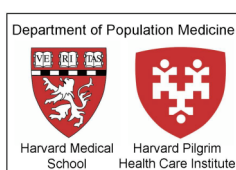


Table of Contents

I. INTRODUCTION.....	5
II. KEY QUESTIONS TO ANSWER RELATED TO DATA DISCLOSURE	6
III. INFORMATION CATEGORIES AND POSSIBLE DATA SOURCES	7
1. Medicines Registration and Quality Assurance	7
1.1 Market registration procedures and registration status of all medicines.....	7
1.2 Good manufacturing practice (GMP) for domestic and foreign manufacturers.....	7
1.3 Quality assurance processes in public and non-profit tenders	8
1.4 Quality assurance data during registration or procurement	8
1.5 Routine quality testing and adverse event monitoring	8
2. Medicine Availability	9
2.1 Standard treatment guidelines	9
2.2 Essential medicines list	9
2.3 Pharmaceutical patents held in the country	10
2.4 Volume and value of medicines procured in the public and non-profit sectors	10
2.5 Volume and value of medicines supplied in the private sector.....	11
2.6 Availability of medicines to consumers	11
2.7 Routine audits for public, private, and non-profit medicines outlets	12
3. Medicine Prices	12
3.1 Consumer and ex-manufacture prices of medicines in the public, private, and non-profit sectors	12
3.2 Public sector medicines procurement prices	13
3.3 Medicines price components in the public, non-profit, and private sectors	13
4. Medicine Promotion	14
4.1 Medicines promotion regulations, policies, and industry practices	14
IV. FORMS FOR SUMMARIZING DATA DISCLOSURE STATUS	15
1. Medicines Registration and Quality Assurance	15
1.1 Market registration procedures and registration status of all medicines.....	15
1.2 Good manufacturing practice (GMP) for domestic and foreign manufacturers.....	17
1.3 Quality assurance processes in public and non-profit tenders	18
1.4 Quality assurance data during registration or	19
1.5 Routine quality testing and adverse event monitoring	20
2. Medicine Availability	21
2.1 Standard treatment guidelines	21
2.2 Essential medicines list	22
2.3 Pharmaceutical patents held in the country.....	23
2.4 Volume and value of medicines procured in the public and non-profit sectors	25
2.5 Volume and value of medicines supplied in the private sector.....	27
2.6 Availability of medicines to consumers	28
2.7 Routine audits for public, private, and non-profit medicines outlets	29

Assessment of Pharmaceutical Data Disclosure in Ghana

3. Medicine Prices	31
3.1 Consumer and ex-manufacture prices of medicines in the public, private, and non-profit sectors	31
3.2 Public sector medicines procurement prices	32
3.3 Medicines price components in the public, non-profit, and private sectors	33
4. Medicine Promotion	34
4.1 Medicines promotion regulations, policies, and industry practices	34

I. Introduction

MeTA pilot countries are developing strategies to promote greater transparency and accountability regarding policies, practices, and outcomes in the pharmaceutical sector. They have committed to disclosing, analyzing, and using over time data in the following four core areas described in the MeTA project document:

1. Medicines registration and quality assurance
2. Availability of medicines
3. Price of medicines
4. Policies and practices concerning the promotion of medicines

For each core area, disclosed information should cover **policies** – the laws and regulations that are in place; **practices** – suggested procedures to follow and actual practices; and **results** – achievements in the core area.¹ The objectives of describing the current disclosure status of information in the core areas are to: (1) enable the national MeTA stakeholders to prioritize potential MeTA country activities to facilitate progressive disclosure over time; and (2) create a baseline against which changes in transparency and disclosure during the MeTA pilot implementation can be measured.

This brief describes a process for accounting of data disclosures as envisioned by MeTA. The first section provides a brief framework for exploring disclosure status in a systematic way. The second section reviews the rationale for disclosing each type of pharmaceutical sector data and gives an overview of some possible data sources and key items to be disclosed in each area of disclosure. The third section provides a series of tables for collecting and presenting data on the disclosure status of key categories of pharmaceutical sector information.

To aid understanding, this information on data disclosure should be supplemented by contextual information on the medicines supply chain, access, price, affordability, and rational use of medicines. These data is available in an accompanying Pharmaceutical Sector Scan baseline assessment in Ghana. These contextual data will aid in the interpretation of the information on the status of disclosed data.

¹ Medicines Transparency Alliance. Implementing our pilot phase. Document presented at the MeTA launch, May 2008

II. Key Questions to Answer Related to Data Disclosure

In completing its baseline summary of disclosure, each MeTA country team is answering the questions below for each of the pharmaceutical sector topics targeted in the MeTA pilot phase project document. This information is then organized in a brief summary document (see Section 3) that will allow for convenient display of results for each topic.

The summary for each pharmaceutical sector topic covers the following issues:

Policies

- Do relevant laws and/or policies exist?
- Are these laws and/or policies published?
- Do laws and/or policies exist to make the relevant data publicly available?

Practices

- Are required and/or recommended practices published?
- How are those practices implemented and enforced?
- What data sources exist and how are they organized?
- Where do the data reside and who has access?
- What is the quality of published data?

Results

- Are results, achievements, or outcomes disclosed?
- What are the disclosed data used for and by whom?
- What barriers exist to using the disclosed data more widely?
- Which strategies might encourage expanded data access and use?

During the process of conducting the baseline scan of data disclosures, the MeTA Ghana Secretariat obtained copies of key pharmaceutical sector data that have already been publicly disclosed. These disclosures take the form of available publications, reports, lists, databases, or websites. These disclosed data (or information about their location) is appended to the summary report.

III. Information Categories and Possible Data Sources

1. Medicines Registration and Quality Assurance

1.1 Market registration procedures and registration status of all medicines

Rationale

Maintaining a transparent and organized process for registering medicines allowed to be used in a country is essential for ensuring that only high quality medicines are available on the local market. Through the registration process, manufacturers and importers demonstrate their compliance with pharmaceutical sector regulations on registered products. Drug supply managers and clinicians need to know which medicines are registered for use so that they can make appropriate therapeutic choices.

Possible data sources

- Explicit policies guiding registration along with decision making criteria (initial and renewal, patented and generic products)
- Information on registration fees, steps in registration process, regulations for general and/or restricted registration, for expedited review
- Policies and processes for de-registration of registered products
- Information on decision makers and potential conflicts of interest
- Dossiers submitted for medicines registration with dates and disposition

Key disclosure data

- Detailed information on process for registering and de-registering medicines
- List of registered products by therapeutic class, patent status, and registration date
- Average length of time required to register a product, both patented and generic
- Average cost to register a product, both patented and generic

1.2 Good manufacturing practice (GMP) for domestic and foreign manufacturers

Rationale

A key prerequisite to the production of safe medicines is adherence by manufacturers to Good Manufacturing Practices (GMP). Monitoring GMP adherence is a key function of the drug regulatory agency.

Possible data sources

- Regulations concerning GMP criteria and certification processes for domestic and foreign manufacturers
- GMP compliance monitoring procedures
- GMP certificates for domestic and foreign manufacturers
- Reports of inspections of manufacturing plants for compliance with GMP

Key disclosure data

- List of GMP compliant manufacturing plants of suppliers/manufacturers and dates of last inspection
- List of manufacturing plants that failed GMP inspection and dates of inspection and recommendations to plants

1.3 Quality assurance processes in public and non-profit tenders

Rationale

Making efficient, cost-effective, and safe procurement decisions requires information on the quality and reliability of medicines suppliers. Public disclosure of tender results can lead to more assured medicines quality and more cost-effective procurement.

Possible data sources

- Explicit criteria for supplier pre-qualification
- Procedures for pre-qualifying suppliers
- Ministry of Health, government procurement agency, or drug regulatory authority reports
- Non-profit medicine supply system reports

Key disclosure data

- List of pre-qualified suppliers for public, non-profit, or private sector tenders
- List of suppliers who failed to meet pre-qualification standards in the past
- Proportion of medicines by volume and value procured from prequalified suppliers in public sector and non-profit medicines supply systems

1.4 Quality assurance data during registration or procurement

Rationale

Prescribers, patients, and procurement agencies need to be able to trust the quality of medicines in the market place. Safe, appropriate, and cost-effective decisions depend on documented product quality assurance, specifically for generic products.

Possible data sources

- Regulations and procedures for assuring quality of domestic and imported products during registration or procurement processes
- Product quality assurance documents (both domestically produced and imported products)
- Bioavailability studies (generic products)
- Reports of violations of quality standards

Key disclosure data

- List of products that failed quality assurance procedures during registration or procurement processes and dates of failure and steps taken to address problems

1.5 Routine quality testing and adverse event monitoring

Rationale

Assuring safe use of medicines requires routine surveillance to detect substandard and counterfeit products, as well as routine reporting of adverse events identified after a drug has been marketed. The drug regulatory authority needs to establish systems to monitor drug quality and adverse events, and make these results publicly available.

Possible data sources

- Regulations and procedures for testing the quality of products in the market
- Regulations and procedures for monitoring and reporting adverse events
- Routine and ad hoc reports of products tested by quality testing laboratories
- Reports of adverse events identified in post-marketing surveillance studies
- Data and reports from voluntary adverse event reporting systems

Key disclosure data

- Number of samples from the market that were sent to quality control laboratories by government inspectors for routine testing in last year
- List of products that failed quality testing, date of testing, and steps taken to resolve problem
- Number of adverse event reports that were submitted to the government adverse event reporting system in last year

2. Medicine Availability

2.1 Standard treatment guidelines

Rationale

Standard treatment guidelines are one strategy for ensuring the availability of appropriate medicines to treat common health problems. Evidence-based and up-to-date standard treatment guidelines (STG) for key illnesses can guide the therapeutic decisions of health providers and the formulary decisions of health institutions and systems. STGs can be tailored for different levels of care and used as the basis for monitoring prescribing according to STGs.

Possible data sources

- Policies and procedures for creating and updating guidelines
- Procedures for selecting national STG committee members
- Processes to declare and document conflict of interest of STG committee members
- Processes for disseminating guidelines
- Policies and regulations to enforce or encourage guideline use (public and private sector)

Key disclosure data

- List of members of national STG committee with qualifications and affiliations
- Existing STGs for key adult and paediatric illnesses, including organization that created STG and year last updated

2.2 Essential medicines list

Rationale

A national or institutional essential medicines list (EML) provides guidance about the medicines recommended to treat common health problems seen in that setting. EMLs typically include all of the medicines recommended on STGs, as well as other medicines needed to address most of the clinical problems seen at a given level of care. By prescribing from an EML, health providers are more likely to offer the most cost-effective and affordable care. An essential medicines list also structures the process of procurement and pharmacy management, helping to ensure the availability of appropriate medicines.

Possible data sources

- Policies and procedures for creating and updating EML
- Procedures for selecting EML committee members
- Processes to declare and document conflict of interest of EML committee members and other stakeholders
- Processes for disseminating EMLs

Assessment of Pharmaceutical Data Disclosure in Ghana

- Policies and regulations to enforce or encourage EML use (in prescribing, procurement, supply management)

Key disclosure data

- List of members of national essential medicines committee with qualifications and affiliations
- Essential medicines lists for defined levels of care (primary health centre, secondary or district hospital, tertiary care centre) and year of last update

2.3 Pharmaceutical patents held in the country

Rationale

Policy makers and regulators need to be able to determine the patent status of products on the market to ensure compliance with intellectual property (IP) agreements and patent regulations, and to develop appropriate incentives for generic importation and manufacturing.

Possible data sources

- Laws and regulations governing IP, pharmaceutical patents, and market exclusivity
- Documentation of the status of relevant IP and trade agreements
- Explicit procedures governing filing for patents and market exclusivity arrangements

Key disclosure data

- List of registered medicines, their patent status, and the date of patent expiry (individually and by therapeutic class)

2.4 Volume and value of medicines procured in the public and non-profit sectors

Rationale

Public sector policy makers and regulators need to know which products are used, in what volumes, and at what cost in order to project need, identify potential over- and underuse, and design policy interventions to increase use of desired and decrease use of undesired alternative products. Transparent procurement data are also useful for ensuring accountability of public resources. The non-profit health sector operates like a quasi-governmental system in many countries, filling gaps in the public health delivery system. Non-profit institutions also receive tax advantages in most countries in return for their role in promoting the public good. Disclosure of procurement data from non-profit institutions can encourage greater accountability.

Possible data sources

- Government budget documents
- Policies and regulations governing the disclosure of drug procurement or utilization data in the public and non-profit sectors
- Ministry of Health, Central Medical Stores, regional, or institutional medicines procurement or utilization reports
- Non-profit sector medicines procurement or utilization reports

Key disclosure data

- Government budgets for health care and pharmaceuticals for last fiscal year
- 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)

2.5 Volume and value of medicines supplied in the private sector

Rationale

Policy makers and regulators need to know which products are used in the health system as a whole in order to understand trends in use, identify possible over- and underuse, and develop effective pharmaceutical policies. Detailed data on the quantity and price of medicines imported, manufactured, and sold in the private sector have commercial value and are generally considered confidential. However, some level of reporting of private sector pharmaceutical supply system data is often required to comply with drug regulatory and tax regulations.

Possible data sources:

- Policies and regulations governing the disclosure of drug supply data in the private sector
- Procedures and practices concerning release of private sector data on drug importation, manufacturing, and sales
- Data on type, volume and value of products imported, manufactured, or sold (by region; by therapeutic category, by level of the supply system)

Key disclosure data

- Type, volume, and value of medicines imported in the private sector (by innovator vs. generic, by therapeutic category)
- Type, volume, and value of medicines supplied in the private sector (at import vs. wholesale vs. retail level, by innovator vs. generic, by therapeutic category)

2.6 Availability of medicines to consumers

Rationale

To ensure effective treatment, appropriate medicines need to be available where and when patients seek care. Patients who seek care in public health facilities can expect that essential medicines recommended in relevant STGs and on the EML should be available at all times; poor availability of medicines is one common reason why patients bypass the public sector. Patients who seek care in the private or non-profit sector can expect adequate availability of medicines of reasonable quality.

Possible data sources

- Policies and procedures governing the procurement and stocking of essential medicines in public and non-profit health facilities
- Stock records for key medicines from public and non-profit health facilities (by region, by facility type, by therapeutic category)
- Documented follow-up on reports of pharmacy stock-outs in public health facilities, including time to resolution
- IMS data or other surveys of availability of medicines in private importers, wholesalers, or private retail pharmacies
- WHO-HAI medicines price or WHO Level II monitoring surveys

Key disclosure data

- Percent availability in public sector or non-profit health facilities of a list of key essential medicines (by region, by product, by innovator vs. generic, by therapeutic class, if available)
- Percent availability in private retail pharmacies of a list of key essential medicines (by region, by product, by innovator vs. generic, by therapeutic class, if available)

2.7 Routine audits for public, private, and non-profit medicines outlets

Rationale

Routine audits of medicines outlets are needed to ensure adequate compliance with laws and regulations concerning physical environment, types of products stored, staffing, record keeping, sales practices, and accounting.

Possible data sources

- Laws and regulations governing the operation of a pharmacy or medicines store (by public, non-profit, and private sector)
- Regulations and procedures for auditing practices in medicines stores
- Ministry of Health or drug regulatory agency reports

Key disclosure data

- Number, characteristics, training, and case load of drug regulatory agency auditors
- Number and percent of facilities audited in last year (by region, by type of facility)
- Number, type, and resolution of violations reported during audits

3. Medicine Prices

3.1 Consumer and ex-manufacture prices of medicines in the public, private, and non-profit sectors

Rationale

Prices charged in public, non-profit, and private sector medicines outlets determine the affordability of medicines for consumers. End-user prices are a function both of the original price charged by a manufacturer (ex-manufacture price) and various mark-ups that are added on as the medicine proceeds through the supply system. Some countries regulate end-user price or allowable mark-ups at various points in the supply chain. Medicines are often provided free or with high levels of subsidy in public sector health facilities. Knowledge about the comparative prices of alternative products, or about the prices of the same product in different outlets, can guide consumers to more cost-effective care.

Possible data sources

- Laws and regulations governing ex-manufacture and end-user pricing of medicines in the public, non-profit, and private sectors
- Procedures for auditing compliance with pricing regulations and procedures for handling violations
- Results of audits for compliance with pricing regulations
- Insurance program policies and procedures for medicines reimbursement
- Results of WHO-HAI medicines price surveys or of routine public or private medicines price monitoring systems
- Ex-manufacture price from manufacturers or importers/wholesalers² (both innovator and available generic versions)
- Insurance system reimbursement data

² 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.

Key disclosure data

- Private sector retail prices for list of key essential medicines (by region, by innovator vs. generic versions)
- Private sector ex-manufacture price for a list of key essential medicines as above
- 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
- 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
- Amount charged and reimbursed to patients by insurance programs for list of key essential medicines (by insurance program type, by innovator vs. generic versions)

3.2 Public sector medicines procurement prices

Rationale

The prices that public sector agencies and health facilities pay to procure medicines are a key determinant of their ability to afford the medicines they need, and in some systems, of the prices charged to patients. Procuring medicines requires specialized technical skills that may not be present in all settings, especially in decentralized health systems. Transparent procurement processes, effective negotiation, and pooled procurement may decrease public procurement prices. Transparent procurement data enables public sector policy makers and system managers to benchmark bid prices, track prices over time, estimate budget requirements, and assess the overall efficiency of the procurement process.

Possible data sources

- Laws and regulations governing the disclosure of public sector medicines procurement prices
- Notifications about explicit procedures to be followed in handling bids in the public procurement process
- Audits for compliance with public medicines procurement regulations
- Ministry of Health medicines procurement records

Key disclosure data

- 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)

3.3 Medicines price components in the public, non-profit, and private sectors

Rationale

Taxes, tariffs, mark-ups, and other charges levied as medicines move through the supply chain can add substantially to the costs of medicines to consumers. To develop effective policies to make medicines more affordable, government policy makers need information about the levels and variations in medicines price components in both the public and non-profit sectors; countries that regulate private sector mark-ups need similar information from the private supply system.

Possible data sources

- Laws and regulations governing mark-ups of medicines in the public and non-profit sectors (and in the private sector, if applicable)
- Procedures for auditing compliance with regulations concerning mark-ups in the medicines supply chain and procedures for handling violations

- Results of audits for compliance with regulations concerning price mark-ups
- WHO-HAI price components studies

Key disclosure data

- Data on price components (duties, taxes, mark-ups and other charges) for key essential medicines, both domestically manufactured and imported (by region, by sector, by level of care, and by therapeutic class)

4. Medicine Promotion

4.1 Medicines promotion regulations, policies, and industry practices

Rationale

Through their promotional activities and materials, pharmaceutical manufacturers are the main source of information on medicines in many countries. Many countries have mandatory or voluntary **codes of conduct** governing the promotion of medicines to institutional purchasers, prescribers, retail sellers, and consumers. Some countries vet advertisements and promotional materials for accuracy. It is crucial that promotional activities comply with codes on ethical behaviour and balanced information content; inappropriate or unethical promotion can contribute to inefficient or unsafe patterns of care.

Possible data sources

- Laws and regulations on pharmaceutical industry promotion, including codes of conduct adopted by professional organizations
- International and domestic pharmaceutical manufacturers' codes of conduct
- Public procurement agencies' standard operating procedures related to relationships with representatives of pharmaceutical manufacturers and wholesalers
- Procedures for handling complaints, and for identifying, sanctioning, and publicizing violations of codes
- Documentation on the membership of monitoring committees and declarations of potential conflicts of interest

Key disclosure data

- List of manufacturers and distributors that subscribe to internationally or nationally recognized codes of conduct
- List of individuals with their affiliations who are on the national committee to monitor adherence to industry codes of conduct
- Reports of numbers and types of complaints submitted to the national monitoring committee regarding promotional practices, numbers of violations, and resolution of the complaints

IV. Summaries of Data Disclosure Status in Ghana

1. Medicines Registration and Quality Assurance

1.1 Market registration procedures and registration status of all medicines

Sources:	Food and Drugs Board
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? Yes National Drug Policy (MOH), 2004 FOOD AND DRUGS LAW, P.N.D.C.L 305B, 1992 available at www.fdbghana.gov.gh Food and Drugs (Amendment) ACT, Act 523 1996 available at www.fdbghana.gov.gh</p> <p>Are they published? Yes copies of Laws are available for sale at State Press i.e. Assembly Press Ghana Publishing – copies attached) National Drug Policy Available at available at http://collections.infocollections.org/whocountry/en/d/Js6860e/ and http://ghndp.org/images/stories/downloads/ghana_national_drugpolicy_2nd_edition.pdf</p> <p>Do associated regulations exist? Yes. Embodied in Food and Drugs Board (FDB) Law</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? Yes Guidelines and application forms available in PDF on FDB Website fdbghana.gov.gh/drugguide.htm. Standard Operating Procedures (SOPs) - but these are documents for internal operational use.</p> <p>How enforced? Enforced by use of sanctions. For example Section 18 of the FDB Act, 1992 makes it an offence to manufacture, label package, sell or advertise any food or drug or other chemical substances in a manner that is false, misleading or deceptive, in relation to the character, nature, value quality, composition, substance merit and safety. A person who commits the offence is liable on conviction to a fine not exceeding 500 penalty units (6,000GH Cedis) or to a term of imprisonment not exceeding two years or to both. In addition the FDB applies civil remedies such as the forfeiture, seizure and destruction of all counterfeit and pirated merchandise.</p> <p>Which data exist? Guidelines for the registration of allopathic medicines</p> <p>Who has access? Everyone, available on the website. www.fdbghana.gov.gh and also in hard copy in FDB offices</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	

Assessment of Pharmaceutical Data Disclosure in Ghana

Which data are available? List of registered medicines (This is updated bi-monthly or quarterly); List of banned medicines (This is updated as and when necessary i.e. when there a drug is banned) Updating the above information on the FDB website is however irregular and not in tandem with the documentary updates.

Who uses data? Medicine importers, Buyers, Procurement and Supply units of both public and private sectors

Barriers to use? Challenges in internet access; Limited public awareness.

How to promote wider use? Create more awareness in the media; Making copies of the register freely available.

1.2 Good manufacturing practice (GMP) for domestic and foreign manufacturers

Sources:	Food and Drugs Board
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? Yes FOOD AND DRUGS LAW, P.N.D.C.L 305B, 1992 National Drug Policy (MOH) 2004</p> <p>Are they published? Yes - The LAW is available for sale at State Press i.e. Assembly Press Ghana Publishing – copies attached) - The Drug Policy is available and distributed for free at GNDP</p> <p>Do associated regulations exist? Yes ‘Guidelines on licensing of manufacturing industries’ is available at FDB website www.fdbghana.gov.gh The Ghana Standards Boards (GSB) inspection and audit in support of product certification is also optional for domestic manufacturers who want GSB certification for their products</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? Yes Guidelines on website www.fdbghana.gov.gh</p> <p>How enforced? Inspection of local manufacturing plant annually and issuance of manufacturing license; routine inspection may be carried out during the year for local manufacturers, e.g. upon addition of any new line; inspections every 5 years for foreign manufacturing plants.</p> <p>Which data exist? Data available on request</p> <p>Who has access? FDB, Manufacturing Plant inspected and Procurement and Supplies unit of MoH.</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Which data are available? List of GMP Compliant manufacturing plants</p> <p>Who uses data? Importers, manufacturers, FDB, Procurement and Supplies Unit</p> <p>Barriers to use? List not published</p> <p>How to promote wider use? Bring to discussion whether lists of GMP plants should also be available on the web and not just on request)</p>	

1.3 Quality assurance processes in public and non-profit tenders

Sources:	Food and Drugs Board
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? Yes National Drug Policy (2004) Public Procurement Act 663 (2003) available at http://moh-ghana.org/UploadFiles/Procurements/Public%20Procurement%20Act%202003%20Act%20663090812103250.pdf	
Are they published? Yes, copies annexed Published in public procurement Act 2003 (Act 663) by Government Printer, Assembly Press	
Do associated regulations exist? Yes Quality of service in accordance with professional standards Drug Advertisement and Promotion must be of high ethical standards in accordance with FDB Law 1992 (PNDCL 305B)	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? Yes	
How enforced? Drug registration process of FDB Testing at point of delivery during registration and dispensing point as post market surveillance by FDB	
Which data exist? List of registered medicines (FDB Website) Central Medical Stores Analytical Reports Tender Procurement Evaluation reports	
Who has access? Bid participants; Public Procurement Authority; Central Tender Review Board; Ministerial Entity Tender Review Board; Ministerial Entity Tender Committee	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
Which data are available? List of registered medicines (FDB Website)	
Who uses data? Everyone but most often MoH, Procurement and supplies units and Importers of medicines	
Barriers to use? Available only on the website and therefore limited to those with such access	
How to promote wider use? Print and circulate list of monthly updated medicines	

1.4 Quality assurance data during registration or

Sources:	Food and Drugs Board
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? Yes FDB Law - PNDCL 1992 305B and its amendment ACT 523 1996	
Are they published? Yes	
Do associated regulations exist? Guidelines for registration of all categories of medicines – via FDB Website	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? Yes FDB Website www.fdbghana.gov.gh	
How enforced? All applications should be submitted with the requisite application forms	
Which data exist? List of registered medicines available at the FDB website	
Who has access? Available to everybody	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
Which data are available? List of registered medicines (FDB Website)	
Who uses data? FDB inspectorate and post market surveillance staff, FDB Port officials and zonal and regional officers Importers of products, Pharmacy Council and other regulators	
Barriers to use? Slow internet connection; outdated information; US style date given for registration expiry, which could be confusing to some users.	
How to promote wider use? Make the list sections into booklets and update them regularly for free distribution; keep FDB website list up to date.	

1.5 Routine quality testing and adverse event monitoring

Sources:	Food and Drugs Board
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? YES FDB Law - PNDCL 1992 305B and its amendment ACT 523 1996 Not explicit but revised bill takes care of it</p> <p>Are they published? No for routine quality testing, but Yes for Adverse Event Monitoring (AEM) – guidelines and forms are available at the FDB website and health facilities; Training manuals on AEM available at FDB for free</p> <p>Do associated regulations exist? YES for AEM, but only SOPs for routine quality testing</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? YES for AEM for three categories: Manufacturer, health professional and consumer; Training manuals and Adverse reaction forms</p> <p>How enforced? According to the Standard Operating Procedures (SOPs) for all activities in the laboratory, in accordance with ISO 17025 requirement For AEM only the manufacturer and researcher are mandated to report but the health provider and pharmaceutical or medical device manufacturer is not mandated</p> <p>Which data exist? Quality Manual, Technical Manual</p> <p>Who has access? FDB Laboratory, Applicants and Ministry of Health for Monitoring and Evaluation purposes</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Which data are available? Drug, vaccine and medical devices alerts; press releases (varying levels of detail about counterfeit products identified on the market); photographs of some counterfeit products. Analytical Reports and Laboratory Notebooks Confidential Marketing Authorization Applications</p> <p>Who uses data? FDB for regulatory decisions MoH for procurement decisions Public for consumer awareness</p> <p>Barriers to use? Confidential reports are not declared Misinterpretation of press release sometimes; also some alerts and press releases are not dated (so it is not clear how current the information is). Illiteracy on the part of the public hinders information consumption</p> <p>How to promote wider use? Enhanced skills in press reporting Engage civil society and consumer groups, patient groups etc</p>	

2. Medicine Availability

2.1 Standard treatment guidelines

Sources:	Ghana National Drugs Programme
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? Yes National Drug Policy 2004</p> <p>Are they published? Yes (available for free at Ghana National Drugs Programme (GNDP))</p> <p>Do associated regulations exist? Yes – National Health Insurance Regulation 2004, (L.I.1809) available at http://www.nhis.gov.gh/Uploads/dbsAttachedFiles/LI18091.pdf</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? Yes, broadly stated in the National Drug Policy Fully Outlined in the Standard Treatment Guidelines The current edition (5th) was published in 2004 and available online at http://collections.infocollections.org/whocountry/en/d/Js6861e/</p> <p>How enforced? Some enforcement is also done through the National Health Insurance Regulation 2004, (L.I.1809) which ensures that those who prescribe outside the EML are not reimbursed</p> <p>Which data exist? List of standing committee members with affiliations Conflict of Interest form</p> <p>Who has access? GNDP, Other interested parties on demand</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Which data are available? Standard Treatment Guidelines The guidelines list the preferred treatments for common health problems experienced by people in the health system</p> <p>Who uses data? Primarily Healthcare providers, other stakeholders such as regulators, students , CSOs</p> <p>Barriers to use? Lack of reference culture during consultation Although widely available some facilities especially in the private sector do not have them in their facilities.</p> <p>How to promote wider use? More copies should be printed to meet increasing demand; Institute mechanisms to enforce compliance Include teaching of STG in curricula in medical and pharmacy schools, as well as the part of advice and guidance given in teaching hospitals.</p>	

2.2 Essential medicines list

Sources:	Ghana National Drugs Programme
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? Yes National Drug Policy 2004	
Are they published? Yes (available for free at Ghana National Drugs Programme (GNDP))	
Do associated regulations exist? Yes National Health Insurance Regulation 2004, (L.I.1809)	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? Yes, broadly stated in the National Drug Policy	
How enforced? Public procurement cannot procure outside the EML	
Which data exist? List of standing committee members with affiliations Conflict of Interest form	
Who has access? GNDP, Procurement and Supplies Unit, Central and Regional Medical Stores, and other interested parties on demand	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
Which data are available? Essential Medicines List	
Who uses data? Primarily Procurement and Supplies Units, Healthcare providers, other stakeholders such as regulators, students, CSOs	
Barriers to use? Although widely available some providers especially in the private sector do not have them in their facilities.	
How to promote wider use? More copies printed to meet increasing demand. Advocacy to encourage regular use by providers	

2.3 Pharmaceutical patents held in the country

Sources:	Registrar Generals Department
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? Yes Patent Law 1992; P.N.D.C.L.305A The Patents Act, 2003, Act 657: Section 1 provides the definition of a patent; Section 11 deals with the rights conferred by a patent and Protection is for a period of 20 years. The Act empowers right holders to initiate court action for the grant of injunctions, award damages and any other relief provided for in the general law. Before TRIPS came into being, there were no patent protection rights Ghana National Drug policy 2004 A new edition is currently being finalized in print	
Are they published? Yes YES:- The Law and ACT are available for sale at State Press i.e. Assembly Press Ghana Publishing – copies attached) The National Drug Policy is available for free at Ghana National Drugs Programme (GNDP)	
Do associated regulations exist? Yes - using an old Legal Instrument (LI) but the government/parliament is in the process of enacting a new LI for the current ACT	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? Yes; <i>Embodied in the Act.</i> <i>Administrative Guidelines to TRIPS</i>	
How enforced? According to Act 657, any person who makes import, export, offer for sale, selling and using the product or process without the consent of the owner constitutes an infringement. Offences are spelt out under Section 5. Any person who knowingly uses a misleading designation commits an offence and is liable on summary conviction to a fine not exceeding two thousand penalty units (24,000 Ghana cedis) or to a term of imprisonment not exceeding two years or to both. Patents are however private rights and whoever invents something has to seek the necessary protection so enforcement of patents rights depends solely on what the individual chooses to do	
Which data exist? Registered patents	
Who has access? The Public	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	

Assessment of Pharmaceutical Data Disclosure in Ghana

Which data are available?

Registered patent holders

Who uses data?

MoH, Attorney Generals Department, Council for Scientific and Industrial Research (CSIR)

Anybody

Barriers to use?

Lack of awareness / Ignorance

Lack of financial resources

How to promote wider use?

Awareness creation and education

Set up a support fund

2.4 Volume and value of medicines procured in the public and non-profit sectors

Sources:	MoH Procurement and Supplies Directorate
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? Yes ACT 663, Public Procurement Act 2003 ; National Drugs Policy, 2004, FDB Law 309B; NHIS Act 2004; Internal Audit Agency Act 203; latter available at http://www1.worldbank.org/publicsector/pe/BudgetLaws/IAAAct.pdf</p> <p>Are they published? Yes (available for sale at State Press i.e. Assembly Press Ghana Publishing; National Drugs Policy available for free at Ghana National Drugs Programme – copies attached)</p> <p>Do associated regulations exist? Yes; Part of the existing ACTs and LIs.</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? Yes “Internal Audit Agency Training Materials - Relevant laws and regulations” Published and available to all stakeholders (public sector practitioners funded through public funds) Public procurement manual</p> <p>How enforced? They are enforced through governance and enforcement structures that have been put in place</p> <p>Which data exist? Evaluation reports provide information on the entire procurement process</p> <p>Who has access? The Public; the law makes it mandatory for anybody to have access; and the Right to Information Bill will also strengthen that.</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Which data are available? Quantities, Cost and Availability of medicines at procurement units of various public entities,</p> <p>Who uses data? Managers for planning, monitoring and evaluation purposes</p> <p>Barriers to use?</p> <ul style="list-style-type: none"> – Culture of non-disclosure despite existing policy – Dealing with sensitivities of various interest groups – Mistrust among stakeholders – Low literacy among the population – Dormant consumer groups – Right Information Bill yet to be passed into legislation <p>How to promote wider use? Broader engagement of key stakeholders in a very transparent manner</p>	

2.5 Volume and value of medicines supplied in the private sector

Sources:	MoH Procurement and Supplies Directorate
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? Yes ACT 663, Public Procurement Act 2003 ; National Drugs Policy, 2004, FDB Law 309B; NHIS Act 2004; Internal Audit Agency Act 203;	
Are they published? Yes (available for sale at State Press i.e. Assembly Press Ghana Publishing; National Drugs Policy available for free at Ghana National Drugs Programme – copies attached)	
Do associated regulations exist? Yes; Part of the existing ACTs and LIs.	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? Yes	
How enforced? Private to Government follow laid down regulations Enforcement is left to the discretion of professionals involved and some private sector practitioners are however less keen to enforce and practice the existing laws.	
Which data exist? Product and price list available on demand from manufacturers and importers/wholesalers,	
Who has access? Everybody on demand	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
Which data are available? Consumption data, pricing data and price built up	
Who uses data? Internally only once a while when it is in their interest to do so Government departments like GNDP and the MoH headquarters	
Barriers to use? Proper documentation Lack of understanding of importance of data Poor knowledge on how to analyse the data	
How to promote wider use? Education- in-service training Diffuse suspicion and provide assurance about benefits of data sharing.	

2.6 Availability of medicines to consumers

Sources:	MoH Procurement and Supplies Directorate
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? YES National Drug Policy 2004	
Are they published? YES (available for free at the Ghana National Drugs Programme (GNDP))	
Do associated regulations exist? National Health Insurance Regulation 2004 (L.I.1809)	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? YES	
How enforced? Standard Operating Procedures (SOPs) for distribution of health commodities; they are available to the entities of the public sector but not enforceable by law yet.	
Which data exist? Essential Medicines List; Standard Treatment Guidelines (available at http://www.who.int/countries/gha/publications/Ghana_Essential_Medicine_List_5th_Edition2004.pdf)	
Who has access? Health Care Providers	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
Which data are available? National Health Insurance Data, Health Facility Data, Periodic Surveys by Programmes and Research Institutions, CMS and Procurement Unit Data; Periodic Surveys by MoH/WHO/HAI	
Who uses data? Ministry of Health, Ghana Health services, Research Institutions, Students and CSOs	
Barriers to use? Assess to NHIA data is very difficult due to legal and bureaucratic reasons; Data is not routinely analysed	
How to promote wider use? Improving data collection, extraction, manipulation and analysis within the NHIA / NHIS Promote public awareness and education on medicines access	

2.7 Routine audits for public, private, and non-profit medicines outlets

Sources:	Pharmacy Council
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? YES <i>Pharmacy Act 489, 1994</i> <i>FDB Law, PNDC Law 305B, 1992</i> <i>Traditional Medicine Practice Act, 2005</i> <i>National Drug Policy (MOH), 2004</i>	
Are they published? YES copies of Laws are available for sale at State Press i.e. Assembly Press Ghana Publishing – (copies attached) National Drug Policy Available at available at http://collections.infocollections.org/whocountry/en/d/Js6860e/ and http://ghndp.org/images/stories/downloads/ghana_national_drugpolicy_2nd_edition.pdf	
Do associated regulations exist? YES, <i>Regulation for premises inspection;</i> <i>Practice Standards for Pharmacists and Licensed Chemical Sellers</i>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? YES <i>Checklist of Pharmacy Council</i>	
How enforced? <i>Sections 41 to 45 describe the enforcement procedures and generally there are two ways in which sanctions are enforced</i> 1) <i>Through disciplinary procedure for professional misconduct as specified in the Pharmacy Practice Disciplinary Procedure and Fee Regulation, 1998 LI 1645</i> 2) <i>The Pharmacy Act 1994 also specifies criminal procedure for professional misconduct by summary conviction at a law court</i>	
Which data exist? <i>Annual report,</i> <i>Quarterly and monthly reports are for administrative purpose</i>	
Who has access? <i>Pharmacy council, MoH, Public on request.</i>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	

Which data are available?

Annual and Monthly reports are published as statutory duty

Who uses data?

Pharmacy Council, MoH for performance review, policy measurement, planning

Barriers to use?

No hindrance for accessing information

Lack of resources to disseminate widely

Poor use of ICT

How to promote wider use?

Fashion out a national theme that we make annual reporting relevant to the objective set; More stakeholder consultation; National forum; State of the Medicines Sector report; Education

3. Medicine Prices

3.1 Consumer and ex-manufacture prices of medicines in the public, private, and non-profit sectors

Sources:	MoH Procurement and Supplies Directorate
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? No, ex-manufacture and consumer prices are not controlled by law or regulation, but are determined by market forces. These are however influenced by existing regulations i.e. existing taxes</p> <p>Are they published? N/A</p> <p>Do associated regulations exist? No, but the NHIS however has a presumptive consumer price control through reimbursement to its accredited health institutions. The NHIA Medicines list is also used to regulate prescribing and dispensing</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? Yes - The NHIA medicines list</p> <p>How enforced? Through NHIS reimbursement mechanism.</p> <p>Which data exist? NHIS medicines price list</p> <p>Who has access? Any health affiliated institution (hospitals, Pharmacies, manufacturers) who makes a formal requisition for it. The list was also published in the national dailies.</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>This is a gap in Ghana's medicines supply system. In the public sector the available data includes the following:</p> <ul style="list-style-type: none"> - MoH/WHO/HAI medicines survey reports - NHIA monitoring reports <p>Who uses data? NHIA, WHO, researchers and MoH and its entities</p> <p>Barriers to use? Limited access to data</p> <p>How to promote wider use? Greater publicity, wider access to data</p>	

3.2 Public sector medicines procurement prices

Sources:	MoH Procurement and Supplies Directorate
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? YES <i>Public procurement ACT 663</i></p> <p>Are they published? YES <i>Embodied in the ACT</i></p> <p>Do associated regulations exist? <i>The schedule that gives the various kinds of committees is found in Section 1 of the ACT. And it depends on the review price. Prices are determined by market forces</i></p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? YES The ACT 663 requires entities to publish the outcome of any public buying process on the PPA website</p> <p>How enforced? The laws have punishable offenses embodied in them</p> <p>Which data exist? Prices, Quantities and Quality</p> <p>Who has access? Public; System managers for procurement for planning, monitoring and evaluation purposes</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Which data are available? Quantities, Cost and Availability of medicines at procurement unit of various public entities,</p> <p>Who uses data? Managers for planning, monitoring and evaluation purposes</p> <p>Barriers to use?</p> <ul style="list-style-type: none"> – Culture of non-disclosure despite existing policy – Sensitivities of various interest groups and mistrust among stakeholders – Low literacy among the population – Dormant consumer groups – Non passage into legislation of the Right Information Bill yet to be passed into legislation <p>How to promote wider use? Broader engagement of key stakeholders in a very transparent manner</p>	

3.3 Medicines price components in the public, non-profit, and private sectors

Sources:	WHO/HAN/MeTA Secretariat
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
Do laws/policies exist? Yes <ul style="list-style-type: none">• Customs Excise and Preventive Service (Management) Law 1993 (PNDC Law 330);• Customs Excise and Preventive Service (Duties and other Taxes) Act 1996 (Act 512);• Value Added Tax Act 1998 (Act 546) available at http://www.ragb.gov.gh/documents/ragb_act.pdf• Value Added Tax Regulations 1998 (LI 1646)• National Health Insurance Act 2003 (Act 650)• VAT (Amendment) Act 2004, (Act 670)	
Are they published? Yes (available for sale at State Press i.e. Assembly Press Ghana Publishing – copies to be attached)	
Do associated regulations exist? Yes; Embodied in the various Acts and Legislative Instruments	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
Are procedures published? Yes and available on sale at the State Press, Ghana Publishing Costs that relate to institutional procedures and requirements and which affect importation of medicines include <ul style="list-style-type: none">• Food and Drugs Board Drugs Importation Guidelines (Attached)• Ministry of Trade Import Procedures (Attached)• Bank Charges for Letters of Credit (LCs) (Attached)	
How enforced? They are enforced by the respective institutions as above	
Which data exist? Guidelines for Importation of Drugs, Cosmetics, Medical Devices and Household Chemical Substances from the Food and drugs Board) Import Procedure for High Risk Goods' from Ministry of Trade and Industry	
Who has access? Everybody but especially registered importers and manufactures	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
Which data are available? List of importers and local manufacturers and retailers	
Who uses data? Various regulatory agencies and importers and manufactures	
Barriers to use? None readily identifiable	
How to promote wider use? Publicize MoH/WHO/HAI medicines price components study Create more public awareness	

4. Medicine Promotion

4.1 Medicines promotion regulations, policies, and industry practices

Sources:	Food and Drugs Board
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Do laws/policies exist? YES Food and Drugs Law 1992 (PNDCL 305B)</p> <p>Are they published? YES, Available on sale by State Printer, at Assembly Press Also available at FDB Website www.fdbghana.gov.gh</p> <p>Do associated regulations exist? YES, Guidelines for Advertisement of Products</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Are procedures published? Yes</p> <p>How enforced? Approval is required for advertising medicines from the regulator</p> <p>Which data exist? Guidelines for drug advertisement</p> <p>Who has access? Everybody</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Which data are available? List of approved adverts</p> <p>Who uses data? FDB, Advertisers Association, Advertisers Council and everybody interested.</p> <p>Barriers to use? Short time frame of adverts (One year) make their regular distribution limited</p> <p>How to promote wider use? Make the law, guidelines and list of approved adverts more frequently available on the FDB website</p>	