DATA DISCLOSURE SURVEY

Final Report

MeTA Philippines

July 2010

1. Medicines Registration and Quality Assurance

1.1 Market registration procedures and registration status of all medicines

Sources:

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

1. Laws and policies provide the mandate for the FDA to regulate drugs and are widely published in the websites of the Department of Health, Food and Drug Administration and law internet sites.
   a. RA 3720 - Food, Drug and Cosmetic Act of 1967: http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691
   b. RA 6675 - Generics Act of 1988: http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=818
   c. RA 9502- Universally Accessible Cheaper and Quality Medicines Act of 2008 : http://www.doh.gov.ph/ndp-pmu50/index.php?option=com_content&view=article&id=48&Itemid=55
   d. AO 67 s.1989 Revised Rules and Regulations on Registration of Pharmaceutical Products presents a comprehensive guidelines on the registration of pharmaceutical products and to be consistent with R.A. 6675 known as the “Generic Act of 1988”.
   e. AO 66 s.1989 Rules and Regulations on the Process of Review and Evaluation of Questioned Drug or Drug Products prescribes the procedure of review and evaluation of questioned drug or drug products with the end in view of banning the same from the market or restricting the conditions of their (BFAD) registration. The same procedure or process of review and evaluation may also result to a confirmation of the efficacy, safety or therapeutic value found by BFAD during the initial registration of the drug product.
   f. AO 21 s. 2006 - Supplemental Guidelines to Administrative Order (AO) 67 s.1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 in evaluating New Drug Applications: http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf
2. A new law was recently passed (Republic Act 9711) to strengthen the regulatory agency in terms of technical capacity to handle the growing list of drugs (human & veterinary use), biologics (vaccine), human reagents, processed food and cosmetics that it regulates. The complete title of the new law is ”An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain Its Income, Renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No. 3720, As Amended, and Appropriating Funds Thereof.” (http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1232 and Philippine Senate: http://www.senate.gov.ph/republic_acts/ra%209511.pdf)

3. There are laws compelling FDA to disseminate information with regard to actions it may take as for instance Section 29 of RA3720 which states: *“The Secretary may cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this Section shall be construed to prohibit the Secretary from collecting, reporting and illustrating the results of the investigations of the Department.”* While this applies to the Department of Health DOH) and not specifically to FDA, but since FDA is under the DOH, the Secretary can simply issue an Administrative Order instructing FDA to provide the public with information covered by Sec. 29 of the Food, Drugs and Cosmetics Act. While Sec. 29 applies only to drug information relating to imminent danger and gross deception to consumer, it could include such information as cGMP, BE, quality, etc. Needless to say, there is no legal impediment for FDA to provide such information to the public. There is no prohibition. Hence, it can be done, even without the Freedom of Information Act *(refer to comments validating baseline data disclosure in Appendix)*.

Appendix 1 - Complete list of Laws and Regulations

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

1. The regulatory's agency's website have information on the registration of drugs as well as herbal products and registration fees, processed food and cosmetics (initial and renewal). There is also information on monitored release registration.(Appendix 1A)
2. Registration pathways basically same for both patented and generic product with average length of time from submission of patented product application to decision covering 6 to 9 months and that of generic drug product from 3 to 6 months.

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

1. Detailed information on registered products is available from FDA only upon request in CD-ROM format. There were 19,727 pharmaceutical products including veterinary medicines were registered at the close of 2008 (Appendix 1A-1) and this has increased to 22,981 by November 2009. Each form/dosage is separately registered. New pharmaceutical product applications are posted on the FDA website: http://www.bfad.gov.ph/default.cfm?page_id=1192&parent=0 (Appendix 1A-2)
2. As the FDA website currently does not have drug product database with specific information on drugs approved for use in the Philippines, the public relies mainly on private compendia (e.g., MIMS) as information source; these, however, do not contain information on all registered pharmaceutical products.
3. A committee of technical consultants evaluates pharmaceutical product applications.
4. The list of registered medicines by therapeutic class, patent status, patent expiry and registration dates is publicly available from the Intellectual Property Office (IPO) Philippines - Philippine Patent Online Search System (PhilPAT) at http://patents.ipophil.gov.ph/PatSearch/
5. There is no link between patents and drug registration (no patent linkage) - A01s.1995 - Revised Policies and Guidelines Governing Patent and Trade Secret Rights in relation to the Registration of Pharmaceutical Products : http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO1s2005.pdf

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

Sources:

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

1. Main policies mandating manufacturers to adopt cGMP certification to manufacture medicines:
   a. AO 220 s. 1974 - Drugs: Current Good Manufacturing Practice in Manufacture, Processing, Packing or Holding at http://www.bfad.gov.ph/oldsite/AO/ao%20220%20s%201974.pdf
   b. The current cGMP guide: AO 43 s. 1999 - Current Good Manufacturing Practice For Drugs and AO 43_A s. 1999 -Amendment of Administrative Order No. 220 S. 1974, Current Good Manufacturing Practice at http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO43-As1999.pdf
   c. For biologicals and vaccines: AO 27 s. 2001 - Rules and Regulations for Licensing Local Manufacturers of Vaccines and Biologic Products at http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO27s2001.pdf
   d. MC 3 s. 1991 Procedure in the Processing of Certificate of Good Manufacturing Practice (GMP), Certificate of Free Sale and Certificate of GMP and the Free Sale
2. FDA enforces inspection leading to GMP certification for local manufacturers. For imported products FDA participates in the WHO certification scheme but does not conduct inspections. Challenges include reaching high level of validation and communication with issuing national drug regulatory authority in order to establish authenticity/validity of WHO certificate.

3. Public Procurement of medicines requires GMP certificate (Procurement Law or RA 9184 - An Act Providing For the Modernization, Standardization and Regulation of the Procurement Activities of the Government and For Other Purposes: http://www.lawphil.net/statutes/repacts/ra2003/ra_9184_2003.html)

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

1. FDA website (http://www.bfad.gov.ph/default.cfm?page_id=1302&parent=0) has list of GMP-certified establishments (Appendix 1B)

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

1. At the end of 2008, there were 275 licensed pharmaceutical manufacturers and 448 drug traders producing or importing medicines and 4,165 licensed pharmaceutical wholesalers (distributors).
2. While policy Section 2.2 of AO 43 s. 1999 states that *"License to manufacture drugs shall be issued only upon compliance with Current Good Manufacturing Practice guidelines,"* not all manufacturers are GMP-certified.
3. FDA does not publish the complete list of all licensed manufacturers and the list of non-GMP compliant manufacturers.
4. The challenge is to find out why there are barriers and resistance to adopting GMP especially by local manufacturers (lack of technical knowledge/skills? Financial barriers?, lack of trade incentives/support from government in form of tax breaks etc. ?, legacy equipment and lack of capital for upgrading HVAC, water systems etc. ? GMP is a critical area for generic manufacturers to break the barrier of perception of inferior quality compared to originator brands and truly compete on equal quality at lower prices and contribute to increased access to affordable quality medicines.
5. FDA working towards membership of the Philippines to Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) whose mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."
6. FDA is in charge of the ASEAN Harmonization project (ACTR/ACTD Guidelines).

1.3 Quality assurance processes in public and non-profit tenders

Sources:

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

1. There is a law on procurement (RA 9184: Government Procurement Reform Act) that stipulates procedures and methods to be followed and that requires procurement to be generally competitive bidding with rare exceptions.
2. There is a tender board (Government Procurement Policy Board) overseeing public procurement that is independent from the procurement office.
3. The Department of Health (DOH) does not have a list of pre-qualified suppliers for public, non-profit tenders.
4. Public procurement is limited to medicines on the national Essential Medicines List. Health service devolved in 1992 from central government to local government units (LGU) and procurement of medicines became responsibility of LGU. The DOH through the Central Office Bids and Awards Committee (COBAC) undertakes limited central procurement of medicines for vertical programs (e.g., tuberculosis program, Vitamin A supplementation, National Filiariasis Elimination Program) PITC Pharma, a public corporation, performs some centralized procurement of essential medicines for Botika ng Barangay program and P100 project which was launched in 2008 and under which PITC would make available designated packs of selected essential medicines at 100 pesos.

AO 138 s. 2004 Guidelines for the Implementation of the Simplified Supplier Registration System (SSRS): http://home.doh.gov.ph/ao/ao138-04.pdf was instituted for central COBAC level procurement which institutes prequalification of suppliers and the blacklisting of suppliers but the practice is not in place (?)

5. In 1993, the PNDF was officially adopted as the basis for procurement of drug products by all government agencies and for reimbursements for drugs by the Philippine Health Insurance Corp. by virtue of Executive Order No. 49 s.1993 and the Philippine Health Insurance Act of 1995 (http://portal.doh.gov.ph/pndf).

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

The Procurement Law initiated a central electronic system (Philippine Government Electronic Procurement System (PhilGEPS) for advertising tenders for interested suppliers making public sector tenders publicly available. (http://www.philgeps.net/) Appendix 1C

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

There are civil society organizations (Coalition Against Corruption, Procurement Watch, Inc) that promote procurement reform, conduct seminars in government institutions to create awareness of corruption involved in procurements and lobby for laws (Procurement Law).

1.4 Quality assurance data during registration

Sources:

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

1. FDA pre-registration evaluation of new drug applications relies heavily on data submitted by applicant. Decision to conduct actual analytical assays not done on all new product applications but is based on risk-based assessment (manufacturer/applicant).
2. Bioequivalence programme started in 1997 required testing of selected drugs with safety/efficacy issues associated with non-bioequivalence but moratorium lifted requirement for all drugs in 1999 except rifampicin. In 2006 bioequivalence testing was reinstated but required testing for only 12 generic drugs which was recently (January 2010) subject to a restraining order by the court which questioned the authority of the FDA to compel pharmaceutical companies to have their products undergo bioequivalence testing. The DOH Secretary issued AO 34 s. 2010 on February 18 (Reiteration on the Implementation of the Requirement of a Bioavailability/Bioequivalence Study in the Registration of Drugs and Medicines) ordering the FDA to "*strictly implement the requirements laid down in Republic Act Nos. 3720, as amended, 6675, 9502, 9711 and Administrative Order No. 67 series of 1989, including the requirement of the submission of a Bioavailabilitv/ Bioeguivalence study for Tried and Tested Drugs, Established Drugs and Pharmaceutical Innovation of Tried and Tested or Established Drugs, in support of their application for registration or renewal of registration. The Head of the Food and Drug Administration is, thUS, tasked to ensure that the above reiteration is carried out. DOH procurement relies on Certificate of Product Registration issued by the FDA for ensuring quality. "*

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

1. FDA website does not publish results of analysis that it has conducted especially those that may have failed standards.
2. FDA issues advisories on problematic products; it also issues ADR alerts, recalls of food & drugs with issues and procedures for food processes. FDA delists drugs with serious safety and efficacy issues based on alerts from OECD, ASEAN and WHO (Bureau Circular 3 series 2001: http://www.bfad.gov.ph/oldsite/BC/bc%203%20s.%202001.pdf). FDA information on product recalls are published at http://www.bfad.gov.ph/default.cfm?page_id=851

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

1. No info is given to the public on drugs that fail quality assurance testing or bioequivalence testing and these drugs are not removed from the market. For the FDA to act there must be a thrid-party complainant but as a general rule, drug failures secondary to use of substandard medicines is very rarely reported.
2. There is a published study reporting on anti-TB drugs that failed bioequivalence testing against the standard branded product (Dalmacion, G: Comparative Bioavailability of Three Rifampicin Preparations, Acta Medica Philippina, July-December 2006). The popular perception is that many generic drugs fall below standards and many prescribers do not feel confident to use generic drugs in general. (Appendix 1D)
3. This lack of confidence is reflected by the practice of many hospitals to require their own testing for drug products seeking entry into their pharmacies which not only duplicates the work of the FDA but appears to validate the registration approval of the product.
4. The FDA is very cautious about publishing negative results. The personnel is not covered from litigation filed by pharmaceutical companies. Even worst, the government will not shoulder legal fees; the FDA workers (who are low-salaried) will have to spend their own money to pay for lawyers. This problem has to be addressed

1.5 Routine quality testing and adverse event monitoring

Sources:

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

1. FDA has policy to conduct routine quality testing and special testing based on reports of possible issues (counterfeit or substandard drugs). It is legally mandated to inspect premises and collect samples as well as ensure quality control testing of imported medicines (RA 3720 - Food, Drug and Cosmetic Act, RA 9711 - FDA Act of 2009).
2. Legal provisions (RA 6675-Generics Act of 1988) grant FDA authority to ensure the quality of locally-produced and imported medicines.
3. Philippines is a Full Member of the WHO ADR Monitoring since 1995 but had low ADR reporting. FDA is attempting to improve ADR reporting through training and campaigns. There were only 1167 reports in 2008, very low relative to the size of the population (about 92 million). (Appendix 1E)

4. There is a law on counterfeit drugs (RA 8203 - Special Law on Counterfeit Drugs).

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

1. Total number of samples tested for quality which includes those tested at importation, registration and from the market are not published by the FDA but in a recent survey (Pharmaceutical Sector Scan) it was noted that this may be requested from the FDA.

   This claim needs to be validated further based on experience of previous BFAD deputy director (Appendix 5 -Stakeholder Comments on Data Disclosure Survey Report, Section 1.1, No.3)

2. ADR Unit has newsletter but circulation is very small; information should be published on the web. The ADR unit must link up with specialty organizations and hospitals with DTCs.
3. Medical organizations and hospitals are initiating pharmacovigilance activity such as ophthalmology specialists who have organized a registry on ethambutol-associated optic neuritis (ETON) and actively promoting awareness of the condition to prevent blindness of patients on TB therapy. There are also plans to set up a vaccine registry by experts in the field.

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

1. Information on counterfeit drugs are kept confidential (reports kept confidential by government). Pharmaceutical companies also hesitant to share information for fear that the public's confidence in their products may be eroded.
2. FDA maintains a programme against counterfeit as well as unregistered medicines but lacks support from other government agencies to more aggressively pursue goals (stronger sanctions on erring parties).
3. In the fight against counterfeit drugs, the challenge is to form linkages among government agencies (regulatory, judicial and police) to coordinate and improve the implementation of the law.
4. There is a need to overcome the barriers to spontaneous ADR reporting by health professionals (fear of litigation? lack of knowledge how to detect and report adverse events? lack of quality and/or patient systems implemented in health facilities? Further there is a need to address the poor quality of reports received.
5. There is recent move to form a national alliance for patient safety which will involves all sectors involved with health (PMA, specialty organizations, private sector, DOH, academe) and a summit was recently convened.

2. Medicine Availability

2.1 Standard treatment guidelines

Sources:

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

1. The national health insurance organization, Philippine Health Insurance Corporation PHIC) has a policy on the use of the following clinical practice guidelines to serve as basis for quality assurance and accreditation of physicians and hospitals (The HTA Forum Volume 04, No. 1, 2006):
   a. Community-acquired pneumonia (CAP) in adults and in children
   b. Asthma in adults and in children
   c. Urinary tract infection in adults and in children, hypertension, acute bronchitis, acute gastroenteritis, dyspepsia, dengue hemorrhagic fever, cataract, diabetes mellitus, normal spontaneous delivery, chronic cough in children, first simple febrile seizure, cholecystitis, and acute appendicitis

Appendix 2A - Treatment Guidelines

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

1. These treatment guidelines are published in medical journals, compendia and websites.
2. Professional society organizations develop and release Clinical Practice Guidelines (CPGs) using evidence-based (anti-TB treatment regimens, hospital-based antimicrobial treatment regimens) or consensus-based approaches or adaptation of US guidelines (treatment of hypertension). These are only recommendatory to provide clinicians with "best care" approaches.
3. Specialty organizations have programmes to encourage members to use treatment guidelines. The Philippine College of Physicians has a Hospital Accreditation Committee which accredits private hospitals nationwide and compliance to treatment guidelines is an important criteria for accreditation.

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

1. In general, especially for non-PCP accredited hospitals, practices vary widely, and in some cases even within a hospital. Challenge is to have up-to-date treatment guidelines in hospitals.
2. Challenge for PHIC is to regularly monitor prescribers' adherence to CPGs and to provide incentives and penalties to encourage compliance.

2.2 Essential medicines list

Sources:

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

1. National Drug Policy implemented in 1987. (The Philippine National Drug Formulary (PNDF) is the essential medicine list to guide public sector EM selection.
2. Implementing guidelines and Procedures in the Procurement and Requisition of Drugs and Medicines by the Department of Health (EO 49, series 1993) provided basis to ensure requisition of essential drug by government sector and inclusion of drugs in the Philippine National Drug Formulary.
3. The PNDF Volume I became the basis for claims reimbursement for medicines through the Philippine National Health Insurance Corporation in 1999.

Appendix 2B - Essential Medicines

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

1. The PNDF is made up of Volume I (Essential Drugs List) and Volume II (Essential Drugs Monographs). It is published (as hardcopy and DOH website and updated regularly.
   a. PNDF Vol. I, 7th edition 2008: http://portal.doh.gov.ph/files/pndf%20vol.1,%20sec.17-22-final%20with%20corrections.pdf
   b. PNDF Vol II, 3rd edition 2006: http://portal.doh.gov.ph/files/pndf2006.pdf
2. The PNDF hardcopy version is very limited in distribution and is used to a lesser degree compared to the privately published drug references (e.g., MIMS).

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

1. There has been no recent analysis or validation to determine if the current PNDF is responding to the needs of society.
2. The process for selecting members of the formulary committees is not open even to health sector and is thus perceived as lacking in transparency. Proceedings, appraisals, assessments, and outputs by all the committees are supposed to be made publicly available through publication in both the DOH and the PHIC websites.
3. There is criticism that the list of essential drug is too big.

2.3 Pharmaceutical patents held in the country

Sources:

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

1. Law on Intellectual Property Code passed in1997.
2. RA 9502 –Cheaper and Quality Medicines Act of 2007 amended the Intellectual Property Code to allow parallel importation of patented drugs and also compulsory licensing under certain conditions.
3. A significant public health contribution of RA 9502 is to prohibit data exclusivity, a TRIPS Plus provision, by providing the legislative support to improve access to affordable generic medicines.
4. Guidance on the roles of the FDA and the Intellectual Property Office on the patent issue in relation to drug registration is provided by AO 2005-0001 Revised Policies and Guidelines Governing Patent and Trade Secret Rights in Relation to the Registration of Pharmaceutical Products

(Appendix 2C)

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

1. Laws are published in gazettes and websites.
2. As previous stated patent linkage does not exist in the Philippines. FDA evaluates drug product applications for safety and efficacy and the Intellectual Property Office is responsible for resolving all patent-related matters

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

IPO office has an online patent search facility which is open to the public and is useful to owners of prospective generic drug products

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

Sources:

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

1. Most of the public sector procurement is channeled through the Local Government Units (LGUs) but no law to compel LGUs to make available medicines in their respective facilities (RHU, LGU hospitals)

   RA 7160 - Local Government Code: http://www.pcij.org/blog/wp-docs/LGC1991.pdf

2. DOH undertakes procurement through the Central Office Bids and Awards Committee (COBAC) of central procurement of medicines for vertical programs (HIV, TB and malaria).
   a. Foreign aid is a source of public sector drug procurement - Global Fund provides assistance for medicines on TB, malaria and HIV: http://www.theglobalfund.org/programs/country/?countryID=PHL&lang=en Total approved: $317,300,969 (Appendix 2C - Philippines and the Global Fund)
   b. PhilHealth reimbursement of medicines for hospitalization is allowed for drugs that are in the PNDF Formulary. Drug payments constitute about 21% of benefits (Appendix 2 F)
3. All government transactions subject to audits by the Commission on Audit.

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

1. Bids in the public sector must conform with Procurement Law and must be competitive.
2. DOH Budget for drugs based on 2008 Annual Procurement Plan (data available on request):

Agency	Amount
BIHC/GFR6	13,514,260.72
BHIC/WHSMP	3,059,259.67
EPI	501,871,565.76
Family Health	88,550,000.00
HEMS	3,188,150.00
Doctors to the Barrio	9,768,960.00
NCDPC/IDO/DDO	346,236,385.00
TOTAL……..……...966,188,581.15	

Appendix 2D - Data from DOH, November 2009

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

1. Procurement is widely recognized to be an area at high risk of corruption and ascertaining transparency in transactions a strategy to prevent corruption
   a. Philippine Electronic Procurement System:The PhilGEPS is the central portal of all public procurement activities that provides both government agencies and suppliers a more open, transparent and competitive environment
   b. PhilGEPS for drugs & medicines: http://www.philgeps.net/GEPS/Tender/SplashOpportunitiesSearchUI.aspx?menuIndex=3&BusCatID=99&type=category&ClickFrom=OpenOpp
2. Civil society organizations (Procurement Watch, Coalition Against Corruption) monitor that the procurement processes comply with provisions of RA 9184 -Procurement Law
3. Good Governance for Medicines jointly undertaken by the WHO, DOH and MeTA Philippines is now on its second year in conferring awards to LGUs who and other government health institutions that excel in complying with proper procedures including procurement in the delivery of healthcare services to the community.

2.5 Volume and value of medicines supplied in the private sector

Sources:

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

1. Transactions in the private sector, unlike the public sector, is not subject to Commission on Audit inspection or the Procurement Law.
2. The private sector is subject to rules on bidding for government tenders.
3. Customs and BIR have data on imports but the data is not published.

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

1. The private sector comprise major portion of the pharmaceutical market
   a. 90% of PHP 103.58 billion (IMS MAT September 2007).
   b. Ethical products comprise 69%, OTC 24% and nutritionals 7% of the pharmaceutical market
   c. Government has small share of the pharmaceutical market (2.6%)

Appendix 2 E - Volume and Value of Medicines in the Private Sector

2. While foreign companies dominate sales (69.6% in 2007), there is an increasing trend in the number of registered local companies from 2003 to 2007. Local companies had a 31.3% share of the market.
3. IMS maintains operations in the Philippines for several decades now and monitors pharmaceutical sales data which it furnishes to subscribers. It also conducts commissioned researches.

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

1. There are two main associations of pharmaceutical companies:
   a. Pharmaceutical Healthcare Association of the Philippines (PHAP) - comprised mainly of multinational companies: http://www.phap.org.ph/
   b. Philippine Chamber of the Pharmaceutical Industry (PCPI) - made up of local manufacturers: http://pcpi-org.com/about.aspx?newsID=7
   c. Many companies are not associated with the above associations; Pfizer withdrew its membership from PHAP recently.

2.6 Availability of medicines to consumers

Sources:

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

1. DOH supports vertical programs that include provisions of free medicines in the public sector (HIV, malaria, TB).
2. No law compelling LGU to make medicines available in their respective facilities (RHU, LGU hospitals); it is up to the LGU if they want to spend money for medicines to give to constituents or just send patients to private pharmacies.

   There are model municipalities (e.g., Mayor Sonia Lorenzo of San Isidro, Nueva Ecija - a shining example of an enlightened leader who has scored remarkable success in instituting a successful health program to serve the needs of her community and in the process exceed agricultural production. (Appendix 2G)

3. PhilHealth accreditation does not mandate the availability of any set of essential medicines in the hospitals. In fact, hospitals often send patients to other pharmacies if they want a cheaper alternatives (based on RA 9502, consumers have the choice whether to use expensive brands or cheaper generic alternatives). Appendix 2 F

4. RA 9502-Cheaper Medicines Act of 2008 has mandatory carry provision to force pharmacies to stock lower cost generic alternatives in addition to expensive brands. “Section 5. Mandatory Carry. Imported drugs to be carried by retail outlets shall be based on the reported health needs of a community. A mechanism that will determine the carrying capacity and demands for parallel imports at the level of retailers shall be established so that demands for drugs to be covered will match their carrying capacity. After proper determination by BFAD, the concerned LGUs shall ensure that retail outlets in the area of distribution shall carry said patented drugs. This is not being strictly enforced.

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

Laws are published.

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

1. A study published in the Lancet showed that availability of generics was low in the public sector in the Philippines (22.2%) and also in the private sector (33.6%)

   Appendix 3A - Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis by A Cameron, M Ewen, D Ross-Degnan, D Ball, R Laing at www.thelancet.com Published online December 1, 2008 DOI:10.1016/S0140-6736(08)61762-6

2. A study that assessed costs, availability and affordability of diabetes care in the Philippines from multilevel interviews and patient interviews showedvery few sustainable measures for maintenance of regular medications because of cost constraints leading to very irregular treatment and could lead to complications and hospital admissions.

   Appendix 3E - Costs, availability and affordability of diabetes care in the Philippines by Michiyo Higuchi, Foundation for Advanced Studies on International Development (FASID)

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

Sources:

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

1. There is an FDA policy to audit pharmacies.
2. Audits include operations against pharmacies dealing in counterfeit and unregistered products

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

1. Data are not published but reported in relevant seminars/workshops (e.g., pharmacovigilance seminars as topics on counterfeit drugs)
2. Target number of audits are not met due to personnel and budget constraints.

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

1. Botika ng Barangay (small community pharmacies) that supply remote barrios/communities should be monitored regularly by a licensed pharmacist but this rarely happens in practice due to lack of available pharmacists (http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO144s2004.pdf)
2. Audit reports are generally for internal use of the FDA.
3. New FDA Law endows FDA with quasi-judicial authority to use against erring establishments.

3.Medicine Prices

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

Sources:

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

1. RA No. 7581 also known as the "Price Act" and its Implementing Rules and Regulations (IRR) explicitly identifies the Department of Health (DOH) as the lead implementing agency in identifying essential drugs "basic necessities" and monitoring their corresponding prices.
2. Department Order No. 238-T s. 2000, and as amended by Department Order No. 285-H s. 2002, were created in order to provide a system and procedure for the data collection on prices of selected essential drugs which is now known as the Essential Drug Price Monitoring System (EDPMS). EDPMS aims to provide information on prices of essential medicines along the full supply chain and was pilot tested in 2009. (http://www.doh.gov.ph/ndp-pmu50/indexf92d.html?option=com_content&view=article&id=5&Itemid=68)
3. President Arroyo issued Executive Order (EO 821) which took effect on August 15, 2009 ordering the compulsory 50% reduction of 5 medicines (amlodipine, atorvastatin, cytarabine, doxorubicin and azithromycin). Sixteen (16) other essential medicines were subject to voluntary price reductions.
   http://www.bfad.gov.ph/default.cfm?page_id=1304&parent=0

   a. The 5 drugs are not in the essential medicines list but are supposedly the most highly sold drugs (based on sales).
   b. On ongoing debate is still being waged as to the impact of this ruling on the state of drug access and whether there will be future compulsory reductions to follow (there were drugs submitted for voluntary price reduction.

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

Laws are published in DOH and FDA websites and newspapers.

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

1. Pharmacies are compelled to make daily submissions for posting in the EDPMS . eedback from pharmacies state that EDPMS requirement of daily submissions of prices is tedious and impractical work.
2. EDPMS website is not always operational.
3. MDRP has been criticized as a politically-motivated move. There were negative feedbacks from industry (pharmaceutical companies and pharmacies) while some patient groups hail gains especially in the purchase of anti-cancer medicines by private institutions helping indigent cancer patients.
4. Another criticism is that while the middle class who have resources benefited from the price reductions, the poorest segment still are not able to afford these medicines.

3.2 Public sector medicines procurement prices

Sources:

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

There are laws and policies on procurement (Procurement Law)

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

Yes the laws are published but enforcement is weak

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

Published data (WHO-HAI funded study on Public procurement prices of medicines by Douglas Ball, 2008) studied efficiency of procurement of essential medicines showed that while few health facilities were procuring essential medicines at comparable prices, most were procuring medicines at prices as high as 3 times the international reference prices. (Appendix 3B)

A study published in the Lancet showed that public sector procurement prices of lowest-priced generics in the Philippines, a lower-middle income country was 2.94 times the international reference price for a basket of 15 medicines studied. Appendix 3 D

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

Sources:

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

1. In 2007 RA 9502 or Cheaper Medicines Act endows the President with the power to control retail prices of medicines - this was the basis for EO 821 issued on August 15, 2009 which reduced the prices of 5 medicines by 50% (16 other drugs complied voluntarily). See Item 3.1
2. Following EO 821 issuance, most pharmacies posted MDRP and GMAP menu cards which listed prices of price-controlled brands and available generic medicines (commonly < 3 generics) .
3. DOH requested manufacturers to disclose ex-manufacturer prices of commonly used medicines before introduction of MDRP with limited success (such manufacturer prices are not available publicly) which it intended to use in price regulations. (see Appendix 5 - Comments of MeTA Stakeholders on Data Disclosure Report of November 2009)

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

Laws are published.

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

HAI-WHO survey on components of medicine prices (Douglas Ball, 2009) found that there is a lack of transparency in the pricing of generic and originator brand medicines in the private sector. Generic products have mark-ups that range from 5% - 355% at the retailer level, and 18-117% at the distributor level. Mark-ups on originator brand products were usually of the order of 5% -8% at private retail pharmacies. Value-added tax adds significantly to the price of medicines. Public pharmacies tend to charge fixed retail mark-ups of up to 30%. The senior citizen's discount has been minimized by price increases and is essentially paid by patients. The market structure, market segmentation and low confidence in generics perpetuates the observed pricing structures and lower than desired

use of low-priced generic medicines. (Appendix 3C)

4. Medicine Promotion

4.1 Medicines promotion regulations, policies, and industry practices Sources:

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

1. AO No. 65 s. 1989 -Guidelines on Advertisement and Promotions to Implement the Generics Act of 1988 (http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf) Section 2.0 Guidelines On Advertisement And Promotion Based On Prior Laws:
   a. 2.1 No person shall advertise or promote a pharmaceutical product unless such product is duly-registered by Bureau of Food and Drugs (BFAD).
   b. 2.2 All therapeutic claims for drugs, medicines or any pharmaceutical product made in advertising or promotional materials must be based on adequate scientific pharmacological, and clinical evidence, responsible medical opinion or long experience demonstrating their safety, efficacy and therapeutic value, and must be within their therapeutic indications approved by the BFAD.
   c. 2.3 No pharmaceutical product classified by BFAD as a Prescription or Ethical Drug shall be advertised or promoted in any form of mass media except through medical journals, publications and/or literature solely intended for medical and allied professions.
   d. 2.4 The pharmaceutical company which owns the pharmaceutical product, and its Medical Director shall be responsible and accountable for the content and form of its advertisement and promotional materials.
2. Of the 2 pharmaceutical associations in existence (see item 2.5), only the Pharmaceutical Healthcare Association of the Philippines (PHAP) has a Code of Ethics which adopts in full the IFPMA code. It monitors industry practices of its members (Appendix 4)
3. The Philippine Medical Association has a Code of Ethics with implementing guidelines (published in Ambi-Health M.D. Vol. 2, No.1 Jan-Mar 2009)
4. The Philippine College of Physicians also has a Code of Ethics (http://www.pcp.org.ph/index.php?option=com_content&view=article&id=95:pcp-code-of-ethics&catid=59:ethics)
   a.

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

1. Section 2.2 is poorly controlled. Content of adverts in case of OTC is often poorly controlled due to limited capacity of FDA to screen advertisements, especially in TV and radio. “No approved therapeutic disclaimer” of household remedies does not stop exaggerated claims.
2. Section 2.3 is enforced -ban on direct-to-consumer advertising of prescription item and generally adhered to with the exception of certain medical doctors/society that endorse informercials disguised as “ scientific news” (see Appendix 5 - Comments of MeTA Stakeholders on Data Disclosure Report of November 2009)

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

1. Unethical promotions and advertising and other industry practices must be addressed through legislation and reforms in the regulatory agency.
2. There are no laws governing dermatologists, pediatricians and oncologists from selling prescription drugs, vaccines and concocted medicines ((see Appendix 5 - Comments of MeTA Stakeholders on Data Disclosure Report of November 2009)
3. Academic curricula of all medical schools must include material ethics of pharmaceutical promotions.

APPENDICES

Appendix 1	Laws & Policies
Appendix 1-A	Market registration procedures and registration status of all medicines
Appendix 1A-1	List of Registered Drug Products (2008)
Appendix 1A-2	List New Drug Product Applications (2009)
Appendix 1B	GMP-Certified Philippine Establishments
Appendix 1C	The Philippine Electronic Procurement System (PhilGEPS)
Appendix 1D	Rifampicin Bioequivalence (Acta Medica Philippina)
Appendix 1E	ADR Reporting in the Philippines
Appendix 2A	Treatment Guidelines
Appendix 2B	Essential Medicines
Appendix 2C	Pharmaceutical Patents
Appendix 2D	Volume and value of medicines procured in the public and non-profit sectors
Appendix 2E	Medicines in the Private Sector
Appendix 2F	Availability of Medicines
Appendix 3A	Medicines price components in the public, non-profit, and private sectors Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis by A Cameron, M Ewen, D Ross-Degnan, D Ball, R Laing www.thelancet.com Published online December 1, 2008 DOI:10.1016/S0140-6736(08)61762-6
Appendix 3B	Medicines price components in the public, non-profit, and private sectors Public Procurement Prices of Medicines in the Philippines by Douglas Ball and Klara Tisocki (HAI-WHO funded study)
Appendix 3C	Medicines price components in the public, non-profit, and private sectors Medicines Price Components in the Philippines by Douglas Ball and Klara Tisocki (HAI-WHO funded study)
Appendix 3D	Medicines price components in the public, non-profit, and private sectors Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis by A Cameron, M Ewen, D Ross-Degnan, D Ball, R Laing www.thelancet.com Published online December 1, 2008 DOI:10.1016/S0140-6736(08)61762-6
Appendix 3E	Medicines price components in the public, non-profit, and private sectors Costs, availability and affordability of diabetes care in the Philippines Michiyo Higuchi Foundation for Advanced Studies on International Development (FASID)
Appendix 4	Medicines promotion regulations, policies, and industry practices Philippine Pharmaceutical and Healthcare Association (PHAP) PHARMACEUTICAL DATA DISCLOSURE: POLICIES AND PRACTICES CONCERNING THE PROMOTION OF MEDICINES
Appendix 5	MeTA stakeholder comments on initial Data Disclosure Report of November 2009 (validation)