

Medicines Transparency Alliance (MeTA) Pharmaceutical Sector Scan Framework—Philippines

Executive Summary

I. Country Profile

A. Demographic and Social Indicators

- There were over 88 million Filipinos in 2007, with projected 2009 estimates of 92 million.
- More than 60% (64%) of these live in urban areas.
- More than 1/3 of the population is younger than 15 years old
- Only 6% of the Filipino Population is over 60 years old.
- 26 Filipinos are born while around 5 Filipinos die for every 1000 population.
- The GNI per capita (3430-3900 PPP int \$ depending on source) reflects a low to middle income country.
- GDP increased by just below 4% in 2008
- The adult literacy rate of Filipinos is 93.4%, which puts it above some neighboring countries (Malaysia – 91.9% Indonesia – 92.0) but below others (Thailand – 94%)
- 90% of Filipino children are enrolled in primary-level schools, with females (92%) having a slight predominance over males (90%)

B. Mortality and Causes of Death

- The life expectancy at birth rose from 70 in 2000 to 71 in 2007
- The maternal mortality rate from a WHO survey (2005 data) is at 230 deaths while it is 162 deaths per 100,000 live births from the National Family Planning Survey conducted in 2006.
- Infant mortality rate, adult mortality rate, and under 5 mortality rate have improved from 29 (2000) to 23 (2007), from 183 (2000) to 178 (2007), and from 37 (2000) to 28 (2007), respectively based on the WHO World Health Statistics 2009.
- However the National Demographic Survey 2008 states that infant mortality and under 5 mortality rates are higher than the WHO data at 25 and 34 respectively.
- Deaths attributed to HIV/AIDS are lower (less than 10 per 100,000) than neighboring countries such as Cambodia (48/100,000), Malaysia (15/100,000), Myanmar (51/100,000), Thailand (47/100,000), and Vietnam (47/100,000)
- Cardiovascular diseases cause more than deaths than cancer, Tuberculosis, or HIV/AIDS combined.
- Neonatal causes account for most deaths in children <5 years.
- Diarrhea kills more children <5 years than pneumonia.

C. Health Care Expenditures

- Data on health expenditure are taken mostly from WHO World Health Statistic 2009 and Philippine National Health Accounts 2006-National Statistical Coordination Board (NSCB).

- Data on share of health expenditure to GDP from both sources are still below the 5 percent standard set by the World Health Organization (WHO) for developing countries. Among the other ASEAN countries, Brunei Darussalam, Indonesia and Myanmar had lower percentage share of total health expenditure to GDP than the Philippines in 2005.
- Per capita health expenditure of the government decreased by almost 1% to 603 (pesos) in 2006 from 609 in 2005. (Philippine National Health Accounts 2006, National Statistical Coordination Board)
- The share of government on health expenditure in 2006 declined to 23.2% from previous 29% in 2005, which is below the target of 40% based on the Health Sector Reform Agenda (HSRA).(Philippine National Health Accounts 2006)
- Based on the local data of National Statistical Coordination Board in 2006, private sources' share to the country's total health expenditure increased to 67.1% compared to 63.3% of previous year.
- Share of private out-of-pocket payments increased to 56.9% in 2006 from 49% in 2005, way above the out-of-pocket target of 20% based on HSRA. (Philippine National Health Accounts 2006)
- Data on health insurance coverage refer only to PhilHealth coverage in the entire country based on the 2008 annual report of the institution. Officially, 76% of the population is covered by PhilHealth, however a local study conducted by Quimbo states that coverage rate is lower (50%).
- Data on actual utilization rate of those covered by PhilHealth would also be informative

D. Health Personnel, Infrastructure and Primary Health Care

- There are approximately 12 Physicians (private and government combined) for every 10,000 Filipinos according to 2007 data.
 - At the time of data collection, there were over 90,000 licensed physicians in the country, but not all of them are practicing medicine.
 - Some have either retired, taken other jobs or have emigrated to other countries.
 - The raw estimate from the Philippine Field Health Survey (2006) of practicing physicians is closer to around 40,000.
- Nurses and midwives are at 61 per 10,000 Filipinos.
- There are less (6 per 10,000) pharmacists than doctors or nurses in the country, although they are assisted by 11 per 10,000 personnel
- There are almost 200,000 barangay health workers (BHW), the country's version of the community health worker, in the Philippines, from a national BHW association total of around 500,000. The rest of the BHWs are either inactive or retired.
- Although data suggests 2 hospitals for every 100,000 people, this figure can be misleading due to the placement of hospitals in the country. There are 9 level 1 hospitals and 8 level 2 hospitals for every 1,000,000 Filipinos.
 - City centers of provinces usually have more hospitals as compared to far-flung regions that do not have them.
- There are 2 Barangay Health Stations for every 100,000 people.
- 65% of neonates are protected at birth against neonatal tetanus
- 92% of one-year olds are vaccinated against measles.

II. Medicines Policy and Regulatory Framework

- National Health Policies, National Drug Policies, and policies for implementing these exist and are regularly updated.
- The Food and Drug Administration (FDA), formerly known as the Bureau of Food and Drugs (BFAD), has powers and responsibilities set by Republic Act 3720 (Food, Drug and Cosmetic Act) and was further strengthened by Republic Act 9711 (Food and Drug Administration Act of 2009). The FDA regulates drugs/medicines and has 249 regulatory staff nationwide.
- All FDA staff follows a formal code of code which also requires transparency and accountability.
- The FDA is actively involved in regional/international harmonization initiatives such as with the ASEAN Consultative Committee on Standards & Quality (ACCSQ).
- A drug has to comply with the WHO Certification Scheme and other requirements before the FDA grants market authorization.
- The current website of the FDA is <http://www.bfad.gov.ph>

III. Medicines Market

- As of November 2009, medicines registered in FDA stand at 22,981. This number does not include food supplements and herbal medicines.
- The list of registered medicines by class, patent status, patent expiry and registration dates is not publicly available but the FDA can provide the list upon presentation of written request with acceptable reason/s.
- The Philippine pharmaceutical industry is valued at PhP 103.58 billion and is growing at CAGR of 10% as of September 2007.
- There is currently no accurate local data on the value of market share of generic medicines but it is estimated at 40%. Due to the implementation of Maximum Retail Price, the market has not stabilized and a more accurate value may be obtained by March 2010.
- The Top 20 brands in the market amount to PhP 16.419 billion or 15.85 percent of total pharmaceutical market. Ten of these brands are prescription products and the other 10 are classified as over-the-counter or OTC products. Norvasc, Pfizer's antihypertensive takes number 1 slot as the country's leading pharmaceutical brand. (Philippine Pharmaceutical Industry Factbook 7th Edition, November 2008)
- The annual growth rate of generic market value is estimated at 15%. Due to the implementation of Maximum Retail Price, the market has not stabilized and a more accurate value may be obtained by March 2010.

IV. Medicines Financing

A. Government Expenditures and Health Insurance

- The Department of Health (DOH) roughly spends PhP 4-5 billion, or 15% of its annual budget, for medicine procurement. If PhilHealth acquisitions were included, the total expenditure would be estimated at PhP 12-15 billion. However these are just estimates as the exact amount the DOH and PhilHealth utilizes for medicines expenditure is generally not available.
- Total expenditures on medicines by the public and private sector account to around PhP 110 billion.
- The current National Health Insurance program, PhilHealth, is the evolution of the original Social Health Insurance system created in 1969 by Republic Act

6111, known as the Medicare act of 1969. This was replaced in 1995 with Republic Act 7875, which established the current system.

- The system covers public health services for all groups such as women, children, indigenous people, and displaced communities in environmentally endangered areas.
- The program also covers preventive and promotive public health services, which, according to the law, are “essential for reducing the need and spending for personal health services.” This includes medicines.

B. Public Programs Providing Free Medicines

- Citizens can obtain certain medicines for free from the government at public health care facilities.
- Medicines that can be obtained for free include:
 - Vaccines listed under the Expanded Program on Immunization (EPI)
 - Malaria medicines
 - Tuberculosis medicines
 - Antiretrovirals for HIV/AIDS
- Medicines can be obtained for free through reimbursement by insurance programs.

C. Patient Fees and Copayments

- The sources of data are from anecdotal experiences of the authors/researchers and personal one-on-one interview with Dr. Robert So (Head Executive Assistant, Department of Health).
- Medicines in public hospitals are sometimes paid by inpatients. There are also certain medicines given free of charge in public hospitals.
- Registration/consultation fees are generally not common in public primary care facilities.
- Some local health centers encourage giving voluntarily “donations” from patients.
- Medicines copayments are not used to pay salaries of public health care workers.
- A formal, credible local data could show the true picture on medicine financing in terms of patient fees and co-payments.

V. Medicines Trade

A. Intellectual Property Laws

- The Philippines has signed the World Intellectual Property Organizations’ conventions on intellectual property.
- The local government office that handles IP is the Intellectual Property Office of the Philippines.
- Republic Act 8293 (Intellectual Property Code of the Philippines) governs patents, trademarks, service marks and trade names.
- Republic Act 9502 (Cheaper Medicines Act) amends the above law to properly cover for the intellectual property rights for drugs and other related products.

B. Registration

- There are explicit and transparent procedures to follow when registering a drug as outlined by the FDA. International Non-proprietary Names (INN) and fees are required for registration.

- Drug samples are tested for quality, purity and other physico-chemical qualities during the registration process.
- Patented products take an average of 180 to 270 days (6 to 9 months) before a decision (approval or denial) is made while generic products take an average of 90 to 180 days (3 to 6 months) before a decision (approval or denial) is made.
- A list of all registered products is not publicly accessible. A letter requesting for the list is required.
- A list of products pending registration is available on the FDA website (<http://www.bfad.gov.ph>). The application status of a product is not listed on the website and should be verified with the FDA by telephone.
- Drug registration may be appealed and follows certain procedures.
- The Inspection and Licensing Division of the FDA is in charge of assessing application for registration of products. Like all FDA and DOH employees, conflict of interest statements are submitted when required.

C. Manufacturing

- FDA provides list of establishment with certificate of Good Manufacturing Practice on its official website. However, results of latest inspection are not available online.
- List of sanctions is available upon official request.
- Type of sanctions given includes:
 1. Record of violation
 2. Cease and Decease Order
 3. Revocation of License to Operate.
- FDA has regulation on standards and requirements for license to operate domestic and multinational drug manufacturers.
- There is also legal provision for licensing importers. Some of the requirements include:
 1. Foreign Agency Agreement between the Philippine importer and foreign supplier duly authenticated by the territorial Philippine Consulate
 2. A certificate that the manufacturer of the raw materials, active ingredients and/or finished product is registered in the country of origin, duly authenticated by the territorial Philippine Consulate
 3. Evidence that the manufacturer meets BFAD standards
 4. In case of finished products, Certificate of Free Sale of the product in the country of origin, duly authenticated by the territorial Philippine Consulate and evidence that such certificate is issued in substantial compliance with BFAD standards
- There is increasing trend in the number of registered pharmaceutical companies per year from 2003 to 2007. (Philippine Pharmaceutical Industry Factbook 7th Edition)
- In terms of counting units sold, the local pharmaceutical companies cumulatively sold 21.36 billion units in the market for a 47.7% share in total actual units sold in 2007. (Philippine Pharmaceutical Industry Factbook 7th Edition)
- In terms of peso sales growth, local companies cumulatively registered a PhP 32.46 billion sale (31.3% share) in 2007 with a double-digit four-year CAGR of 12.67%. (Philippine Pharmaceutical Industry Factbook 7th Edition)
- Domestic manufacturers are not involved in R&D to discover new active substances and production of pharmaceutical starting material.

D. Quality Assurance

- Republic Act 3203 gives the FDA the power to inspect and collect samples for quality testing.
- Republic Act 8203 deals with screening and detecting counterfeit medicines and makes illegal the sale, distribution and production of counterfeit medicines.
- Sections 7 and 10 of Republic Act 6675 (Generics Act of 1988) details the provisions of procurement of drugs through importation and how the DOH must be responsible for quality control.
- The list detailing the results of quality control for the past year is not available to the public but can be requested from the FDA/BFAD with a letter requesting the said information.

E. Price Control and Transparency

- Republic Act 9502 (Cheaper Medicines Act) gives the Government, particularly the President, the power to set maximum retail price of drugs. Prices at all levels of the supply chains including but not limited to manufacturer's price, trader's price, distributor's price and wholesaler's price, and retailer's price are affected by this. This was recently implemented August 2009.
- Local government units and the Department of Trade and Industry (DTI) actively monitor drug prices.
- Controlling medicine prices vary for different types of medicines.
- Medicine prices, whether controlled or not, should always be available to the public.
 - Drugstores are mandated by law to list all their medicine prices. This list would also include the prices of the top 20 medicines.
 - PhilHealth has a Drug Pricing Reference Index available on the Internet but was last updated in 2006

F. Price Comparison in the Private-for-Profit Sector

- The data on medicine price comparison in the private-for-profit sector was obtained from the local study by Batangan D. et al entitled "The Prices People Have to Pay for Medicines in the Philippines."
- The median MPR for the originator brand medicines was 17.28 while that of the lowest priced generic equivalent was 5.64. As seen in the public sector, patients are buying medicines from the private sector at many times their international reference price. (Batangan D et al. 2005)
- The data on price components were taken from secondary sources and represent the maximum potential price components in the study by Batangan.
- The pharmacist mark-up (29.8%) contributed the biggest chunk in the final pricing of medicines in the market.
- Manufacturer selling price and wholesaler selling price each accounted for 26.8% and 23.5% of the final price of medicines, respectively.
- The contribution from taxes in final pricing of medicines includes VAT, national corporate taxes and import tariff, accounting for 10.7%, 1.6% and 1.1% of final price, respectively.

G. Consumer Prices of Medicines on HAI Global Core List

- Amytryptiline is not located in the Philippine National Drug Formulary (PNDF); imipramine, fluoxetine and sertraline are PNDF included antidepressants.

- Philippine data on Diazepam and Simvastatin were not included in the HAI Global Core List, but they are included in the study on procurement prices.
- Only the originator brand of Salbutamol and Omeprazole is included in the public sector. It is cheaper compared to the same brand in the private for profit sector, although the lowest price generic is available for a lower price.
- Glibenclamide is cheaper in the public sector by at almost 40% compared to the private sector.
- The originator brand of Atenolol is almost 40% cheaper in the public sector. The lowest price generic for the drug has a relatively similar price in both public and private sectors.
- The price for the originator brand of Captopril and Ciprofloxacin is almost the same in the private and public sectors. However the lowest price generic brand is more expensive in the public sector.
- Data for Co-trimoxazole is not available in the formulation described in the questionnaire. However data for a formulation of 40 +200 mg/ml Suspension is available, where the price of the lowest price generic is more expensive
- Amoxicillin, Ceftriaxone and Paracetamol are all available in both public and private sectors. Overall the public prices are cheaper than those in the private sector.
- Some drugs only have data on the private sector like Diclofenac.

H. Promotion and Advertising – Legal and Regulatory Provisions

- There are laws, namely Republic Act 6675 (Generics Act of 1988) and DOH Administrative Order 1989-065, to control the promotion and advertising of medicines:
 - Direct advertising is prohibited. Prescription or ethical drugs can only be advertised through medical journals, publications and/or literature solely intended for medical and allied professions
 - Drugs that can be advertised should emphasize the generic name, then the brand name.
- Promotion or advertising of a registered drug product does not need the approval of the FDA.
- No laws yet exist controlling the giving of gifts from the pharmaceutical industry to prescribers.
- Procurement offices have standard operating procedures regarding interactions with sales representatives/wholesalers.
- There were 2 violations regarding advertising of medicines in the year 2008.

I. Promotion and Advertising – Code of Conduct and Spending

- The Code of Ethics of Philippine Medical Association (PMA) provides the guidelines on professional conduct and relationship of physicians in dealing with pharmaceutical industry.
- Article VI, Section 3 of Code of Medical Ethics: Only gifts of reasonable value that primarily entail benefit to patient care or related to physicians' work may be accepted by a physician from a health product company.

- The pharmaceutical industry organized under the Pharmaceutical and Healthcare Association of the Philippines (PHAP), whether domestic or multinational companies, has also its own code of ethics concerning promotion and advertising of medicines.
- Adherence to the code is promoted by self-monitoring among PHAP members. The PHAP code put to task its members to ensure that internal compliance procedure exists that strives for compliance with all the provisions of the Code. Specifically, the general manager/president/managing director is responsible for the proper implementation of the Code. They are tasked to ensure that all company employees and company's external advertising agencies are conversant with the PHAP Code.
- According to PHAP Code of Ethics, the pharmaceutical industry has obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines.
- Violations of the code of ethics by any pharmaceutical companies are subject to sanctions. The list of complaint and sanctions is available upon written request stating the objective for the request.
- The administration of the Code of Ethics is supervised by the PHAP Ethics Committee.
- Violations committed by companies not members of PHAP nor under the umbrella of the IFPMA are handled by BFAD or other proper authorities.
- Pharmaceutical companies are required to report budget on advertising and promotion in tax disclosures.

VI. Medicines Supply System

A. Selection

- PhilHealth, the National Health Insurance System, adopts the Clinical Practice Guidelines for the following common illnesses:
 - Pediatric and Adult CAP
 - Acute Appendicitis
 - Hypertension
 - Acute Bronchitis
 - Dyspepsia
 - Acute Bronchitis
 - Adult Asthma
 - UTI
 - Acute Gastroenteritis
 - Maternity Care
- The PNDF is also the national essential drugs list. It contains a list of all the formulations of drugs categorized into their clinical use (Gastrointestinal Drugs, Anti-infectives, etc.)
 - The Formulary has been revised seven times, with the latest revision being 2008
 - The 2008 revision is not yet available as a hard copy; an online version can be found on the DOH website.
 - The 2005 revision is the currently available published version in most hospitals.
 - The process of selection of medicines is detailed in the appendix section.

- There is also a list of committee members in the published version (2005 6th edition)

B. Procurement in the Public Sector

- The Government Procurement Policy Board (GPPB) oversees all public procurement.
- Prequalification of suppliers is not needed to bid.
- All public procurement bids/tenders and awards/winning bids are publicly available and are listed at the PhilGEPS website (<http://www.philgeps.net>).
- An electronic bidding process for public procurement is slated to be operational in the last months of 2010.
- The public can be invited to view quality testing of products during the procurement process; however some testing sites (laboratories) may have policies that do not allow public access. Results of testing are not published or disseminated but may be requested with a written letter.
- Public procurement of medicines is limited to the national essential drugs list / PNDP. Suppliers awarded bids for medicine may supply medicines from both local and international manufacturers.
- Public procurement of medicines on the essential medicines list was around PhP 4-5 billion in 2008 according to Dr. So. The Commission on Audit has yet to publicly release the National Government's Annual Financial Report for 2008. In 2007, public procurement of medicines was 4.67% of public procurement expenditure.

C. Procurement Price of Medicines (HAI Global List)

- The list of prices in MPR was obtained from the July 2008 report by Ball and Tisocki entitled "Public Procurement Prices of Medicines in the Philippines."
- There was no data on Amitriptyline.
- Some generic essential medicines can be procured at prices below or equal to those available in the international market with low MPR (e.g. generic Ciprofloxacin, generic Amoxicillin, generic ceftriaxone injection and generic paracetamol suspension).
- However, all the originator drugs and majority of low price generics are being procured in the public sector at a much higher price compared to international reference prices.
- The originator brand of Diclofenac registered the highest MPR (72.5) compared to reference price.

D. Distribution

- The FDA along with DTI has instituted guidelines for good distribution practices
- The government procures medicines but does not have a physical facility in which these procured medicines are stored.
 - These procured medicines are monitored and traced using a database/software system.
- DOH Administrative Order 1989-056 deals with the regulation of licensing of Drug Establishments and outlets.
 - To date there are 3759 licensed wholesalers in the market.
- There is no unified national association of wholesalers in the Philippines
 - There is however an association of Drug Stores, the Drug Store Association of the Philippines

- 45 domestic manufacturers in the Philippines have integrated wholesale activities.

VII. Medicines Access

- It takes more than 1 hour for 5% of the population to reach a primary care facility.
- 60% of key medicines are available at public pharmacies, while 96.7% are available in private pharmacies.
- 90.5% of prescribed medications are actually dispensed.
- Less than 1 day's wage of the lowest paid government worker is needed for standard treatment of a child respiratory infection.
- Twice the number of days' wages of the lowest paid government worker is needed for 30 days' treatment with the highest price of atenolol and simvastatin compared with the lowest price.
- There are information (quintile data, percentage of households) that can be obtained from the WHO World Health Survey once the survey is publicly available

VIII. Medicines Use

A. National Structures

- The National Drug Policy-Pharmaceutical Management Unit 50 under the DOH is assigned to coordinate medicine use policies and promote rational use of medicines. It envisions providing quality health care through improved access and rational use by the Filipino people of safe, effective, quality and affordable drugs to all, especially the poor. Its main goal is to attain universal (at least 85%) regular access to essential medicines by 2015.
- In the previous two years, public education campaigns about rational medicine use have been conducted by the DOH. The P100 Project is a case in point.
- There is no formal written national strategy on controlling antimicrobial resistance. Instead, the WHO standards are adopted in dealing with antimicrobial resistance using the WHO surveillance standards for antimicrobial resistance and manual for laboratory identification of bacterial pathogen.
- DOH provides guidelines on the accreditation of aerobic bacteriology laboratory in the country.
- The Antimicrobial Resistance Surveillance Program under Research Institute for Tropical Medicine (RITM) is in charge of monitoring antimicrobial resistance.
- Under the Department Personnel Order No. 2009-1972, the Committee on Antimicrobial Resistance Surveillance Program is reconstituted under RITM. The Committee has the following duties:
 1. To establish a national surveillance program for antimicrobial resistance
 2. To standardize laboratory procedures for antibiotic susceptibility testing
 3. To conduct meetings/seminars for national and regional laboratory personnel
 4. To collect and analyze data on the prevalence of antimicrobial resistance of organisms of clinical and public health importance
- 34.8% of facilities have a copy of national STGs while all facilities have a copy of the national EML.

B. Prescribing

- Republic Act 6675 (Generics Act of 1988), and DOH Administrative Orders 1989-062 and 1990-090 governs the prescribing practice of prescribers (mainly physicians)
- Republic Act 6675 makes mandatory the inclusion of the generic name in the prescription. This holds true for all prescribers.
 - However anecdotal reports state that some prescriptions are made that do not contain the generic name (Brand name is placed in parentheses)
- The PMA has a code of conduct, but there is no specific reference to conduct regarding prescribing medicines.
- Public district and regional and private hospitals have functioning DTCs.
- Ideally, all public referral, district or regional hospitals are mandated to have a functioning DTC, but no data has been collected so far on the percentage of these hospitals that has a DTC.
- 96% of cases of acute respiratory tract infection (ARI) are treated with antibiotics. This data interchanges the terms ARI with pneumonia. There is no data on non-pneumonia ARI treated with antibiotics
- Only 14% of cases of diarrhea in children under age 5 are treated with ORT. The data does not specify whether the cases were bacterial or not.
- Based on experiences, 3-4 medicines are written per prescription. A recent WHO Level II Survey puts this number at 2 medicines per prescription.
- Only 84% of medicines are prescribed by the INN name despite the Generics Act of 1988 mandating all prescriptions to use the generic or INN name.
- Of all prescriptions, 66.2% are for antibiotics, and 18.4% for injections.
- 90.9% of prescriptions are prescribed from the EML or formulary.
- 78.2% of non-pneumonia acute respiratory tract infections are treated with antibiotics, while 52.4% of non-bacterial diarrheas of children under 5 are treated with oral rehydration therapy.

C. Dispensing

- Republic Act 5921 (Pharmacy Law) governs licensing and dispensing practice of pharmacists and pharmacy establishments.
- The Philippine Pharmaceutical Association has an established code of ethics for pharmacists.
- Drugs can only be prescribed by physicians, veterinarians, and dentists.
- Prescriptions are needed in dispensing antibiotics, injections, narcotics, and psychotropic drugs. However some pharmacies dispense some antibiotics without the need for prescriptions. Dispensing of narcotics, psychotropic drugs and precursors require special prescriptions (S2) and is heavily regulated.
- Substitutions for generics are allowed and highly encouraged by Republic Act 6675 (Generics Act of 1988). Prescriptions with “no substitutions” are violative prescriptions and commit an offense.
- 89.4% of medicines are dispensed at the facility where they were prescribed.
- 92.9% of medicines are adequately labeled.
- Only 52.9% of patients know the correct dosing of all dispensed medications.

D. Pharmacovigilance

- The responsibility of routine monitoring of adverse drug reactions (ADRs) belongs to the FDA.

- Republic Act 9711 (Food and Drug Administration Act of 2009) requires all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers to report to the FDA any incident that indicates the product has caused or contributed to the death, serious illness or injury to a consumer or patient.
- There is a functioning Adverse Drug Reaction Monitoring Unit under FDA.
- The National Adverse Drug Reaction Advisory Committee (NADRAC) has the responsibility to conduct nationwide post-marketing surveillance of ADRs.
- As of 2008, there are 1,358 reports of adverse drug reactions being kept in the registry of FDA.
- Monitoring of adverse drug reactions involves as well reports on alleged side effects of food/herbal supplements which are being advertised with label “no therapeutic claims”