



Essential Drug Price Monitoring System

“Drugs and medicine price transparency for informed and better choices.”

The Essential Drug Price Monitoring System or EDPMS is one of the basic tools for collecting data that can be used for measuring performance, appropriateness and effectiveness of the policy options and interventions in making drugs and medicines available and affordable. Generics Act of 1988 (RA 6675) and Price Act of 1992 (RA 7581) called for the implementation of a price monitoring system especially for essential drugs or the so-called “basic necessities” to ensure adequate supply of drugs with generics names at the lowest possible cost.

RA 9502 otherwise known as the “Universally Accessible Cheaper and Quality Medicines Act of 2008” and its implementing rules and regulations further emphasized the need for EDPMS (Chapter V, Rule 26). Under the transitory provision, every manufacturer, importer, trader, distributor, wholesaler and retailer are required to submit the minimum prices and inventory of all drugs and medicines it manufactures, imports, trades, distributes, wholesales or retails and all other data that may be required by the Secretary of Health. Enforcement of this policy is expected to start this year, every 31st of December.

Evidence-based policy making and implementation of interventions to ensure access to medicines necessitates use, availability and access to drug price and availability data. It is therefore a need that an information monitoring system for price, availability data and its accessibility be in place. Data transparency, which is an important feature of the system, obtains price information and allows for comparison of prices for more informed choices and better knowledge on how prices are obtained. Accessibility and use to posted price information leads to better choices, more efficient outcomes and access to low-priced quality medicines.

Why do we need to monitor the price of medicine?

The free market by definition does not control medicine prices, necessitating price monitoring and control mechanisms. We need to know what policy options can be adopted to improve affordability and availability of medicines. We need to monitor progress of the implementation of the law and the relevant issuances and impact of identified policy and regulatory decisions. We need to know which drug and medicine prices leads to poor medicine access and all these can be responded by a well-functioning, equipped and supported EDPMS.

Consumer Protection

Primary to the objectives of EDPMS is to protect consumers from excessively unjustifiable high priced medicines. Free market economics does not work acceptably well in containing the cost of medicines. There is information asymmetry or information regarding medicine pricing and cost is only known to some sectors within the pharmaceutical markets. Another related example concerns medicines unduly sustained under the protection of patent laws where production, use and selling by another party is legally prohibited. Without government intervention, these drugs can extremely be unaffordable to the people and the poor and for government-funded health systems.

With information transparency, consumers are able to exercise their right to choose and can rightly decide from a variety of options and select what they need according to their ability to pay. Consumers are also able to know the acceptable price data through the reference price index of drugs.

Regulation

Implementing the policies under the law shall require a price monitoring and regulatory system to track the implementation of the law and improve achievement of health goals particularly on access to medicines by the poor. Over time there is a need to measure the impact of these policies and interventions for medicine access. Regular monitoring of prices is needed to assess impact of pricing policies and in deciding for subsequent actions to take. Government needs price data to decide when it can impose price regulation or control and in monitoring adherence to price regulations.

There is also the need for data to gauge whether there are a significant number of players at each level of the pharmaceutical supply chain that shall ensure availability and affordability of drugs and medicines to ensure a healthy competitive environment. When full competition on the supply and demand of quality and affordable medicines is not successful and effective, government then can impose price regulation as an alternative. The determination of the Maximum Retail Price of a drug and implementation of a fair price or cost containment measures or even imposing sanctions to erring suppliers or entities, also require accurate price data.

Procurement Efficiency

The availability of price data objectively allows procuring entities to estimate their approved budget of contract for various drugs and medicines. Making prices transparent also fosters competition among various suppliers and providing the procuring entities a wider selection of offers and evidenced-based procurement decisions. It also allows comparison of purchase prices among public procuring entities, thus reducing overpricing and ensuring the procurement process is efficient, transparent and with integrity.

Methodologies for Obtaining Price Data

There are two main methodologies being used for collecting price and availability data and these are: formal survey and regular monitoring. The latter comprises a price reporting system and a price trend monitoring system.

A standard medicine prices and availability survey methodology was developed by the World Health Organization (WHO) and the Health Action International (HAI) and is being used to conduct national medicine price and availability survey globally. This standard methodology permits collection and analysis of prices of essential medicines, affordability, availability and component costs in various sectors and regions in a country. The survey collects data for thirty (30) essential medicines from 20 public and 20 private pharmacies for originator brand and lowest priced generic equivalent.

In 2002, the instrument was pilot tested in the Philippines in four cities (Manila, Baguio, Legazpi and Iloilo), 77 facilities for private for-profit sector survey and 25 outlets for public sector survey. In 2005, using the standardized survey methodology, prices and/or availability data were collected for public sector procurement prices and for public and private sector patient prices in the cities of Baguio, Manila, Cebu and Cagayan de Oro. Using the tool provides data to measure availability in terms of public procurements and actual inventories in the outlets for selected core and supplementary medicines for both innovator brands and generic medicines. A comparison of availability between the sectors was also done as well as comparison with the International Reference Price (IRP). Also, analysis on affordability was done based on a standard treatment requirement for a disease and the monthly salary of the lowest paid government worker for innovator brands and equivalent generic medicines. The survey also looked into the component cost. Among others, the survey in 2005 recommended the consolidation of the survey results and for the National Drug Policy to initiate the conduct of a regular price monitoring survey.

In 2004, a medicine price monitoring methodology for routine data collection was also proposed by WHO/HAI and was pilot tested in Kenya, Malaysia and Pakistan. To date, there is still no agreed methodology on regular price monitoring for medicine prices and availability (WHO, 2008). With the dearth of data on how much people and government pay for their medicines and the inaccessibility of the industry and market research data from the private sector and the lack of

patient price data, it is recommended that each country set-up their own price monitoring system. The main features of the proposed methodology include:

- Establishment of routine price monitoring coordination unit with at least a manager, encoder and an analyst
- Selection of a target sample size of eighty (80) facilities, that is, 40 public and 40 private medicine outlets to serve as sentinel monitoring sites
- Monitoring a total of 30 medicines; 10 medicines per month on a three month rotation providing a minimum of four price data points for each medicine per year
- Selection of medicines for monitoring from the core list
- Collection of data is only from the lowest-priced product
- Monthly data collection using a simple, sustainable method e.g., e-mail, fax, phone, mail with no data collectors and area supervisors
- Comparison of medicine price variations to basic commodities such as eggs, sugar
- Analysis of availability and affordability of pre-selected standard treatments for the lowest-paid unskilled government worker
- Data entry in Excel Spreadsheets
- Brief standard monthly reports showing median unit prices, ranges and variation over the last three months, affordability and availability
- Annual reporting showing information for each sector and median unit prices and percent changes from zero to twelve months
- Annual review of medicine selection and rotation of sentinel sites

The pilot studies concluded the need for customization of the proposed methodology in each country (WHO, 2008). The selection of medicine should reflect common diseases, prescribing and treatment patterns. The selection of facilities were likewise modified in Malaysia and Pakistan which opted to monitor availability and affordability in secondary and tertiary health-care level facilities since medicines are used in these facilities. Kenya on the other hand also monitored prices in lower-level facilities since its objective for monitoring includes determination of availability of medicines at all levels. Active data collection method was also adopted by the three countries in contrast to the recommended passive voluntary reporting.

For Pakistan, baseline and quarterly data were collected by trained personnel from each district for private and public health facilities and procurement prices from government facilities every 6 months. In Kenya data collection were undertaken by two trained public sector pharmacists for each province every three months using standard data collection

forms for all the medicine that are identified to be the lowest-priced product. In Malaysia, the hospital pharmacists and pharmacy inspectors assigned in each state collected data from both public and private sector every three months for commonly used prescription and non-prescription medication (List A) in both public and private sector and every six months for patented medicines recently registered (List B) in private sector and procurement prices medicines for speciality medicines (List C).

Experience in Collecting Drugs and Medicines Price Data

Even before the enactment of the Universally Accessible Cheaper and Quality Medicines Act of 2008, the Bureau of Food and Drugs through the Licensing and Regulatory Officers nationwide have been collecting price data from pharmacies in their areas of responsibility. A limited analyses were done and were irregularly published by the National Drug Policy Program. The latest analysis and publication was conducted in 2007 for data collected in 2004 and 2005 and is posted in the DOH portal (<http://www.doh.gov.ph>).

Department Order No. 238-T s. 2000 authorized all Philippine National Drug Policy Compliance Officers and Food and Drugs Regulations Officer at the BFAD and regional field offices to monitor prices of thirty seven (37) essential drugs on a monthly basis in accordance with the Price Act of 1992. This is to help lower drug prices by providing consumers with the information on the most affordable drugs and medicines and from which drug outlets. The order provided a schedule of data collection, submission of accomplished survey forms, accomplishment of regional and national reports, and dissemination of analysis.

The order was amended by Department Order No.285-H in 2002 with the difficulties in complying with the order. This consequently contributed to the intermittent reporting of the Department of Health of drug price data to the National Price Coordinating Council. The sampling and the frequency of the data collection was revised and was limited to only three (3) outlets per region composed of the leading private store chain in terms of sales, and the pharmacy of a public and private hospital located in the capital city or province with the highest number of bed capacity for the monthly data collection. For the rest of the drug outlets, the collection is twice a year on January and June. In 2003, an electronic EDPMS was developed and the National Drug Policy Program collected the results of the monthly and the semi-annual surveys through a diskette or thru e-mail.

A month after submission, a Price Bulletin is issued to all CHD's and later posted on the DOH website. The use of this policy for mitigating increasing drug prices was never evaluated. Moreover, compliance to the various orders to submit the pricing data was a problem, submission of reports were irregular and some did not comply at all (Memorandum No.36, 67, 138 s 2004).

Analysis was limited to the presentation on a quarterly basis of the most frequently occurring or observed prevailing price

by month and a presentation of the highest and lowest price including information on which outlets and region has the lowest price, aggregately or by generic or brand name. The limitations of the analysis were aggravated by the incompleteness of the data being submitted from the regional offices.

With the failures and lessons in implementing the EDPMS, Administrative Order 2006-0009 was issued providing guidelines on the institutionalization and strengthening of the Essential Drug Price Monitoring System with the main intent of implementing the Price Act. The Price Act requires the identification of essential drugs considered as "basic necessities" and monitoring and analysis of their prices. It stressed the necessity to sustain the operations of the system and to respond to emerging issues of drug pricing information and its uses. Coordination issues among major stakeholders and unifying efforts including providing data analysis skills and dissemination were noted.

Chapter V, Rule 26 of the "Universally Accessible Cheaper and Quality Medicines Act of 2008" and its IRR further emphasized the need for EDPMS, thus the need to expand and modify the previously conceptualized system. To wit, 'to implement the policies of this Act, the Secretary of Health shall establish and initiate an electronic price monitoring and regulation system for drugs and medicines.'

Price Monitoring Functions

Stipulated in the law is the creation of an institutional office with functions on policy development and system implementation. In the mean time, the National Drug Policy Program and the Pharmaceutical Management Unit (PMU50)'s manpower complement undertakes most of the jobs with technical support from the various offices and committees, but not limited to the Bureau of Food and Drugs, Information Management Service, National Center for Health Facilities Development, Centers for Health Development, Bureau of Health Facilities and Services, Health Policy Development and Planning Bureau, Bureau of Local Health Development, and the Philippine Health Insurance Corporation. The law authorizes the Secretary of Health to deputize the functions at various levels.

DTI (Rule 64) and LGUs (Rule 65) shall also monitor prices on a quarterly basis, the list of which shall be decided upon by both Secretaries. Likewise, DTI and DOH shall conduct independent periodic studies and surveys of the selling prices to determine the effect on family income of various groups.

The Electronic-EDPMS

The current E-EDPMS is a computer-based solution with the functionalities to capture, process, store, and generate reports on essential drug prices and inventories from pharmaceutical companies. E-EDPMS will be able to monitor and track where a drug originates and the chain of custody from the manufacturer to the dispensing pharmacy or drug outlets. The system has five (5) functional components, namely:

1. Stand-Alone Sales and Stock Inventory System (SSIS) for use of establishments and outlets without existing computer-based systems.
2. Web-based Data Upload System for establishments and outlets to electronically send the required DOH price and inventory data to the central data repository or warehouse. For establishments and outlets with computer-based systems, standard data sets or data dictionary is available to facilitate data conversion and electronic data uploading.
3. Web-based Data Download System facilitates retrieval of updated list of standard references, computer programs and software patch for updating the system at the data source workstation.
4. Data Consolidation and Report Generation for processing the data and providing reports required by the DOH.
5. Web-based Consumer Price Monitoring System for consumers to voluntarily report prices of drugs purchased.

Data Sources

Source of data will directly come from the reporting establishments or outlets through the Web-based Data Upload System.

There are no other layers or hierarchies of reporting. These drug establishments or outlets are as follows:

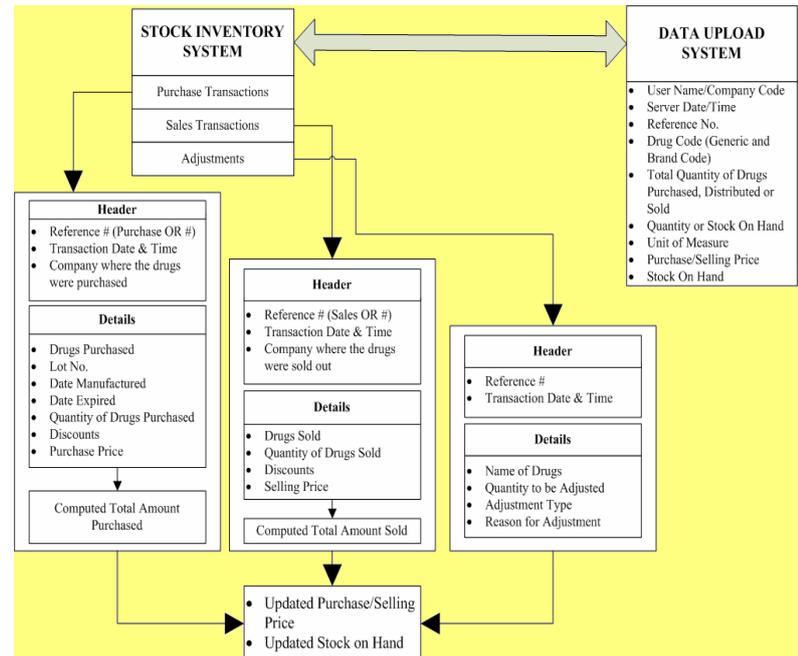
- Organizations or companies involved in the manufacture, importation, repacking and/or distribution of drugs and medicines
- Drugstores, pharmacies and other establishments which sells drugs or medicines
- Government procuring entities

Data Collected

Purchase and sales transactions data, and resulting inventories are the data collected from different sources. These are procurement or purchase prices, selling prices at the manufacturer, distributor or retail outlets, and data from

patient or customer on a voluntary basis. Details and process flow of data sets are shown in Figure 1.

Figure 1. EDPMS Data Elements



Data Collection and Submission

Drug establishments and outlets are required to upload data on a daily basis. If the Stand-Alone Sales and Stock Inventory System are used, it has the facility to retrieve or extract purchase and sales transaction data, as well as compute stock inventories based on the transactions. The extracted data conforms to the DOH standard format and can be readily uploaded via the Web-Based Uploading System of the E-EDPMS.

Pilot Testing and Implementation

Ten (10) data sources are included in the pilot testing and implementation of E-EDPMS. These are as follows:

- | | |
|---------------------------------------|--------------------------|
| 1. Hizon Laboratories | - Drug Manufacturer |
| 2. Watson Drug Store | - Major Chain Drug Store |
| 3. Mercury Drug Store | - Major Chain Drug Store |
| 4. Manila Doctors Hospital | - Private Hospital |
| 5. University of Sto. Tomas | - Private Hospital |
| 6. Quirino Memorial Medical Center | - Government Hospital |
| 7. San Lazaro Hospital | - Government Hospital |
| 8. Tondo Medical Center | - Government Hospital |
| 9. Jose Reyes Memorial Medical Center | - Government Hospital |
| 10. Valenzuela General Hospital | - Government Hospital |

Product Selection

Thirty (30) essential drug prices and inventories from drug establishments and drug outlets were selected for monitoring for the current E-EDPMS. However, the design of the system is comprehensive and flexible enough to accommodate other drugs in the future.

There are about 600 essential drugs coded, i.e. without brand names. A total of 8,000 registered essential drugs (with and without brand names) are now in the DOH Central Reference Library. The pilot test and implementation will target to upload data for about 8,000 generic drugs and originator brands based on RA 9502, public health importance, consumption patterns, sales value, and inclusion in the essential drug list, among others. RA 9502 lists drugs and medicines subject to price regulation when trading flexibilities fail, thus, must be included in the system. These drugs and medicines are:

- those in the current Philippine National Drug Formulary Essential Drug List
- for treatment of chronic illnesses and life threatening conditions such as, but not limited to, endocrine, gastrointestinal, pulmonary, cardiovascular, pulmonary auto immune, skin, neuron-psychiatric disease or disorders, other infectious diseases or disorders and other infectious diseases and conditions such as organ transplants and neoplasm
- for the prevention of diseases. e.g., vaccines, immunoglobulin, antisera
- those indicated for the prevention of pregnancy
- anesthetic agents
- intravenous fluids
- and other drugs and medicines which from time to time, the Secretary of Health, in accordance with relevant provisions of the IRR determine to be in need of price regulation

Analysis of Prices and Availability

Sample reports have been identified but are limited to presentation of drugs inventories and prevailing prices by type using summary statistics. Given the data elements to be collected, the following can be done among others in some cases with other data from other sources:

- Price monitoring unit prices presented in basic summary statistical measures such as median, minimum, maximum, or percentiles
- Price trend monitoring and analysis to show changes over time (e.g., by total purchases, drug classification or type)
- Price indices
- Retail price comparison of essential drugs compared to international reference prices (IRP) at least for WHO/HAI core list or other international bulk prices such as those found in other international database such as the International Drug Price Indicator Guide (IDPIG) or WHO Drug Price Monitor

- Determination whether retail price are high or low in relation to standard retail prices with in a sector, locality, or region. The comparison may show how many times above the cost of original purchase and the price at which these medicines are sold in other outlets.
- Originator brand and generic price comparison by source or sector such as comparison of public outlet prices and private pharmacies of generics and originator brands
- Total purchase by drug groups
- Government procurement price compared to IRP or by procuring entity or procurement method or differentials among government purchase prices by level
- Measure affordability such as comparison of a standard treatment using low priced generics and/or originator brands with minimum wage or salary of the lowest paid unskilled government worker; or looking at the cost of treatment and determining its equivalence to the daily wage or determining one month supply for example for preventing hypertension and its equivalence to the minimum wage
- Availability of medicines by major location and sector, whether in the private or government sector or somewhere else
- Analysis that will support price control or calculation of the maximum retail price considering current retail price, supply availability in the market and analysis with data from other sources depicting cost of manufacturer, importer, trader distributor, wholesaler or retailer such as changes in exchange rate, amortization cost, labor, transport or distribution
- Analysis that will support increases in prices due to changing inflation rate, exchange rate and raw material
- Determination ratios for manufacturers list-prices of most widely-used drugs
- Analysis to better understand effect of competition on drug pricing, relationship of price ratios and the number of manufacturers, or analysis whether competition alone guarantee affordable pricing and when to invoke other options such as MRP and massive public-procurement and distribution systems.

POLICY AND OPERATIONAL IMPLICATIONS

Management

Price monitoring is a gigantic task and will require the organization of a Medicine Price Monitoring Body. The law requires the creation of institutional body to undertake this function and the sooner this is established the better.

Forming advisory and technical committees composed of members with expertise in medicine selection and analysis of utilization, pricing, drugs procurement and distribution, pharmacoeconomics, pharmaceutical policy development, advocacy and monitoring and evaluation, and statistics must be organized now to provide technical assistance in the development of the system, data analysis and interpretation, and dissemination of results.

Since DTI and the LGUS are also mandated to conduct price monitoring, clarification is needed on the scope and extent of their monitoring tasks specially in the integration or harmonization and coordination mechanisms relative to data collection and validation, and reporting.

With the very ambitious collection of price data from various sources for so many products, the system will need a central data warehouse with capacity for data management.

The implementation of EDPMS will require close coordination among the DOH PMU50, Bureau of Food and Drugs (BFAD), and Information Management Service (IMS) at least at the onset. At this stage, establishment of the standard data elements, definitions, coding schemes to be used by the EDPMS and the updating and/or amendments must be undertaken.

The existing issuance for managing the system should be updated to define responsibilities of involved agencies for better coordination and engagement. Sustained human, technical and financial resources over time based on the expertise required, methodology and technology solution should be adopted. Support from various groups especially from consumers groups and even politicians, advocates, academics and health workers for affordable and available drugs and medicines will help ensure acceptability and sustainability of the system.

Process

a) Product selection

The IRR identifies the universe of drugs and medicines for price regulation. The pilot testing identified about 8,000 products to be reported from the ten (10) initial data sources. This number should be tied up with the monitoring system objectives and plan of analysis which should already be formulated.

b) Data Collection

Collecting data from a very huge pharmaceutical industry (Table 1) is a challenge in terms of management and compliance. Unless, reporting becomes part of the regulatory system or an incentive system is put in place, collecting data from the pharmaceutical industry numbering about 28,000 (BFAD,2006 data) is difficult. If reporting becomes erratic, the minimum number to make a certain data set representative is not gathered, this might present problems in analysis and drawing conclusions.

Table 1. Pharmaceutical Industry, 2006
(BFAD data)

Drug manufacturer	246
Drug Trader	391
Drug Distributors	3,450
Retail outlets	23,901
Botika ng Barangay	2,338
Botika ng Bayan	1,135
Chinese	210
Drug store	18,450
Pharmacy in Government Hospital	649
Pharmacy in Private Hospital	1,064
Other retail outlets	248

Government procurements also will be included specially from the DOH procuring entities. Collection of data from the transactions of the various field offices and hospitals in the previous years is not at all encouraging even with directives and reminders from the Executive Committee. Even the Phil. Government Electronic Procurement System (PHILGEPS) laments the non-posting procurement awards by most DOH procuring entities as required by the government procurement law. At this point, it is crucial that DOH offices appreciate the need to monitor the prices of medicines and be advocates for the need of regular reporting for better policy options and regulation.

Other sources of procurement data are the Philippine Pharmaceutical Trading Corporation and the local government units and PHILGEPS. Coordination with these agencies should be done soonest.

The system also includes voluntary consumer reporting of treatment provided and the cost of purchase of treatment. Since the reporting is voluntary and not all have access to the internet, uploaded data may not be representative enough to permit an accurate analysis. Other mechanism of collecting consumer data should be studied and easier mechanisms must be put in place such as drop boxes, etc.

c) Data objectivity and utility

Regular review of the utility or usefulness of the information collected for intended users, including the public must be undertaken. If necessary indicators collected and even methodologies must be regularly reviewed and must be modified accordingly based on monitoring system objectives.

Information for dissemination must be accurate, reliable, and unbiased and that information is presented in an accurate, clear, complete, and impartial manner.

d) Data quality assurance and integrity

Guidelines for appropriate data verification and validation have to be discussed, identified and implemented. It must be clear who undertakes the validation and how this should be done. Design of the quality assurance must include data checking for data accuracy and validity.

The introduction of standard structures and codes in the data management is needed and adhered to and would require regular and timely updating by the BFAD. The standards are needed for data transformation and aggregation.

Ensuring information integrity should be part of the design and implementation of security architecture which among others include access controls and policy on data sources identification during data analysis and reporting. Regular audit and review must be undertaken for implementation of appropriate security controls.

The reports to be disseminated using collected data from a range of sources and perspectives must be validated to the extent practicable. A clearance system or a review process involving experts or advisory panels that can offer constructive inputs must be established before public dissemination.

e) Use of Standards and References

Critical to the operation of EDPMS is the maintenance and/or updating and posting of the standard data references to be used. The standard data references to be used are:

- a. Drugs with Approved Registration Numbers;
- b. Licensed Pharmaceutical Companies; and
- c. Drugs and medicines by Generic Names, by Route of Administration, by Form, by Strength and by Unit of Measurement.

These references will help ensure quality of data in terms of accuracy, completeness, and timeliness.

The reporting units need to adopt the standard data elements, definitions and coding system. Most critical is the standard drug coding scheme which is part of the National Health Data Dictionary. Initial agreement on the adoption was already informally forged among BFAD, PMU50, IMS, PHIC, and PPTC, but need support from various sectors. The unique code is the BFAD Certificate of Product Registration (CPR). Other data sets included in the master reference of drugs are as follows:

Figure 2. Master Reference of Drugs

Description	Type of Character (Size)
Generic Code Based on BFAD's Standard Reference Code	Char (5)
Strength Code Based on BFAD's Standard Reference Code	Char (5)
Form Code Based on BFAD's Standard Reference Code	Char (5)
Route Code Based on BFAD's Standard Reference Code	Char (5)
License to Operate Number Based on BFAD's Standard Reference Code	Char (10)
Brand Code Based on BFAD's Standard Reference Code	Char (5)

The BFAD shall be responsible for regularly updating, and disseminating the data element for each drug and pharmaceutical establishment in a prescribed format, sequence, and structure.

f) Plan for Data analysis and information dissemination

Collecting data is an initial step since data by itself will not bring down medicine prices. These data need to be analyzed and translated into information and knowledge and made accessible to governments, health professionals, civil society, consumers and other stakeholders.

A plan for data analysis will have to be developed and documented including identification of other data that will be needed based on the identified indicators to monitor progress in implementing of the law. When the monitoring indicators have been identified and agreed upon, other data sources and/or data collection system which are not covered by EDPMS will have to be developed.

The plan for publishing and information dissemination should indicate what level of detail should be reported, target audience, presentation format and media for dissemination. The frequency and timing of release of reports by type and dissemination mechanism should be decided upon.

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