



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

AUG 19 2014

DEPARTMENT ORDER

No. 2014 - 0146

SUBJECT: Implementing Guidelines on the Philippine Drug Price Reference Index (DPRI)

I. BACKGROUND AND RATIONALE

Access to medicines remains a serious challenge in the Philippines. Medicines constitute a major share in the out-of-pocket health expenditures of many Filipinos (i.e. at least 50%). While the Generics Act (Republic Act 6675) requires the promotion of generic medicines, the more expensive branded or innovator products still dominate the Philippine market, thus imposing substantial financial barriers in accessing health services. The Philippines is considered to have one of the highest drug prices when compared to other countries of similar income status and even Western markets.

The enactment of the *Universally Accessible and Affordable Quality Medicines Act of 2008 (Republic Act 9502)* has created a momentum to improve access to medicines in the Philippines.

The law provides the government the mandate to institute a fair, transparent and rational drug pricing system in the country, where the cost of drugs consider the 'public interest' nature of access to essential medicines. It likewise ensures that transparency is guaranteed in the determination of medicine prices and mark-ups to give consumers informed choice and to help government in reducing cost of its procurement of essential medicines. The same mandate is articulated in the Philippine Medicines Policy (PMP), which proposes measures to ensure access to affordable medicines.

Early initiatives of the Philippine government to develop a transparent system of monitoring drug prices include the reference price scheme of the Philippine Health Insurance Corporation (PHIC) in the year 2000, whereby a survey of retail prices from public and private drug outlets was conducted across 16 regions of the Philippines. The average of prices for the 100 most commonly utilized drugs was then used by PHIC as the reference price for reimbursements.

In 2008, the DOH implemented the Electronic Drug Price Monitoring System (EDPMS) to facilitate the timely monitoring of drug prices in public and private pharmacies and guide the national pricing policy for medicines. However, there are limitations in the price data provided by the EDPMS because of the historical low compliance of drug establishments to the uploading requirements and the restriction of

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information to final prices to patient, thus missing important details on mark-ups applied to medicines at each level of the supply chain.

To improve the transparency of drug pricing in the Philippines, the DOH is hereby creating a Drug Price Reference Index (DPRI) that is meant to reduce the current wide and extreme variations in the procurement prices of medicines in the public sector. The objective of the DPRI is to serve as a mandated price ceiling to ensure the fair and efficient acquisition of quality drugs from cGMP suppliers across the government. The DPRI is envisioned to improve the efficiency of procurement, stretch the health care budget by generating savings and prevent corruption in the sourcing of essential medicines across the national and local governments.

II. OBJECTIVES

To set national guidelines for creating the Philippine Drug Price Reference Index (DPRI) that will improve the efficiency of procurement and sourcing of medicines in DOH facilities (DOH Central Office, DOH Attached Agencies, DOH Hospitals and Regional Health Offices).

Its specific objectives include:

1. To establish systems and methods for creating and maintaining a database of reference prices for essential medicines from DOH Hospitals;
2. To create a formula for setting reference prices of medicines in the Philippine National Formulary;
3. To set the DPRI as the mandated ceiling price for DOH facilities; and
4. To provide guidelines for the enforcement, implementation and monitoring of the DPRI system across DOH facilities nationwide.

III. SCOPE AND COVERAGE

This Order is issued to provide technical guidelines for DOH Central Office, DOH Attached Agencies, Regional Health Office (RHO) and DOH Hospitals, in implementing the DPRI as the unified pricing system for the procurement of medicines in the public sector.

IV. DEFINITION OF TERMS

1. Access - refers to the ability to utilize health services and its logistics support without barriers or obstacles.
2. Affordability - cost of treatment in relation to peoples' income. In the WHO/HAI survey, this is defined by the number of days the lowest paid unskilled government worker would have to work in order to afford the cost of the complete course of treatment.



3. Anatomic Therapeutic Classification (ATC) system - divides the drugs into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into 14 main groups (first level), with two therapeutic/pharmacological subgroups (second and third levels). The fourth level is a therapeutic/pharmacological/chemical subgroup and the fifth level is the chemical substance. The second, third and fourth levels are often used to identify pharmacological subgroups when these are considered to be more appropriate than therapeutic or chemical subgroups.
4. Bioavailability - refers to the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.
5. Bioequivalence - refers to the rate and extent of absorption to which the drugs do not show a significant difference from the rate and extent of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. Bioequivalence shall also refer to the absence of a significant difference on the rate and extent-to-which the active ingredient(s) of the sample and reference drug becomes available at the site of drug action when administered under the same molar dose and under similar conditions.
6. Approved Budget for the Contract (ABC) - refers to the budget for the contract duly approved by the head of procuring entity.
7. Current Good Manufacturing Practice (cGMP) - refers to the current system of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate for intended use. It is thus concerned with both manufacturing and quality control processes and procedures.
8. Drug Price Reference Index (DPRI) - refers to the mandated ceiling price of essential medicines for government bidding and procurement set by the DOH for all DOH facilities in order to have a transparent and unified pricing scheme in medicines procurement. Winning bid prices of essential medicines shall therefore not exceed the DPRI.
9. Essential Medicines - refers to those medicines that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on safety and efficacy, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
10. External Reference Pricing - the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
11. Generic drugs - refer to drugs that have the same active pharmaceutical ingredient as the innovator drugs and are not covered by patent protection. These drugs are labeled by their international nonproprietary or generic name and may or may not have brand name.
12. Interchangeable Pharmaceutical Product - an interchangeable pharmaceutical product is one which is therapeutically equivalent to a comparator product and can be interchanged in clinical practice (WHO Technical Report Series 937, 2006).
13. Internal Reference Pricing - refers to the practice of using the price(s) of identical medicines (ATC 5 level) or similar products (ATC 4 level) or even with therapeutically

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equivalent treatment (not necessarily a medicine) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.

14. Mark ups - refers to the amount added to a cost price in calculating a selling price, especially an amount that takes into account overhead and profit.
15. Philippine National Formulary - refers to a list of drugs prepared and periodically updated by the DOH on the basis of health conditions obtaining in the Philippines as well as on internationally-accepted criteria. It shall consist of a core list and a complementary list.
16. Procurement - refers to the acquisition of Goods, Consulting Services, and the contracting of Infrastructure Projects by the Procuring Entity. Procurement shall also include the lease of goods, and real estate.
17. Procuring entities - refers to any branch, department, office, agency, or instrumentality of the government, including state universities and colleges, government owned and/or controlled corporations, government financial institutions, and local government units procuring goods, consulting services, and infrastructure projects.

V. IMPLEMENTING GUIDELINES

The implementation of the DPRI is in accordance with RA 9502 or the Universally Accessible and Affordable Quality Medicines Act of 2008 and the Philippine Medicines Policy.

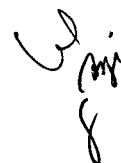
A. GENERAL GUIDELINES

1. The Drug Price Reference Index (DPRI) shall be calculated every year based on prevailing procurement prices of medicines in government health facilities with data collected by the DOH-NCPAM from Regional Health Office (RHO), DOH Retained Hospitals, Central Office Bids and Awards Committee (COBAC) and the PITC Pharma, Inc. (PPI).
2. For innovator products and drugs with limited competition (i.e. less than three local suppliers), the DOH may derive the DPRI from the lowest bid price or through external reference pricing with countries of similar income status (i.e. Thailand and India).
3. The DPRI shall include all medicines listed in the Philippine National Formulary.
4. The DPRI shall be implemented in all DOH facilities as the ceiling price for medicine procurement.
5. The DPRI shall be reviewed and updated annually and shall be made public by the DOH through web-based posting, publication in newspaper of general circulation and distribution of price booklets to all government health facilities.

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B. SPECIFIC GUIDELINES

1. All RHOs, DOH Retained Hospitals, COBAC and PPI must submit a copy of their Annual Purchase Orders (PO) to NCPAM. The PO shall include: active pharmaceutical ingredient, strength, dosage form, quantity procured, acquisition cost per unit, total cost, mode of procurement, supplier and manufacturer (with current Good Manufacturing Practice Certificate both Local and International issued by FDA).
2. All PO from the previous year should be submitted to the NCPAM on or before the end of first quarter of the succeeding year.
3. The NCPAM shall consolidate, process, analyze and synthesize the price data coming from DOH facilities and generate a price report to be disseminated every third quarter of the year through an official website and medicines price booklet.
4. The DPRI shall be calculated from the winning bid prices of essential medicines sourced from reputable cGMP suppliers as certified by the Philippine FDA.
5. The DPRI shall reflect the final acquisition cost to government health facilities which should include the landed cost, packaging, drug content, quality assurance, manufacturing overheads and FDA fees. The DPRI excludes other costs such as pharmacy services, preparation and storage fees and applicable taxes to medicines (i.e VAT) and other reasonable pharmacy mark-ups to be determined by the DOH.
6. In case of failed biddings, provisions of RA 9184 and its IRR shall be applied.
7. In general, for essential drugs with sufficient competition (i.e. drugs with three or more suppliers), the DPRI shall be set at the median of the range of prices collected from the previous year for every drug preparation and formulation (see Annex A for sample computation).
8. Where there is limited (i.e. drugs with less than three suppliers) participation in government tenders for particular medicines because of few generic suppliers, existing market exclusivity for patented medicines or a non-responsive bid in the previous year, the government shall develop a pooled sourcing mechanism and a system of price-volume negotiation with suppliers guided by external reference pricing and economic evaluations conducted in the Philippines to determine the best value for money for such products. The DOH may also set the DPRI at the lowest winning bid price achieved for this product for the previous year plus an allowable margin to consider inflationary cost.
9. In situations where there is difficulty in achieving the mandated price ceiling, the DOH and PPI shall develop an alternative procurement mechanism accessible to all national and local government procuring agencies.
10. The DOH-NCPAM shall monitor and assess the compliance of DOH facilities to the mandated price ceiling for the procurement of essential medicines.
11. PHIC shall consider the DPRI when reviewing the rates or costing its new benefits.
12. All Cluster Heads through the directors of RHOs, and medical directors of DOH retained hospitals shall disseminate this Order to have a proper channeling in the regions.



VI. ROLES AND RESPONSIBILITIES

The following roles and responsibilities of all parties concerned shall be observed for the purpose of the implementation of the system:

A. DOH-NCPAM

1. Set policies, procedures and guidelines relative to DPRI which will serve as a tool in setting a standard pricing scheme that shall be used in all DOH facilities in procuring medicines;
2. Oversee and manage the overall implementation of the DPRI;
3. Develop tools to monitor the adherence of all DOH facilities covered by this Order;
4. Provide technical assistance to the RHOs and DOH hospitals on the implementation of the program;
5. Address issues and concerns encountered in the implementation of the program to guide its improvement;
6. Conduct a regular assessment of the program together with all the stakeholders in public health facilities, other government agencies, health providers, patients and the industry; and
7. Monitor the compliance of DOH facilities to the set guidelines for the DPRI and impose appropriate sanctions for overpricing when necessary.

B. PHIC

1. Ensure the adoption of DPRI as reference in the costing of health services that will be paid by PHIC.

C. FDA

1. Set the minimum standards of safety, efficacy and quality as a basis for qualification of the suppliers in all government sourcing and procurement of medicines; and
2. Provide an updated list of cGMP certified suppliers and manufacturers (local and international) through their official website.

D. PPI

1. Adhere with the prescribed DPRI of the DOH when conducting its procurement activities;
2. Serve as the procuring arm of the DOH and other government agencies as mandated by law and ensure the selection and identification of legitimate suppliers which may provide quality pharmaceutical products and services advantageous to the government; and

E. DOH Hospitals and Regional Health Offices

1. Adhere to the price reference set by the DOH;
2. Regularly submit the updated procurement price data to the DOH-NCPAM through actual Purchase Orders and standard forms prescribed by the DOH; and
3. Ensure the fair and efficient pricing of essential medicines through good governance in procurement using PPI or other mechanisms as allowed by RA 9184.

VII. ENFORCEMENT AND SANCTIONS


Non-compliance to any provisions of this DO, shall be subject to administrative liability based on applicable provisions under RA 7581 or RA 9502.

VIII. SEPARABILITY CLAUSE

In the event that any provision or part of this Department Order is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

IX. EFFECTIVITY

This Order shall take effect immediately.


ENRIQUE T. ONA, MD
Secretary of Health

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ANNEX A

Sample Computation of the Drug Price Reference

1. For drugs with three (3) or more suppliers the reference price is set at the median of the range of prices collected for every drug preparation and formulation.

Paracetamol 500mg Tablet

| Name of Hospital | Lowest Procurement Price | Quantity | Brand Name | Manufacturer | Supplier |
|--|---------------------------------|-----------------|-------------------|---------------------|-------------------------|
| Jose Reyes Medical Center | 2.50 | 10,000 | Rapidol | Ad- Drugstel | Metro Drug, Inc. |
| Philippine Heart Center | 1.25 | 20,000 | Biogesic | JB Orchid Pharma | Unilab Inc. |
| Western Visayas Medical Center | 1.00 | 15,000 | Selegesic | Health Saver | Qualifirst Health, Inc. |
| Cagayan Valley Medical Center | 0.75 | 5,000 | Aspirin | Ad- Drugstel | Sel-J Pharma, Inc. |
| Northern Mindanao Medical Center | 0.50 | 22,000 | Biogesic | Flamingo Phil. Ltd. | Unilab Inc. |
| Drug Price Reference: Php 1.00 (median) | | | | | |

Note: The above table is an example and does **not** reflect the actual procurement data of the hospitals.

2. For drugs with less than three (3) suppliers the reference price is set at the lowest procured price.

Amoxicillin 500mg Capsule

| Name of Hospital | Lowest Procurement Price | Quantity | Brand Name | Manufacturer | Supplier |
|---|---------------------------------|-----------------|-------------------|------------------------------|-------------------------|
| National Children's Hospital | 5.00 | 13,000 | Amoxil | Harbin Pharmaceuticals | Phil Pharmawealth, Inc. |
| Quirino Memorial Medical Center | 4.00 | 20,000 | Globapen | JB Orchid Pharma | Endure Medical Inc. |
| Eastern Visayas Medical Center | 2.95 | 8,200 | Harbimox | Singapore Pharmawealth, Inc. | Phil Pharmawealth, Inc. |
| Davao Regional Hospital | 1.98 | 10,000 | Moks | GX Int'l., Inc. | Phil Pharmawealth, Inc. |
| Zamboanga City Medical Center | 1.05 | 20,000 | Harbimox | New Myrex Laboratories | Phil Pharmawealth, Inc. |
| Drug Price Reference : Php 1.05 (lowest) | | | | | |

Note: The above table is an example and does **not** reflect the actual procurement data of the hospitals.