Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 17 2015

ADMINISTRATIVE ORDER
No. 2015 - 0051

SUBJECT: Guidelines in the Implementation of the Philippine Drug Price Reference Index (DPRI) to All Public Hospitals and Health Facilities

I. BACKGROUND AND RATIONALE

The high and extremely variable prices of medicines in the Philippines impact on access to effective, efficient and equitable health care. In 2009, a study conducted by Health Action International revealed that there was extreme variability in the procurement prices of essential medicines in the national and local public health facilities in the country. On average, originator brands and generic equivalents were procured almost 16 times and 3 times higher, respectively, compared to prices available on the international market.

In addition, the common unavailability of essential medicines in public health facilities forces patients to obtain their medicine requirements at a higher cost from private outlets. Furthermore, the No Balance Billing (NBB) policy implemented by PhilHealth in 2011 has so far only been adopted by few public health facilities, further limiting access to medicines, especially for the indigent population in the Philippines.

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. Under Chapter 3, Section 19 C, the "Secretary of the Department of Health shall have the power to implement the fair price of drugs and medicines for purposes of public health insurance and government procurement based on the order of the President of the Philippines imposing maximum retail prices". The law provides the government the mandate to institute a fair and rational drug pricing system in the country, where the cost of drugs consider the 'public interest' nature of access to essential medicines.

The law 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.

Republic Act 6713, otherwise known as " Code of Conduct and Ethical Standards for Public Officials and Employees", Rule IV, Section 2 also states that, "it is the responsibility of heads of departments, offices and agencies to establish measures and standards that will ensure transparency of and openness in public transactions in their respective offices such as in

biddings, purchases, other financial transactions including contracts, status of projects and all other matters involving public interest".

The Philippine Department of Health (DOH) introduced the Drug Price Reference Index (DPRI) in 2014 through the Department Order (DO) No. 2014-0146, making it mandatory for all DOH hospitals and Regional Offices (ROs) to adhere to a price ceiling when procuring drugs listed in the Philippine National Formulary (PNF).

The DPRI aims to guide all public health facilities in the fair pricing of essential medicines and to increase efficiency of the drug procurement process in the public sector.

Among all the medicines procured by DOH hospitals, analysis showed that the top ten most commonly procured medicines costs the DOH around Sixty Seven million pesos. After using the Drug Price Reference, the DOH could potentially save as much as Fifty percent (50%) or around Thirty Two Million pesos.

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 not only across DOH hospitals but also across all public health facilities.

II. OBJECTIVES

A. GENERAL OBJECTIVE

To set national guideline for the implementation of the Philippine Drug Price Reference Index (DPRI) that will improve the efficiency of procurement and sourcing of medicines in all public health facilities nationwide and government agencies procuring medicines.

B. SPECIFIC OBJECTIVES:

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

III. SCOPE AND COVERAGE

This Order is issued to provide technical guidelines for all government agencies, government hospitals, hospitals managed by the DOH including specialty centers, government-owned and controlled hospital corporations, local government hospitals, and all other types of government 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 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-Pharmaceutical Division from Regional Offices

(ROs), DOH Retained Hospitals, Central Office Bids and Awards Committee (COBAC) and the PITC Pharma, Inc. (PPI).

2. The DPRI shall be the maximum procurement price of essential medicines across all government facilities and government agencies except in cases where the previous years' procurement is lower than the set DPRI of the DOH. In which case, the government health facility or agency should set the ABC at the level of the previous years' procurement with an allowable variation of plus 10% to account for the inflation.
3. For innovator products and drugs with limited competition (i.e. less than four (4) manufacturers), 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).
4. The DPRI shall include all medicines listed in the Philippine National Formulary.
5. The DPRI shall be implemented in all public health facilities as defined in the scope and coverage as the ceiling price for medicine procurement.
6. 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 or distribution of price booklets to all government health facilities.

B. SPECIFIC GUIDELINES

1. All ROs, DOH Retained Hospitals, COBAC and PPI must submit a copy of their Annual Purchase Orders (PO) to the DOH-Pharmaceutical Division. 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 DOH-Pharmaceutical Division on or before the end of first quarter of the succeeding year.
3. The DOH-Pharmaceutical Division 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 apply.
7. In general, for essential drugs with sufficient competition (i.e. drugs with four or more manufacturers), 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 participation in government tenders (i.e. drugs with three or less) for particular medicines because of few generic manufacturers, 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 such as importation as provided for by law accessible to all national and local government procuring agencies.
10. PHIC shall consider the DPRI when reviewing the rates or costing its new benefits.
11. DOH-Office for Health Operation through DOH-Pharmaceutical Division shall disseminate this Order to the directors of ROs, and medical directors of DOH retained hospitals to have a proper channeling in the regions.
12. In the event that there is undue increase in the price of a certain medicine (i.e more than 10% of the previous year's procurement price) the DOH-Pharmaceutical Division shall notify the facility to justify the sudden increase in prices.

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-Pharmaceutical Division

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 public health facilities procuring medicines;
2. Oversee and manage the overall implementation of the DPRI;
3. Develop tools to monitor the adherence of all public health facilities covered by this Order;
4. Provide technical assistance to the ROs 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 imposed appropriate sanctions for overpricing and/or illegal act of price manipulation when necessary and submit it to FDA.
8. Advise the Secretary of Health on appropriate pricing strategies on essential medicines that will ensure their affordability across the government.

B. Philippine Health Insurance Corporation (PHIC)

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

C. Food and Drug Administration (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.
3. Act on reports for sanctions and collect the charged imposed that have accrued as a consequence under the provision of Implementing Rules and Regulation of RA 9502.

D. PITC Pharma, Inc. (PPI)

1. Adhere with the prescribed DPRI of the DOH when conducting its procurement activities;
2. May serve as the procuring arm of the DOH and other government agencies as mandated by law and ensure the selection and identification of national and international legitimate suppliers which can provide quality pharmaceutical products and services advantageous to the government; and
3. Establish a system that will ensure fair pricing and the efficient supply and distribution of medicines through pooled procurement, parallel importation and other means of sourcing as accorded by RA 9502.

E. DOH Hospitals and Regional Offices

1. The Head of agency shall ensure the compliance and adherence to the price reference set by the DOH;
2. Regularly submit the updated procurement price data to the DOH-Pharmaceutical Division 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.

4. Report suspected illegal acts of price manipulation to the DOH through DOH-Pharmaceutical Division as specified in the law such as hoarding, profiteering and cartel.
5. The Regional Offices in coordination with the DOH-Pharmaceutical Division shall conduct annual monitoring of DOH hospitals in adherence to the DPRI. The post-monitoring reports shall be submitted by the ROs to the DOH-Pharmaceutical Division.

F. Local Government Units (LGUs) and Other Public Health Facilities

1. The Head of agency shall ensure the compliance and adherence to the price reference set by the DOH;
2. In cases of bid failures, the LGUs may opt to source out their medicine procurement at PITC Pharma, Inc.
3. Report to the DOH-Pharmaceutical Division suspected illegal acts of price manipulation as specified in the law such as hoarding, profiteering and cartel.

G. Commission on Audit

1. Monitor the compliance of all government health facilities and agencies when procuring medicines.
2. Enforce applicable sanctions subject to the usual auditing rules and regulations in the public sector.

H. Department of Interior and Local Government

1. Adopt the DPRI as the ceiling price for essential medicines procurement across all local government units.
2. Help the DOH to ensure compliance of the LGUs to the DPRI.
3. Report to the DOH cases of LGU non-compliance to the DPRI.

I. Department of Trade and Industry

1. Help the DOH monitor the compliance of drug manufacturers and suppliers to the DPRI when participating in the government sourcing of medicines.
2. Enforce policies and sanctions pertinent to illegal acts of price manipulations of medicines as provided for in RA 7581.

VII. ENFORCEMENT AND SANCTIONS

Non-compliance of this AO shall be subject to administrative penalties based on applicable provisions under Republic Act Nos. 7581 and 9502.

1. First offense- written warning requesting the Chief of Hospital to explain/justify the violation or non-compliance.

2. Second offense- endorse to Legal Service for prosecution and/or appropriate action in accordance with Republic Act 7581 and Republic Act 9502.

VIII. SEPARABILITY CLAUSE

In the event that any provision or part of this Administrative 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. REPEALING CLAUSE

All other existing issuances whose provisions are inconsistent with this order are hereby repealed.

X. EFFECTIVITY

This Administrative Order shall take effect after (15) days following its publication in a newspaper of general circulation.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health

ANNEX A

Sample Computation of the Drug Price Reference

1. For drugs with four (4) or more manufacturers 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.	PhilPharmawealth, 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 three (3) or less 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	Globapen	JB Orchid Pharma	Sel-J Pharma, Inc.
Zamboanga City Medical Center	1.05	20,000	Harbimox	Singapore Pharmawealth, Inc.	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.