Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

AUG 20 2020

ADMINISTRATIVE ORDER
No. 2020 - 0039

SUBJECT : **Guidelines in the Implementation of Maximum Retail Price (MRP) on Drugs and Medicines**

I. RATIONALE

The increasing prices of new medics and high out-of-pocket spending are among the biggest challenges to the Philippine health system. High medicine costs is one of the main barriers to patient treatment access and medication adherence, especially for major burdens of disease in the country.

Republic Act (RA) No. 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008", and its Implementing Rules and Regulations, intends to protect public health and to make quality drugs and medicines more affordable and accessible to all Filipinos. Pursuant to Chapter 3, section 17 thereof, the President of the Philippines, upon the recommendation of the Secretary of Health, shall have the power to impose Maximum Retail Prices (MRP) over any or all drugs and medicines as provided by law. The MRP shall be construed as the imposition of maximum prices across all levels of the supply chains, including, but not limited to, prices set by manufacturers, traders, distributors, wholesalers, and retailers.

The government recognizes that effective competition in the supply and demand of quality affordable drugs should exist in an environment where consumers are well informed and are able to exercise their right to choose. In the current Philippine context, market competition alone is insufficient without government intervention because of existing information asymmetry between and among: patients and consumers as the buyers of goods; physicians as the primary authority on treatment decisions; and industry players which may hold monopoly power by virtue of trade, regulations, and intellectual property rights. Hence, there is an urgent need to set out the national guidelines for the MRP implementation for drugs and medicines in the Philippines.

The DOH has been actively promoting generics since the enactment of the Generics Act in 1988 as well as promoting consumer choice through drug price transparency efforts. However, despite ongoing reforms to ensure better affordability of medicines, medicine prices have continued to escalate making it challenging for consumers to afford and sustain their treatment and the government to help reduce out-of-pocket expenses even as there has been increasing investments on healthcare coverage over the last decade.

Essential medicines continue to be disproportionately expensive in the Philippines when compared internationally, particularly for branded counterparts of already off-patent medicines. Generic drug prices are still approximately up to four times higher than international reference prices (Batangan, 2017).

Given the above landscape on pharmaceutical pricing in the local and international markets, this Order is therefore issued to achieve the goals of the Universal Health Care Act that all Filipinos are guaranteed equitable access to quality and affordable health care goods and services and protected against financial risk.

II. OBJECTIVES

This Order is being issued to set out the national guidelines for the implementation of MRP on drugs and medicines in the Philippines and provide policy recommendations and guidance to DOH to ensure implementation of appropriate measures that promote and ensure access to affordable quality drugs and medicines for all consumers in the Philippines created pursuant to Section 18 of RA 9502. Specifically, the policy seeks to:

A. Establish the framework, criteria, methodology and processes in imposing MRP for drugs and medicines that will foster transparency, accountability and fairness to all stakeholders.

B. Institutionalize the implementation arrangements for the creation of the Drug Price Advisory Council (DPAC).

C. Identify the roles and responsibilities of the different DOH offices, technical committees, and National Government Agencies (NGAs) involved in the price regulation of drugs and medicines.

III. SCOPE AND COVERAGE

This Order shall apply to all those who manufacture, trade, distribute, import, export, and wholesale or retail FDA-registered drugs and medicines, including medical and allied health practitioners, and to all persons, juridical or natural, involved in the provision of healthcare.

IV. DEFINITION OF TERMS

A. **Drug Price Advisory Council (DPAC)** refers to an independent technical body/committee duly authorized and delegated by the Secretary of Health to provide technical advice and guidance to the DOH in implementing appropriate measures that promote and ensure access to affordable quality drugs and medicines for all consumers in the Philippines created pursuant to Section 18 of RA 9502.

B. **Electronic Drug Price Monitoring System (EDPMS)** refers to a web-based platform used by the DOH to collect essential medicine prices across the different levels of the supply chain including prices from medicine manufacturers / distributors, hospital pharmacies, independent drugstores, and chains.

C. **External Reference Pricing (ERP)** refers to 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.

D. **Maximum Retail Price (MRP)** refers to the imposition of maximum 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. (Chapter VI Sec 3 of IRR RA 9502).

E. **Maximum Retail Price (MRP) for Drugs and Medicines Manual of Procedure (MOP)** refers to the procedures in the process of medicine price review, setting the MRP and decision.

F. **Maximum Wholesale Price (MWP)** refers to price given by the manufacturer/wholesaler/ trader / distributor to the retailer.

V. GENERAL GUIDELINES

A. The DPAC shall be created to guide the Secretary of Health on the appropriate pricing of drugs and medicines marketed in the Philippine to ensure that their final prices are affordable to consumers.

B. The selection of medicines to be put under MRP shall be premised upon conditions that address the country's public health needs. It shall also consider the affordability and budget impact of medicines to consumers including the minority and disadvantaged populations.

C. In order to ensure the responsiveness of the list to the need of the consumers, the DOH shall solicit input from patients, health care providers (HCPs), and consumers in determining medicines to be subjected to price review, and possible price regulation in the Philippines.

D. The DOH shall obtain relevant price and market information on medicines from publicly available databases locally and internationally such as third party research firms, manufacturer, importers, traders, distributors, wholesalers, and retailers to enable the DPAC to fulfill its mandate to review drug prices and/or recommended medicines to be subjected to MRP.

E. The DOH shall ensure transparency, accountability and good governance in the process of setting the MRP through the conduct of public hearings and consultations involving various stakeholders such as academic institutions, patient advocacy organizations, consumer groups, HCPs, the industry, and the members of the inter-agency advisory Council for the implementation of RA 9502.

F. The MRP of all medicines as approved by the President of the Philippines, through an Executive Order (EO), shall be imposed in all retail outlets whether public or private, including drugstores, hospitals and hospital pharmacies, health maintenance organizations (HMOs), convenience stores and supermarkets and the like.

G. The DOH shall publish the MRP list using different available venues, such as the official DOH website, other social media platforms, and major newspapers.

H. All drug outlets shall be required to carry and make available the official MRP list posted in conspicuous areas within their premises to the consumers.

I. All drug establishments, outlets, manufacturers, wholesalers, distributors and retailers shall upload all pertinent data in the Electronic Drug Price Monitoring System (EDPMS).

J. The existing MRP list shall be reviewed every three months unless otherwise deemed necessary by the DPAC or by the DOH, if the DPAC is non-existent between the periods.

VI. SPECIFIC GUIDELINES

A. Drug Price Advisory Council

1. Composition:

a. The DPAC shall be composed of public health, epidemiology, pharmaceutical policy, law, clinical, and economic experts to provide technical advice and guidance to the DOH in implementing appropriate measures that promote and ensure access to affordable quality drugs and medicines for all consumers in the Philippines.

a. The number of the Council members shall be odd and to be determined by the SOH for the purpose of determination of majority voting.

b. The members of the Council shall be co-terminus with the SOH subject to reappointment by the new SOH, unless an earlier termination is warranted due to conflict of interest and/or the, inability to perform duties for reasons within or beyond his/her control.

c. The Council shall have a Chairperson selected by the SOH from the members. The Chair shall hold his/her position not exceeding three (3) years unless he/she relinquishes his/her position for reasons beyond his/her control.

2. Qualifications:

The Chair and members of the DPAC shall be selected based on the following criteria:

a. Of good moral character and with high level of integrity;
b. Known expert in their field; and
c. Willing to disclose perceived and actual conflicts of interest which can influence and/or compromise their recommendations to the DOH.

3. Specific Functions:

The DPAC shall:

a. Draft transparent and clear procedures in the selection of medicines to be subjected under MRP and the final retail prices at which they shall be made available to the consumers;
b. Conduct drug price evaluations and provide technical advice and support to the SOH to subject a medicine to price regulation to ensure that prices are comparable to other countries;
c. Evaluate and propose to the SOH the maximum prices of drugs to consumers and also prices at which the government can pay for drugs using transparent rules which take into consideration R&D costs, manufacturing and/or production costs, cost of packaging, distribution costs, marketing costs, relevant taxes, other relevant costs at each level of the supply chain, local, and international pharmaceutical market trends, as well as the status of the supply and competition in the market;
d. Consult with relevant health professional organizations, patient groups, consumer groups, and civil society organizations to ensure an open and inclusive manner in considering medicines to be placed under mandatory price regulation;
e. Recommend the list of medicines to be placed under MRP with their maximum price to the SOH asfter a transparent review process. The maximum price shall reflect the final retail price sold by drug outlets to the consumers before the application of the Value Added Tax (VAT). It shall be applied at all levels of the supply chain including but not limited to manufacturer's price, trader's price, distributor's price, and wholesaler's and retailer's price; and
f. Analyze other parameters affecting drug pricing, if necessary.

4. The DPAC shall be supported by a technical Secretariat under the Pharmaceutical Division in the collection and analysis of pharmaceutical market and pricing data, technical reports, researches and publications, and other sources of relevant data to effectively perform its mandate to carry out drug price review.

5. A representative from the Food and Drug Administration (FDA), Philippine Health Insurance Corporation (PHIC), and other agencies that may be deemed necessary by the DPAC shall be called upon as resource persons during DPAC meetings.

6. The technical advice of the DPAC shall form the basis of the SOH in recommending drugs for MRP to the President of the Philippines for approval.

B. **Expert Panel**

1. Composition:

   a. The Expert Panel shall be composed of public health, epidemiology, pharmaceutical policy, law, clinical, and economic experts to provide technical advice and guidance to the DPAC in implementing appropriate measures that promote and ensure access to affordable quality drugs and medicines for all consumers in the Philippines.

2. Qualifications:

   a. Active practice or teaching on the above fields;
   b. Willingness to declare and manage conflicts of interest;
   c. Willingness to sign in contract of service; and
   d. At least master's degree holder in the above fields

3. Specific Functions

   a. Conduct a comprehensive drug price review and make recommendations to the DPAC to subject a medicine to price regulation to ensure that prices are not excessive to consumers.
   b. Conduct systematic review of maximum prices of drugs to consumers.
   c. Deliver oral presentations and report the results of the drug price review to the DPAC.

C. **Annexes / Forms**

The following forms shall be accessed through the official DOH Pharmaceutical Division website - www.pharmadiv.doh.gov.ph : a) Declaration of Conflict of Interest, b) Non-Disclosure Agreement, c) Basket of Countries for External Referencing, d) Algorithm for the Selection of Medicines to be Subjected under Price Regulation, e) Calculation of the Maximum Wholesale Price (MWP) and Maximum Retail Price (MRP), f) MDRP Form No. 1 Recommendation Form for Patient groups: Medicines for Possible Inclusion to then Maximum Drug Retail Price (MDRP) List; Form 2. Recommendations on Medicines for Possible Inclusion to the Maximum Drug Retail Price (MDRP), g) MDRP Form No. 2 Recommendation form for Medical Societies: Medicines for Possible Inclusion to then Maximum Drug Retail Price (MDRP) List; Form 2. Recommendations on Medicines for Possible Inclusion to the Maximum Drug Retail Price (MDRP), and h). Process Flow and procedures on MRP Violations.

D. **Disclosure of Conflicts of Interest**

To protect the process from outside interference, the DPAC, Expert Panel, secretariat, technical specialists, and other invited resource persons shall conform with the principles of integrity and shall therefore declare all circumstance with real or potential conflicts of interests, and shall comply with existing policies for declaring and managing these conflicts using the form prescribed form.

E. **Non-Disclosure and Confidentiality Agreement**

The DPAC, Expert Panel, secretariat, and invited experts shall also accomplish a Non-Disclosure and Confidentiality Agreement to ensure protection of the process from outside interference that shall compromise public health objectives of this Order.

F. **Medicines Review Process**

Medicines review, setting the MRP and decision shall be assessed following the prescribed process outlined in the MRP manual of procedure which shall be publicly available through the official DOH PD website.

G. **Implementation**

1. Upon effectivity of the EO:
   a. No person, manufacturer, importer, trader, distributor, wholesaler, or any other entity shall sell drugs and medicines at the maximum wholesale price (MWP) corresponding to the MRP approved by the President.
   b. No person, retailer, drug outlets, or any other entity shall sell drugs and medicines at the retail price exceeding the MRP approved by the President.

2. A transition period of ninety (90) days shall be implemented to allow for disposition of existing inventories.

3. Senior Citizens and Persons with Disabilities discounts shall continue to be honored.

H. **Publication and Posting of MRP List**

1. The EO imposing MRP on drugs and medicines shall be published within fifteen (15) days from issuance in at least two (2) newspapers of general circulation. All wholesalers, manufacturers, distributors, importers, or traders shall have a copy of the EO and provide the same to their clients and customers that transact with them.

2. The DOH through the CHDs shall release an electronic version of the MRP poster to be distributed to drug outlets.

3. All drug outlets are required to post in a conspicuous area within their premises a clear copy of the MRP list. It shall be made available to the consumers and regularly updated as the situation may warrant.

4. The standard DOH developed Information, Education and Communication (IEC) material shall be part of the licensing and inspection checklist for drug outlets of the FDA.

I. **Review and Monitoring**

1. A regulatory impact assessment shall be conducted by the DOH through a third-party research firm the year after it has been implemented. The said assessment considers whether or not the MRP has led to (1) improved patient compliance / adherence to medication, (2) reduce out-of-pocket health expenses; and (3) patient satisfaction.

2. The existing list of medicines under MRP shall be subject to review after three to six months by the DOH through the Pharmaceutical Division (PD) and as shall be recommended thereafter upon the effectivity of the EO to be issued by the Office of the President or as often as necessary as determined by the SOH.

3. The DOH-PD, FDA, and Department of Trade and Industry (DTI) shall continuously monitor for MRP violators.

4. The process flowchart for MRP violations shall be found in Annex A of this Order.

VII. **ROLES AND RESPONSIBILITIES:**

1. **Department of Health**
   a. Appoint members of the DPAC through the SOH;
   b. Recommend to the President the list of drugs and medicines for MRP through the SOH; and
   c. Provide oversight functions to the DPAC.

2. **Pharmaceutical Division**
   a. Conduct the hiring of the DPAC;
   b. Provide technical and administrative support to the DPAC;
   c. Undertake overall coordination with internal and external partners;
   d. Facilitate the conduct of public hearings;
   e. Continuously monitor the prices of all drugs and medicines through the EDPMS and consumer complaints;
   f. Monitor for MRP violators; and
   g. Commission a third-party researcher to conduct an impact review of the MRP policy.

3. **Legal Service**
   a. Provide legal assistance on all matters related to the implementation of this Order.

4. **Health Promotion and Communication Service**
   a. Propose and develop a communication plan on the dissemination of information related to the imposition of MRP;
   b. Publish the MRP list in the Official DOH website and other social media platforms; and
   c. Develop a standard IEC material for the list of medicines under MRP and Frequently Asked Questions (FAQs) which shall be used by all drug outlets.

5. **DOH Centers for Health Development and Ministry of Health - BARMM**
   a. Monitor the compliance of all drug outlets to the implementation of the MRP through the EDPMS;
   b. Disseminate IEC materials and/or information campaign related to the imposition of MRP; and
   c. Submit MRP violator to the FDA for investigation.

6. **Food and Drug Administration**
   a. Investigate alleged violations of MRP and MWP in accordance with RA 9502 and its Implementing Rules and Regulations and other laws relevant to drug pricing, and to impose administrative fines, sanctions and penalties, in accordance with Book III (Uniform Rules of Procedure) of the Implementing Rules and Regulations of RA 9711 (FDA Act of 2009);
   b. Conduct random on-site monitoring for MRP and MWP compliance in both drug outlets and suppliers;
   c. Issue labeling requirement guidelines for MRP medicines;
   d. Include MRP compliance and availability of IEC materials in their inspection checklist; and
   e. Impose appropriate sanctions for drug outlets not complying on the standard IEC material issued by the DOH.

7. **Department of Trade and Industry**
   a. Submit quarterly price monitoring reports to the SOH of drugs and medicines under MRP, including a list of its violators for investigation.

VIII. ADMINISTRATIVE SANCTIONS

The following administrative fines shall be imposed upon any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, for violations of the MWP and MRP approved by the President of the Philippines:

A. 1st violation – Administrative fine of a minimum of Fifty Thousand Pesos (P50,000.00) to Five Hundred Thousand (P500,000.00) Pesos depending on the gravity, extent and duration of the violation;

B. 2nd violation – Administrative fine of a minimum of Five Hundred Thousand (P500,000.00) to One Million Five Hundred Thousand Pesos (P1,500,000.00) depending on the gravity, extent, and duration of the violation;

C. 3rd violation – Administrative fine of a minimum of One Million Five Hundred Thousand (P1,500,000.00) to Three Million Pesos (P3,000,000.00), depending on the gravity, extent, and duration of the violation;

D. 4th violation – Administrative fine of Three Million Pesos (P3,000,000.00) to Five Million Pesos (P5,000,000.00); and

E. 5th and succeeding repeated violations – Administrative fine of Five Million Pesos (P5,000,000.00).

Further, the maximum penalty for every range shall be applied for violations of the MWP.

IX. INTERPRETATION

If any defined term or provision of this Order should admit of several meanings, it shall be resolved in favor of protecting public health, pursuant to Article II, Section 15 of the 1987 Constitution.

X. SEPARABILITY CLAUSE

If for any reason, any portion of this Order shall be declared unauthorized or rendered invalid by any court of law or any competent authority, parts or provisions not affected shall remain in full force and effect.

XI. REPEALING CLAUSE

All orders, rules, regulations, and other related issuances inconsistent with or contrary to this Order are hereby repealed, amended, or modified accordingly. All other provisions of existing issuances which are not affected by this Order shall remain valid and in effect.

XII. EFFECTIVITY

This Administrative Order shall take effect within fifteen (15) days after its publication in a newspaper of general circulation and upon filing with the University of the Philippines Law Center of three (3) certified copies of this Order.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

CERTIFIED TRUE COPY
AUG 26 2020
MARIA CRISTINA P. RIVERA
KMITS - RECORDS SECTION
Department of Health

ANNEX A: PROCESS FLOW AND PROCEDURES ON MRP VIOLATIONS