ADMINISTRATIVE ORDER

No. 2019 - _____

SUBJECT : **GUIDELINES FOR THE IMPLEMENTATION OF MAXIMUM RETAIL PRICE (MRP) ON DRUGS AND MEDICINES**

I. RATIONALE / BACKGROUND

The increasing prices of new medicines 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, intend 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). In addition, launch prices of specialized therapies, such as new cancer treatments, biologics, and genetic therapies, which have emerged in recent years, are priced beyond what patients, private insurers, and the government can fairly afford. The excessive prices of medicines undermine the health of millions of Filipinos, with the poor and middle-income sectors bearing the increased risk of being trapped in the vicious cycle poverty, inequality, and debt.

Globally, the emergence of high cost drugs addressing cancer, orphan disorders, Hepatitis B and C, multidrug–resistant tuberculosis and HIV/AIDS threaten the sustainability of health systems. The pivotal Report of the *UN High Level Panel on Access to Medicines* released in September 2016 called for alternative approaches to redress the current situation of monopolistic high drug prices resulting from the current market-driven model of funding innovation of healthcare technologies. Key recommendations include the maximization of TRIPS flexibilities for developing countries; enhancing drug price transparency to reflect taxpayer's funding for medical research; the use of competition policy to ensure that markets work for the benefit of patients and consumers, and more government involvement in setting the prices of medicines

In January 2019, the WHO also published a comprehensive technical report on the excessive prices of cancer drugs with recommendations to governments and the international community on strengthening pricing policies for cancer medicines such as: (1) designing differential pricing sensitive to health system's ability to pay; (2) enforcing price caps on cancer medicines: (3) creating competition on substitutable cancer medicines; (4) enhancing health system ability to review and adjust drug prices; and to (5) withdraw funding from superseded less cost-effective medicines.

Given the above landscape on pharmaceutical pricing in the local and international markets, the Secretary of the Department of Health shall have the power to determine the MRP of drugs and medicines that shall be recommended to the President of the Philippines for approval. Pursuant to its mandate, the Secretary of Health (SOH) created the Drug Price Advisory Council (DPAC) for the implementation of MRP on drugs and medicines as stipulated under Rule 28, Chapter V of the IRR of RA 9502. This Order is therefore issued to achieve the goals of the Philippine Health Agenda 2016-2022, thereby: (1) Financial Protection: Filipinos, especially the poor, marginalized, and vulnerable are protected from excessively prices of health care; (2) Better Health Outcomes: Filipinos attain the best possible health outcomes with no disparity; and (3) Responsiveness: Filipinos feel respected, valued, and empowered in all of their interactions with the health system.

II. OBJECTIVE

This issuance aims to:

A. To set out the national guidelines for the implementation of MRP on drugs and medicines in the Philippines.

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

C. To institutionalize the implementation arrangements for the creation of the Drug Price Advisory Council (DPAC).

D. To 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

For purposes of this Order, the following terms are defined:

A. **Access** refers to the ability to utilize health services and its logistics support without barriers or obstacles.

B. **Affordability** for individual patients, this is defined by the number of days the minimum wage earner would have to work in order to afford the cost of the complete course of treatment. For the government as purchaser, affordability refers to the cost implications of the drug expressed as total treatment cost per patient and the budget impact to the government if all eligible patients are given the treatment; and for the health system, affordability refers to the proportion of spending on medicines compared to existing expenditures on other health products and services.

C. **Burden of Disease** refers to the impact of a health problem as measured by financial cost, mortality, morbidity, or other indicators. It is often quantified in terms of quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs).

D. **Disability Adjusted Life Year (DALY)** refers to the measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death.

E. **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.

F. **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 government health 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.

G. **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.

H. **External Reference Pricing (ERP)** refers 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.

I. **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.

J. **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.

K. **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).

L. **Price differentials** refers to a difference in the prices of two products or of the same product in different places.

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 imposition of MRP for medicines shall be based from RA 9502 which mandates DOH to adopt appropriate measures in ensuring affordable access to medicines for all and to carry out such a mandate in favor consumer protection and the protection of public health.

C. 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.

D. 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.

E. The DOH shall obtain relevant price and market information on medicines from manufacturer, importers, traders, distributors, wholesalers, and retailers to enable the DPAC to fulfill its mandate to review drug prices and/or recommend medicines to be subjected to MRP.

F. 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.

G. 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.

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

I. 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.

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.

K. To provide policy recommendations and guidance to the DOH to ensure the 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.

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.

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

c. The members of the Council shall be co-terminus 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.

d. 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:

i. Of good moral character and with high level of integrity;

ii. Known expert in their field; and

iii. 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:

i. 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;

ii. 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 not excessive to consumers;

iii. 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; and

iv. 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 may be called upon as resource persons during DPAC meetings.

6. The DPAC shall commission academic partners in conducting its review and request information from the industry in accordance with existing provisions under RA 9502 as the duly authorized body of the SOH.

7. The DPAC shall 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 place under mandatory price regulation.

8. The DPAC after a transparent review process shall recommend the list of medicines to be placed under MRP with their maximum price to the SOH. 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.

9. 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. **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 in Annex A of this Order.

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

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

E. **Medicine Price Review Process**

1. The drug price review shall be based on most current available evidence of medicine prices to assess whether a medicine is priced excessively and should therefore be subjected under price regulation.

2. The DOH through the DPAC employs both internal and external reference pricing in carrying out the drug price review process.

3. The following are among the sources of price data:

a. DPRI

b. EDPMS

c. Third Party Research Firms - the DOH shall avail of the market intelligence service of third-party research firms providing drug pricing and pharmaceutical market trends both locally and internationally; Provided, third party research firms comply with existing policies on conflict of interest.

d. Publicly available drug price data sources from recognized bodies such as, but not limited to:

i. World Health Organization (WHO) (e.g. PIEMEDS, PAHO, MIA4A Vaccine Purchase)

ii. United Children's Fund (UNICEF)

iii. United Kingdom – British National Formulary

iv. Australia – Pharmaceutical Benefits Scheme

v. Thailand – Government Procurement Price

vi. Canada – Patented Medicine Price Review Board

vii. New Zealand – PHARMAC

4. Selection of Medicines for Price Regulation

a. Screening Criteria

The DPAC shall conduct review of all prescription medicines registered in the Philippine market as they generally impose a more significant cost burden to consumer compared with over-the-counter (OTC) medicines which are taken generally on an acute or limited basis. The following criteria are considered by

the DPAC in determining whether a prescription drug shall be subjected to price regulation:

i. Burden of Disease

Medicines addressing diseases with the highest burden in the country in terms of both magnitude (i.e., the size of the population affected by the disease) and/or severity (i.e., the impact of the disease on a patient's quality of life and overall well-being including the ability to perform normal activities).

ii. Marginalized and Disadvantaged Populations

Medicines which address diseases of low prevalence / frequency but which affect special and disadvantaged populations (e.g., orphan diseases, rare cancers, diseases of persons with disability) may be considered by the DPAC provided that the patients perceived that the cost of the medicines acts as a barrier to patient access.

iii. Limited Competition

Medicines with monopolistic (i.e., patented) and oligopolistic market due to certain barriers in the health care market which hinders effective competition such as intellectual property barriers, regulatory barriers, trade barriers, and information asymmetry.

b. Qualifying Criteria

Medicines screened based on burden of disease, patient and/or public demand and market concentration are further evaluated through price evaluation to determine if local prices are excessive and should therefore be subjected to regulation:

i. High wholesale price differential against external reference price (ERP)

Medicines found to have grossly higher absolute price in the Philippine market relative to prices in the basket countries will be subject to price regulation.

5. Selection of Basket Countries for External Reference Pricing (ERP)

a. The criteria for the selection of basket countries include the following:

i. Countries with publicly available price data;

ii. Asian countries that share geographical proximity, socioeconomic status, consumer protection mandates and other health system factors based on the WHO classification of member states by mortality data or World Bank classification on economic status; and

iii. Developed countries which have established Health Technology Assessment (HTA) systems able to provide guidance on the clinical and economic value as well as cost-effective prices of innovative medicines in their own contexts.

b. Basket of Countries for ERP

The selected basket countries are enumerated in the Annex C of this Order.

6. Algorithm for the Selection of Medicines to be subjected under the MRP

   a. The Council shall follow the algorithm prescribed in Annex D.

   b. All medicines that meet the requirements of both screening and qualifying criteria shall be recommended by the DPAC be included under MRP.

F. **Setting the MRP**

1. In general, the MRP shall be calculated using the ERP plus regressive mark-up method prescribed in Annex E.

G. **Decision**

1. The final recommendation shall be obtained through a majority (50% + 1) vote provided that there is a quorum. In the absence of a quorum and in an urgent situation, votation through ad referendum may be conducted.
2. The DPAC shall recommend the list of medicines and their corresponding MRPs based on the specific guidelines under the Medicines Price Review Process and Setting the MRP.
3. The list of medicines and their corresponding MRPs shall be endorsed by the cluster head in charge of the Pharmaceutical Division to the SOH.
4. The DOH shall hold a public hearing on the proposed medicines for MRP. It shall involve different stakeholders including but not limited to: government offices or agencies, civil society, patient organizations, HCPs, and pharmaceutical industry.
5. The SOH shall recommend the MRP list to the President of the Philippines.
6. Upon approval by the President, an EO shall be issued ordering the imposition of MRP on selected drugs and medicines.

H. **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 one hundred and twenty (120) days shall be implemented to allow for disposition of existing inventories.
3. Senior Citizens and Persons with Disabilities discounts shall continue to be honored.

I. **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) newspaper of general circulation. All wholesaler, 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 distribution 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.

J. **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 improved health status, financial risk protection, health system responsiveness and efficacy.
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 may 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.

K. **Roles and Responsibilities**

1. **Office of the Secretary**
   a. The SOH shall appoint members of the DPAC; and
   b. The SOH shall recommend to the President the list of drugs and medicines for MRP.
2. **Undersecretary / Assistant Secretary of the HRT**
   a. Provide oversight functions to the DPAC.
3. **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.
4. **Drug Price Advisory Council**
   a. Establish framework and methodology in imposing MRP on drugs and medicines;
   b. Regularly review prices of drugs and medicines in the market to evaluate if price regulation is necessary;
   c. Recommend the list of drugs to be put under MRP with their maximum prices to the SOH; and
   d. Review the existing list of MRP.

5. Expert Panel

a. Conduct a comprehensive drug price review and make recommendations to the DPAC to subject a medicine to price regulation.

6. Legal Service

a. Provide legal assistance on all matters related to the implementation of this Order.

7. 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 relevant Information, Education and Communication (IEC) materials.

8. DOH Centers for Health Development

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.

9. Food and Drug Administration

a. Investigate alleged violations and impose sanctions in accordance with RA 9502 and laws relevant to drug pricing.

10. 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.

VII. 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 – Warning;

B. 2nd 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;

C. 3rd 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;

D. 4th 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;

E. 5th violation – Administrative fine of Three Million Pesos (P3,000,000.00) to Five Million Pesos (P5,000,000.00);

F. Succeeding repeated violations – Administrative fine of Five Million Pesos (P5,000,000.00); and

G. An additional penalty of Two Thousand Five Hundred Pesos (P2,500.00) per day shall be made for every day violation continues after having received the order from the DOH or such other appropriate body, notifying and penalizing the offending person or company for the infraction.

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

VIII. 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.

IX. 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.

X. REPEALING CLAUSE

All other existing issuances whose provisions are inconsistent with this Order are hereby repealed or modified accordingly.

XI. EFFECTIVITY

This Administrative Order shall take effect within fifteen (15) days upon publication in the Official Gazette.

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

ANNEX A

DECLARATION OF CONFLICT OF INTEREST

1. CURRENT FINANCIAL INTEREST

To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustees, general partner, or employee and/or 3) entity with whom you are negotiating or have any arrangement concerning prospective employment have any current involvement of financial link with the meeting/task issues (including competing companies)?

a. **INVESTMENTS** (e.g. stocks, bonds, retirement plans, trust, partnerships, sector funds, etc.) ☐ **NONE** (if "none", skip to item b.)

ESTABLISHMENT	TYPE OF INVESTMENT	OWNER (self, spouse, etc.)	NUMBER OF SHARES	CURRENT VALUE	CHECK PERCENTAGE NET WORTH		
					LESS THAN 5%	5-15%	MORE THAN 15%

b. **EMPLOYMENT** (Full or Part Time) (Current or Under Negotiation) ☐ **NONE** (if "none", skip to item c.)

ESTABLISHMENT	RELATIONSHIP	POSITION IN FIRM	DATE OF EMPLOYMENT OR NEGOTIATION BEGAN

c. **CONSULTANT / ADVISOR** (Current or Under Negotiation) ☐ **NONE** (if "none", skip to item d.)

ESTABLISHMENT	TOPIC/ISSUE	AMOUNT RECEIVED	DATE FROM	DATE TO	RELATED TO LISTED PRODUCTS / INDICATIONS ISSUES

d. **CONTRACTS/GRANTS** (Current or Under Negotiation) ☐ **NONE** (if "none", skip to item e.)

TYPE OF AGREEMENT (contract/grant)	PRODUCT UNDER STUDY AND INDICATION	AMOUNT OF REMUNERATION TO		TIME PERIOD	SPONSOR*	YOUR ROLE**	AWARDEE	RELATED TO LISTED PRODUCTS /INDICATIONS/ISSUES
		INSTITUTION	YOU					
								☐ YES ☐ NO
								☐ YES ☐ NO
								☐ YES ☐ NO

*Government, Establishment, Institution, Individual

**Site Investigator, Principal Investigator, Co-investigator, Employee, Partner, Non-involvement, or Other

IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES

1. CURRENT FINANCIAL INTERESTS (Continued)

e. **INTELLECTUAL PROPERTY** ☐ **NONE** (if "none", skip to item f.)

FOR	ESTABLISHMENT	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES	IF "YES", EXPLAIN BELOW AND INDICATE INCOME RECEIVED
		☐ YES ☐ NO	
		☐ YES ☐ NO	
		☐ YES ☐ NO	

f. **EXPERT WITNESS (Last 12 months or under negotiation)**
I appeared for or against the following listed establishment(s) and issue(s) ☐ **NONE** (if "none", skip to item g.)

FIRM AND ISSUE	AMOUNT RECEIVED	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES	IF "YES", EXPLAIN BELOW
		☐ YES ☐ NO	
		☐ YES ☐ NO	
		☐ YES ☐ NO	

g. **SPEAKING/WRITING (Last 12 months or under negotiation)**

FIRM	TOPIC/ISSUE	AMOUNT RECEIVED		DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
		HONORARIUM	TRAVEL		
					☐ YES ☐ NO
					☐ YES ☐ NO
					☐ YES ☐ NO

IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES

2. PAST FINANCIAL INTERESTS

a. To your knowledge, do 1) you, your spouse, minor child, general partner, 2) organization in which you serve as an officer, director, trustee, general partner, or employee have any past involvement with the meeting/task issues:

☐YES ☐NO ☐NOT TO MY KNOWLEDGE

b. If "Yes", describe involvement.

FIRM/PRODUCT	FINANCIAL INVOLVEMENT (e.g. contract/consultant)	ROLE	DATES	RELATED TO LISTED PRODUCTS/ INDICATIONS/ ISSUES
				☐ YES ☐ NO
				☐ YES ☐ NO
				☐ YES ☐ NO

3. OTHER INVOLVEMENTS (Other Kinds of Relationship) ☐**NONE** (if "none," skip to Item 4.)

Using the list of products/firms/issues, identify anything that would give an "appearance" of a conflict which has not been disclosed above (e.g. involvement in a lawsuit, researcher-initiated study, gift of research materials, etc.)

_____
_____
_____
_____

CONSENT TO DISCLOSURE

By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

DECLARATION

I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of the DOH and complete a new declaration of interests form that describes the changes. This includes any change that occur before or during the meeting or work itself and through the period up to the publication of final results or completion of the activity concerned.

Date	Signature

IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL PAGES

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ANNEX B

NON-DISCLOSURE AGREEMENT

I, _____, an employee of the _____ _____, and assigned as the _____ for the project _____, is hereby legally bound, consents, and accepts the following obligations, terms and conditions as set forth in this Agreement in consideration of being granted *conditional access* to certain information that is owned by, produced by, or in the possession of the Department of Health (DOH), Philippines; and in compliance with the requirements of the DOH regarding confidentiality, privacy and security of information:

1. As used in this Agreement, *information* refers to confidential and/or sensitive information in which the loss of, misuse of, or unauthorized access to or modification can adversely affect the *national interest of the country, conduct of the DOH's programs*, or the *privacy* to which an individual is entitled. Confidential *information* is marked CONFIDENTIAL or unmarked CONFIDENTIAL but was declared confidential, and oral communications that have been declared CONFIDENTIAL by an Authorized Officer of the Department of Health (DOH);
2. I understand and accept that by being granted conditional access to *information*, confidence and trust are placed in me by the DOH and I am obligated to protect the *information* from unauthorized disclosure, in accordance with the terms of this Agreement and applicable laws, regulations, issuances and directives;
3. I have been informed that unauthorized disclosure, unauthorized retention, or negligent handling of *information* confidential information by me, may deprive the DOH, the rightful owner of the system of its intellectual property rights and could cause damage or irreparable injury to the Department and Government of the Philippines or could be used to the undue and unethical advantage of another nation/s or people such as myself and my company;
4. I shall not disclose or release *information* provided to me to anyone without proper authority or authorization from the DOH. Should there are situations that warrant the disclosure or release of *information,* I shall do so only under approved circumstances and in accordance with applicable laws, regulations or directives, and shall comply with any and all dissemination restrictions as required or relayed by the proper authority;
5. I shall not alter or remove markings which indicate a category of *information* or require handling instructions from any materials I may come in contact with, unless such alteration or removal is authorized by the DOH or consistent with applicable laws, regulations or directives;
6. Upon completion of my engagement as a/an _____ under the project's contract, or completion of my work whichever occurs first, I shall return all *information* to which I have access or which are in my possession. Further, I shall surrender promptly to the DOH any documents whatsoever that are in my possession;
7. I solemnly swear that any *information* given to me shall remain confidential even after the completion of the project itself;
8. I shall not retain any documentation, source code or other *information* both in soft and hard copies used in this project;
9. I shall not modify, reverse engineer, decompile or disassemble any subsystems, modules, and/or software program codes, and sell to any government or private entities later the outputs of this project;

10. I shall promptly report to the appropriate DOH officials any loss, theft, misuse, misplacement, unauthorized disclosure, or other security violations in which I have knowledge of and whether or not I am personally involved.
11. Unless and until I am released in writing by the authorized personnel of the DOH, I understand that all conditions and obligations imposed upon me by this Agreement apply during the time that I am granted conditional access, and at all times thereafter;
12. If any provision of this Agreement is held to be invalid or unenforceable, all other provisions shall remain in full force and effect;
13. I am aware that violations of the terms and conditions of this Agreement may result in the cancellation of my conditional access to *information* or subjected to sanctions provided by pertinent laws and statutes of the Philippines.

IN WITNESS WHEREOF, I have hereunto set my hand this _____ day of _____ 201x in the City of Manila, Philippines.

_____
Affiant

SUBSCRIBED AND SWORN to before me this _____ day of _____ 201x, in the City of _____, Philippines.

_____
Notary Public

Doc. No. _____;

Page No. _____;

Book No. _____;

Series of 201x.

ANNEX C

I. Basket of Countries for External Referencing Pricing

Country	Available Price Data	SE Status	Consumer Protection Mandates	Health System Factors	Established HTA Systems
Thailand	Yes	UMIC		WPRO B	
Malaysia					
Vietnam		LMIC			
India			NPPA		
Indonesia				WPRO B	
UK		OECD	PPRS		NICE
Australia		OECD	PBAC		PBAC
Canada		OECD	PMPRB		CADTH

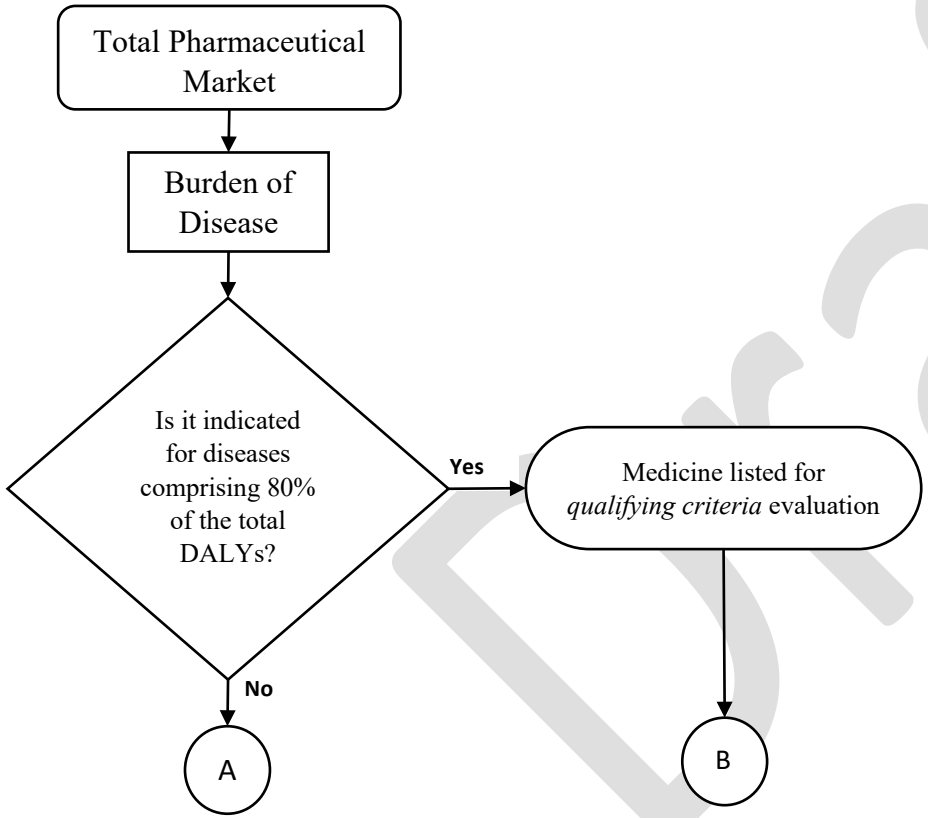
a. The reference countries were divided into two (2) baskets:
   i. Asian Countries: (1) Thailand; (2) Malaysia; (3) Vietnam; (4) India; and (5) Indonesia
   ii. Developed Countries: (1) United Kingdom; (2) Australia; and (3) Canada

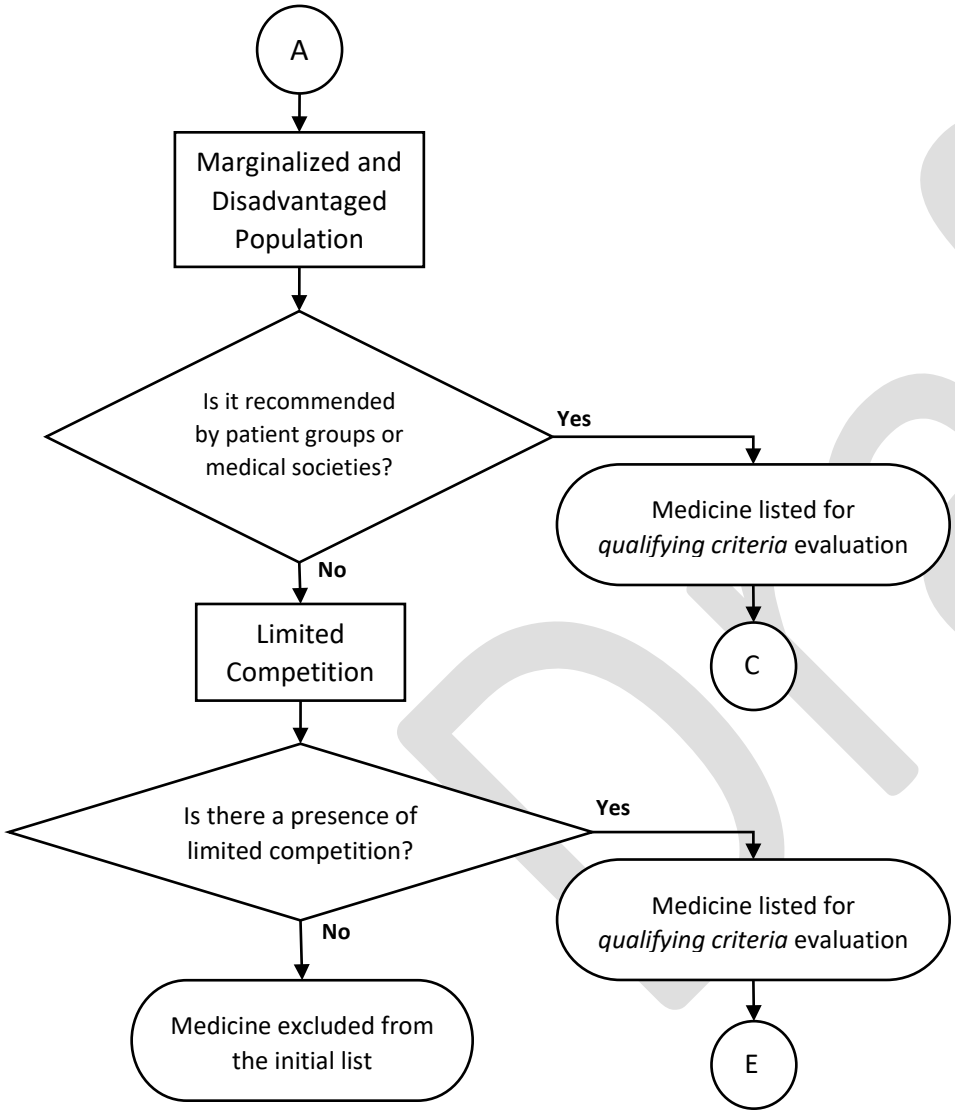
UMIC – Upper Middle-Income Country
LMIC – Lower Middle-Income Country
OECD – Organization for Economic Cooperation and Development (Developed Countries)
WPRO B – Mortality Stratum B of the WHO (low child and low adult mortality)
NPPA – National Pharmaceutical Pricing Authority
PPRS – Pharmaceutical Price Regulation Scheme
PBAC – Pharmaceutical Benefits Advisory Committee
PMPRB – Patented Medicine Prices Review Board
NICE – National Institute for Health and Care Excellence
CADTH – Canadian Agency for Drugs and Technologies in Health

ANNEX D

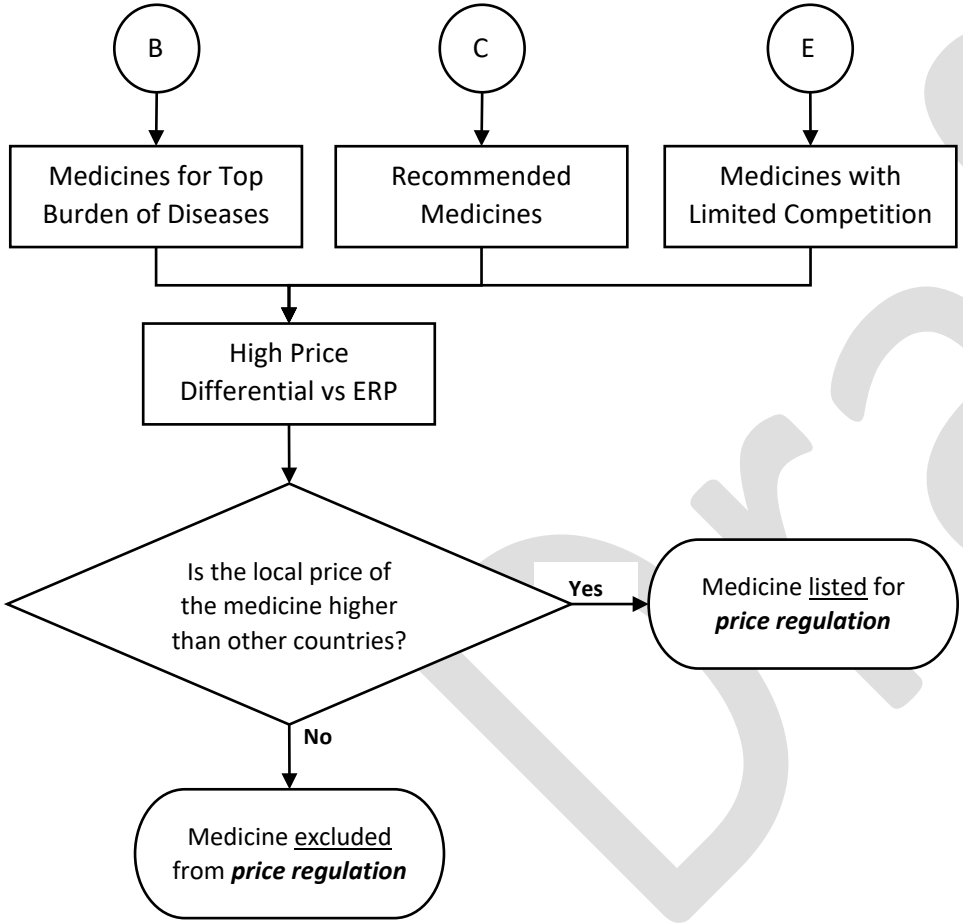
I. Algorithm for the Selection of Medicines to be Subjected under Price Regulation

A. All prescription FDA-registered medicines shall be evaluated using the screening criteria stipulated under section VI.E.4.a

Criteria	Criteria Type	Measure	Threshold
	Screening	***Disability Adjusted Life Years (DALYs)*** which refer to the years of life lost due to premature mortality and disability in the population brought by a disease.	All medicines indicated for diseases comprising ***80%*** of the total DALYs in the country will be considered for price regulation.

Criteria	Criteria Type	Measure	Threshold
	Screening	***Recommendations submitted by patient organizations and medical societies*** to subject certain medicines to price regulation	**All** medicines recommended by patient organizations and medical societies will undergo further evaluation for price regulation.
	Screening	***Herfindahl – Hirschman Index (HHI)***, a commonly accepted measure of market concentration to assess cases of oligopolies or monopolies.	All medicines with an HHI equal to or greater than **0.4** signify a concentrated market with approximately no more than three (3) firms/manufacturers/ producers existing in the country.

B. All medicines that will qualify on either one of the screening criteria, shall be evaluated using the qualifying criteria (price evaluation) stipulated under section VI.E.4.b.

Criteria	Criteria Type	Measure	Threshold
	Qualifying	***Median local wholesale price*** per SKUs.	***Median price*** of economically or epidemiologically similar countries or ***Lowest price*** of the developed countries, whichever is lower

C. Top Burden of Diseases

1. All prescription medicines in the market shall be evaluated if it addresses the diseases which comprise top 80% of the total local DALYs. Qualified medicines shall undergo price evaluation.

2. All medicines not addressing the top BOD shall only be assessed if it is recommended by patient organizations and medical societies for price regulation.

D. Marginalized and Disadvantaged Populations

1. Patient organizations and health care professional organizations may submit a request to the DOH to subject certain medicines to price regulation when they perceive such medicines as clinically important but unaffordable to patients.

2. Medicines recommended by the aforementioned groups shall automatically be subjected to price evaluation. The remaining medicines which did not qualify for either the two (2) criteria shall be assessed for limited competition.

3. Submission of patient organizations and health care professional organizations shall adhere to the prescribed format of the DOH found in Annex F and G, respectively.

E. Medicines with Limited Competition

1. Using volume sales data, the Herfindahl – Hirschman Index (HHI) shall be calculated for medicines with similar molecule/s, dosage strength, route-of-administration and drug delivery system.

In example, different HHIs shall be calculated for slow-release and ordinary-release preparations of medicines with similar molecule and strength.

2. Formula:

$$HHI = \sum S_n^2$$

Where:

S_n is the market share percentage of pharmaceutical firm *n* expressed as a decimal.

3. Example A *(Paracetamol 500 mg Tablet)*:

Firm (*n*)	**Percentage Share (*S*) in terms of volume**	S_n^2
Manufacturer A	0.30	0.09
Manufacturer B	0.25	0.0625
Manufacturer C	0.15	0.0225
Manufacturer D	0.30	0.09
	TOTAL ($\sum S_n^2$):	0.2425

The HHI for Paracetamol is lower than 0.4 threshold and therefore shall no longer be subjected to further evaluation.

4. Example B *(Amlodipine 10 mg Tablet)*:

Firm (n)	**Percentage Share (S) in terms of volume**	S_n^2
Manufacturer A	0.70	0.49
Manufacturer B	0.10	0.01
Manufacturer C	0.13	0.0169
Manufacturer D	0.03	0.0009
Manufacturer E	0.04	0.0016
TOTAL ($\sum S_n^2$):		0.5194

The HHI for Amlodipine is higher than 0.4 threshold. It shall be included in the list of medicines for price evaluation.

5. All medicines with HHI equal or greater than 0.4 shall be included in the list of medicines for price evaluation.

6. Medicines which did not pass any of the screening criteria shall no longer undergo further evaluation.

F. High Wholesale Price Differential Against External Reference Price

1.External Reference Price (ERP) is set by the DPAC as the median price of economically or epidemiologically similar countries or the lowest price of the developed countries, whichever is lower.

2.An example of setting the ERP is provided in Annex E.

3.A medicine shall be subjected to price regulation if the local median price for each medicine (SKU) exceed the calculated ERP.

4.All medicines which did not qualify for this criterion shall be excluded from the list of medicines for price regulation.

ANNEX E

I. Setting the Maximum Wholesale and Retail Price

A. The Maximum Retail Price (MRP) is determined through external reference pricing plus a regressive mark-up method.

B. Formula:

$$MRP = P_{ER} + m$$

$$P_{ER} = \min\{mid\{P_{ac}\}, min\{P_{dc}\}\}$$

Where:

P_{ER} External Reference Price (Prescribed Wholesale Price)

m Mark-up, value identified at Section IV

P_{ac} Is the median price per SKU of the reference Asian country *ac*

P_{dc} Is the median price per SKU of the reference developed country *dc*

C. Calculation of External Reference Price (P_{ER})

1. Example (Paracetamol 500 mg Tablet)

Asian Country Basket *(ac)*	Median Price (P_{ac})	Developed Country Basket *(dc)*	Median Price (P_{dc})
Vietnam	0.50	United Kingdom	0.64
Indonesia	0.89	Canada	1.50
Malaysia	1.02	Australia	0.35
Thailand	0.23		
India	0.15		

Therefore:

$$P_{ER} = min\{mid\{P_{ac}\}, min\{P_{dc}\}\}$$

$$= min\{mid\{0.50,0.89,1.02,0.23,0.15\}, min\{0.64,1.50,0.35\}\}$$

$$= \min\{P_{ac}^{MID}(0.50), P_{dc}^{MIN}(0.35)\}$$

$$= min\{0.50, 0.35\}$$

$$= 0.35$$

$$\boldsymbol{P_{ER} = 0.35}$$

In this example, Php 0.35 will be the maximum wholesale price for Paracetamol 500 mg Tablet.

D. Regressive Mark-up (m) Schedule

The m regressively varies depending on the P_{ER} value:

External Reference Price / Prescribed Wholesale Price (P_{ER})		Mark-up (m)
Over	But not over	
0	50	40%
50	100	Php 20 + 30% of the excess of Php 50
100	1,000	Php 35 + 20% of the excess of Php 100
1,000	10,000	Php 215 + 10% of the excess of 1,000
10,000	(…)	Php 1,115 + 5% of the excess of 10,000

E. Calculation of MRP

Since the calculated P_{ER} (PhP 0.35) is *over 0 but not over 50,* a 40% mark-up will be applied.

$$MRP = P_{ER} + m$$

Derived:

P_{ER}: Php 0.35

Given:

m : 40% of P_{ER}

Therefore:

$MRP = Php\ 0.35 + 40\%(PhP\ 0.35)$

$\boldsymbol{MRP = Php\ 0.49}$

$\boldsymbol{MWP = Php\ 0.35}$

Retailers shall procure products under MRP at prices not exceeding the maximum wholesale price. They shall also sell these products to consumers at prices lower or equal to the MRP.

F. In cases where the calculated MRP is higher than the prevailing market price, the latter shall be set as the MRP.

ANNEX F

MDRP FORM NO. 1
RECOMMENDATION FORM FOR PATIENT GROUPS: MEDICINES FOR POSSIBLE INCLUSION TO THE MAXIMUM DRUG RETAIL PRICE (MDRP) LIST

Date

Honorable _____
Secretary _____
Department of Health

ATTENTION: _____
Chief
Pharmaceutical Division
Department of Health

SUBJECT: RECOMMENDATION ON MEDICINES FOR POSSIBLE INCLUSION TO THE MAXIMUM DRUG RETAIL PRICE (MDRP) LIST

Dear Secretary _____:

The _____recommends the following medicines for possible inclusion to the Maximum Drug Retail Price (MDRP) list.

Please find attached filled proposal form.

(Indicate any additional remark)

Respectfully yours,

NAME
President
Patient Group
Indicate email address telephone and facsimile number

Form 2. Recommendations on medicines for possible inclusion to the Maximum Drug Retail Price (MDRP)

Information on your patient group	
1. Name of patient group	
2. Type of patients/ Disease/s catered	
3. Location	
4. Percent of population affected by the disease	
5. Contact information (Please indicate your email address, contact number)	

Information on the medicine/s requested

Drug	Specific indication	Treatment regimen	Price per pc. (PhP)

Justification/ additional information which you believe would be helpful for the Drug Price Advisory Council (DPAC) to arrive at a decision	
Kindly declare any current or potential conflicts of interest (COIs) (i.e., relationships with the pharmaceutical industry whether direct or indirect)	

ANNEX G

MDRP FORM NO. 2
RECOMMENDATION FORM FOR MEDICAL SOCIETIES: MEDICINES FOR POSSIBLE INCLUSION TO THE MAXIMUM DRUG RETAIL PRICE (MDRP) LIST

Date

Honorable _____
Secretary _____
Department of Health

ATTENTION: _____
Chief
Pharmaceutical Division
Department of Health

SUBJECT: RECOMMENDATION ON MEDICINES FOR POSSIBLE INCLUSION TO THE MAXIMUM DRUG RETAIL PRICE (MDRP) LIST

Dear Secretary _____:

The _____recommends the following medicines for possible inclusion to the Maximum Drug Retail Price (MDRP) list.

Please find attached filled proposal form.

(Indicate any additional remark)

Respectfully yours,

NAME
President
Name of Medical Society
Indicate email address telephone and facsimile number

Form 1. Recommendations on medicines for possible inclusion to the Maximum Drug Retail Price (MDRP)

<table>
<tr><td colspan="2">Information on the medical society</td></tr>
<tr><td>1. Name of medical society</td><td></td></tr>
<tr><td>2. Area of practice</td><td></td></tr>
<tr><td>3. Disease/s catered and estimated percent of population affected by the disease</td><td>
<table>
<tr><th>Diseases</th><th>Estimated Percent of population affected by the disease</th></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>4. Contact information
(Please indicate your email address, contact number)</td><td></td></tr>
<tr><td colspan="2">Information on the medicine/s recommended
<table>
<tr><th>Generic name (indicate strength and form)</th><th>Specific indication</th><th>Treatment regimen</th><th>Price per pc. (PhP)</th><th>Justification/ additional information which you believe would be helpful for the Drug Price Advisory Council (DPAC) to arrive at a decision</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td></tr>
</table>

Kindly declare any current or potential conflicts of interest (COIs) (i.e., relationships with the pharmaceutical industry whether direct or indirect)	