DEPARTMENT OF HEALTH DEPARTMENT OF TRADE AND INDUSTRY

JOINT ADMINISTRATIVE ORDER
2021

Subject: Guidelines in the Implementation of the Guidelines in the implementation of the RA 7581 or the Price Act provisions for medicines and medical devices

I. RATIONALE

Republic Act No. 7581, otherwise known as the Price Act, as amended, declared as one of its basic policy that the State shall ensure the availability of basic necessities and prime commodities at reasonable prices at all times without denying legitimate businesses a fair return on investment.

Section 10 of the same law provides that the Department of Health (DOH) as one of the implementing agencies, from time to time, may issue suggested reasonable prices for any or all basic necessities and prime commodities under its jurisdiction for the information and guidance of producers, manufacturers, traders, dealers, sellers, retailers and consumers. Further, it is also stated in that the the implementing agency has the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that it may deem necessary to care out the purposes of the said Act

On the basis foregoing, the Secretary of Health hereby authorizes the Department of Trade and Industry (DTI) to impose and enforce the SRP over any or all drugs or medicines or medical devices in carrying out the provisions of the said Act. The DOH deputizes and enlists the assistance of the DTI to conduct price monitoring and handle consumer complaints for violation of the Price Act pertaining to medicines and medical devices;

Given the above landscape on the price monitoring for essential drugs and medicines and medical devices in the 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:

- A. To establish the setting of SRPs of essential drugs and medicines and medical devices:
- B. To deputize the DTI to undertake and conduct price monitoring and surveillance of the Price Act pertaining to medicines or medical devices.
- C. To identify the roles and responsibilities of the different DOH offices and National Government Agencies (NGAs) involved in the implementation of the Price Act pertaining to medicines and medical devices.

III. SCOPE AND COVERAGE

This Order shall apply to offices and attached agencies under the DOH, Ministry of Health Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), Local Government Units, National Government Agencies, and all others concerned.

IV. DEFINITION OF TERMS

- A. **Basic necessities** refers to goods vital to the needs of consumers for their sustenance and existence in times of any of these cases provided under Section 6 of RA 7581 as amended.
- B. **Cartel** refers to any combination of or agreement between two or more persons engaged in the production, manufacturing, processing, storage, supply, distribution, marketing, sale or disposition of any basic necessity or prime commodities designed to artificially and unreasonably increase or manipulate its prices.
- C. Electronic Drug Price Monitoring System (EDPMS) refers to a computer-based solution with the functionalities to capture, process, store and generate reports on essential drug prices from drug companies, establishments and outlets.
- D. **Hoarding** refers to the undue accumulation by a person or combination of persons of any basic necessity or prime commodity beyond his/their normal inventory level, or the unreasonable limitation of or refusal to dispose, sell or distribute said commodities, or the unjustifiable taking out of said commodity from the channels of production, trade commerce and industry.
- E. Letter of inquiry refers to a letter issued to the establishments selling basic necessities and prime commodities, requiring an explanation or justification as to why the prices of above-stated goods are higher that what is indicated in the SRP.
- F. **Prime commodities** refers to goods not considered as basic necessities but are essential to consumers in times of any of the cases provided under Section 7 of RA 7581 as amended.
- G. **Profiteering** refers to the sale or offering for sale of any basic necessity or prime commodity at a price grossly in excess of its true worth. A price shall be deemed grossly in excess of its true worth if the price thereof has been raised by more than ten percent (10%) in the immediately preceding month.
- H. **Suggested Retail Price (SRP)** refers to the reasonable retail price of any or all basic necessities and prime commodities for the information and guidance of producers, manufacturers, traders, sellers, retailers and consumers.

V. GENERAL GUIDELINES

- A. The selection of medicines and medical devices to be put under SRP shall be premised upon conditions that address the country's public health needs and the needs of a particular health emergency situation.
- B. The following shall be the basis of the DOH to determine the SRPs of drugs and medicines nationwide:

- 1. Validated data from the Electronic Drug Price Monitoring System (EDPMS)
- 2. Procurement / purchase prices of public and private health facilities
- 3. Prevailing prices of the suppliers
- C. The DOH shall deputize the DTI to undertake and conduct price monitoring and handle consumer complaints on violations of the Price Act pertaining to medicines or medical devices. A Memorandum of Agreement (MOA) shall be agreed and signed to carry out the deputation.
- D. The DOH shall deputize the FDA to undertake the investigation on the alleged violations of the Price Act pertaining to medicines and medical devices.
- E. The DOH, in coordination with the Department of Trade and Industry (DTI) and other concerned government agencies, shall monitor, assess, and analyze the price movements of raw materials and other cost components of basic necessities and prime commodities as to its effect on the SRPs.

VI. SPECIFIC GUIDELINES

A. Setting of Prices:

- 1. The DOH shall determine SRPs of medical devices nationwide using prevailing market survey locally and globally, procurement or purchase price of private and public drug outlets.
- 2. For medicines with generic counterparts, prices are set based on the lowest to the median prices prevailing in the market. For medicines with no generic counterpart or where there are single brands in the market, prices are set based on the lowest price prevailing in the market.
- 3. The SRP of medicines and medical devices to be included in the list shall be imposed in all retail outlets whether public or private including drugstores and hospital pharmacies, convenience stores and supermarkets and the like.
- 4. The DOH shall require submission of documents from the manufacturers, distributors and retailers that are material in the review / audit of prices, if necessary.
- 5. The DOH shall conduct dialogues with manufacturers, retailers, and distributors on price and supply –related matters whenever necessary.
- 6. For purposes of monitoring and setting the SRP of drugs and medicines, all public and private drug retail outlets shall submit their prevailing market prices to the DOH through the Electronic Drug Price Monitoring System (EDPMS).
- 7. The DOH shall notify the CHDs, DTI, retailers and the general public of any adjustment in the SRPs of drugs and medicines and medical devices through a Department Circular, at least three (3) working days before its effectivity date.

8. The ABC for the procurement of drugs and medicines of the public health facilities shall in accordance with the latest policy of the Drug Price Reference Index while for the medical devices shall be based on the previous year's procurement provided that the ABC shall not exceed the current SRP issued.

B. Monitoring and Surveillance Activities:

- 1. The DTI shall be deputized to undertake monitoring and surveillance activities to confirm compliance with the latest SRP list set by the DOH or any subsequent issuances related thereto.
- 2. A valid deputation of the designated officers and employees of DTI, through FTEB, shall be in place to give force and effect to the subject Mission Order (MO) or Joint Mission Order (JMO), as the case may be.
- 3. A Mission Order (MO) or a Joint Mission Order (JMO), shall be issued by the Secretary of Trade and Industry or his/her authorized representative prior to the conduct of the abovementioned activities. (OR DTI SEC?)
- 4. The MO or JMO shall indicate the details as follows:
 - a. The date of the MO or JMO;
 - b. The deputized team of monitors;
 - c. The type of medicines or medical device to be monitored and its description;
 - d. The specific location of the establishment or premises subject of the visit or the monitoring activity;
 - e. The specific name/s and address/es to where the orders may be served, when applicable;
 - f. The period of validity of the MO or JMO to conduct the specified activity.
- 5. The MO or JMO shall have a validity period of one week or more, depending on the attending circumstances.
- 6. The MO or JMO shall not authorize the DTI to issue any letters of inquiry (LOI), notices, or order to monitored establishments.
- 7. The deputized DTI monitors shall carry with them the original or a certified true copy of the MO or JMO when conducting monitoring and surveillance activities.
- 8. A post-monitoring report (PMR) or a post-visitorial report (PVR), as the case may be, shall be prepared after every activity is conducted, and said report shall be submitted to the Secretary of Health within ten (10) working days from date of the actual activity. The prescribed forms herein attached as Annexes "A" and Annex "B", respectively, are made an integral part of this Agreement.

C. Enforcement Activities

- 1. DOH may call on the DTI to assist in conducting enforcement activities.
- 2. The enforcement team shall be headed by a DOH authorized personnel who shall discharge the following functions:
 - a. Serve the notice/warning to the respondent/s to observe compliance with the provisions of the *Price Act*;
 - b. Serve the visitorial order on the subject premises indicated in the complaint;
 - c. Serve the compliance order against the respondent/s.

- 3. A Mission Order (MO) or a Joint Mission Order (JMO), shall be issued by the Secretary of Health or his/her authorized representative prior to the conduct of the abovementioned activities which shall indicate the following:
 - a. The date of the MO or JMO;
 - b. The head of the enforcement team who shall be a DOH employee;
 - c. The members of the enforcement team from the DTI and DOH;
 - d. The type of medicines or medical device to be monitored and its description;
 - e. The specific location of the establishment or premises subject of the visit or the monitoring activity;
 - f. The specific name/s and address/es to where the orders may be served, when applicable;
 - g. The period of validity of the MO or JMO to conduct the specified activity.
- 4. The MO or JMO shall be issued quarterly.
- 5. The DOH lead and the DTI team members shall carry with them the original or a certified true copy of the MO or JMO when conducting enforcement activities.
- 6. A post-monitoring report (PMR) or a post-visitorial report (PVR), as the case may be, shall be prepared after every activity is conducted, and said report shall be submitted to the Secretary of Health within ten (10) working days from date of the actual activity. The prescribed forms herein attached as Annexes "A" and Annex "B", respectively, are made an integral part of this Agreement.

D. Investigation and Hearing

- 1. A subpoena and subpoena duces tecum shall be issued to compel the attendance of witnesses and the production of the necessary information, papers, and documents which it may deem necessary in the exercise of its powers and functions by the FDA;
- 2. Conduct an investigation of any alleged violation of the Price Act and its Implementing Rules and Regulations (IRR) and require submission of evidence material in the determination of the violation as provided in Section 10 (10) of the same Act;

E. Review and Monitoring of SRP:

- 1. Ensure that drug establishments and drug outlets, as defined in Administrative Order No. 2018-0020 or its latest policy, upload prices of essential drugs and medicines in the Monitoring Drug Establishments for Electronic Drug Price Monitoring System (EDPMS).
- 2. The existing list of medicines and medical devices under SRP shall be subject to review quarterly by the PD and shall recommend updating whenever necessary.
- 3. The DOH-PD and the DTI shall conduct supply chain studies to assess the reasonableness of the SRPs of medicines and medical devices.
- 4. The process flowchart for SRP monitoring and violations shall be found in Annex of this Order.

V. DUTIES AND RESPONSIBILITIES

The DOH, through the following offices, shall perform the following responsibilities:

1. Pharmaceutical Division

- Ensure that drug establishments and drug outlets, as defined in Administrative Order No. 2018-0020, upload prices of essential drugs and medicines in the Monitoring Drug Establishments for Electronic Drug Price Monitoring System (EDPMS);
- b. Provide the DTI with the latest list/information on the following:
 - i. Medicines and medical devices which are subjected to SRP; and
 - ii. Business establishments which need to be monitored by DTI
- c. May call on the DTI, upon request, in the conduct of enforcement activities;
- e. Adopt the existing policies on price monitoring of the DTI over any or all drugs as enumerated in the Price Act;

2. DOH - Centers for Health Development and Ministry of Health - BARMM

- a. Monitor the compliance of all drug outlets to the implementation of the SRP through the EDPMS;
- b. Disseminate IEC materials and/or information campaign related to the SRP; and
- c. Submit SRP violators to the FDA for investigation.
- d. Conduct regular price monitoring activities of medicines and medical devices under the SRP to be submitted to the FDA for verification.

3. DOH – Legal Service

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

4. The Food and Drug Administration

- a. Investigate alleged violations of drug outlets of SRP in accordance with RA 7581 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. Issue a letter of inquiry to the business establishments and health facilities covered under this Order that were monitored to be selling medicines and medical devices above the SRP; and,
- c. Conduct random on-site monitoring for SRP compliance in drug outlets.

The DTI, through the Fair Trade Enforcement Bureau, shall perform the following responsibilities:

- 1. Consolidate and submit to the Secretary of Health, through the Secretary of Trade and Industry, quarterly price monitoring reports on the list of medicines and medical devices under the latest SRP issuance;
- 2. Submit SRP violators to the FDA for investigation;
- 2. Conduct monitoring of prices of medicines and medical devices as enumerated and provided for under the latest updated SRP list issued by the DOH.

VI. PENALTIES AND SANCTIONS

Any person found to have committed any illegal act of price manipulation as defined and prohibited under Section 5 of RA 7581, as amended, shall be penalized administratively and criminally in accordance with Rule XII, Section 1 of DTI, DA, DOH, DENR Joint Administrative Order No. 1 Series of 1993 (Rules and Regulations Implementing RA 7581 – An Act Providing Protection to Consumers by Stabilizing the Prices of Basic Necessities and Prime Commodities and by Prescribing Measures Against Undue Price Increases During Emergency Situations and Like Occasions).

F. SEPARABILITY CLAUSE

If any provision or part hereof is held invalid or unconstitutional by a court of competent jurisdiction, the remainder of this Order or the provisions not otherwise affected shall remain valid and subsisting.

G. REPEALING CLAUSE

The provisions of previous Administrative Orders, rules, regulations, and other issuances of the DOH and DTI which are inconsistent with this Joint Administrative Order are hereby repealed, modified or amended accordingly.

H. 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.

RAMON M. LOPEZ

FRANCISCO T. DUQUE III, MD, MSc.

Secretary
Department of Trade and Industry

Secretary
Department of Health