

(DRAFT AS OF 11 DECEMBER 2020)

ADMINISTRATIVE ORDER

No. 2020 - _____

SUBJECT: **Mandatory Provision of Fairly Priced Generics in support of the Universal Health Care**

I. BACKGROUND / RATIONALE

Republic Act 112233 or otherwise known as the *Universal Health Care Act* states (Section 28.d Affordability) provides the government to require all drug outlets to carry the generic equivalent of all drugs at all times in the Primary Care Formulary and shall be required to provide customers with a list of therapeutic equivalents and their corresponding prices when fulfilling prescription or in any transaction.

According to the World Health Organization, medicines account for 20–60% of health spending in low- and middle-income countries, compared with 18% in countries of the Organization for Economic Cooperation and Development. Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food. As a result, medicines, particularly those with higher costs, may be unaffordable for large sections of the global population and are a major burden on government budgets. The Millennium Development Goals include the target: “[I]n cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries”.

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

To set the guidelines for the drug outlets to make available and offer fairly priced generic equivalents of drugs under the DOH Primary Care Formulary (PCF).

III. SCOPE

This Order applies to DOH Central Office bureau and units, attached agencies, DOH Centers for Health Development, Bangsamoro Autonomous Region of Muslim Mindanao (BARMM), and all drug outlets licensed under the Food and Drug Administration FDA).

IV. DEFINITION OF TERMS

1. **Drug Outlets** refers to Drugstores, Pharmacies or Botica, including Hospital Pharmacy / Dispensary, where registered drugs, chemical products, active principles, proprietary medicines or a pharmaceutical specialties and dental medicinal, galenical or veterinary preparations are compounded and/or dispensed.
2. **Drug Price Watch (DPW)** refers to the guide for the consumers on where to get the cheapest medicines within their area. For the consumers with no access to the publications, the DOH will also maintain the Drug Price Watch website to conveniently help consumers search and compare drug retail prices online using their computer.
3. **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.
4. **Fairly Priced Generic** refers to one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines.
5. **Generic medicine** refers to a pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights.
6. **Primary Care Formulary** refers to the list of essential medicines that is used in the primary care level that is prepared and periodically updated by the DOH.

V. IMPLEMENTING GUIDELINES

1. All drug outlets shall be required at all times to make available and offer fairly priced generic equivalent of all drugs in the DOH Primary Care Formulary (PCF) based on the local needs and prevailing disease patterns in the community.
2. All drug outlets shall carry generic equivalent medicines under the PCF based on the common mortalities and morbidities / local needs of the area of its jurisdiction.
3. No retailer or drug outlets shall withhold from sale or refuse to sell to the consumers fairly priced generic equivalents of drugs in the PCF.
4. The DOH shall issue a list of generic drugs in the PCF with their corresponding fair prices through the Drug Price Watch (DPW).

5. The DPW shall be the guide of the consumers on where to get the cheapest medicine within their area.
6. All drug outlets are required to upload their data in the Electronic Drug Price Monitoring System (EDPMS) based on the prescribed uploading schedule on the latest EDPMS issuance.
7. The EDPMS shall be the tool of the DOH on the list of all essential medicines including generic and branded medicines being sold in the market.
8. Prices in the DPW shall be validated and updated quarterly through the EDPMS.

VI. ROLES AND RESPONSIBILITIES

1. Pharmaceutical Division

- a. Set policies and guidelines relative to the drug outlets to make available and offer fairly priced generic equivalents of drugs under the PCF.
- b. Update and maintain the data in the EDPMS and DPW regularly
- c. Monitor the uploading rate of drug outlets in the EDPMS based on the submission of the Centers for Health Development

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

- a. Monitor the compliance of all drug outlets to the implementation of the DPW through the EDPMS;
- b. Disseminate IEC materials and/or information campaign related to the imposition of the DPW; and
- c. Submit non-compliance drug outlets to the FDA for investigation.

3. Food and Drug Administration

- a. Impose corresponding administrative sanctions as stipulated on the latest policy issuance of EDPMS;
- b. Investigate and when necessary, prosecute, hear and decide on administrative cases, subject to the imposition of administrative fines and penalties against drug outlets violating the provisions on the non-compliance in the EDPMS. Appeal on the decisions and the corresponding sanctions shall be filed with the Secretary of Health.

4. Drug outlets

- a. Comply with the standard operating procedures in uploading / submitting reports to the EDPMS.

VII. ADMINISTRATIVE SANCTIONS

Noncompliance to the abovementioned specific provision shall be subject to administrative sanctions under these Rules and relevant laws such as the RA 9711 or the FDA Act of 2009 and the administrative sanctions stated on the latest policy of the EDPMS.

VIII. 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.

IX. REPEALING CLAUSE

Other related issuances not consistent with the provisions of this Order are hereby revised, modified, or rescinded accordingly. All other provisions of existing issuances which are not affected by this Order shall remain valid and in effect.

X. 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

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