



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAY 11 2021

ADMINISTRATIVE ORDER
No. 2021 - 0035

SUBJECT: Mandatory Provision of Fairly Price Generics in support of the Universal Health Care Act

I. BACKGROUND / RATIONALE

As of 2018, out-of-pocket payments remain to be the top source of health expenditure at 53.9 percent (Philippine Statistics Authority, Philippine National Health Accounts), despite a 98% coverage rate of the projected population (PhilHealth, 2018).

Since the enactment of Republic Act No. 6675 or the Generics Act in 1988, the DOH has been actively promoting the use of generic medicines and consumer choice through drug transparency efforts. Despite ongoing efforts in ensuring the improved affordability of medicines, drug prices have continued to escalate in the country over the last decade. With this, challenges have been faced by both the consumer and the government in reducing out-of-pocket expenses even with the increasing investments on healthcare coverage.

Section 28(d) of the Republic Act 11223, or otherwise known as the *Universal Health Care Act* mandates that all drug outlets shall, at all times, carry the generic equivalent of all drugs in the Primary Care Formulary. Additionally, during the filling of prescriptions or any transactions, outlets are required to provide customers with a list of therapeutic equivalents together with their corresponding prices in a conspicuous location or in a booklet that must be updated regularly.

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) in accordance with RA No. 11054 of the Organic Law for Bangsamoro for Muslim Mindanao, and all drug outlets.

IV. DEFINITION OF TERMS

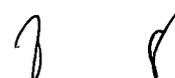
1. **Conspicuous place / location** refers to places which must be public, more or less permanently fixed, must be seen always or frequently noticeable.

A handwritten signature in black ink, appearing to be "J. S. J.", is written over the end of the first list item.

2. **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.
3. **Drug Price Watch (DPW)** refers to the consumer's guide that provides 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.
4. **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.
5. **Fair price** (as defined in the IRR of RA 9502) Unless otherwise stated by the Secretary of Health, fair price shall refer to the lowest price of an available quality, non-branded generic drug.
6. **Generic drugs / medicines** refer to a drugs/medicines that have the same active pharmaceutical ingredient as the innovator drugs and are not covered by patent protection. These drugs are labeled by their international non-proprietary or generic name and may or may not have brand names.
7. **Innovator or Comparator Drug** refers to a drug with an active pharmaceutical ingredient or molecule that was first or originally marketed anywhere in the world on the basis of documentation of quality, safety and efficacy by specific company or an entity which is expressed in its international non-proprietary name and usually carries a brand name. Such may be patented, non-patented or off patent.
8. **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.
9. **Philippine National Formulary (PNF)** refers to a list of essential drugs prepared and periodically updated by the DOH on the basis of health conditions present in the Philippines as well as on internationally-accepted criteria. It consists of a core list and a complementary list.

V. GENERAL GUIDELINES

1. All drug outlets shall be required at all times to make available and offer fairly priced generic equivalents of all drugs in the DOH PCF based on the common mortalities and morbidities, local needs and prevailing disease patterns in the community or the area of its jurisdiction.
2. 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.
3. The Drug Price Watch (DPW) shall be the guide of the consumers on where to get the cheapest medicine within their area.

4. The Electronic Drug Price Monitoring System (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.
5. Prices in the DPW shall be validated and updated as per the uploading schedule of the EDPMS.

VI. SPECIFIC GUIDELINES

1. The formulation of the PCF in the Province-wide and City-Wide Health System (P/CWHS) shall be informed based on common mortalities and morbidities, local needs and prevailing disease patterns in the community or area of its jurisdiction.
2. Essential medicines under the PCF shall be reviewed and updated periodically by the Health Technology Assessment Unit (HTAU) in coordination with the Pharmaceutical Division (PD) based on succeeding operational guidelines.
3. The corresponding fair prices of the medicines under the PCF shall be the lowest price of an available quality, non-branded generic drug.
4. All drug outlets shall upload their data in the EDPMS based on the prescribed uploading schedule on the latest EDPMS issuance.
5. The DOH shall issue a list of generic drugs in the PCF with their corresponding fair prices through DPW (<https://dpw.doh.gov.ph/>).
6. The list of the fairly priced generics shall be reviewed and updated annually through the DPW by the PD.
7. For any amendment in the medicines under the PCF (inclusion / deletion), an advisory shall be issued by the DOH for the reference of drug outlets.

VII. ROLES AND RESPONSIBILITIES

1. The **DOH Pharmaceutical Division** shall:
 - a. Update the list of the medicines under the PCF in coordination with HTAU;
 - b. Issue a list of generic medicines under the PCF with fair prices;
 - c. Update and maintain the data in the EDPMS and DPW regularly; and
 - d. Monitor the uploading rate of drug outlets in the EDPMS based on the submission of the Centers for Health Development.
2. The **DOH Health Technology Assessment Unit** shall review the medicines to be included in the PCF.
3. The **DOH Centers for Health Development** and the **Ministry of Health – BARMM** shall:
 - 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 to the FDA non-compliance drug outlets to the EDPMS for investigation.

8/3/20

4. **The Food and Drug Administration shall:**

- 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 to the EDPMS.

5. **The Drug Outlets shall comply with the standard operating procedures in uploading / submitting reports to the EDPMS.**

VIII. ADMINISTRATIVE SANCTIONS

Noncompliance to the abovementioned specific provision shall be subject to existing rules and administrative sanctions as stipulated in Republic Act 11223 (UHC Act) and other relevant laws, such as the RA 9711 (FDA Act of 2009), RA 9502 (Cheaper Medicines Act of 2008) and RA 7394 (Consumer Act of the Philippines).

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. TRANSITION PERIOD

To give the drug outlets an ample time to make the supplies available in their outlets, this Order shall be implemented one (1) year after the generic medicines in the PCF with their corresponding fair prices through the Drug Price Watch (DPW) has been published.

XI. 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