FDA CIRCULAR
No. _____

SUBJECT : Guidelines on Labeling Requirements of Drug Products under Maximum Retail Price (MRP)

I. BACKGROUND

It is the policy of the state to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all. Chapter 3, Section 26(a) of Republic Act (RA) No. 9502 entitled "Universally Accessible Cheaper and Quality Medicines Act of 2008" stipulated that every drug product that is subject to price regulation shall reflect the retail price which shall not exceed the maximum retail price. To achieve the goal of this law to promote and ensure access to affordable quality drugs and medicines for all, Executive Order (EO) No. 821 s. 2009 "Prescribing the Maximum Drug Retail Prices for Selected Drugs and Medicines that Addresses Diseases the Account for the Leading Causes of Morbidity and Mortality", was issued wherein 5 drug molecules or 27 drug formulas are subjected to price regulation. The list of drug product under Maximum Retail Price (MRP) was expanded into 122 drug molecules or 205 drug formulas under EO No. 104 s. 2020. On 07 December 2021, EO No. 155 s. 2021 was issued for further improving access to healthcare through the regulation of prices in the retail of drugs and medicines and repealing EO No. 821 s. 2009. The price regulation through MRP under EO No. 155 shall be imposed on the additional 34 drug molecules or 71 drug formulas.

Section VII, 6.c of Administrative Order (AO) No. 2020-0039 "Guidelines in the Implementation of Maximum Retail Price (MRP) on Drugs and Medicines" states that the Food and Drug Administration (FDA) shall issue labeling requirement guidelines for MRP medicines. Relative to this, AO No. 2016-0008 "Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use" stipulated the minimum mandatory requirements that shall be required to appear on the label of products under MRP.

To reduce the regulatory burden in the application and approval of the inclusion or update of the MRP statement to the labeling materials of drug products, this Circular is hereby issued.

II. OBJECTIVES

To provide a streamlined and rational application process for the change of labeling materials of drug products under MRP.

III. SCOPE

This shall apply to all licensed drug manufacturers, traders, and distributors of drugs products under MRP.

IV. GUIDELINES

A. The following MRP statement shall be printed on the primary and secondary packaging label of the drug product on a red strip (red background or red font) following Section VI.B.7 of AO No. 2016-0008:

UNDER DRUG PRICE REGULATION
RETAIL PRICE NOT TO EXCEED *[PRICE]*

OR

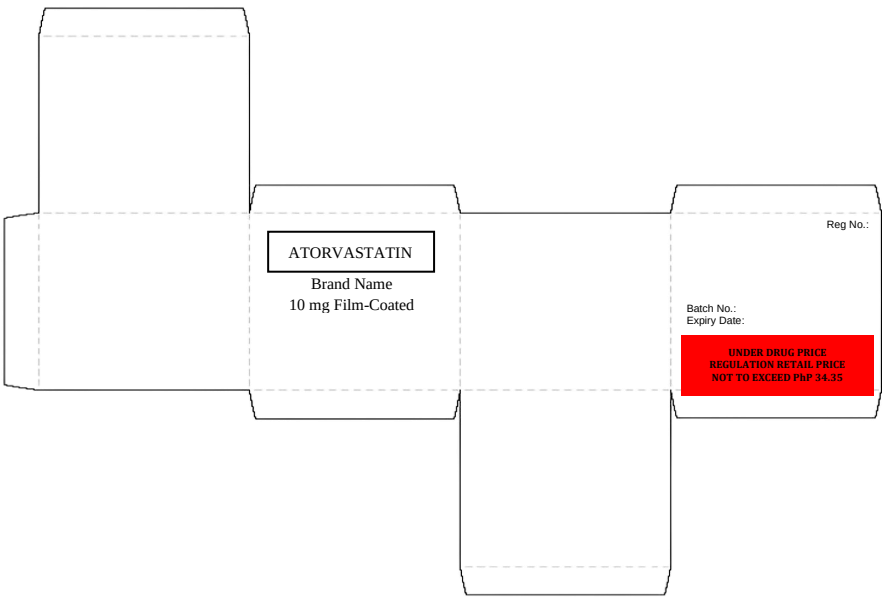
UNDER DRUG PRICE REGULATION
RETAIL PRICE NOT TO EXCEED *[PRICE]*

OR

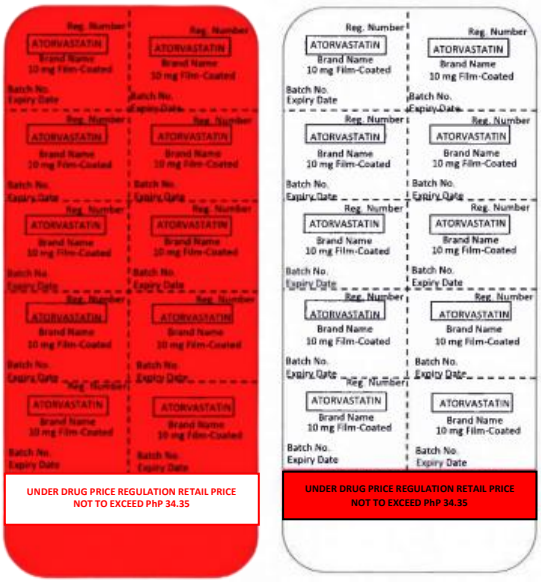
UNDER DRUG PRICE REGULATION
RETAIL PRICE NOT TO EXCEED *[PRICE]*

Example:

SECONDARY PACKAGING



PRIMARY PACKAGING



For primary label such as blister pack/foil strip, MRP statement shall be printed on every standard blister pack/foil strip. This shall exclude drug products in small containers.

B. Existing registered drug products shall follow FDA Circular No. 2016-017 "Additional Post-Approval Changes for Pharmaceutical Products". The following documentary requirements shall be submitted for applications of Minor Variation-Notification [MiV-PH-N1] for the change or inclusion of the price or MRP statement:

1. Notarized Application Form – Notification for Minor Variation/s of Registered Pharmaceutical Product
2. Integrated Application Form (IAF) in excel format
3. Portable Document Format (PDF) copy of the signed IAF
4. Electronic copy of the complete documentary requirements and pertinent evidences supporting the changes (currently approved and proposed labeling materials)
5. Declaration, signed by the Head of the Regulatory Office, that there is no other changes except for the proposed variation; and
6. Proof of payment

C. Drug products for registration (New Drug under Monitored Release, Initial, and Drug Product for Emergency Use) shall bear the MRP statement in the labels upon submission of the application.

V. TRANSITION PERIOD

Registered drug products under the prescribed MRP shall be given one (1) year exhaustion period of old labeling materials at the manufacturing level after the effectivity of this Circular.

Drug molecules or drug formula that will be included in succeeding EO of MRP shall likewise be given one (1) year from effectivity of the EO to transition to the provisions of this issuance and exhaust old labeling materials at the manufacturing level.

VI. PENALTY

Violations of this Circular shall warrant the application of the penalties under the applicable provisions of RA No. 9711 and RA 9502 and the Implementing Rules and Regulations thereof.

VII. SEPARABILITY CLAUSE

If any provision in this Circular or application of such provision to any circumstances is held invalid, the remainder of the provisions in this Circular shall not be affected.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) calendar days after publication in one (1) newspaper of general circulation and upon filing with the University of the Philippines, Office of the National Administrative Register (ONAR).

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