

Republic of the Philippines Department of Health

OFFICE OF THE SECRETARY

21 July 2016

DEPARTMENT MEMORANDUM

No. 2016- 0258

FOR:

ALL DIRECTORS OF BUREAUS AND REGIONAL OFFICES,

SECRETARY OF HEALTH DOH-ARMM; CHIEFS OF

MEDICAL CENTERS, HOSPITALS AND SANITARIA; AND

OTHERS CONCERNED

SUBJECT:

Further clarification and guidance on the bidding specifications of

solid oral dosage forms (tablets) in the Philippine National

Formulary (PNF)

This is to inform everyone that, as per clarification and recommendation of the Food and Drug Administration (FDA), the bidding of **TABLET** shall be open to both uncoated and coated (film- and sugar-coated) tablets, unless otherwise specified in the PNF.

On the other hand, for the bidding of the following solid oral dosage forms, the specific type of tablet should be clearly reflected in the purchase request:

- 1. film-coated tablets:
- 2. soluble tablets:
- 3. dispersible tablets;
- 4. effervescent tablets:
- 5. chewable tablets:
- 6. tablets for use in the mouth (including orally disintegrating, sublingual and buccal tablets); and
- 7. modified-release tablets (including delayed-release tablets (gastro-resistant/enteric-coated tablets) and sustained-release tablets (extended-/prolonged-release tablets)).

For urgent and strict implementation.

PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II

Secretary of Health



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



15 July 2016

MEMORANDUM

FOR

: AGNETTE P. PERALTA, MSc, CESO III

OIC- Undersecretary of Health Office for Health Regulation

cc:

ANNA MELISSA S. GUERRERO, MD, MPH (HTA)

Division Chief

Pharmaceutical Division

FROM

M.ZAMUDIO, RPh, MGM-ESP MELODY

OIC. Center for Drug Regulation and Research

SUBJECT:

Comment on Department Memorandum No. 2015-0286:

Clarification on the Solid Oral Dosage Form (Tablet) in the

Philippine National Formulary

This has reference to your request for clarification on the interchangeability of all tablet forms, in connection with the comment of the Philippine Children's Medical Center on the abovementioned issuance.

Respectfully informing your Office that tablets may vary in disintegration, dissolution, and release characteristics depending on their intended use. Not all of the tablet forms listed in the said memorandum can be used interchangeably as some are immediate-release (uncoated, film-coated, or sugar-coated) while some are modifiedrelease which include extended-release (also known as controlled-release, prolongedrelease, and sustained-release) and delayed-release products. As per the 19th edition of the World Health Organization Model List of Essential Medicines, the term 'tablet' without qualification is never intended to allow any type of modified-release tablet. In addition, the mode of administration differ among the tablet preparations stated in the Memorandum.

In this regard, the proposed amendment to the said Memorandum, as attached, is positively recommended so as to avoid possible confusion and misinterpretation relative to the proper procurement of the said products.

We hope this clarifies our position on the matter.

For your information and guidance.

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