FDA CIRCULAR
No. 2023-008

18 AUG 2023

SUBJECT : **Guidelines on the Publishing of Package Insert and Patient Information Leaflet of Registered Drug Products in the Food and Drug Administration (FDA) Verification Portal System**

I. BACKGROUND

Article I Section 2 of the Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" states the declaration of the policy to establish and improve processes that are designed to protect and promote the right to health of the Filipino people. Such processes shall include ensuring immediate access to the list of approved drug product information, including but not limited to approved indications, and known adverse effects, among others.

Administrative Order (AO) No. 2016-0008 entitled "Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use" and AO No. 105 s. of 1991 entitled "Requirement for Labelling Materials of Veterinary Drugs and Products" provide comprehensive guidelines for labeling requirements, such as contents, formats and mandatory information required in labeling materials [e.g., package insert (PI) and patient information leaflet (PIL)] for human and veterinary drug products. These PI and PIL are public documents readily available and intended to be accessed by Healthcare Professionals (HCPs) and general consumers as primary sources of information about the drug. They provide useful information such as those dealing with the safe and effective use of a drug product (e.g., indication(s), pharmacologic class and dosage), and information dealing with quality.

The FDA, in its commitment to provide stakeholders with improved government services and access to registered drug product information, hereby issues this Circular to further guide all HCPs and general consumers of the Summary of Product Characteristics (SPC) – like information of registered drugs. Thus, publication of SPC-like information shall ensure accessibility, transparency, and promotion of improved patient safety to the general public.

II. OBJECTIVES

This Circular shall provide guidelines to all Marketing Authorization Holders (MAHs) of drug products on the publishing of the package insert and patient information leaflet of registered drug products.

This Circular shall also provide the healthcare professionals and consumers with the latest information on drug safety and use, through PI and PIL publication on the FDA Verification Portal System.

III. SCOPE

This Circular shall apply to the following:

1. Marketing Authorization Holders and other drug establishments;
2. Healthcare professionals;
3. Patients of drug products

IV. DEFINITION OF TERMS

For the purpose of this issuance, the following terms shall be defined as follows:

A. Facsimile / Soft copy refers to the exact copy of package insert and patient information leaflet.

B. Package Insert (PI) is the document defining information that is supplied with prescription drug products by the MAH. The PI is intended for use by healthcare professionals.

C. Patient Information Leaflet (PIL) is the document defining information that is supplied with non-prescription drug products by the MAH. The PIL is intended for use by patients and is written in layman's language.

D. Summary of Product Characteristics (SPC) is the product information as approved by the regulatory authority. It also serves as the source of information for healthcare professionals as well as for consumer information on labels and leaflets of drug products, and for control of advertising.

E. SPC-like Information refers to documents such as package insert and patient information leaflet.

F. FDA Verification Portal is the online portal that provides comprehensive list of establishments and health products with License to Operate (LTO) and Certificate of Product Registration/Notification (CPR/NN), respectively. This is the public's access to safe and quality commodities in the market.

V. GUIDELINES

A. Approved PI and PIL of all registered drug products shall be published by the FDA in the Verification Portal System at https://verification.fda.gov.ph and shall be updated monthly.

B. All MAHs of existing registered drug products prior to the effectivity of this Circular shall submit the facsimile/soft copy of the latest approved package insert or patient information leaflet through email at cdrr.label@fda.gov.ph with the following details:
    1. Subject of email: PI/PIL for Posting [Drug Registration No.]
    2. PI/PIL in readable PDF format
    3. Date of Revision indicated in the PI/PIL

C. The MAH shall ensure that the format of the Summary of Product Characteristics (SPC)-like information shall be compliant with AO No. 2016-0008 and AO No. 105 s. 1991 and/or any amendment or new issuances.

D. Upon effectivity of this Circular, the FDA shall publish the PI/PIL of the newly approved drug products.

VI. TRANSITION PERIOD

MAHs of all existing registered drug products upon the effectivity of this Circular shall submit the latest approved facsimile/soft copy of PI and PIL following the respective schedules provided below:

A. Monitored Release Status (Chemical/Biological) – within 2 months from the effectivity of this Circular
B. Generic Prescription drug – within the 3rd to 8th month from the effectivity of this Circular
C. Biologicals – within the 9th month from the effectivity of this Circular
D. Over-the-counter drug – within the 10th to 12th from the effectivity of this Circular
E. Traditional Medicine/Herbal Medicine/Home Remedy/Veterinary drug – within the 13th month from the effectivity of this Circular

VII. PENALTY CLAUSE

Any establishment found to be in violation of the provision of this issuance shall be subject to sanctions and penalties as prescribed under RA No. 9711 otherwise known as "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations"

VIII. SEPARABILITY CLAUSE

If any part, term of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term or provision.

IX. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and be filed with the University of the Philippines Law Center Office of the National Administrative Register (ONAR).

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Director General