FDA CIRCULAR
No. 2024-002

15 MAR 2024

SUBJECT : **Recall and Withdrawal of the Classification and Registration of Topical Corticosteroids as Over-the-Counter and Household Remedy Drug**

I. BACKGROUND

It is the policy of the State to promote and protect the right to health of the people and instill health consciousness among them. In the implementation of the foregoing policy, the Food and Drug Administration (FDA), in accordance with the provisions of Republic Act (RA) No. 3720, as amended by Executive Order (EO) No. 175 and further amended by RA No. 9711, is mandated to adopt measures to ensure pure, safe, efficacious and good quality drugs and devices in the country, and the rational use of drugs and devices, such as, but not limited to, banning, recalling or withdrawing from the market drugs and devices which are not registered, unsafe, inefficacious or of doubtful therapeutic value.

Topical corticosteroids are used to treat the symptoms of many skin disorders, such as eczema, dermatitis, and psoriasis. These drug products play a major role in the treatment of many dermatologic conditions. Topical corticosteroids may be dispensed either by its classification, prescription, Over-the-Counter (OTC) and Household Remedy (HR). OTC and HR drug products are accessible to the general public as these drugs are sold without physician's prescription.

The FDA conducted a literature review to assess the safety of Topical Corticosteroids considering regulatory actions made by other countries. On 02 September 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) of United Kingdom released a drug safety update on the Risk of Topical Steroid Withdrawal (TSW) from misuse and abuse (prolonged, frequent and inappropriate use of moderate to high potency corticosteroids, especially on the face and genital area) reactions after long-term continuous or inappropriate use of moderate to high potency products. To reduce the risk of these events, topical corticosteroids should be prescribed on its lowest potency and ensure that the patients are informed on the safe and effective use of these drug products.

Section 4 of Administrative Order (AO) No. 23-C s. 2000 entitled "Policies and Guidelines on Over-the-Counter (OTC) Drug Products" states that the Secretary of Health, through the Director General of the FDA shall retain the authority to recall and withdraw the approval of the classification as OTC of a drug product in the event of any documented and verified adverse reactions endangering public health and safety.

The FDA, in its commitment to guarantee the safety, quality, purity, and efficacy of registered health products to the general public, hereby issues this Circular recalling and withdrawing the classification and registration of existing Topical Corticosteroid as OTC/HR drug for guidance of the Marketing Authorization Holders (MAHs).

II. OBJECTIVE

This Circular aims to recall and withdraw the classification and registration of existing registered Topical Corticosteroid products as OTC drug.

Specifically, this Circular shall provide guidelines in the submission of labeling materials and additional requirements for Topical Corticosteroid products under initial and renewal applications as Prescription drug.

III. SCOPE

This shall apply to all MAHs, licensed drug manufacturers, traders, distributors, retail drugstores, healthcare professionals, and advertisers of Topical Corticosteroid.

IV. DEFINITION OF TERMS

A. **Topical Corticosteroids (TCs)** are drug products used for the relief of the inflammatory and pruritic manifestations of various dermatoses, including eczema, dermatitis and psoriasis.
B. **Topical Steroid Withdrawal (TSW)** refers to a mixed group of symptoms that has also been referred to as topical steroid addiction, red skin syndrome or steroid dermatitis.
C. **Processed Application** refers to an application that has been evaluated and a decision or outcome has been determined.
D. **On-going Application** refers to an application that is currently in active phase of evaluation.

V. GENERAL GUIDELINES

A. All topical corticosteroids shall be classified as Prescription drug considering the associated risks identified on the use of this drug.

B. All currently registered topical corticosteroid as OTC/HR drug shall be reclassified as Prescription drug.

1. The MAH shall recall existing inventory of their products.
2. The MAH shall update the labeling materials and package inserts to reflect the information on the misuse and abuse that will result to TSW. The information shall be reflected under Contraindications and Special Warnings and Precautions.
3. MAHs that have not yet revised the package inserts in relation to the above safety concern shall submit a variation application and the following statement shall be printed on the package insert:

Special warnings and precautions for use:

Misuse, abuse, and abrupt stop of topical corticosteroids result in ***Topical Steroids Withdrawal*** *(TSW) (*"***Topical Steroid Addiction***" *or* "***Red Skin Syndrome***"*. It results from prolonged (usually more than 12 months), frequent, and inappropriate use of moderate to high potency topical corticosteroids, especially on the face and genital arca. Several different medical conditions that can result from excessive Topical Corticosteroids (TCs) use were identified such as atrophy, rosacea, acne, perioral dermatitis and symptoms includes redness of the skin, burning sensation, followed by skin peeling, which appears to be distinct from a flare-up of the underlying condition. The signs and symptoms occur within days to weeks after TCs discontinuation.*

4. A new Certificate of Product Registration (CPR) shall be issued to reflect changes in classification from OTC/HR to Prescription drug.
5. Distribution of Dear Healthcare Professional (DHCP) Letter is subject to the MAH's initiative on disseminating safety information.

C. Receiving of any application for registration and other related actions for topical corticosteroids shall be based according to existing regulations on Prescription drugs.

D. All Post-Marketing Surveillance (PMS) activities shall be implemented accordingly.

VI. SPECIFIC GUIDELINES

A. Topical Corticosteroid with existing CPR as OTC/HR drug

1. Recall notification shall be submitted by the MAH

a. All MAHs of existing topical corticosteroids shall submit the notification through email at fdac.letters.cdrr@fda.gov.ph with the Subject: Recall (Reclassification of Topical Corticosteroid from OTC/HR to Rx)
b. Notification shall indicate existing stock inventory and distribution record list.
c. Facsimile of Rx stick-on label for primary and secondary labels shall be submitted.
d. Relabeling for existing inventory and recalled products shall be allowed for stickering of the Rx symbol.
e. An exhaustion period for one (1) year until retail level shall be allowed for relabeled products.
f. Any excess printed OTC/HR label shall undergo inventory and appropriate destruction.

2. The MAHs of Topical Corticosteroids shall apply for variation (MaV-2) for labeling changes and surrender their CPR to reflect the Prescription classification.
3. Any advertisement and/or sales promotion of Topical Corticosteroid shall be discontinued, accordingly.

B. Topical Corticosteroid under Initial Application as OTC/HR

1. Processed Application
   a. The Center for Drug Regulation and Research (CDRR) shall issue an electronic-Notice of Deficiencies (e-NOD) to MAH requiring to submit facsimile of labeling materials as prescription drug within 20 working days.
   b. The CDRR will issue the CPR once revised labeling materials are submitted and a Post-Approval Commitment (PAC) letter requiring the MAH to submit additional requirements as prescription drug within one (1) year.
2. On-going Application
   The CDRR shall issue an e-NOD requiring the MAH to submit revised labeling materials as prescription drug within 20 working days and a PAC letter for additional requirements as prescription drug within one (1) year.

C. Topical Corticosteroid under Renewal Application as OTC/HR

The CDRR shall issue an e-NOD requiring the MAH to submit revised labeling materials as prescription drug within 20 working days and a PAC letter for the additional requirements as prescription drug within one (1) year.

As part of the PAC letter, the MAH shall submit the Bioavailability (BA)/Bioequivalence (BE) studies for Topical Corticosteroid within three (3) years after the effectivity of this Circular.

All applications for Topical Corticosteroids affected by this Circular shall be facilitated.

VII. 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.

VIII. PENALTY

Those found in violation of the provisions of this Circular shall be penalized under RA No. 9711, and other applicable laws.

IX. EFFECTIVITY DATE

This Circular shall take effect immediately due to imminent danger to public health, safety, and welfare, and to be published in a newspaper of general circulation and filed with the University of the Philippines – Office of the National Administrative Register (UP-ONAR).

DR. SAMUEL A. ZACATE
Director General