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RECLASSIFICATION AND REVISION IN THE USE OF HYDROQUINONE AND/OR TRETINOIN (RETINOIC ACID) PREPARATIONS

DOH ADMINISTRATIVE ORDER NO. 90, SERIES OF 2003, September 18, 2003

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The existing rules and regulations governing the use of Hydroquinone and/or Tretinoin (Retinoic Acid) Preparations were rationalized, re-examined and reviewed in the light of recent clinical studies and changing consumer preferences and practices.

Therefore, in accordance with the provisions of Republic Act No. 3720, as amended, otherwise known as the Food, Drugs, Devices and Cosmetics Act, the use of Hydroquinone and/or Tretinoin (Retinoic Acid) Preparations are hereby reclassified and revised as follows:

A. All preparations containing Hydroquinone as the only active ingredient with the corresponding concentrations are classified as:

- HOUSEHOLD REMEDIES - for preparations containing less than or equal to two percent (2%) Hydroquinone. They can be dispensed without the supervision of a licensed pharmacist;

- OVER-THE-COUNTER DRUGS - for preparations containing more than two percent (2%) but less than or equal to four percent (4%) Hydroquinone. They must be dispensed under the supervision of a licensed pharmacist;

- PRESCRIPTION DRUGS - for preparations containing more than four percent (4%) but less than five (5%) Hydroquinone. They must be dispensed only by licensed pharmacists of registered drug outlets upon the presentation of proper prescription;

- NOT-REGISTRABLE - for preparations containing five percent (5%) or more Hydroquinone. They are not allowed and are prohibited from being registered.

B. All preparations containing Tretinoin (Retinoic Acid) as the only active ingredient with the corresponding concentrations are classified as:

- HOUSEHOLD REMEDIES - for preparations containing less than or equal to 0.025% Tretinoin for gels and lotions, and 0.05% Tretinoin for creams. They can be dispensed without the supervision of a licensed pharmacist;

- PRESCRIPTION DRUGS - for preparations containing more than 0.025% Tretinoin for gels and lotions, and 0.05% Tretinoin for creams. They must be dispensed only by licensed pharmacists of registered drug outlets upon the presentation of proper prescription;

C. All preparations containing combinations of Hydroquinone and Tretinoin (Retinoic Acid) as the active ingredients with the corresponding concentrations are classified as:

- HOUSEHOLD REMEDIES - for preparations containing combinations of:

(a)

less than or equal to two percent (2%) Hydroquinone, and

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(b)

less than or equal to 0.025% Tretinoin for gels and lotions, and 0.05% Tretinoin for creams.

They can be dispensed without the supervision of a licensed pharmacist;

- OVER-THE-COUNTER DRUGS - for preparations containing combination of:

(a)

more than two percent (2%) but less than or equal to four percent (4%) Hydroquinone, and

(b)

less than or equal to 0.025% Tretinoin for gels and lotions, and 0.05% Tretinoin for creams.

They must be dispensed under the supervision of a licensed pharmacist;

- PRESCRIPTION DRUGS - for preparations containing combinations of:

(a)

more than four percent (4%) but less than five percent (5%) Hydroquinone, and

(b)

more than 0.025% Tretinoin for gels and lotions, and 0.05% Tretinoin for creams.

They must be dispensed only by licensed pharmacists of registered drug outlets upon the presentation of proper prescription.

Appropriate labeling as to their proper use, and adequate warnings as to their possible local or systematic adverse effects or reactions, must be clearly indicated for all approved products with Hydroquinone, Tretinoin (Retinoic Acid), or any combinations thereof.

All other administrative issuances or parts thereof, inconsistent with the provisions of this Order are hereby amended, modified, repealed and/or revoked accordingly.

This Order shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Adopted: 18 September 2003

(SGD.) MANUEL M. DAYRIT, M.D., MSc.
Secretary of Health

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