

Therapeutic Products Directorate
Holland Cross, Tower "B"
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To:

Provincial and Territorial Deputy Ministers of Health
Provincial and Territorial Drug Program Managers
Deans of Pharmacy
Registrars of Provincial Medical and Pharmacy Associations
Industry and Consumer Associations
Regulatory and Health Professional Associations
Other Interested Parties

Dear Sir/Madam:

Re: **Amendment to the *Food and Drug Regulations* - Schedule 1421 - clobetasone**

This is to provide you with an opportunity to comment on the Therapeutic Products Directorate's proposal to allow an exemption from the requirements of Schedule F to the *Food and Drug Regulations* for 0.05% clobetasone butyrate in a cream formulation for topical use on the skin. All strengths and dosage forms of clobetasone are currently included in Part II of Schedule F within the listing:

Adrenocortical hormones and their salts and derivatives,
(except hydrocortisone or hydrocortisone acetate, when sold as a single medicinal ingredient in a concentration that provides 0.5% hydrocortisone in preparations for topical use on the skin)

Schedule F is a list of medicinal ingredients, the sale of which are controlled specifically under sections C.01.041 to C.01.049 of the *Food and Drug Regulations*. Part I of Schedule F lists medicinal ingredients that require a prescription for both human and veterinary use. Part II of Schedule F lists medicinal ingredients that require a prescription for human use, but do not

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require a prescription for veterinary use if so labelled or if in a form unsuitable for human use.

Clobetasone, applied topically, is indicated in the treatment and control of patches of eczema (an itching disease of the skin, characterized by dry, flaky skin) and dermatitis (inflammation of the skin). It is classified as a moderately potent corticosteroid. Two mild topical corticosteroids, hydrocortisone and hydrocortisone acetate (both containing the equivalent of 0.5% hydrocortisone), are currently available as nonprescription drugs and indicated for temporary relief of minor skin irritations, itching and redness due to eczema and dermatitis.

Nonprescription status of clobetasone would provide a more active substance that is more likely to effectively treat itchy, red, dry and inflamed skin to clear the flare-up and to break the itch-scratch cycle of eczema and dermatitis. The nonprescription availability of clobetasone would enable sufferers of eczema and dermatitis to control mild to moderate outbreaks of their skin condition before it deteriorates and becomes more difficult to treat. If such conditions are not treated promptly, they may result in skin infections and other conditions that may require the intervention of a physician.

Clobetasone was approved as a nonprescription product in the UK in 2001, and in Australia and Hong Kong in 2002. The safety and effectiveness of clobetasone as a prescription product have been established. Topical preparations of clobetasone have been widely used over many years without any serious or untoward effects.

The proposed nonprescription product would have identical strength, dosage form and route of administration to the prescription product, however, certain restrictions on its use have been proposed to help ensure that consumers would use the product appropriately. These restrictions would be included in the labelling.

Nonprescription clobetasone would be indicated for use in a more limited range of skin conditions than the prescription product. Also, the age range of the target population would be restricted to adults and children aged 12 years and over. Use of the product on certain areas of skin and on broken or infected skin would be excluded to avoid confusion with other skin conditions. In addition, duration of treatment and package size would be limited.

The proposal to remove clobetasone 0.05% in a cream formulation for topical use on the skin from Schedule F is based on a review of the clinical evidence and safety data provided in a supplemental New Drug Submission. It has been concluded that the benefits of having clobetasone 0.05% available as a nonprescription drug outweigh the potential risks.

Any comments regarding this proposed amendment should be addressed to Heather Van Dusen, Policy Division, Policy Bureau, Therapeutic Products Directorate, 1600 Scott Street, Holland Cross, Tower 'B', 2nd Floor, Address Locator 3102C5, Ottawa, Ontario, K1A 1B6, by facsimile at 613-941-6458 or by email to Heather_Van_Dusen@hc-sc.gc.ca within **thirty days**.

Yours sincerely,

Robert G. Peterson, M.D. PhD. MPH
Director General