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POLICY STATEMENT

Advertising Campaigns of Branded and Unbranded Messages

Health Canada recently conducted an investigation on an advertising campaign directed to consumers involving the dissemination of branded and unbranded messages for a prescription drug. In the advertising campaign, branded messages provided the name of the prescription drug with no mention of its use and unbranded messages, discussed the therapeutic indication without naming the drug.

Health Canada reviewed the advertising campaign with respect to the application of *Section C.01.044 (1)* of the *Food and Drug Regulations* and associated Health Canada guidelines and policies, in particular, *The Distinction Between Advertising and Other Activities*. Health Canada concluded that the Direct-to-Consumer campaign, as a whole, did constitute a violation of *C.01.044 (1)* of the *Food and Drug Regulations*. In order to provide guidance to independent preclearance advertising agencies for future opinions in this area, the following elements should be considered:

Canada's *Food and Drugs Act*, (*FDA*) defines "advertisement" to include "*any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device*". *Section C. 01.044* of the *Food and Drug Regulations* requires that advertising of prescription medicines (e.g. drugs listed in *Schedule F of the Regulations*) be limited to the drug's name, price and quantity:

C.01.044. (1) Where a person advertises to the general public a *Schedule F Drug*, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.

Applying this definition and rule, a drug firm cannot **combine** promotional information on a specific prescription only drug and a particular disease or condition in a single advertisement. Further, if a typical consumer could easily link two announcements and the messages contained in such announcements taken together similarly contravene this prohibition then the airing of such announcements sufficiently close in time is also prohibited by the rule. A sponsor seeking to broadcast non-branded messages discussing treatments and branded messages identifying a prescription drug product in question concurrently, would contravene *Section C.01.044 of the Regulations*.

Health Canada recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access non-promotional information regarding drugs for human use. The policy "*The Distinction Between Advertising and Other Activities*", issued in 1996 (http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/actv_promo_vs_info_e.html) is intended to fulfill the need for guidance on the distinction between advertising and non-promotional activities. The purpose of the above-mentioned policy is to set the limits between information and advertising. This policy does not explicitly address the issue of advertisements which may be aired consecutively or simultaneously. However, it does express that no one factor in itself will determine whether or not a particular message is advertising. The content and the context in which a message is disseminated must be evaluated.

Therefore, even though the individual ads, taken independently, met the *Food and Drugs Act and Regulations*, as a whole (unbranded and branded messages), the campaign was considered to contravene the *Food and Drugs Regulations*. When a particular information piece can be characterized as part of a larger campaign that **combines** promotional information on a specific prescription only drug and a particular disease or condition in a single advertisement then it may be part of a larger set of activities that can be argued to constitute a violation of these Regulations.

In the Direct-to-Consumer campaign, the fact that similar context, style, music and actors were used in both the unbranded and branded messages was taken into consideration.

The sponsor was advised that the basis for Health Canada's decision must be considered when developing future advertisements.