

Confusion in Drug and Health Product Names:

Health Canada's New "Look-Alike, Sound-Alike" Policy

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Manufacturers who wish to sell drug and health products in Canada may need to revisit their branding strategies as a result of Health Canada's new policy regarding the premarket regulatory approval process. The new policy, entitled "Drug Name Review: Look-alike Sound-alike Health Product Names,"¹ is Health Canada's response to concerns about the medical risks associated with "look-alike, sound-alike" (LA/SA) names for drugs and other health products. Before this new policy was introduced, these concerns were generally dealt with informally on a case-by-case basis.²

LA/SA names refer to names that are similar when written or spoken. The concern is that such orthographic and phonetic similarities create confusion between two or more product names, which could lead to errors when prescribing, dispensing, or administering the products.

Health Canada's new LA/SA Policy took effect January 1, 2006, with respect to brand or proprietary names for drugs—that is, Schedule C drugs (radiopharmaceuticals), Schedule D drugs (biologics), Schedule F drugs (prescription drugs), and prescribed drugs for human use.³ Over-the-counter drugs, natural health products,⁴ veterinary drugs, and medical devices are scheduled to become subject to the policy on July 1, 2006.

The Food and Drug Administration (FDA) reviews only proposed brand (proprietary) names of prescription drugs for LA/SA name risks; thus, Health Canada will be reviewing the names of a broader range of products than FDA.⁵

LA/SA Names

Name confusion is thought to account for one in every four medication errors. Statistics show that 12.5%

of the 25,000 medication error reports received by FDA relate to names. Furthermore, a recent FDA study of 400 deaths caused by medication errors found that five percent of the deaths were attributed to brand (proprietary) name confusion and four percent to generic (nonproprietary) name confusion.⁶ Because most of the drug names that exist in the United States are also used for Canadian products, it is reasonable to hypothesize that these statistics are applicable in Canada as well.

Of particular concern to Health Canada is the health risk associated with the following:

- *Similarities in brand (proprietary) names.* Health Canada discourages products from having similar or identical brand names, especially when the products do not contain the same active ingredients.



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- *Brand names that are similar to generic (nonproprietary) names.* Health Canada is concerned when a brand name is confusingly similar to the proper or common name⁷ of a drug ingredient.
- *Product line extensions.* Health Canada cautions drug companies against using similar names in their product line extensions. Specifically, Health Canada is concerned about the practice of adding a modifying prefix or suffix to the name of a product to distinguish it from the original product.

Table 1 lists examples of drug names that Health Canada has identified for their potential LA/SA confusion.⁸

Premarket Drug Name Review Process

Under the new LA/SA policy, Health Canada will review all proposed drug names included in a submission for marketing approval to

ensure that 1) the name is unlikely to be confused with existing brand or generic names and thus cause medication errors, and 2) the brand name is not misleading (i.e., does not imply therapeutic claims).

The name review is separate from the assessment of the eligibility of the name for trademark registration. The Canadian Trademarks Office reviews a proposed trademark to determine whether, from a marketing perspective, it is confusingly similar to other trademarks (i.e., to protect trademarks from being used by others for financial gain), whereas Health Canada examines the product's name from a safety perspective (i.e., to reduce medication errors).

To determine whether the similarity between the two names is problematic, Health Canada will consider a variety of factors including:

- Marketing status (prescription versus over-the-counter);
- therapeutic category;

- indications and directions for use;
- clinical setting for dispensing or use (inpatient or outpatient hospital or clinic versus retail);
- packaging and labeling;
- strength of the products;
- dosage form or routes of administration;
- dose and dosing interval;
- patient populations;
- storage; and
- potential for harm.

An initial review of the proposed drug name will take place within 90 days of the submission, and a second review will take place within 90 days of the drug's anticipated approval date. Because the name review will take place concurrently with the rest of the product review, it is not expected to have any impact on the total drug review time.⁹

The sponsors of the drug submission are encouraged to submit a prioritized list of up to two alternative names so

Table 1: Common Look-Alike, Sound-Alike Drug Names

<i>Products that have similar brand names, but treat different conditions.</i>		
Celebrex™ (treatment of inflammatory arthritis)	Celexa® (treatment of depression)	Cerebyx® (seizure control)
Accutane™ (treatment of acne)	Accupril™ (treatment of hypertension)	
Sarafem® (treatment of premenstrual dysphoric disorder)	Serophene® (fertility aid)	
Lamictal® (treatment of bipolar disorder)	Lamisil® (treatment of nail fungus)	
Serzone® (treatment of depression)	Seroquel® (treatment of mania)	
Losec® (treatment of stomach acid production)	Lasix® (diuretic)	
Zantac® (treatment of stomach acid production)	Zyrtec® (allergy medication)	
<i>Product line extensions—names appear similar but treat different conditions.</i>		
Depakote® (treatment of bipolar disorder)	Depakote® ER (treatment of seizures)	



that if Health Canada identifies the proposed name as potentially confusing, the department will consider the alternative names. Sponsors are also encouraged to submit a risk assessment and an evaluation of the product's proposed name, supported with studies, data, and analysis. Health Canada recommends that sponsors consult with pharmacists and healthcare providers when preparing the name review analysis.

Currently, Health Canada will not undertake its own risk assessment or evaluation of the drug's proposed name to determine whether a LA/SA name issue exists. Instead, Health Canada will rely on the information provided by the sponsor. Although Health Canada plans to implement a computer application that screens health product names for potential LA/SA confusion, currently, the application is still being developed. In the United States, FDA carries out an independent name review of the proposed drug name using an expert panel review, handwriting and verbal analyses, computer-assisted analysis, labeling and packaging analysis, and overall risk evaluation.¹⁰

If sponsors have not submitted alternative proposed drug names with a drug submission or if all the names have been rejected, the drug submission will be placed on "name hold" until a proposed alternative name is acceptable to Health Canada.¹¹

Sponsors have the right to appeal Health Canada's LA/SA name review decisions, in accordance with Health Canada's general appeal procedure for drug submissions.¹²

Postmarket Drug Name Review

Although Health Canada will not review the names of products already on

the market, the department will monitor the names of these products, as well as the names of products that underwent a name review but for which a name safety issue was not identified during the premarket approval process. Health Canada is investigating the possibility of developing a more formal process for monitoring and reviewing marketed products for safety issues.

The current postmarket review procedures are outlined in the policy entitled "Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names."¹³

When LA/SA drug and health product names are identified as a concern postmarketing, the product manufacturers will be given an opportunity to suggest a strategy that will mitigate identified risks. For example, the manufacturer may suggest issuing fact sheets, sending "Dear Healthcare Professional" letters, or changing the packaging or labeling of the product. If the suggestions are not acceptable to Health Canada as a viable way to reduce the risks associated with the LA/SA name issue, the manufacturer may be required to change the name of the health product.¹⁴

Health Canada acknowledges that significant brand equity and identity may have developed in a marketed health product by the time a LA/SA name issue is identified. If a manufacturer is required to change the name of a marketed product, the manufacturer may incur an economic loss due to costs associated with product recalls and loss of brand recognition. The health and safety of Canadians is of foremost importance to Health Canada, however. Thus, as a last resort, a name may need to be changed or modified to avoid errors.¹⁵

Conclusion

Health Canada's new LA/SA policy represents an additional tool for ensuring the safety of drugs and other health products used by Canadians. The policy also represents a regulatory hurdle that manufacturers need to be aware of while developing their marketing and branding strategies. ▲

¹ Health Canada, Guidance for Industry, Drug Name Review: Look-alike Sound-alike Health Product Names (Oct. 31, 2005), available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa_premkt-noms_semlables_precomm_e.pdf.

² Health Canada, Issue Analysis Summary: Look-alike Sound-alike Health Product Names: The Development of a Comprehensive Policy Recommendation for Look-alike Sound-alike Health Product Names (Mar. 23, 2004) [hereinafter Health Canada, Issue Analysis Summary], available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa-pspcs_ias-ra_e.pdf.

³ Prescribed drugs are neither over-the-counter products nor listed in Schedule F. Examples include potassium chloride and dextrose injections.

⁴ These include herbal products, vitamins, and minerals, as well as a variety of consumer products that contain these substances. For example, many toothpastes and antiperspirants are classified as natural health products because they contain mineral compositions (fluoride, aluminum).

⁵ See Health Canada, Issue Analysis Summary, *supra* note 2.

⁶ *Id.*

⁷ A proper name is the name by which the drug is designated in scientific or technical journals. A drug ingredient is given a common name when there is no proper name.

⁸ The examples were retrieved from Health Canada, Look-alike Sound-alike (LA/SA) Health Product Names: Comments and Responses to the Related Draft Guidances 6 (Aug. 3, 2005), available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa_comm_rep-noms_conson_seml_comm_rep_e.pdf and Health Canada, Look-alike Sound-alike Health Product Names, What Are Look-Alike Sound-Alike (LA/SA) Health Product Names? (Aug. 14, 2003), available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa-pspcs_factsheet-faitsaillant_e.pdf.

⁹ Health Canada, Look-alike Sound-alike (LA/SA) Health Product Names: Comments and Responses to the Issue as Presented in the Issue Analysis Summary 21 (Mar. 24, 2004) [hereinafter Health Canada, Comments and Responses to Issue Analysis Summary], available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa-pspcs_com_response-reponse_e.pdf.

¹⁰ Health Canada, Issue Analysis Summary, *supra* note 2, at App. A.

¹¹ *Id.* at 18.

¹² Health Canada, Guidance for Industry, Reconsideration of Final Decisions Issued for Human Drug Submissions (effective Mar. 1, 2006), available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/decisions_hum_drug_drogue_e.pdf.

¹³ Health Canada, Draft Guidance for Industry, Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names (Nov. 10, 2005), available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/lasa-pspcs_post_market-comm_guidance-directive_2_e.pdf.

¹⁴ *Id.* at 7.

¹⁵ Health Canada, Comments and Responses to Issue Analysis Summary, *supra* note 9, at 22.