Archived Content

Health Canada Santé Canada

November 10, 2005

NOTICE

Our file number: 05-113786-463

Release of Revised Draft Guidance Document: Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names

The purpose of this note is to inform you that a revised draft guidance entitled *Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names* has been posted on the Health Canada Website. The document has been updated to, where possible, incorporate stakeholder feedback, as well as reflect the status of work in progress on this issue. Currently, HPFB has dedicated resources to investigating avenues by which Health Canada can work together with the pharmaceutical industry, health care professionals and related organizations in responding to health product-related post-market safety issues arising from medication incidents, with the goal of preventing medication errors, and improving patient safety.

The results of this work, in combination with other consultation and analysis, will provide the basis for defining the specific details that are currently not available in this post-market guidance document. The goal of the final document will be to provide clarification to Market Authorization Holders (MAH) regarding the way in which the Health Products and Food Branch (HPFB) intends to assess risk of harm from potential name confusion among marketed health product names, to work in conjunction with MAHs in identifying potential options to mitigate these risks and in implementing appropriate market interventions.

The proposed *Marketed Health Product Name Assessment: LA/SA Health Product Names* guidance is being developed to implement the post-market recommendations outlined in the *Issue Analysis Summary: Look-alike Sound-alike (LA/SA) Health Product Names: The Development of a Comprehensive Policy Recommendation.* Recommendations were developed to respond to a specific safety issue involving the potential for confusion between two approved biologics, as well as long-standing unresolved issues relating to LA/SA health product names.

Ideally, health product names will have been reviewed prior to being approved for use in Canada as outlined in the pre-market guidance, *Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names**. A separate post-market guidance is however essential for: marketed drugs for which a safety issue regarding the name was not foreseen; for those products for which the guidance, *Drug Name Review: Look-alike Sound-alike (LA/SA) Health*

.../2

Canada

product Names does not yet apply*; and for those drugs marketed prior to the development of a consistent pre-market process to review health product names.

If you have questions regarding this guidance document in its revised draft form, please contact:

Ms. Lili Loorand-Stiver,
Patient Safety Section,
Policy and Partnerships Division,
Marketed Health Products Directorate,
Health Canada,
Address Locator: 0701C
Tunney's Pasture,
Ottawa, Ontario K1A 0K9

E-mail: Lili_Loorand-Stiver@hc-sc.gc.ca
Phone: (613) 952-8416
Fax: (613) 948-7996

Original signed by

Dr. C. Turner
Director General
Marketed Health Products Directorate

*A phased implementation of this policy is planned where priority will be given to Schedule C, Schedule D (Biologics), Schedule F and prescribed drugs for human use before over-the-counter, natural health products, veterinary drugs and medical devices. Of note, prescribed drugs are neither over-the-counter products nor are they listed on Schedule F. Examples include potassium chloride for injection and dextrose injection.

Health Canada Santé Canada

DRAFT GUIDANCE FOR INDUSTRY

Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names

Published by authority of the
Minister of Health

Draft Date	2004/09/10
Revision Date	2005/11/03

Health Products and Food Branch

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	HPFB's Mandate is to take an integrated approach to the management of the risks and benefits to health related to health products and food by: • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a health product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidances.

TABLE OF CONTENTS

1. PURPOSE

The purpose of this guidance is to provide clarification to Market Authorization Holders (MAH) regarding the way in which the Health Products and Food Branch (HPFB) intends to assess risk of harm from potential name confusion among marketed health product names, to work in conjunction with MAHs in identifying potential options to mitigate these risks and in ensuring MAHs implement appropriate market interventions.

The benefits of a Guidance document for Marketed Health Product Name Assessment include:

- providing a framework for Health Canada to assess marketed health product names;
- the identification of Health Canada's and submission MAH's roles when a risk/safety issue is identified for a marketed health product name; and
- clarification to MAHs as to how they can rectify a safety issue or potential safety issue that relates to the name of their marketed health product.

Ideally, health product names will have been reviewed prior to being approved for use in Canada. This guidance is essential however for: marketed health products for which a safety issue regarding the name was not foreseen; for those health products for which the guidance, *Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names* does not yet apply* ; and for those marketed prior to the development of a consistent process to review drug names, as outlined in the guidance, *Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names.*

*A phased implementation of this policy is planned where priority will be given to Schedule C, Schedule D (Biologics), Schedule F and prescribed drugs for human use before over-the-counter, natural health products, veterinary drugs and medical devices. Of note, prescribed drugs are neither over-the-counter products nor are they listed on Schedule F of the Food and Drug Regulations. Examples include potassium chloride for injection and dextrose injection.

2. BACKGROUND

Look-alike sound-alike (LA/SA) health product names refer to names of different health products that have orthographic similarities and/or similar phonetics (i.e. similar when written or spoken). These similarities may pose a risk to health by causing confusion and subsequent errors in prescribing, dispensing or administration of a product.

Various stakeholders, including the Canadian Medical Association (CMA), Canadian Pharmacists Association (CPhA), the Canadian Society of Hospital Pharmacists (CSHP) and the Institute for Safe Medication Practices Canada (ISMP Canada), have been concerned about the

LA/SA health product names issue for a number of years.

As outlined in the *Issue Analysis Summary: Look-alike Sound-alike (LA/SA) Health Product Names: The Development of a Comprehensive Policy Recommendation*, marketed health product names should be explicitly monitored and, if sufficient risk of harm due to potential name confusion is identified (i.e., LA/SA similarities), appropriate market interventions should be initiated (e.g., informing health care professionals and consumers about the risks with letters to health care professionals, public advisories, postings on the Health Canada website, publication in scientific journals, and/or name or labelling change to one of the products).

HPFB is involved in minimizing health risk factors to Canadians while maximizing the safety of the regulatory system for health products and food. Specifically, the Marketed Health Products Directorate (MHPD) within HPFB is responsible for coordination of consistency of post-market surveillance and assessment of signals and safety trends concerning all marketed health products. In collaboration with other Directorates in HPFB, and with other involved branches, MHPD's activities include: collecting and monitoring adverse reaction and medication incident data, reviewing and analyzing marketed health product safety data, conducting risk/benefit assessments, communicating product-related risks to health care professionals and the public, and developing post-approval policy. For veterinary drugs, these post-market responsibilities reside in the Veterinary Drugs Directorate (VDD). The Public Health Agency of Canada is responsible for the post-market surveillance of adverse events following immunization with preventative vaccines.

3. SCOPE

This guidance aims to articulate Health Canada's expectations and generate a level of consistency regarding the implementation of appropriate post-market interventions to minimize the chance of medication incidents related to marketed health product names, particularly those resulting from LA/SA similarities.

Prior to marketing a product, MAHs should have carefully considered the potential for LA/SA similarities of their proposed name with other existing health product names, in order to reduce potential medication incidents and subsequent need for post-market interventions. Please refer to the guidance *Drug Name Review: LA/SA Health Product Names* for more details.

Please note that when a MAH changes a drug name post-market, they are required to submit an administrative new drug submission, supplemental new drug submission (SNDS), abbreviated new drug submission (ANDS) or DIN, as applicable and the *Drug Name Review* guidance will apply to these submissions.

When a MAH changes a natural health product name post-market, MAHs are required to notify Health Canada of the change.

4. DEFINITIONS

Brand name (or proprietary name): *C.01.001.(1) of the Food and Drug Regulations* states that a *"brand name" means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French, (a) that is assigned to the drug by its manufacturer, (b) under which the drug is sold or advertised, and c) that is used to distinguish the drug.*

The use of a brand name or proprietary name is the choice of the MAH. As stated in Section *C.01.004 (1) of the Food and Drug Regulations*, a drug is identified on its inner and outer label by the brand name (if there is one) followed by the proper name, if any. If there is no proper name, the common name is listed instead.

For products with multiple ingredients, the product will have a brand name but no proper or common name for the product; only a proper name for each ingredient.

Chemical name: The chemical name of a drug provides an unambiguous picture of a molecule so that a trained chemist can use it to draw its structure if required {i.e., 4-(4-Chlorophenyl)-1-[3-(4-flurobenzoyl) propyl]-piperidin-4-ol: 4-[4-p-Chlorophenyl]-4-hydroxypiperidino]-4-flurobutyrophenone is the chemical name for Haloperidol}[1].

Common name: *C.01.001.(1) of the Food and Drug Regulations* states that a *"common name" means, with reference to a drug, the name in English or French by which the drug is (a) commonly known and (b) designated in scientific or technical journals, other than the publications referred to in Schedule B to the Act.*

Generic name: The generic or non-proprietary name describes the drug substance. INNs are created to identify generic names as unique, universally applicable and accepted names. A generic name is the proper name of an ingredient, or the common name if the ingredient has no proper name.

Health product: Health products include pharmaceuticals, biologicals, vaccines, medical devices, natural health products, radiopharmaceuticals and veterinary drug products.

---

[1] M. J. Lebelle, Drug Names and Mis-medication- A Canadian Perspective, Bureau of Drug Research, Drugs Directorate, Health Protection Branch, Presented at the Second PMA/PTMG Conference on Trademarks, Washington D.C., May 2-4, 1994.

International Nonproprietary Name (INN): INNs identify a drug substance by a unique, universally applicable and accepted generic name. It is noted that chemicals that do not have a defined chemical composition or structure or that cannot adequately be described cannot be assigned INNs (i.e., mixtures of substances). An INN is the only internationally accepted generic name. In Canada, INNs are used exclusively, when they exist, in Schedule F [2, 3].

Look-alike Sound-alike (LA/SA) health products: Health products that have a similar written name or similar phonetics to those of another health product.

Medication error (or medication incident) : A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professionals practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution;, administration; education; monitoring; and use. [National Coordinating Council for Medication Error and Prevention (NCC MERP) definition].

Product line extension: A product line extension results when a drug is named by using the brand name of another drug with the addition of a modifying prefix or suffix that is intended to distinguish the new product from the original. In some cases, this practice has arisen as a marketing strategy to take advantage of familiarity of an original product name.[4]

Proper name: *C.01.001.(1) of the Food and Drug Regulations* states that a "*proper name" means, with reference to a drug, the name in English or French (I) assigned to the drug in section C.01.002, (ii) that appears in bold-face type for the drug in these Regulations and, where the drug is dispensed in a form other than that described in this Part the name of the dispensing form, (iii) specified in the Canadian licence in the case of drugs included in SCHEDULE C or SCHEDULE D to the Act, or (iv) assigned in any of the publications mentioned in SCHEDULE B to the Act in the case of drugs not included in subparagraphs (I), (ii) or (iii) of this paragraph.*

For products with multiple ingredients, there is no proper name for the product but there is a proper name for each ingredient.

---

2 M. J. Lebelle, Drug names and medication errors: Who is responsible? *Canadian Medical Association Journal*, 1993; 149 (7) : 941-943

3 Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances, 1997, Programme of International Nonproprieatary Names, Division of Drug Management and Policies, World Health Organization, WHO/Pharm S/NOM 1570

4 M. J. Lebelle, Drug names : Who's responsible? *Health Protection Branch Issues*, 1993

With natural health products, if the ingredient is a plant or plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet can be considered the ingredient's proper name. The specific epithet is the second, generally descriptive, part of the standard two-part (binomial) scientific name for an organism. Together the genus and specific epithet comprise the name of a species.

Trade-mark: Section 2 of the *Trade-marks Act* states that a trade-mark is (*a) a mark that is used by a person for the purpose of distinguishing or so as to distinguish wares or services manufactured, sold, leased, hired or performed by him from those manufactured, sold leased, hired or performed by others, (b) a certification mark, c) a distinguishing guise, or (d) a proposed trade mark.*

Trade-name: Section 2 of the *Trade-marks Act* states that a trade name *is the name under which any business is carried on, whether or not it is the name of a corporation, a partnership or individual.*

United States Adopted Name (USAN): USANs identify nonproprietary names for drugs by establishing simple, logical nomenclature based on pharmacological and/or chemical relationship. The USAN committee develops the names, taking into account practical considerations, such as the existence of trademarks, international harmonization of drug, nomenclature, the development of new classes of drugs, and the fact that the intended uses of substances for which names are being selected may change[5].

5. POLICY

When the safety of a marketed health product name is in question, it will be assessed and actions will be considered in accordance with the *Food and Drugs Act and Regulations* and *Natural Health Products Regulations*, as applicable.

Regarding drugs, Section *C.01.013.* of the *Food and Drug Regulations* requires that, upon request, a manufacturer must submit sufficient evidence by a specified date to establish the safety and effectiveness of a drug for the purposes recommended. When sufficient evidence is not provided, further sales of the drug can be suspended. Thus, upon becoming aware of and assessing a safety concern to determine actual or potential risk associated with name confusion following issuance of an NOC and/or DIN for a drug, HPFB can use C.01.013. to require the manufacturer to establish the safety of the drug under its recommended uses.

Regarding natural health products, Section 16 of the *Natural Health Products Regulations* states

[5] United States Pharmacopeia, USP Dictionary of USAN and International Drug Names, 2001

that a manufacturer must submit safety information demonstrating that the natural health product is safe. When sufficient evidence is not provided, further sales of the natural health product can be stopped or suspended based on Section 17 and Section 18, respectively.

MAHs have the responsibility, as outlined in the *Food and Drug Act*, to monitor the safety of products they manufacture. Therefore, they should proactively monitor health product name similarities between their products and those of other products, that have caused or could potentially cause a medication error, and propose an appropriate mitigating intervention.

HPFB intends to investigate how it can best monitor available sources of medication incident information which may include name changes of marketed health products in other countries that occur as a result of medication incidents.

6. PROCEDURES

The details with respect to Health Canada's post-market medication incident management processes, including medication incidents related to LA/SA product naming, product packaging and labelling, are presently being investigated and defined.

Health Canada has an ongoing commitment to quality of care and patient safety. Enhanced medication incident reporting and prevention is viewed as an important strategy for improving patient safety. As such, Health Canada provides a leadership role, and continues to actively participate in, the development and implementation of a national medication incident reporting and prevention system. This system, the Canadian Medication Incident Reporting and Prevention System (CMIRPS) has the objective of reducing preventable medication incidents. The CMIRPS project, currently in the design phases, will have an impact on, as well as help to define, how Health Canada can most effectively collaborate with other organizations, and how to best respond to post-market safety issues related to health product naming, labelling and packaging.

Currently, HPFB has dedicated resources to investigating avenues by which Health Canada can work together with the pharmaceutical industry, health care professionals and related organizations in responding to health product-related post-market safety issues arising from medication incidents, with the goal of preventing medication errors, and improving patient safety. This collaborative approach has potential to give rise to options that are both reasonable and agreeable to stakeholders, and the knowledge gained may, in some cases, contribute to development of specific product safety guidance documents. The desired outcome is to complement existing regulatory requirements related to health product naming, labelling and packaging in order to strengthen the safe use of health products in the context of day-to-day use in the practice environment. Medication system and process-based factors that may have contributed to the incident will need to be investigated in addition to health product

labelling/packaging/naming issues before prevention strategies are considered.

The results of this work, in combination with other consultation and analysis, will provide the basis for defining the specific details that are currently not available in this post-market guidance document.

However, in the interim, when a marketed health product name is assessed to pose a health safety risk due to its potential for confusion with another marketed health product name, the appropriate MAH(s) will be notified in writing, by means of a Request Letter, outlining Health Canada's concerns and will be asked to suggest, within a specified time frame, possible interventions to mitigate risks. Health Canada will assess the proposed interventions and, whenever possible, will work collaboratively with the MAH(s) in order to come up with a strategy that is reasonable, agreeable, and best mitigates identified risks.

In cases where agreement on an acceptable mitigating strategy cannot be reached collaboratively, and where Health Canada is of the opinion that the only effective strategy to mitigate patient safety risk is to change the product name, then Health Canada will exercise its regulatory authority under section C.01.013. of the *Food and Drugs Act*.