Executive Summary: Look-Alike Sound-Alike (LA/SA) Health Product Names Consultative Workshop

A Look-alike Sound-alike (LA/SA) Health Product Names Consultative Workshop was held on October 20-21, 2003 with 38 stakeholders in attendance representing industry associations, government, healthcare professionals and non-government organizations including patient and consumer groups.

The objectives of this workshop were to:
• inform/educate interested and affected parties about LA/SA health product names and the current policy development process;
• ensure accuracy and completeness of the issues identified;
• provide an opportunity for interested and affected parties to give feedback regarding policy options and proposed recommendations; and
• demonstrate an ongoing commitment to relationship-building with affected parties.

After an initial address from Diane Gorman (Assistant Deputy Minister, Health Products and Fortf Branch) and welcome from Julia Hill (Director General, Biologics and Genetic Therapies Directorate), the following were presented over the two days:

1. Look-alike Sound-alike (LA/SA) Health Product Names: Developing a Common Understanding
   Michèle Chadwick, Biologics and Genetic Therapies Directorate (BGTD), Health Products and Food Branch, Health Canada

2. Proprietary Name Evaluation at the Food and Drug Administration (FDA)
   Captain Thomas Phillips, Office of Drug Safety, Centre for Drug Evaluation and Research, U.S. FDA

   Michèle Chadwick, Biologics and Genetic Therapies Directorate (BGTD), Health Products and Food Branch, Health Canada

4. Computer Assisted Decision Analysis in Drug Naming
   Dr. Bruce L. Lambert, Department of Pharmacy Administration, Department of Pharmacy Practice, University of Illinois and Chicago

5. Automatic Detection of Confusable Drug Names
   Dr. Greg Kondrak, Department of Computing Sciences, University of Alberta

6. Phonetic Orthographic Computer Analysis (POCA) System
   Dr. Rick Shangraw, Project Performance Corporation

   Susan M. Proulx, Pharm.D., Med-E.R.R.S.

8. Risk MonitorPro™ and Look-alike/Sound-alike Errors
Jerry Seibert, 'L Solutions

Please refer the PowerPoint presentations that are posted on this website for further details on these presentations.

In attempts to ensure accuracy and completeness of the issues identified and provide an opportunity for stakeholders to give feedback regarding policy options and proposed recommendations, a number of questions were asked of stakeholders (Appendix A)

The feedback from this consultation and that with the Therapeutic Products Directorate (TPD) Advisory Committee on Management will be analyzed along with comments received on the draft LA/SA Issue Analysis Summary (IAS) which has been posted on the Biologics and Genetic Therapies Directorate (BGTD) website. The outcome of these consultations will be considered as part of the policy recommendations put forth to senior officials in the Health Products and Food Branch for their discussion and decision-making.
THE ISSUE

The Proposed Problem Statement:

1. Look-alike sound-alike (LA/SA) health products refer to names of different health products that have orthographic similarities and/or similar phonetics. These similarities may pose a risk to health by contributing to medical errors in prescribing, dispensing or administration of a product.

2. These medication errors may be more likely to occur because of contributing factors such as identical doses, dosage forms or routes of administration, similar packaging or labelling, incomplete knowledge of drug names, illegible handwriting, verbal order errors and even lack of appropriate knowledge base.

3. A specific safety issue involving the potential for confusion between two approved biologic drugs, as well as longstanding unresolved issues relating to LA/SA health product names has prompted the Biologics and Genetic Therapies Directorate to request a review and analysis of the issues associated with health products and to recommend an appropriate course of action.

The Alternate Problem Statement:

- Look-alike sound-alike (LA/SA) health products 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 errors in prescribing, dispensing or administration of a product.

- These errors may be more likely to occur because of contributing factors related to health products themselves or system errors.

QUESTIONS

1. a. Based on your experience and the problem statement as currently written, what components of it would you change to improve its clarity and accuracy? Are there any details you feel are necessary that are missing?

   b. Based on your experience and the alternate problem statement as currently written, what components of it would you change to improve its clarity and accuracy? Are there any details you feel are necessary that are missing?

2. The proposed scope of the issue includes:
   - similarities in brand names
   - similarities between brand names and generic names
   - product line extensions
From your perspective, does this encompass the majority of LA/SA errors? What examples of LA/SA errors come to mind when you reflect on this issue?

3. How would you prioritize (1 being of highest priority) the implementation of the LA/SA health product name project among the following (currently listed in alphabetical order):

___ medical devices
___ natural health products
___ over-the counter-drugs for human use;
___ prescription drugs for human use; and
___ veterinary drugs.

Please explain why you prioritized the list in this way?

4. Health Canada developed rating criteria to help select recommendations. Please refer to this list (LA/SA IAS, pg. 19) Are there any other criteria that should be considered?

5. What do you like best about the recommendations(s) (LA/SA IAS, pg. 25)? What do you like least? From your point of view, is there an alternative recommendation that should be considered?

6. Having looked at the pre-market and post-market actions identified by HC that could be taken to address LA/SA health product name issues), what would be your recommendation for action? Please mark a Yes beside the elements you support, a No beside the ones you do not support or a Maybe beside the elements you would like to discuss further. If you marked No or Maybe, please explain why you believe this is not the most appropriate course of action.

**Pre-market**
- HC policy
- company/sponsor provides name analysis
- prioritized list provided by company/sponsor
- Complex Computer Application Screening
- HC name review
- HC name review committee

**Post-market**
- HC policy
- Monitoring
- Promotion of known LA/SA health products