Look-alike Sound-alike (LA/SA) Health Product Names: Developing a Common Understanding

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DAY 1 OBJECTIVES

➢ 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
LA/SA medication errors

- Research has identified that one of the most frequent causes of pharmacy dispensing errors (29%) is failure to accurately identify drugs because of LA/SA drug names.

- Confusing drug names are responsible for 10,000 patient injuries each year in the U.S.

- More than 770,000 people are injured by medication errors at a cost of $177 billion each year.
Confusion between Seroquel and Serzone

Due to similarities in names, verbal and written prescriptions were incorrectly interpreted, labelled and/or filled

Contributing factors included:
- overlapping strengths (100 mg and 200 mg)
- dosing interval (BID)
- stocked close together in pharmacies

3 patients hospitalized and 4 patients required emergency room visits

One 25-year-old female experienced fever and respiratory arrest after taking Seroquel for 3 days instead of Serzone and eventually died.
Case #2

- Lisa, a 40-year-old Montreal woman with bipolar disorder
- Lamisil prescribed instead of Lamictal
- Contributing factor included:
  - appearance of the drug (round white pill)
- Lack of efficacy
Case #3

- Vincristine instead of vinblastine
- Contributing factor:
  - Both are cancer drugs
- Death by overdose (several cases)
Other cases

- Primaxin I.V. and Primacor (death)
- Taxotere and Taxol (death)
- Lamictal and Lamisil (hospitalization)
- Serzone and Seroquel (antipsychotic incident)
- Tobradex and Tobrex (glaucoma)
LA/SA errors
-more than just drugs

- Diovan (valsartan) and Diavan (herbal remedy for diabetes)

- lab test (anti-factor Xa expressed as Anti-Xa) and Arixtra (factor Xa inhibitor)

- Lamisil (terbinafine hydrochloride) and the medical device Limicel (Osmotic Cervical Dilator)
HPFB LA/SA WG Members

- Gloria Mah Cawthorn, BREC, BGTD
- Julie Clare, SMD, CPRA, BGTD
- Basanti Ghosh, SMD, CPRA, BGTD
- Michèle Chadwick, PPD, CPRA, BGTD (chair)
- Ruth Hansson, PPD, CPRA, BGTD (secretariat)
- Supriya Sharma, MHPD
- Bill Leslie, MHPD
- Micheline Ho, PID, SMAB, TPD
- Marilyn Schwartz, SIPD, BOS, TPD
- Michael Wood, SIPD, BOS, TPD
- Stephanie Pereira, NHPD
- Kerry Reinhard, NHPD
- Vicky Butz, VDD, HPFB
- Michelle L. Boudreau, Legal Services
- Catherine Yen, HPFB Inspectorate
- Julie Desrosiers, Health Policy and Communications Branch
LA/SA Action Plan

**Phase I**
- Establish a WG, Develop draft ToR, Define problem and scope, Development of Issue ID paper

**Phase II**

**Phase III**
- Develop Implementation Strategy, Implement Phase III of PI Plan and Evaluation Report
Problem Statement (draft)

- 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.

- 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.
Current Process

- case by case basis

- no consistent or formal process in place to review look-alike sound-alike health product names

- current computer systems are not set up to flag identical or similar names

- subjectivity

- perception of questionable authority (Can the Food and Drugs Act be used to support a request for a name change?)

- sponsors are encouraged to consider changing their product name when a look-alike sound-alike drug is identified (success has been mixed)
Section C.08.002 and Section C.01.014.1 of the Food and Drug Regulations require that a drug's name be provided in a drug submission as part of the information required to assess safety and effectiveness of a product.

These sections allow HPFB to adopt a pre-market requirement that names not be confusing with one another.

If confusion is considered likely and could result in safety concerns, HPFB need not issue a DIN (old drugs, new drugs) and/or NOC (new drugs only).
Section C.01.013 of the Food and Drug Regulations permits the Director to require a manufacturer to submit evidence sufficient to establish the safety of a drug under the conditions of use for which the drug is recommended by a specified date.

When evidence is not provided or is not sufficient the Director may, by notifying the manufacturer, direct the manufacturer to make no further sales of the drug.
Risks of No Action

➢ the morbidity and mortality of Canadians due to medication errors

➢ the risk that public trust may be lost

➢ If decisions are made inconsistently, HPFB risks a legal challenge based on arbitrariness when trying to act in accordance with the HPFB mandate.

➢ HPFB's potential risk of liability for failure to meet responsibilities outlined in its mandate if beneficiaries of the program suffer morbidity and mortality due to medication errors.
Objectives

A consistent and formal process is required within HPFB to respond to LA/SA health product names. Pre-market and post-market processes must be developed to respond to LA/SA issues of similar brand names, brand names that are similar to generic names and product line extensions.
SCOPE

- **Priority**
  - similarities in brand names including the sub-issue of using abbreviations in brand names
  - brand names that are similar to generic names
  - product line extensions including the sub-issue of marketing products with the same brand name yet different active ingredients

- **Less of a priority**
  - similar generic names—preventative measures only (i.e. labelling changes)
  - similar brand name sub-issue of creating brand names by adding company abbreviations (APO)

- **Not within the scope of the Working Group**
  - similarities in labelling or packaging

- **Not an issue**
  - different brand names for the same active ingredient within the same company
LA/SA Product Prioritization

- prescription drugs
- over-the-counter drugs
- natural health products, veterinary drugs, medical devices