

Canadian Draft Guidance:

**Review of Drug Names for
Look-Alike Sound-Alike
Attributes**

IMSN - October 10, 2013

It should be noted that this presentation contains the proposed processes intended to solicit comments from the industry stakeholders in February 2013. The content of the final revised Guidance is to be decided by Health Canada. Therefore specific processes identified in this presentation may not necessarily be included into the revised Guidance.

Policy Background

Current Guidance

- In January 2006, Health Canada's *Guidance for Industry: Drug Name Review: Look-alike Sound-alike (LASA) Health Product Names* became effective
- In February 2013, Health Canada issued the *Draft Revised Guidance Document for Industry - Review of Drug Names for Look-alike Sound-alike (LASA) Attributes*
 - consultation period ended in May 2013
 - document still under review
 - implementation and final version(s) expected in Fall 2013

2013 Draft Revised Guidance

- Increased transparency and predictability for sponsors regarding the evidence to be submitted to Health Canada
- Original document includes biological and pharmaceutical drugs (prescription and nonprescription) for human use for which a brand name is proposed (innovator or generic)
- Reinforces the importance of end-user testing

Available at:

<http://www.hc-sc.gc.ca/dhp-mps/consultation/medeff/2013/lasa-pspcs/index-eng.php>

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Overview of LASA Brand Name Assessment Process

- Pre-LASA Screening (Initial Review Criteria)
- **SEARCH** - sponsor
- **SIMULATE** - sponsor
- **SYNTHESIZE** - sponsor
- **DECIDE** - regulator

SEARCH

- Systematically search Canadian Drug Product Database, Licensed Natural Health Product Database, and medication error databases
- If name is already marketed in another country:
 - Search for reports of medication errors involving the proposed drug name
 - Include assessment and conclusions of other regulators
- Report all data forward into next step in the assessment

SEARCH

- Use ALINE: same similarity measure used in [FDA's POCA search system](#) (Phonetic and Orthographic Analyzer)
- Three types of similarity
 - Look-alike, spelling (orthographic)
 - Sound-alike, pronunciation (phonetic)
 - Combination (average of look- and sound-alike)

SEARCH

Summary of Requirements

- Search Canadian Drug Product Database and Licensed Natural Health Products Database
- Use ALINE similarity metric (e.g., FDA POCA)
- Identify any names with $\geq 65\%$ ALINE score
- Identify top 5 closest names in orthographic, phonetic and combined ALINE score
- Use identified names in subsequent steps of the process (SIMULATE and SYNTHESIZE)

SIMULATE

- Assess confusability in realistic situations
- Level of detail in simulations reflects compromise between realism, cost and usefulness
- Develop a process map for proposed name and product

SIMULATE

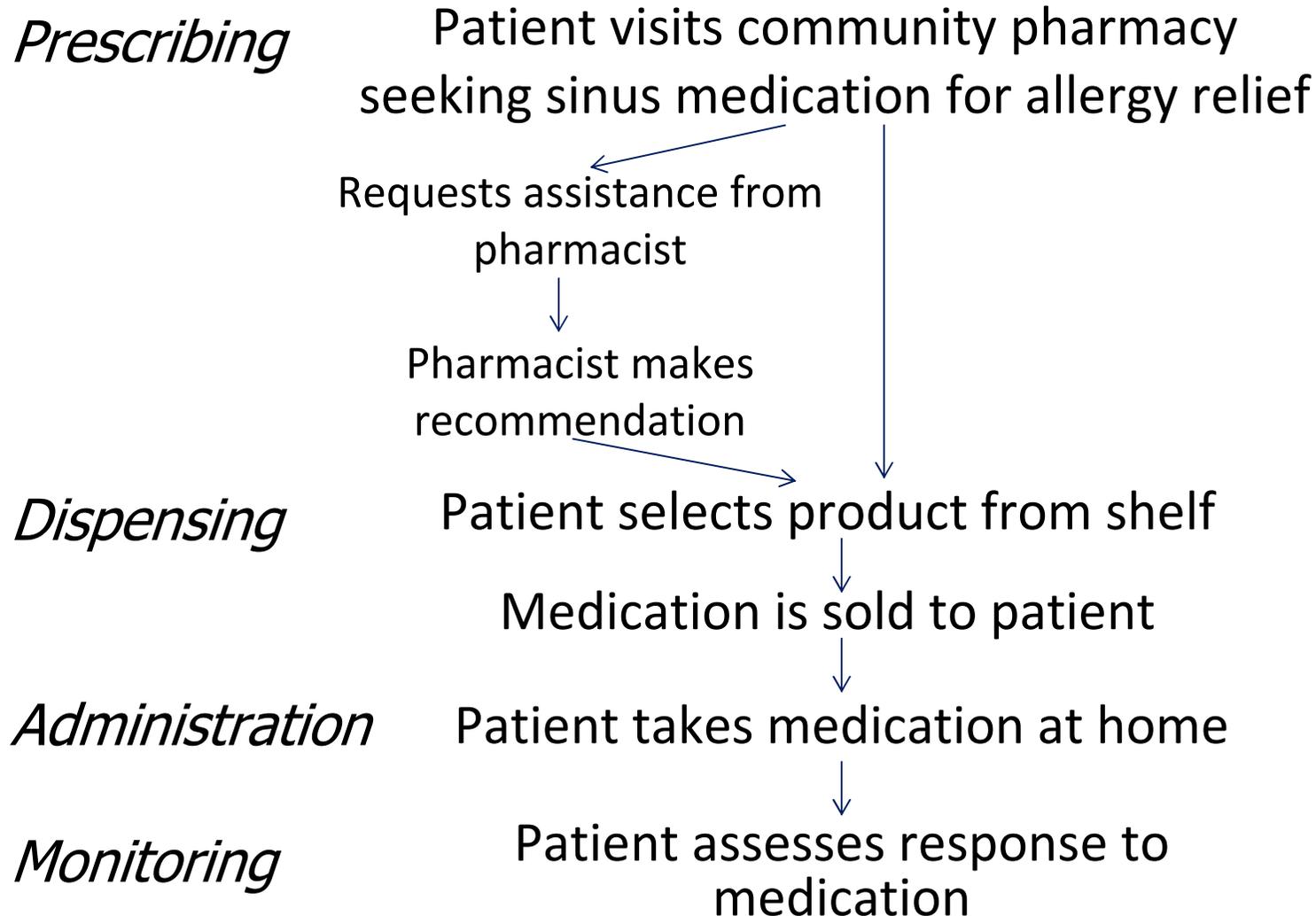
- All observed errors or failures are evaluated in Synthesize step
- To assess potential error frequency
- To assess potential error severity
- To identify potential error causes
- To identify potential error prevention strategies

SIMULATE

- Conduct screen-based simulations
 - Visual perception
 - Auditory perception
 - Short term memory
- Conduct medication-use process simulations
 - Based on process maps
 - Prescribing, transcribing, dispensing, administration
- Report findings in standard format

Sample Medication-Use Process Map

e.g., non-prescription allergy treatment tablet



SIMULATE

Medication-Use Process Simulations

Evaluate Name Performance

- Evaluate safety and clarity of the name when spoken, written, faxed, read in a variety of tasks: prescribing, transcribing, dispensing, self-selection, etc.
 - In this phase consideration of non-name attributes (e.g., strength, dose) is also important
- Identify how confusable each name is with other product names, device names, medical terms, etc.
- Document each error that occurs

***SYNTHESIZE*: Two Steps**

- Conduct failure mode and effects analysis (FMEA)
 - Compare, synthesize and assess results from search and simulations
 - Assess type, frequency, severity and detectability of failures
- Prepare final report with rationale and recommendation for approval

SYNTHESIZE

Failure Mode and Effects Analysis

- Conduct comprehensive failure mode and effects analysis (FMEA)
- Include clinical experts and consumers/patients in the field of use for the product
- Identify potential problems and errors
- Consider role of non-name attributes (e.g., dosage form, strength) in increasing or decreasing the likelihood of confusion
- Prepare summary report – critical to HC decision

SYNTHESIZE

Failure Mode and Effects Analysis

FMEA team:

- Reviews the submitted medication-use process map(s)
- Reviews all drug names identified as potentially confusable in the Search and Simulate steps
- Reviews data from the simulation studies
- Generates potentially confusable names and terms, based on their own experience and current practice

SYNTHESIZE

Failure Mode and Effects Analysis

FMEA team also considers non-name attributes, such as:

- marketing status (Rx or nonprescription)
- therapeutic category
- active ingredient
- indication(s)
- clinical setting for dispensing or self-selection
- strength
- dosage form
- route of administration
- proposed dose, dosing interval/frequency
- storage (e.g., refrigerated or room temperature)

SYNTHESIZE

Failure Mode and Effects Analysis

- FMEA is critical for several reasons
 - Compares, synthesizes and assesses results from search and simulations
 - Assesses type, frequency, severity and detectability of failures
 - Identifies potential mitigating factors
 - Allows panel of qualified experts to integrate all assessment findings and put it into clinical context
- FMEA results become critical input to final report

DECIDE

Making a Decision

- Decisions about the acceptability of a proposed brand name will be made by Health Canada
- Health Canada will review the submitted LASA brand name assessment
- A search of the Drug Submission Tracking Database (DSTS) will also be completed

DECIDE

Making a Decision

- Health Canada reserves the right to ask for additional information if required
- Such requests will be justifiable and clearly documented
- Sponsors may formally appeal a decision according to Health Canada's "*Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions*"

Post-Approval

- Safety issues may arise once a name has been introduced to the market
- If a potential risk is identified, Health Canada will work with the sponsor to address the issue
- Sponsors may be asked to introduce mitigation strategies up to, and including, a name change