Plain Language Labelling & Health Canada Guidance on Look Alike and Sound Alike Brand Name Reviews

November 16, 2016

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Regulatory Authority

The *Food and Drug Regulations* require that a product name and an assessment of the brand name be provided in a drug submission as part of the information required to evaluate the safety and effectiveness of the product. The assessment is to determine that the names of drugs will not be confusable with one another. If confusion with the proposed brand name is considered likely and could result in safety concerns, then the Health Products and Food Branch (HPFB) can refuse to issue an NOC (for new drugs only) or a Drug Identification Number (for new drugs and existing drugs) as per C.01.014 and C.08.004 of the *Food and Drug Regulations*.

- The Regulations aim to improve the safe use of drugs by making drug labels and packaging easier to read and understand. The Regulations impose new obligations on health products sponsors to:
  - Provide information in plain language
  - Assess the name of their health products to avoid confusion
  - Submit mock-ups of labels and packages for review;
  - Indicate how to report harms on their product's label
  - Provide information in an easy-to-read format.
- While these obligations form a coherent set of regulatory obligations, not all of these obligations will apply to all health products and some obligations come into effect at a later date than others.

Medication Error

- ✓ 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

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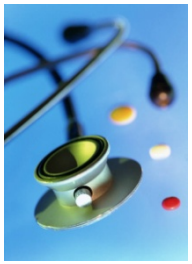
Shared Objective

Health Canada

Drug Safety Institute

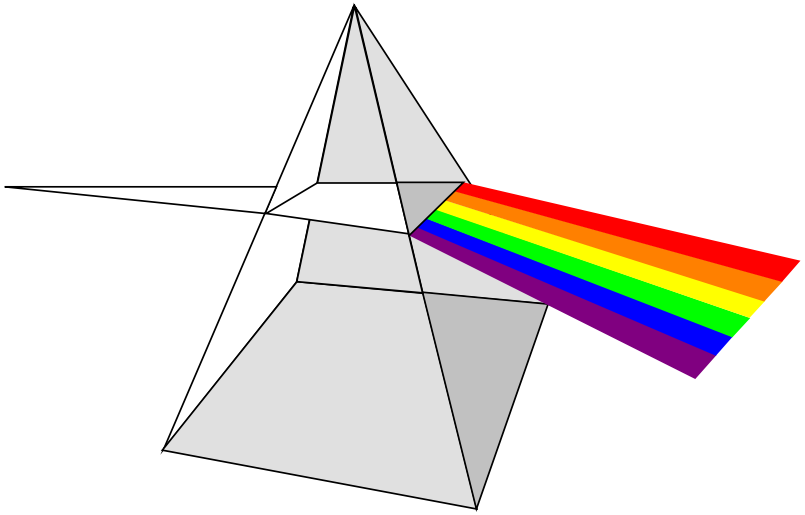


Minimize Medication Errors

Biotechnology, Pharmaceutical & Medical Device Manufacturers

Medication Error

- ✓ Complex Systems
- ✓ Human Interactions
- ✓ Potential for Harm
- ✓ Safety Designs = Decreased Potential for Failure



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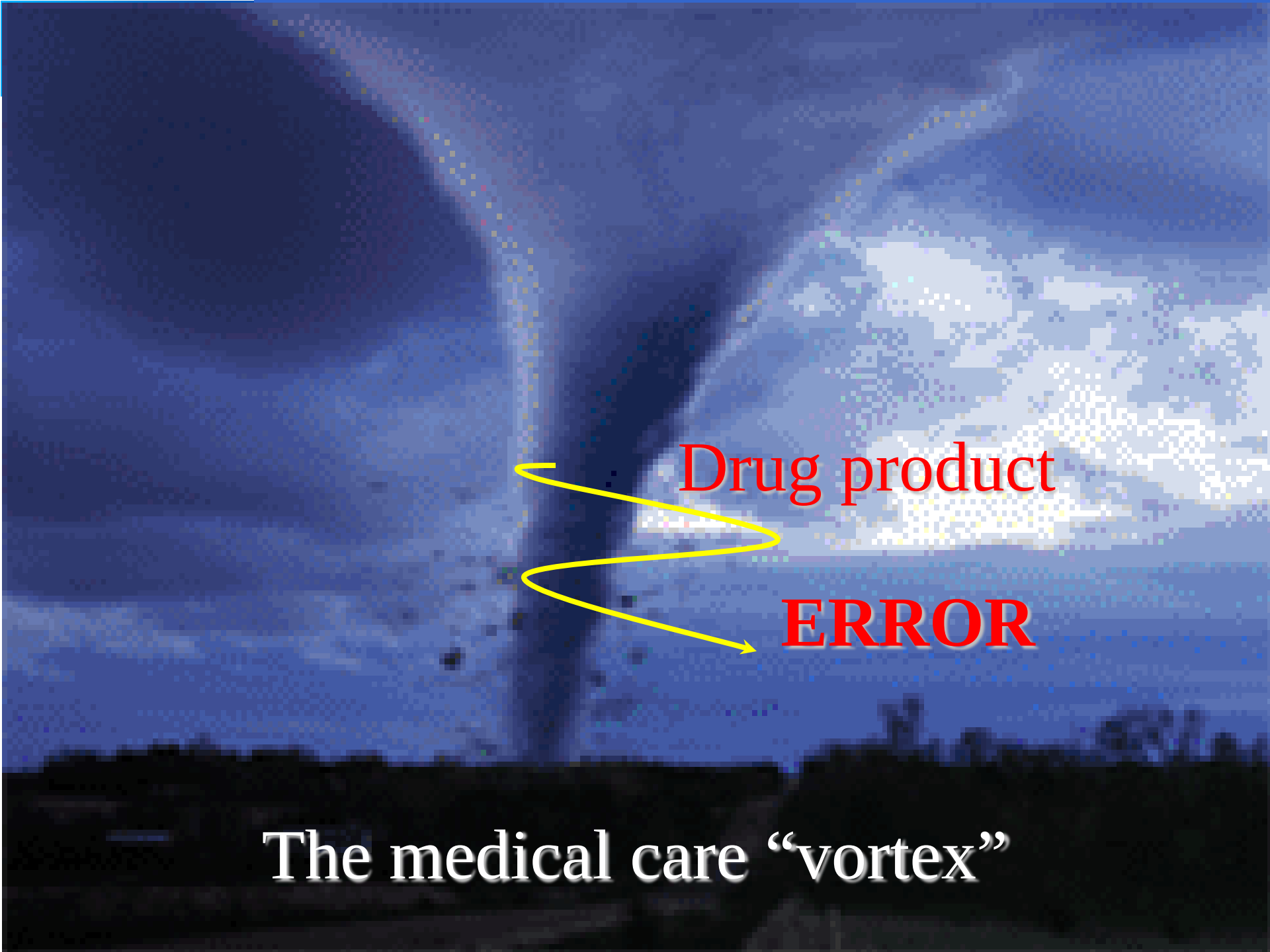

The medical care “vortex”

Causes

- ✓ Poor Communication
- ✓ Product Name Similarity
- ✓ Directions for Use
- ✓ Abbreviations
- ✓ Poor Techniques
- ✓ Knowledge Deficit

Stress

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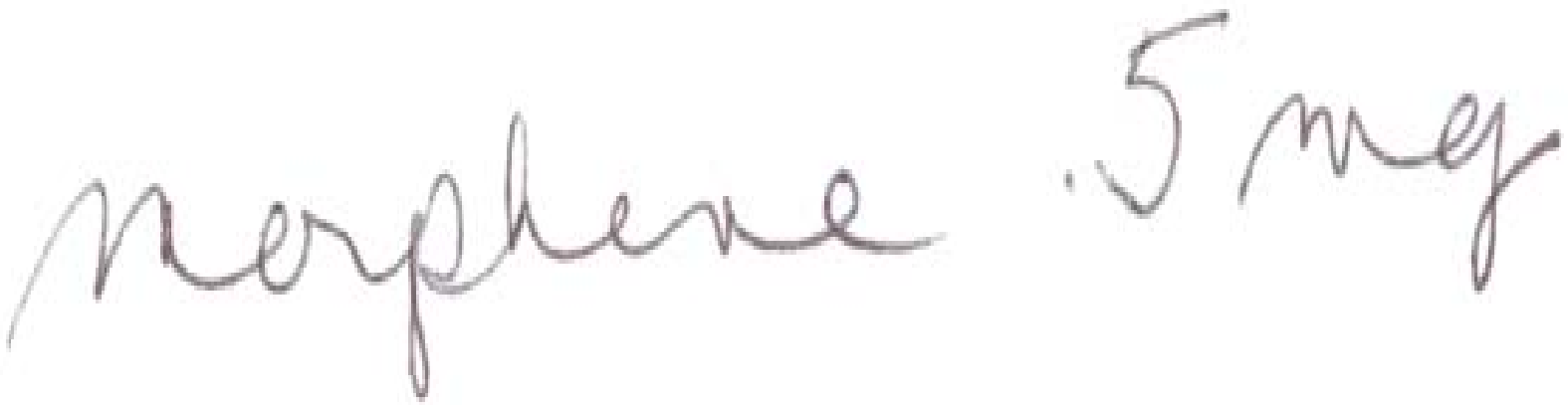
Transcription of Orders

- ✓ Morphine 0.5 mg



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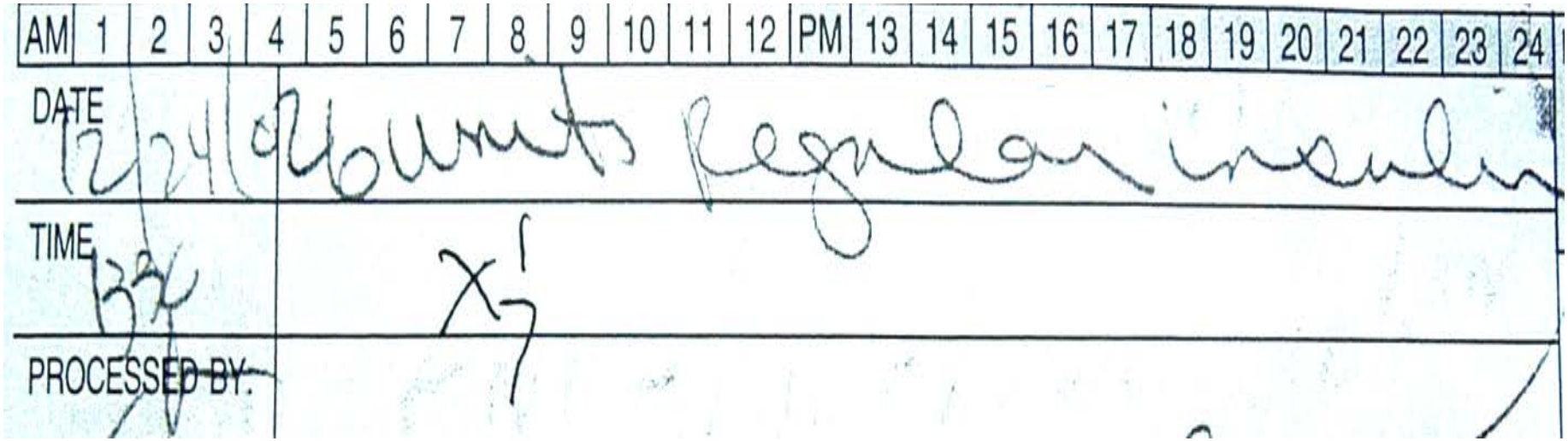
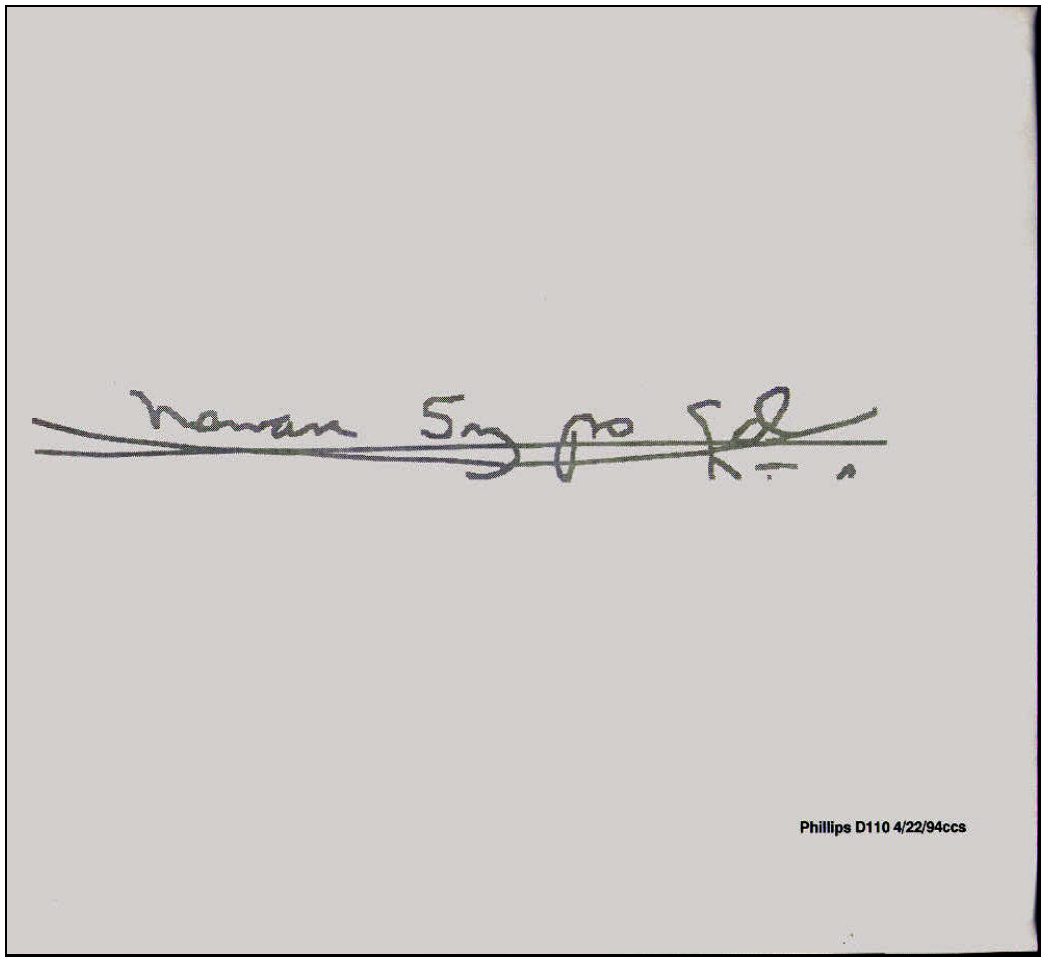


AM	1	2	3	4	5	6	7	8	9	10	11	12	PM	13	14	15	16	17	18	19	20	21	22	23	24
DATE	12/24			Units regular insulin																					
TIME	32						X1																		
PROCESSED BY:																									

Navane or Norvasc?



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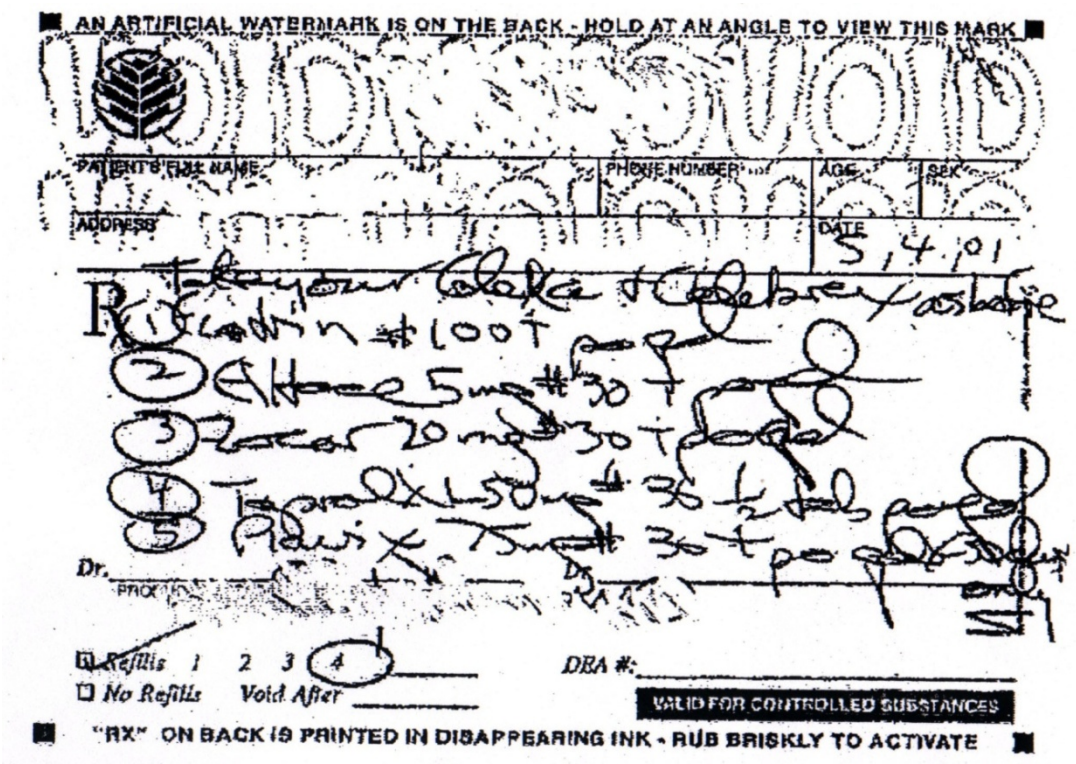
Transcription of Orders

Physician's Handwritten Medication Order Example



Confusion and errors from:
Handwriting interpretation
Dispensing multiple products
Dosing, instructions, administration, etc.

Take your Celexa and Celebrex as before
Ecotrin #100 1 po qd 4 refills
Altace 5mg #30 1 po qd 4 refills
Zocor 20mg #30 1po qd 4 refills
Toprol XL 50mg #30 1/2 tablet po qd 4 refills
Plavix 75mg #30 1 po qd x 30 days only 0 refills

Causes for Dispensing Errors

- ✓ Practitioner's Handwriting
- ✓ Phone-in Orders

"Sound-Alike" and "Look-Alike" Names	
Lamictal	*Lamisil*
Flomax	*Fosamax*
Tobrex	*Tobradex*
Zantac Syrup	*Zyrtec Syrup*
Celebrex	*Cerebyx*
Losec	*Lasix*

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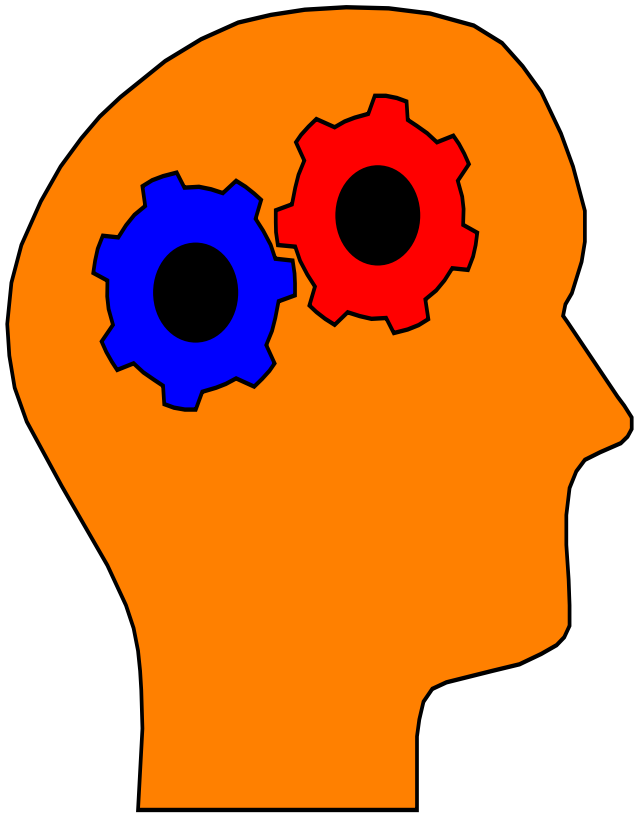
Confirmation Bias



"IT AIN'T WHAT YOU KNOW THAT GETS YOU IN TROUBLE, IT'S WHAT YOU KNOW FOR SURE THAT AIN'T SO"

~ Mark Twain

PARIS

IN THE

THE SPRING

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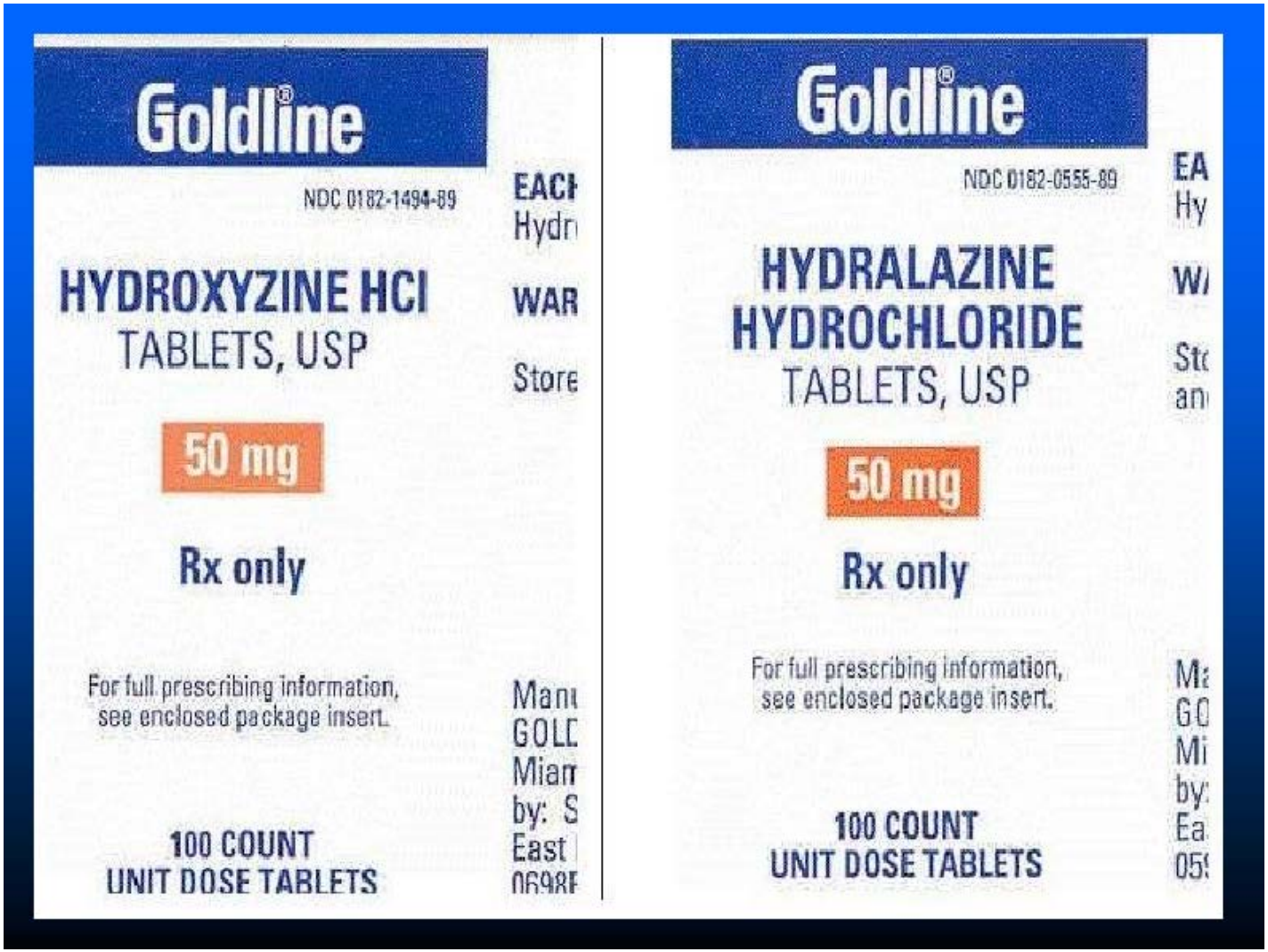

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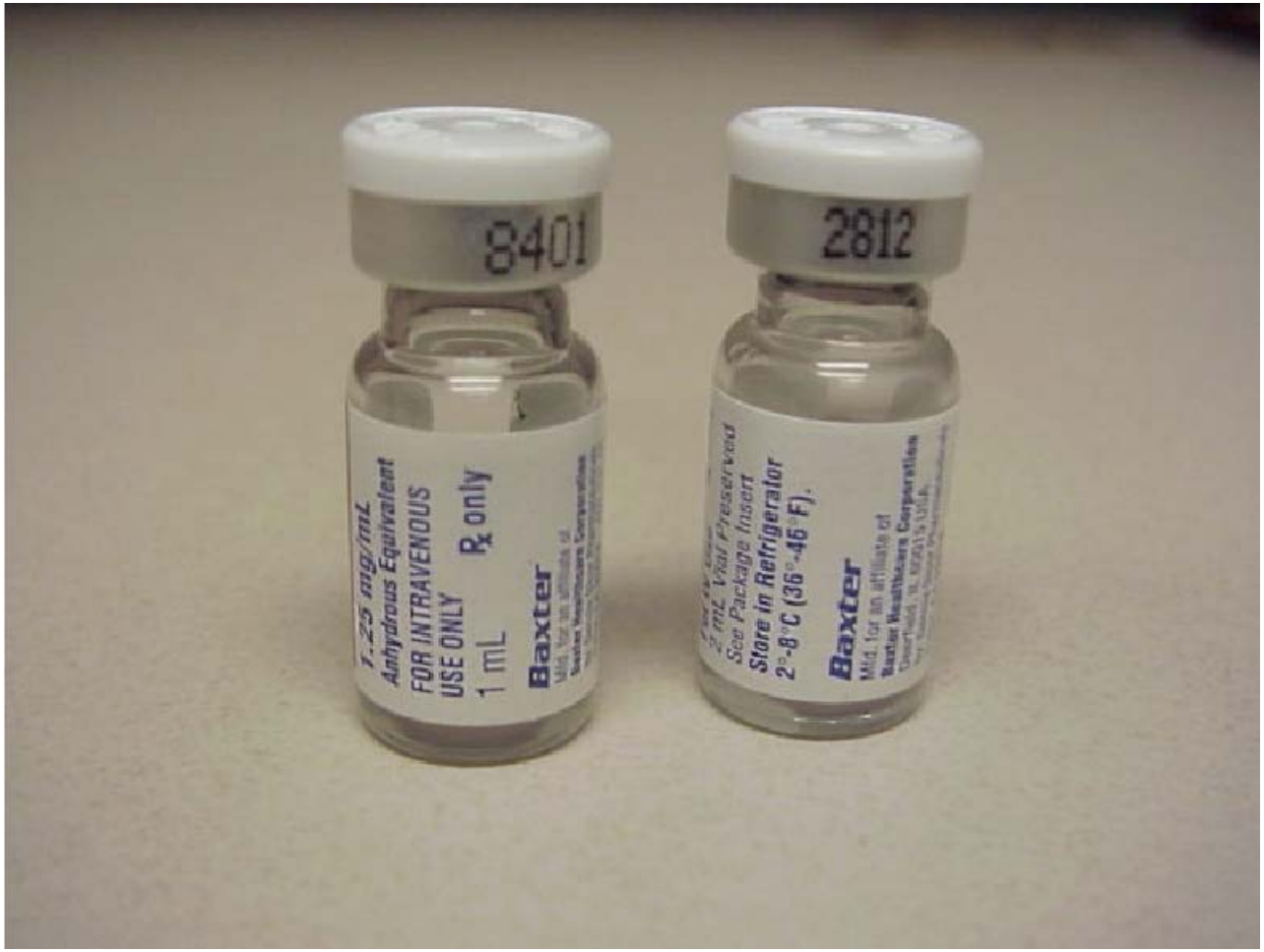
Neo-Synephrine
NASAL DECONGESTANT
INDICATIONS:
For the temporary relief of nasal congestion due to a cold, hay fever or other upper respiratory allergies or associated with sinusitis. Temporarily relieves stuffy nose and restores freer breathing through the nose. Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure.
5301-06-A5
REGULAR STRENGTH SPRAY
Neo-Synephrine
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION
NASAL DECONGESTANT
REGULAR STRENGTH SPRAY
1/2 FL OZ (15 ml)
Neo-Synephrine
NASAL DECONGESTANT
EXPIRES:
REGULAR STRENGTH SPRAY
Neo-Synephrine
NASAL DECONGESTANT
INDICATIONS:
For the temporary relief of nasal congestion due to a cold, hay fever or other upper respiratory allergies or associated with sinusitis. Temporarily relieves stuffy nose and restores freer breathing through the nose. Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure.
5401-06-A5
12 HOUR SPRAY EXTRA MOISTURIZING
Neo-Synephrine
FAST RELIEF
GOES RIGHT TO THE CORE OF YOUR CONGESTION
SOOTHES AS IT RELIEVES!
NASAL DECONGESTANT
12 HOUR SPRAY EXTRA MOISTURIZING
1/2 FL OZ (15 ml)
Neo-Synephrine
NASAL DECONGESTANT
EXPIRES:
12 HOUR SPRAY EXTRA MOISTURIZING
752



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NDC 0173-0642-55
LAMICTAL®
(LAMOTRIGINE)
TABLETS
100 mg
CAUTION:
Verify
Product
Dispensed
100 Tablets
Rx only
Each scored tablet contains 100 mg
of lamotrigine.
See package outsert for Dosage and
Administration.
Store at 25°C (77°F); excursions
15-30°C (59-86°F) in a dry place.
Dispense in a tight, light-resistant
tainer as defined in the USP.
Glaxo Wellcome Inc.
Research Triangle Park, NC 27709
4127951
Rev. 0501
0173-0642-55

Health Canada Guidance for Review of Drug Brand Names

Products Covered by this Guidance

- ✓ Pharmaceutical Prescription Drugs
- ✓ Schedule D products (Biologics)
- ✓ Schedule C products (Radiopharmaceuticals, kits)
- ✓ Drugs sold to the general public with the intervention of a pharmacist (nitroglycerin, insulin, injectable epinephrine)
- ✓ Drugs sold directly to healthcare professionals for their use (e.g., anesthetics)

Products NOT Covered

- ✓ Disinfectants (Separate Guidance issued in January 2014)
- ✓ Non-prescription (OTC) products and natural health products (Guidance is being developed)
- ✓ Non-proprietary names (proper/common name) that contain a modifier, the manufacturer name or an acceptable abbreviation of the manufacturer name.

A LASA Assessment is Required

- ✓ New Drug Submission (NDS)
- ✓ Supplement to a NDS (SNDS)
- ✓ Abbreviated New Drug Submission (ANDS)
- ✓ Supplement to a ANDS (SANDS)
- ✓ Applications for Drug Identification Numbers – DINA and NINB (including labeling only)

Review Timelines

- ✓ 90 day review clock for submissions that involve a target of 180 days or longer. However, our clients experience longer review times.

- ✓ An additional abbreviated review conducted 30 days prior to issuance of NOC/DIN in order to look at recent approvals for conflicts.

International Submission

- ✓ International data and submissions in lieu of Canadian data is **not recommended by DSI**, but Canada allows if:
  - The name is run through POCA within the Drug Product Database (DPN) and Licensed Natural Health Product Database (LNHPD) and the names identified in the International study are IDENTICAL to those identified in Canada.
  - Medication use process and indications, etc. should be the same in Canada as studied in other regions.
  - A similar FMEA process must be conducted

Initial Pre-Screen

- ✓ Is the name/modifier misleading or promotional?
- ✓ Does the name imply an ingredient not included in the product?
- ✓ Is the name identical to another product containing a different ingredient?
- ✓ Does the name have a USAN/INN stem in the position defined by USAN/INN?
- ✓ Does the name favor one ingredient?
- ✓ Does the name conflict with Schedule A of the *Food and Drugs Act?*

Other Pre-Screening Questions

- ✓ Is the name the same/similar to a discontinued product?
- ✓ Does the name have a confusable abbreviation (e.g., OD, QD)?
- ✓ Does the modifier have a single letter or number?
- ✓ Does the name imply a medical term or acronym?
- ✓ Does the name contain a letter sequence/stem that is in a different position designated by USAN/INN?
- ✓ Is the proper/common name abbreviated or truncated?
- ✓ Is the name approved in another country for a product with a different medicinal ingredient?

LASA Brand Name Assessment

- ✓ Search
  - Names with POCA scores of 50% or higher in the Drug Product Database and Licensed Natural Health Products Database
  - Published literature for error reports
- ✓ Simulate
  - Develop a process map
  - Simulations using 100 Canadian HCP's (25% French Speaking) required
  - Simulations not required for Schedule C Drugs (radiopharmaceuticals, kits)
- ✓ Synthesize
  - FMEA (12 active Canadian HCP's)
  - Report

LASA Brand Name Assessment - Modifiers

- ✓ Section 2.2 (Initial Brand Name Review)
  - Should be completed only on the modifier of the proposed brand name
- ✓ Simulations
  - Simulations not required, unless the modifier is new and never been approved/used in Canada
  - Sample size of 100 respondents is not required
- ✓ Appendix 2 – Modifiers/Abbreviations
  - Modifiers need to meet the minimum criteria as outlined in Appendix 2
  - Express clear meaning; useful; not be ambiguous; consideration to the omission of the modifier in the prescribing process.

Summary

- ✓ Went into effect June 13, 2015
- ✓ Data “required” for submissions
- ✓ Requires a Sample Size of 100 Healthcare Professionals and a FMEA panel consisting of 12 additional Healthcare Professionals.
- ✓ OTC products are excluded currently
- ✓ FDA’s POCA is required for selection of all names in Canada exceeding 50% similarity
- ✓ Robust Data Analysis required

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Thank You!!!

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