Assessing the ‘Safety’ of a Brand Name

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Overview

1. Introductory concepts & definitions
2. Look-alike Sound-alike (LA/SA) name examples
3. Evaluation techniques used in assessing name safety
4. FDA and EMEA LA/SA name review processes

Health Product Naming Challenge

-Health product naming presents unique challenges versus naming of typical consumer goods

- Pharmaceutical industry must strive to develop names that balance **patient safety** & **marketing** objectives

Look-alike/sound-alike (LA/SA) Names

- Refers to names of different health products that have:
    - **orthographic** similarities (look similar)
    - **phonetic** similarities (sound similar)
- May pose risk to patient safety by contributing to occurrence of medication errors, which may cause patient harm

Managing risks associated with look-alike/sound-alike names…

…is a **shared** responsibility:

- beginning with pharmaceutical industry & regulatory agencies
- spans entire healthcare continuum (healthcare practitioners, consumers)

Drug Names

Brand/Proprietary Name:

-name assigned and owned by the manufacturer (registered as trademark) and under which the drug is sold or advertised

- valuable intellectual property

- e.g. Viagra™

Drug Names (continued)

Nonproprietary Name (some say 'generic' name):

-name used to describe the drug substance in a product; assigned by regulatory agencies such as United States Adopted Names (USAN) Council, or World Health Organization's (WHO) International Nonproprietary Names (INN) Committee

- e.g. Sildenafil (contains INN and USAN suffix stem '*- afil*' used to denote vasodilators that are PDE5 inhibitors)

Quick Recap…

- Pharmaceutical naming presents special challenges in balancing patient safety & marketing objectives

- LA/SA names can contribute to occurrence of medication errors & patient harm

- Medication errors can occur at any stage of the medication use system

- Managing risks associated with LA/SA names is a shared responsibility amongst all stakeholders

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Health Canada Guidance to Industry

- "Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names"

- Sponsors should consider potential for LA/SA name similarity when developing brand names

- Health Canada will review brand names for potential to be confused with another product and cause patient harm

- Requirement that new health product ***brand names not look or sound similar to marketed brand or nonproprietary names***

Look-alike Names

ATRIVA (hypothetical)

ATIVAN (brand name)

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Sound-alike Names

TOBRAFLEX (hypothetical)

TOBRADEX (brand name)

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Look-alike and Sound-alike Names

OBREVA (hypothetical)

ABREVA (brand name)

TOBRAFLEX (hypothetical)

TOBRADEX (brand name)

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Industry to Submit to Health Canada…

- Supporting evidence of having performed due diligence in evaluating 'safety' of a proposed brand name as part of submission package

- Submit:

    - risk assessment evaluation of proposed brand name supported by **'studies, data and analysis'**

Examples of Name Safety Evaluation Techniques

1. Generating potential LA/SA names of marketed products
2. Prescriptions simulation studies
3. Computerized orthographic and phonetic analysis
4. Product profile comparisons

Identifying LA/SA Names of Marketed Products

- Survey actively practicing healthcare professionals for existing LA/SA names

- Searching various drug databases and reference sources to generate LA/SA names

- NB: Search names reflective of the market for which approval is being sought

Prescription Simulation Studies

- **Verbal and handwritten** prescription examples

- Actively practicing healthcare practitioners interpret simulated orders

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Computerized Orthographic and Phonetic Analysis (COPA)

- Objective, computerized analysis tool uses sophisticated algorithms to assess sound-alike and look-alike similarity between names

- Health Canada will be using POCA tool (same as US FDA's tool) that does orthographic analysis & English phonetic analysis

But name similarity alone is not enough to determine products that could be potentially confused…

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Product Profile Analysis

- Assessment of **product profile characteristics** of potential LA/SA brand or nonproprietary names

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Drawing A Conclusion

- Additional ‘practice-based’ human judgment by human experts in the field and practicing healthcare professionals to assess factors that aren’t easy to automate

- Harm analysis

- Apply lessons learned from previous post-marketing experience

- Based on collective analysis of the multi-faceted data, in combination with human judgment

Not An 'Absolute Guarantee'

- Proactive LA/SA name safety analysis can't possibly 'absolutely ensure' that a drug name will not be confused with a marketed product in 'real-world' practice post marketing

- Shows that due diligence has been performed & may help reduce medication errors related to LA/SA drug names

Promotional/Misleading Brand Names

Overly promotional or misleading brand name could also be a reason for rejection of a name candidate

Name Review by the FDA

Name Safety Review

- Division of Medication Errors and Technical Support (DMETS)

- Provides pre-marketing reviews of all proprietary drug names labels and labeling in order to reduce medication error potential of proposed product

- Also provides post-marketing review and analysis of medication errors received

Name Review by the FDA (continued)

Promotional Aspect Review of Proposed Names

- Division of Drug Marketing, Advertising, and Communications (DDMAC)

- Reviews proposed brand name candidates to ensure that they are not misleading, inappropriate or exaggerative with respect to product composition or activity

- Annual rejection rate of names currently by FDA ~40%

Name Review by EMEA

(Invented) Name Review Group (NRG)

- EMEA Committee for Medicinal Products for Human Use (CHMP) sub-group that reviews acceptability of proposed invented names (ie. brand names) processed through the centralized approval procedure

- NRG composed of representatives from EU Member States

- Annual rejection rate averaging ~50%

Common Name Review Goal of All Regulators…

- Medication error, and potentially related patient harm minimization

- Opinions on acceptability of a proposed brand name not always consistent because based on particular nomenclature landscape

- Approval of name by one regulator does not assure approval by another

In Closing…

- Receiving regulator approval of a preferred brand name is an important regulatory as well as marketing step for sponsors, and is a hurdle that is becoming increasingly tough to clear

- The brand name may only be a *small* part of the overall New Drug Submission (NDS) package, but it is a *critical* one for industry

- Due diligence in proactively assessing name 'safety' should be a standard part of each manufacturer's drug development process

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Thank you!