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DAY 2 OBJECTIVES

- Inform/educate interested and affected parties about LA/SA health product names and the current policy development process

- Provide an opportunity for interested and affected parties to express their concerns and/or endorsement regarding policy options and proposed recommendations to address LA/SA health product names
Proprietary Name Review at FDA

Evaluator performs risk benefit analysis of data

DMETS APLB decision

DMETS APLB

request for consult

request at review (prefer at IND review)

decision delivered

Reviewing Division
decision reviewed for concurrence

Computer Analysis

Handwriting and Verbal Analyses

Expert Panel Review

Evaluator perfroms risk benefit analysis of data

Health Santé
Canada Canada

Biologics and Genetic Therapies Directorate
Direction des produits biologiques et thérapies génétiques
Guideline entitled *Guidelines on the Acceptability of Invented Names for Human Medicinal Products Processed Through the Centralized Procedure*.

EMEA attempts to ensure that a medicinal product not bear an invented name that could be confused with that of another medicinal product (safety issue).

EMEA believes that it is crucial that consistent, non-arbitrary criteria are applied when reviewing the acceptability of proposed proprietary names.

The invented name should only consist of one word and should avoid qualification by letters and numbers including the use of short forms and abbreviations.

The sponsor can provide the EMEA with up to three proposed names per market authorization application.

The Name Review Group reviews proposed invented names.
Proposed Pre-Market Options

- General
  - Status Quo

- Policy
  - SOP/Policy /Guideline
  - Regulations/Legislation

- Computer related
  - use of current Drug Submission Tracking System (DSTS)
  - use of current integrated Records Information Management System (IRIMS) system
  - development of new computer application in-house
  - basic computer application
  - LA/SA-specific complex computer application with added features
Pre-market Options (cont'd)

- Review process
  - Foreign Review (FDA/EMEA etc)
  - Review by Third Party
  - Name review (HC)
  - Name review committee

- Sponsor filing requirements
  - Sponsor provides a prioritized list of name choices
  - Sponsor does search/analysis for LA/SA similarities
  - Require trademarks

- Other
  - Combination of options
Post-market Options

- General
  - Status Quo

- Policy
  - SOP/Policy /Guideline
  - Regulations/Legislation

- Computer related
  - Bar coding - product ID and verification
  - electronic prescribing (printed scripts)

- Industry Requirements
  - require company to change name of the health product
  - require company to modify label (i.e. lettering on label)
Post-market Options (cont'd)

- Monitoring (environmental scans)
  - Incorporate LA/SA errors into ADR reporting
  - LA/SA error reporting (from other jurisdictions) - look back (i.e. Anonymous FDA-MedWatch reporting)
  - Foreign reviews
  - ISMP-watchdog
  - use pre-market system to look for LA/SA approved health products

- Health promotion/stakeholder awareness
  - increase awareness of documented LA/SA health products to stakeholders (e.g. info line, fact sheets, Dear Health Care Professional Letters, comments in ADR newsletter, LA/SA website, education of LA/SA health products in medical schools)

- Other
  - Combination of options
WG agreed to use both a quantitative and qualitative approach to assess options.

The quantitative analysis included the use of a decision analysis technique to review options in which criteria used to assess options were grouped into screening criteria (must haves) or comparative criteria (nice to have). If options did not meet screening criteria, they were eliminated from further consideration. After assigning a weight to comparative criteria (1 to 10), options were ranked according to how well they met the other comparative criteria (using a 10 point scale).

The qualitative technique required that the LA/SA WG members vote on preferred options.
Pre-market

- 1st choice: Policy/Complex Computer Application/name review/name review committee/company provides name analysis and prioritized list

- 2nd choice: Policy/Computer Application/name review/name review committee/company provides name analysis and prioritized list

- 3rd choice: Policy/Build internal system & name review and name review committee/company provides name analysis and prioritized list

- 4th choice: Policy/DSTS system (enhanced with some DPD support) & name review and name review committee/company provides name analysis and prioritized list
RECOMMENDATIONS

Post-market

➢ 1st choice   Policy/Promotion & Monitoring

➢ 2nd choice   Policy/Promotion
Next Steps

- Post-Workshop report will be posted on the Health Canada website and mailed to stakeholders.

- The LA/SA WG will consider and analyze all feedback provided in the consultation period and will revise the Issue Analysis Summary, where necessary.

- Approval of revised IAS and recommendations by senior management and the WG

- Proceed with computer feasibility study, RFP and Phase III of this project