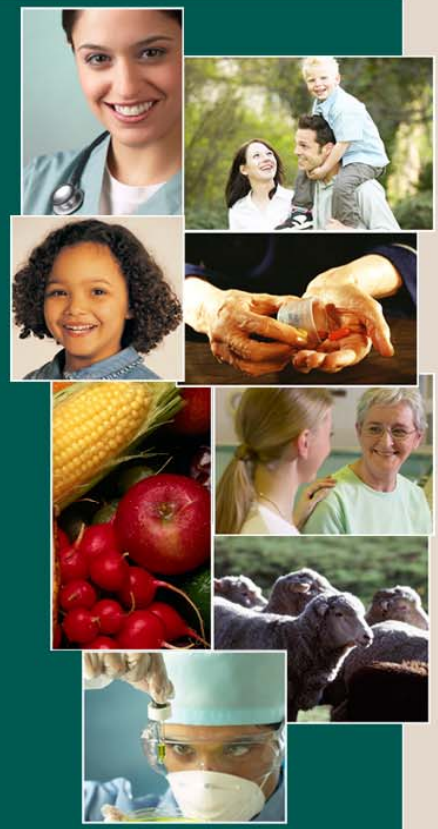
Health Products and Food Branch

Your Health and Safety - Our Priority



Post-Notice of Compliance (NOC) Changes

CAPRA Symposium
April 24,2007

Health Canada Santé Canada

Canada

Outline

- Overview of the Post-NOC Changes Project
- Overview of New Guidances
- Implementation Plan
- Next Steps

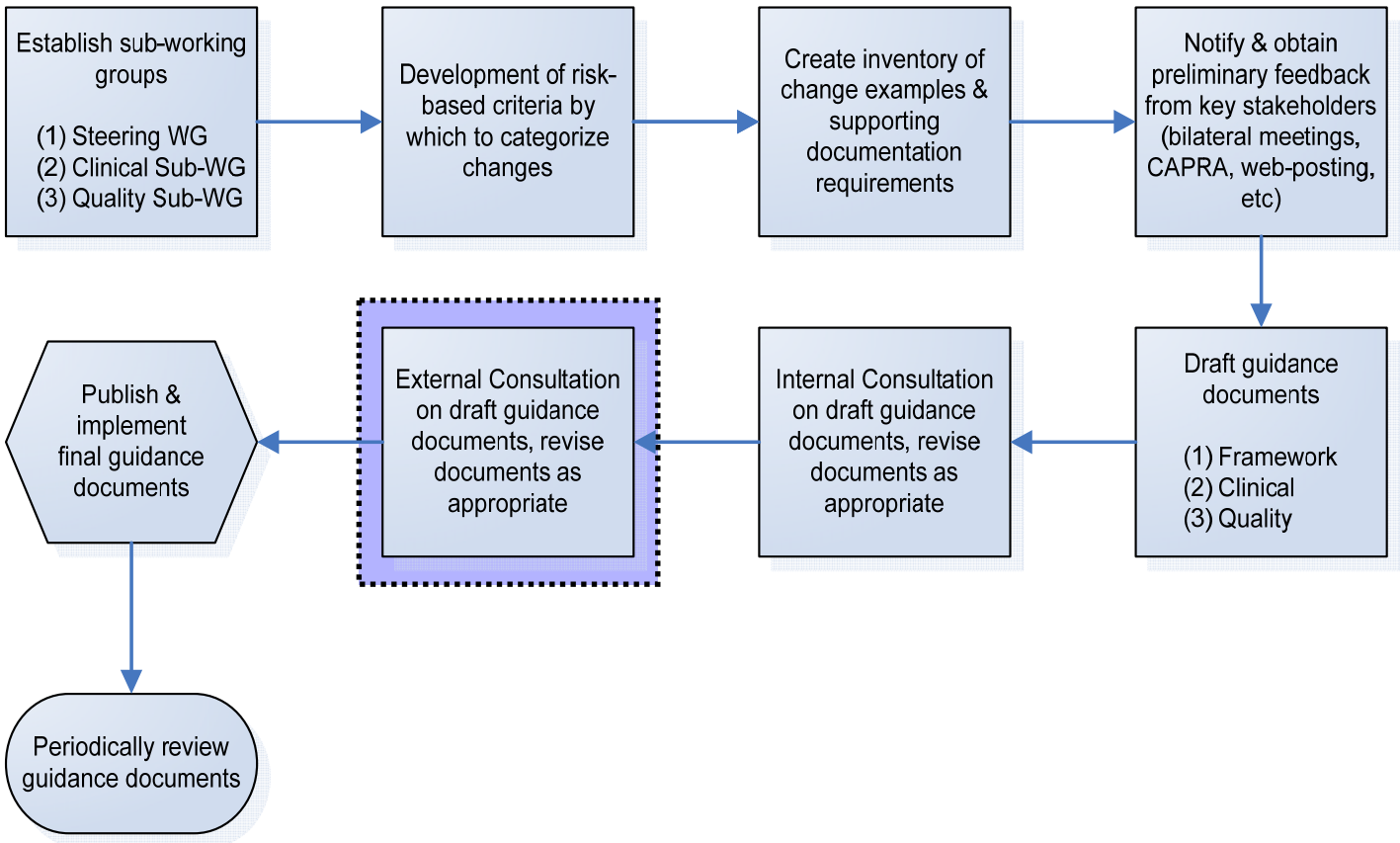
Post-NOC Changes Project

- Project Objectives
  - review how post-NOC changes are managed by examining existing regulatory authorities, policies, guidances and practices of Health Canada and other regulatory agencies
  - develop proposal to address issues

Post-NOC Changes Project

- Key issue identified by internal & external stakeholders:
  - existing policies and guidance documents regarding post-NOC changes lack clarity and detail with respect to classification of a change and documentation needed to support that change
- Working Group proposal:
  - Develop new, more comprehensive guidance documents to manage Post-NOC changes

Guidance Development Process



Post-NOC Changes Project

- Draft Post-NOC Changes guidance documents posted to Health Canada website March 16, 2007
- **Feedback to be obtained from:**
  - Submission of comments during 90 day comment period and;
  - CAPRA symposium

Overview of New Guidances

Scope and Application:

- changes to new drugs that have received an NOC pursuant to section C.08.004 of the *Food and Drug Regulations*
- pharmaceuticals, biologics, and radiopharmaceuticals for human use
- pharmaceutical, radiopharmaceutical and certain biotechnological products for veterinary use
- applies to those submissions for which a NOC has been recommended but issuance of the NOC has been placed on hold

Overview of New Guidances

- Content of new guidances:
  - Greater detail
  - Risk-based criteria/conditions to distinguish between levels of change within existing regulatory/process framework
  - Supporting documentation recommendations
  - Greater number of change examples

Overview of New Guidances

- Structure of new guidance:
  - modelled after EU Variations Guidance format
  - provides “Conditions/Criteria” and “Supporting Documentation” for various change examples
  - consists of three separate documents:
    (1) Framework Document
    (2) Safety & Efficacy Document
    (3) Quality Document

Overview of New Guidances

- Framework ("Parent") Document
  - policy objectives, categories of change, general guidance and procedural requirements applicable to all changes, etc.
- Safety & Efficacy Document
  - detailed criteria and instructions for the categorization and filing of safety & efficacy-related changes
  - follows format of the Product Monograph
- Quality Document
  - detailed criteria and instructions for the categorization and filing of quality-related changes
  - separate appendices for pharmaceuticals, biologics, and radiopharmaceuticals
  - follows ICH CTD progression

Overview of New Guidances

- **Levels of Change:**
  - Supplements (Level I)
  - Notifiable Changes (Level II)
  - Annual Notifications (Level III)
- **Eliminated:**
  - Level 4 – “Changes not listed in Levels 1-3”

Overview of New Guidances

- Guidance documents will supercede:
  - *New Drug: Sufficient Time* policy (1991)
  - *Extension of Expiration Dates* (1991)
  - *Changes to Marketed New Drug Products* policy (1994)
  - *Stability Requirements for Changes to Marketed New Drugs* (1994)
  - *Changes in Product-Specific Facility Information* (revised in 2004)
  - *New Drug: Sufficient Time* notice (2005)
  - *Changes in Product Colours and Markings* (2005)

Implementation Plan

- Phased Approach linked to New Regulatory Framework
- Phase 1:
  - Publish new guidances that include revised classification criteria and recommended supporting documentation for different levels of change
- Phase 2:
  - all levels of change to be incorporated in the modernized regulatory framework as part of the Progressive Licensing Project

Implementation Plan

- Factors to be considered:

- How will submissions already under review be dealt with?
- Will submissions be required for changes that have already been made?
- What is the impact re the Patented Medicines (NOC) Regulations?
- Will there be cost recovery implications?

Implementation Plan

- Factors to be considered:

- What is the impact re e-CTD?
- Will the CPID and PM requested annually be reviewed or simply kept on file?
- What would be an appropriate grace period between release of the final guidances and the effective date?

Next Steps

- Consider stakeholder feedback in finalization of guidance (Summer 2007)
- Implementation plan (Finalize by Summer 2007)
- Posting of Final versions of Guidance (Anticipated Fall 2007)
- Effective date (Early 2008)

Thank You

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