Common Monographs – Over-the-Counter (OTC) Products

Presentation to RCC Stakeholder Dialogue Session

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Content

1. Overview
2. Progress update and current status
3. Looking ahead
4. Lessons learned and catalysts to further alignment
5. Questions

Overview

The objectives of the RCC OTC Monograph Working Group are to:

- Make it easier for US and Canadian firms to do business on both sides of the border through greater regulatory alignment

- Conduct a pilot program that develops and aligns monograph elements for a specific drug category
    - Indications
    - Conditions of Use
    - Directions
    - Warnings

- Provide recommendations on the feasibility for developing an aligned OTC drug monograph
    - Where are the greatest areas for alignment?
    - Where are the current obstacles for collaboration?
    - How will future projects, teams, and communication methods be established?

Progress update: What have we accomplished?

First Step: Scope and Governance

Learning about each other's regulatory system

- Monograph development
- Agency structure
- Recognizable differences

Second Step: Selection of Pilot monograph

Review of the regulatory history for monographed drug products

- Discussion and review of published and unpublished regulatory documents
- Discussion of any foreseeable complexities and potential policy implications

Third Step: Development of Aligned Monograph

Review of the clinical data and discussion of labeling

- Clinical data review
- Label review

Fourth Step: Public Process for Pilot Monographs

- January 2013 FDA and HC announced common cold indications for certain over-the-counter antihistamine ingredients as the first area of alignment

Current Status: Where are we now?

Updates within FDA and HC:

- Have shared their respective draft documents for comment and review within the working group
- Identified any potential areas of conflict
- Continue to meet every two weeks

Current Status:

FDA

Drafted a proposed rulemaking and currently in clearance

HC

Developed a draft guidance document and awaiting internal approvals

Looking Ahead: Where are we headed?

- **Goal**
  - Short Term: Publication of proposed draft documents with aligned elements (ingredients, indication, directions, warnings, etc.)
  - Long Term: Both regulatory agencies are considering opportunities for further monograph alignment
- **Timing**
  - Both agencies will publish their draft and final documents at the same time
  - Working together through the final rulemaking and comment periods
- **FDA**
  - Publish a proposed rulemaking
  - Similar to other proposed rulemakings: there will be a comment period
  - Publication of a final rulemaking
- **HC**
  - Publish a draft guidance document
  - Similar to other guidance documents: there will be a comment period
  - Publish a final guidance document

Recommendations: Lessons Learned and Catalysts to Further Alignment

Lessons Learned

- **Regulation versus Policy:** Addressing safety issues in a timely manner
- **External Communications:** Addressing industry requests for increased participation and notification (progress updates)Managing agency restrictions on external communications
- **'Life Cycle' Approach:** Future projects will require a 'Life Cycle' approach to prevent drift between documents over time
- **Implementation Strategies:** Notable and unique differences for HC and FDA within each regulatory system

Catalysts to Further Alignment

- **Collaboration:** Active participation from both FDA and HC
- **Documentation:** Work plan documentation and meeting agenda/minutes
- **Working Group Discussions:** Selection of the current monograph
  - Consideration of other monographs for future projects
  - Information sharing and exchange in the absence of IT infrastructure
- **Meeting Targeted Timelines and Goals**

Questions

- Is there an interest in aligning a particular class of OTC ingredients?

- Are there better ways to engage stakeholders on the development of monographs given current HC and FDA policies on monograph development?