Health Canada Santé Canada

Product Monographs: Update on Regulations, Guidelines & Templates

Micheline Ho

Manager, Product Information Division

Therapeutic Products Directorate

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Health Products and Food Branch

Direction générale des produits de santé et des aliments

Mission and Vision

- **Health Products and Food Branch's Mandate is to take an integrated approach of the management to the risks and benefits to health related to health products and food by:**
  - **Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,**
  - **Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.**

Therapeutic Products Directorate Strategic Framework and Objectives

- To ensure Canadians have timely access to safe, effective, high quality therapeutic products;
- Are not put at undue risk by the use of therapeutic products available on the Canadian market; and
- Receive appropriate information about the risks and benefits of those therapeutic products

Format and Legal Requirements

- Format revised to meet users needs
- Legal Requirements:
  - Section 9 of the Food and Drugs Act
  - Section C.01.004
    - Requires Adequate Directions for Use

Adequate Directions for Use

- Indications for Use
- Dosage and Administration
- Contraindications, Warnings/Precautions, Side-Effects
- Labels, Package Inserts, Product Monographs

History of Product Monographs

- **1968:** First use of Product Monographs
- **1976:** First Guidance Document on Format and Content of Product Monograph
- **1989:** First Major Revision of Guideline
- **2003:** Second Major Revision of Guideline

History of Project

- **1998:** Study on new template with Health Care Providers
- **Winter 2000:** Workshop with Patient Advocacy Groups
- **Fall 2000:** Stakeholders Workshop on Format / Content / Dissemination

History of Project … continued

- **Fall 2001:** Consumer Focus Groups on Format, Content, and Format of Part III
- **May 2002:** Validation Exercise with Industry
- **Fall 2002:** Final Stakeholders Consultation

Project Objectives

- Revise the format and presentation to meet user needs
- Adopt a standard format
- Revise the guidelines
- Make Product Monograph available to the public

The Commitment:

Key Business Transformation Strategy

Speech from the Throne - 2002

As part of its focus on Smart Regulation, the government .... (will) speed up the regulatory process for drug approvals to ensure Canadians have faster access to the safe drugs they need."

Budget - 2003

Provide $190 million over 5 years "to improve the timeliness of Health Canada's regulatory processes with respect to human drugs – while preserving the principle that safety is of paramount concern."

Health Canada's Response:

The Therapeutics Access Strategy

In the near term, improve regulatory performance around timeliness and transparency, benchmarked against leading international practices

The Initiatives

- Project Management
- Good Review Practices
- International Cooperation
- Transparency
- E-Review
- Regulatory Policy
- Expert Advisory Capacity

Transforming the way we do business:

- **Business Mantra:**
  - Effective and efficient practices for science and review process management
  - Commitment to performance targets and continuous improvement
- **Organizational Transformation:**
  - Culture change
  - The submission is the project

Transforming the way we do business:

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  - **Culture change**
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Revised Format

- Part I - Information for the Health Professional
- Part II - Scientific Information
- Part III - Information for the Consumer

Table of Contents

Part I – Information for the Health Professional

Tablet of Contents

Part II – Scientific Information

- Pharmaceutical Information
- Clinical Trials
- Detailed Pharmacology
- Microbiology
- Toxicology
- References

Part III – Consumer Information

- Derived from Parts I and II

Part I of Product Monograph

% Health Professional Information

- **Summary of Product Information**
  - Table Format – Active Substance, Dosage Forms, Strength, Nonmedicinal Ingredients (NMI's)
- **Indications and Clinical Use**
  - Point Form with Brief Discussion
  - Population subsets – Geriatrics / Paediatrics

Part I of Product Monograph ... continued

- **Contraindications**
  - Point Form
- **Warnings and Precautions**
  - Single Section
  - Boxed Information to Highlight Most Serious Warnings / Precautions
- **Specific Subheadings for Particular Organ Systems and Subpopulations**

Part I of Product Monograph ... continued

- **Adverse Reactions**
  - Overview Narrative
  - Clinical Trial Adverse Drug Reactions – Table Format
    - Show Relative Frequency Drug / Placebo / Active Control
  - Post-market Adverse Drug Reactions
    - Canadian and International
    - Table or Narrative Based on Volume
- **Common Terminology**
  - MEDDRA and CIOMS for Frequency Groupings

Part I of Product Monograph ... continued

- Interactions
  - Drug/Drug, Drug/Herbs, Drug/Food, Drug/Laboratory Tests
  - Box to Highlight Serious Interactions
  - Overview – Narrative
  - Listing – Table Format

Part I of Product Monograph ... continued

- **Dosage and Administration**
  - Dosage Considerations – Point Form
  - Dosage Recommendations *per se*
  - Missed Dose Information
  - Preparation and Administration Instructions

Part I of Product Monograph ... continued

- **Overdosage**
  - Description of signs and symptoms
  - Current Recommendations (e.g., antidotes / interventions)
  - Human Lethal Dose (if known) maximum dose reported with recovery
  - Unnecessary or Unsuitable Procedures

Overdosage (continued...)

- Workshop – February 10, 2004
- CMAJ Article – October 2002 (2001 CPS)
- Industry / PCC / Consumer / HCP / Emerg on D
- Goal – How do we work together to remedy the problem

Overdosage (continued...)

- CPS 2004 – Includes O.D. plus reference to PCC
- CPS 2004 – General Monographs revised
- No Concensus on Deleting O.D. Information from Product Monograph

Overdosage (continued...)

Recommendations before or at workshop

- Delete overdosage information from Product Monograph and CPS
- Replace O.D. with consult PCC
- Retain signs and symptoms, delete treatment and refer to PCC
- Separate O.D. Section in CPS
- Expert Panel to Health Canada to review O.D. information

Part II of Product Monograph

% Scientific Information

- **Clinical Trials – New Section**
  - Pivotal Trials – Table Format
  - Study Demographics and Trial Design
  - Study Results – Statistical and Clinical Significance
  - Dosage Ranges and Study Duration
  - Pivotal Bioavailability Studies

Part II of Product Monograph … continued

- **Detailed Pharmacology**
  - Animal and human Data – *In vitro* / *In vivo* Subsections
  - Pharmacodynamics / Pharmacokinetics
  - Microbiology
  - Pharmaceutical Information
  - Toxicology
  - References

Consumer Information – Part III

- Information derived from Parts I and II that helps the consumer understand what the medication is, how to use it and what the potential side effects are

- Presented in a language and format that is appropriate to a consumer audience

Consumer Information – Part III

- Consumer focus group testing on Part III conducted in August/September 2001 – 16 sessions, 6 locations, both official languages, various segments of the population

- Strong support for Health Canada's involvement in the development and approval of consumer information

Consumer Information – Part III

- Consensus that consumer information is extremely important
- Consistency with respect to type of information that should be included
- Consistency with respect to how the information should be presented

Consumer Information – Part III

- Consensus that consumer information is extremely important
  - For all prescription drugs
  - Most important information up front (box warning)
  - Where to get more information (full product monograph)

Consumer Information – Part III

- **Consistency with respect to type of information that should be included:**
  - How best to use the medication
  - Possible side effects
  - Purpose of the medication
  - List of ingredients
  - Dosage information
  - Contact for additional information

Consumer Information – Part III

- **Consistency with respect to how the information should be presented:**

  - **Clear and easy to understand**
  - **Easy to scan**
  - **Use of point form and bullets**
  - **Large enough font**
  - **Use of bolding, underlining and other highlights**
  - **Standard format so people know where to look for specific information**

PART III: CONSUMER INFORMATION

<Brand name>
<Proper Name>

This leaflet is part III of a three-part "Product Monograph" published when the drug is approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about <brand name>. Contact your doctor or pharmacist if you have any questions about the drug.

WARNINGS

- <text>
- <text>

ABOUT THIS MEDICATION

What the medication is used for:
<narrative> and/or
- <text>
- <text>

What it does:
<text>

When it should not be used:
<text>

What the medicinal ingredient is:
<proper name>

What the nonmedicinal ingredients are:
<alphabetical listing>

What dosage forms it comes in:
<dosage form(s) and strength(s)>

PRECAUTIONS

BEFORE you use <brand name> talk to your doctor or pharmacist if:

- <Activities (Warnings and Precautions, e.g, under Occupational Hazards) >
- <Current conditions (Contraindications, Warnings and Precautions)>
- <Past diseases (Contraindications, Warnings and Precautions)>
- <Reproductive issues (Contraindications, Warnings and Precautions)>
- <Anticipated medical procedures (Warnings and Precautions)>
- <Contraindicated or interacting drugs (Contraindications, Drug Interactions)>
- <Any allergies to this drug or its ingredients or components of the container (Contraindications)>

MEDICATION INTERACTIONS

Drugs that may interact with <brand name> include: <text> .

PROPER USE OF THIS MEDICATION

Usual dose:
<text>

Overdose:
<text>

Missed Dose:
<text>

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

<text>

This is not a complete list of side effects. If you have any unexpected effects while taking this drug, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	<symptom / effect> <symptom / effect>	☐	☐	
Uncommon	<symptom / effect> <symptom / effect>		☐	☐

REPORTING SUSPECTED SIDE EFFECTS

NOTE: THIS IS NOT AN EMERGENCY NUMBER

To help other Canadians use their drugs safely, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
toll-free fax 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Health Canada
Address Locator: 0201C2
Ottawa, ON K1A 1B9

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.website.document
or by contacting the sponsor, <Sponsor Name>, at:
1-800-XXX-XXXX

This leaflet was prepared by <Sponsor Name>

Last revised: <MON DD, YYYY>.

HOW TO STORE IT

<text>

Next Steps

- Posting of Guidance – Fall 2003
- Training of Health Canada Reviewers – Fall/Winter 2003, Spring 2004
- Voluntary Implementation – Fall 2003
  - NDS / SNDS / NCs
- Mandatory Implementation – October 2004

Dissemination

- Interim Proposal – Fall 2002
- Distribution Upon Request
- Responses Analyzed

Dissemination ... continued

- Agreement on Distribution at time of Marketing
- New Communication / Consultation on related Issues
- Release of Updated Product Monographs
- Internal Pilot Project

www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/consult_monograph.html