# Key Elements and Strategies of a Good Review

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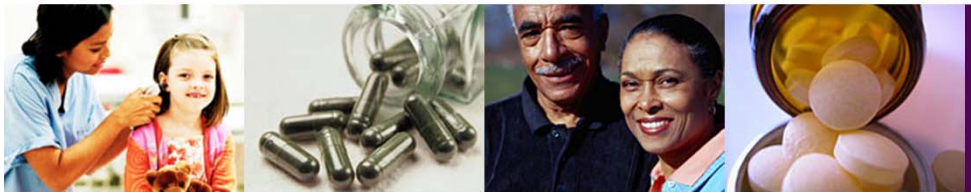
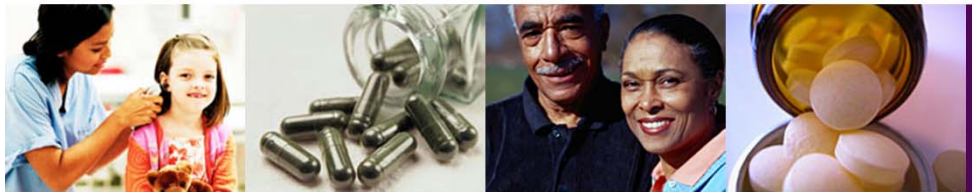
# Session Objectives

1. Understand the basic aspects of a good review.
2. Share experiences on different strategies to produce good reviews.
3. Consider which elements and strategies need to be developed / improved in your own economy.



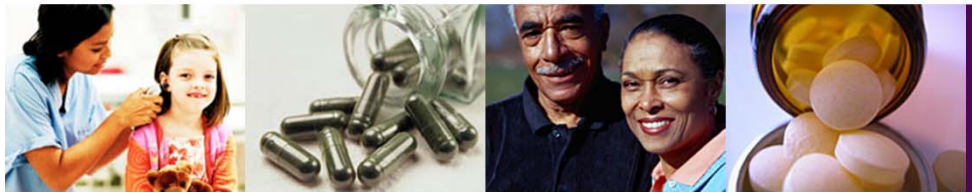
# Session Outline

- Key elements of a good review
  (Caroline Vanneste, Health Canada)
- Pre-filing strategies
  (Mark Goldberger,
  Food and Drug Administration Alumni Association)
- Review initiation strategies
  (Caroline Vanneste)
- Post-initial review strategies
  (Francesca Cerreta, European Medicines Agency)



# Session Outline (2)

- Breakout session A: How to implement / strengthen pre-filing strategies in your own agency
  (Mark Goldberger and Atsushi Tamura, PMDA)
- Breakout session B: How to implement / strengthen review initiation strategies in your own agency
  (Caroline Vanneste and Ming-Hsiao Chan, TFDA)
- Breakout session C: How to implement / strengthen post-initial review strategies in your own agency
  (Francesca Cerreta and Shelley Tang, formerly TGA)



THERAPEUTIC PRODUCTS DIRECTORATE 2006-02-07

# GOOD REVIEW GUIDING PRINCIPLES

The Therapeutic Products Directorate (TPD) regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a manufacturer submits substantive scientific evidence of a product's safety, efficacy and quality, as required by the Food and Drugs Act and Regulations and the Medical Devices Regulations.

Drugs include prescription and non-prescription pharmaceuticals, disinfectants and sanitizers. Medical Devices include a wide range of health or medical instruments used in the treatments, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Drug and medical device submissions are reviewed to assess safety, efficacy and quality of these therapeutic products before being authorized for sale in Canada.

This review process constitutes the core activity of the TPD, the final product of which is the Therapeutic Product Regulatory Review.

## A DESCRIPTION OF THE THERAPEUTIC PRODUCT REGULATORY REVIEW

A good Therapeutic Product Regulatory Review is an independent, objective, scientific and timely written analysis of the information relevant to a therapeutic product submission, which reflects the context of the proposed conditions of use, as described in the submitted labeling, and comprises a collection of documents that provide an account of the following:

All necessary points, in summary, of studies and findings relating to safety, efficacy and quality.

All identified risks and benefits

Potential risk management strategies

Evidence-based conclusions and final recommendations which provide a synthesis of the scientific and regulatory issues.

Thus, a good Therapeutic Product Regulatory Review documents both the sponsor's and reviewers' evidence-based findings, risk-benefit analyses and potential risk-management strategies as well as regulatory decisions taken regarding a therapeutic product submission. The various elements of a review are intended to be read by Health Canada staff and managers and their industry counterparts within the company sponsoring the submission; and potentially, stakeholders and the general public.

### Specific elements of a good Therapeutic Product Regulatory Review should include:

The Scientific Review Reports

The Disposition
*notice of deficiency, notice of non-compliance, notice of compliance.*

Product Information
*reviewed product monographs, prescribing information, labeling*

An Executive Summary

### And May Include:

Regulatory Correspondence
*faxes, emails, minutes of internal / industry meetings, scientific advisory committee deliberations*

An Issue Analysis Summary (IAS)

Summary Basis of Decision (SBD)

Advisories
*dear healthcare professional letter (DHPL), public advisory (PA)*

Visit the Good Review Practices (GRP) intranet for more useful tips and a large collection of reviewer useful resources.

http://hpfb-review.hc-sc.gc.ca/grp-bpe_intranet/welcome_e.html

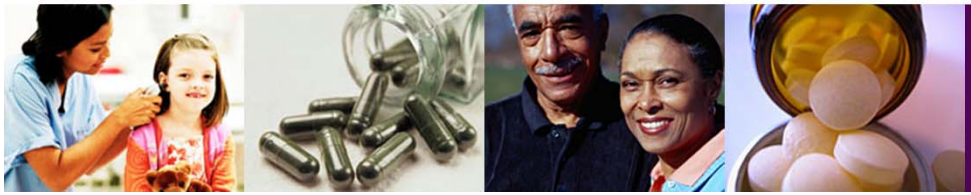
Health Canada / Santé Canada

Canada

GOOD REVIEW PRACTICES GRP BPE BONNES PRATIQUES D'EXAMEN

# Ten key elements of a good review

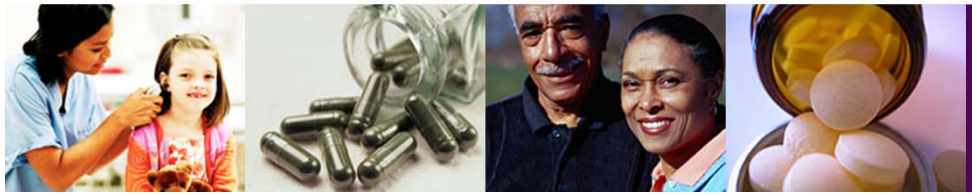
- is learned
- uses critical analyses
- identifies signals
- investigates issues
- makes linkages
- considers context
- involves consultation
- is balanced
- is thorough
- is well-documented



# A Good Review (1)…

…is learned.

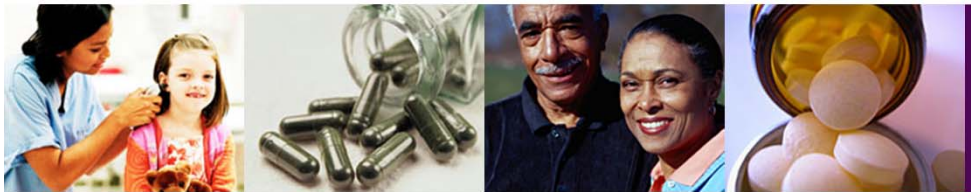
- Knowledge-based: addresses current and emerging therapies, similar dosage forms / devices, international regulatory status, previous clinical trials, etc.
- Reflects scientific and regulatory state-of-the-art: uses scientific papers, Health Canada and other regulatory guidelines, clinical practice guidelines, international standards, etc.



# A Good Review (2)…

…utilizes critical analysis.

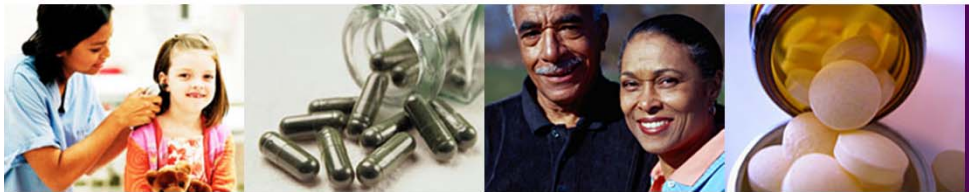
- Questions scientific integrity, relevance, completeness of data and proposed labelling and the interpretation thereof: analyzes rationales, questions conclusions, explains thought processes, etc.



# A Good Review (3)…

…identifies signals.

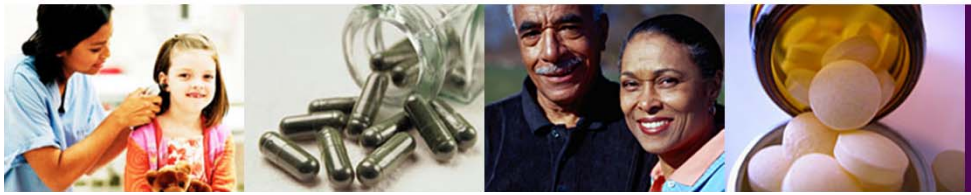
- Comprehensively highlights potential areas of concern identified by the company and the reviewers: recognizes “absence of evidence versus evidence of absence” (identify missing information), analyzes conflicting results, etc.



# A Good Review (4)…

…investigates issues.

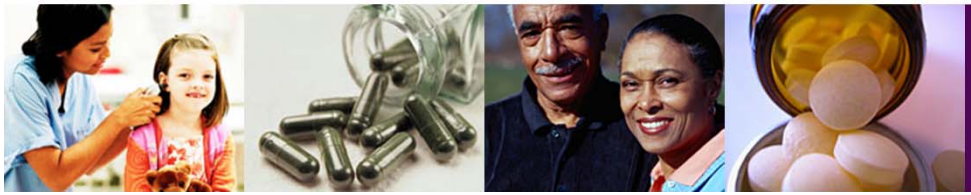
- Provides both the company's and the reviewers' in-depth analyses and findings of critical study reports: recognizes "questionable results versus statistically significant results" (knows when to "dig deep"), etc.



# A Good Review (5)…

…makes linkages.

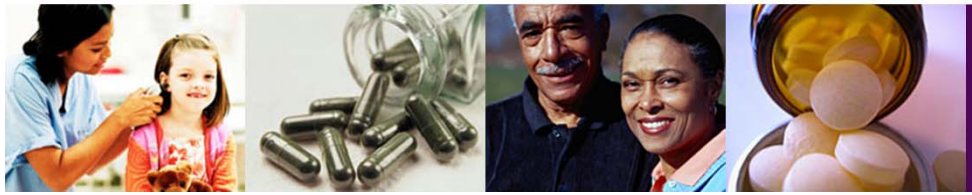
- Provides integrated analysis across all aspects of the submission: links non-clinical and clinical findings, links quality data to non-clinical and clinical findings, links labelling to all aspects, etc.



# A Good Review (6)…

…considers context.

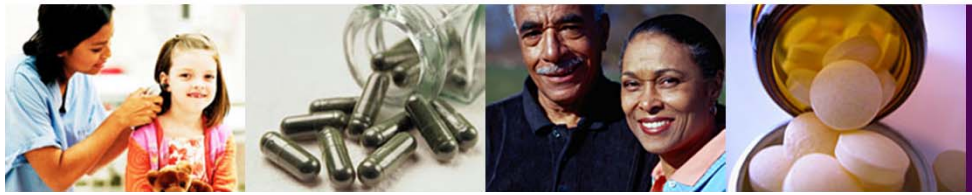
- Places the data, conclusions, risk-benefit analyses and suggested risk management strategies in the context of the proposed conditions of use: recognizes that safety, efficacy, and quality concerns are all relative to conditions of use, that the product is relative to similar products available, etc.



# A Good Review (7)…

…involves consultation.

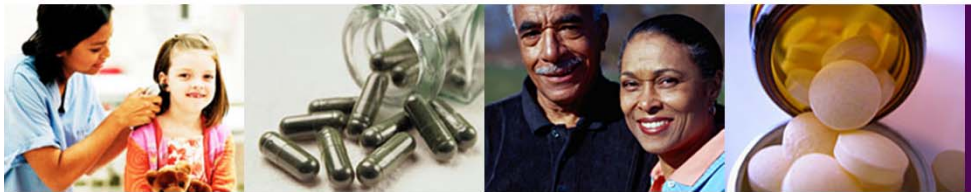
- Reflects input from internal and external sources of expertise: asks questions of colleagues, supervisors, other review areas, other directorates, other regulators, external experts, legal services, etc.



# A Good Review (8)…

…is balanced.

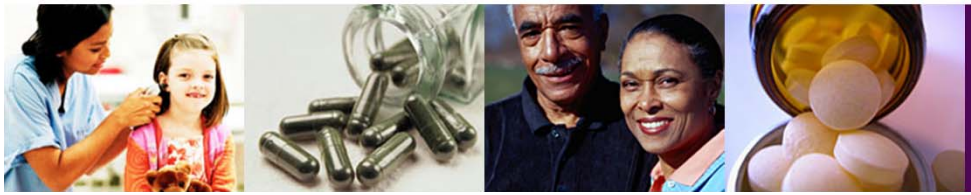
- Is objective and unbiased: examines one's potential biases, re-evaluates one's conclusions, considers conflicting views, etc.



# A Good Review (9)…

…is thorough.

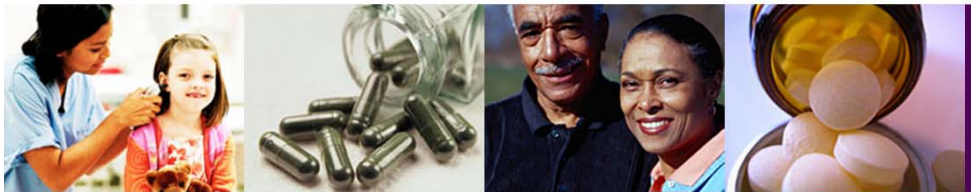
- Reflects adequate follow-through of all the issues: doesn't get side-tracked, ensures adequate time for complete follow-through, etc.



# A Good Review (10)…

…is well-documented.

- Provides well-written and thorough accounts that meet the requirements of a good review: accurately records decision-making process, uses appropriate wording, etc.



# A Good Review…

…stems from good review strategies.

- These ten key elements of a good review can be achieved through the use of good review strategies.