Post-market Initiatives and Agile Regulatory Provisions

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Agenda

Regulatory Project Management Office (RPMO)

Post-market Vigilance—Timeline of Key MHPD Publications

Post-market Guidance Documents

- Notification of Foreign Actions (NFA)
- Preparing and Submitting Summary Reports
- Management of Post-market Vigilance Submissions (MPMVS)
- Safety Monitoring and Reporting Requirements for Biocides

Agile Regulatory Provisions—Risk Management Plans (RMPs)

Questions and Discussion

Regulatory Project Management Office (RPMO)

Health Canada

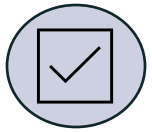
Health Products and Food Branch (HPFB)

Marketed Health Products Directorate (MHPD)

RPMO

Post-market regulatory interpretation, advice and guidance

Screening, validation, and oversight of post-market submissions (RMPs, ASRs, IRSRs, NFAs, etc.)



Oversight of market authorization holder (MAH) post-market commitments and obligations

Collaboration with regulatory project management teams across HPFB

Non-prescription products, biologics, radiopharmaceuticals and biocides: bbrs.rpm-gpr.bbra@hc-sc.gc.ca
Pharmaceuticals: mpb.rpm-gpr.bppc@hc-sc.gc.ca

Post-market Vigilance—Timeline of Key MHPD Publications

Post-market Guidance Document: Notification of Foreign Actions

Notification of Foreign Actions—Changes

Updates to guidance document

- Removal of cover letter requirement for initial filing
- Clarification on actions relating to:
  - communication of risks
  - label changes
- Revisions to list of foreign jurisdictions

Revisions to notification of foreign actions reporting form (safety)

- Initial and follow-up notifications included
- Introduction of mandatory fields

Notification of Foreign Actions—Frequent Clarification Requests

- No info/action from foreign agency
- No serious risk/insufficient information on serious risk
- Incorrect link/product information provided
- Incorrect placement of NFA form within the eCTD structure
- Out of scope products (e.g. OTC)
- Missing third-party authorization form (if applicable)

Post-market Guidance Document: Preparing and Submitting Summary Reports

Preparing and Submitting Summary Reports—Guidance Document Updates

- Annual Summary Report (ASR) note to reviewer
  - Provide reason for submission and additional information for reviewer consideration
  - Include with all ASR submissions in module 1.0.7

- Do not submit a voluntary ASR that was not requested by Health Canada
  - If you want to notify Health Canada of a significant change while you are preparing your ASR, use the significant change form

Preparing and Submitting Summary Reports—Significant Change Form

- When preparing an ASR, notify us if you determine there has been a significant change in what is known about the risks and benefits of the product

Complete the significant change form (to be published in revised guidance document)

Submit as a REG-PV via the Electronic Submissions Gateway (ESG)

ASR submission is not automatically required (to be requested, as needed, after reviewing the significant change notification)

Post-market Guidance Document: Management of Post-market Vigilance Submissions

Management of Post-market Vigilance Submissions (MPMVS)

New guidance document
(post-market complement to MDSA)

Goal

- Address longstanding gaps related to post-market vigilance submissions
  - From filing, screening and review to the decision issuance

Products

- Pharmaceutical drugs (prescription, non-prescription)
- Biologic drugs
- Radiopharmacetical drugs
- Natural health products
- Biocides

Post-market Guidance Document: Safety Monitoring and Reporting Requirements for Biocides

Safety Monitoring and Reporting Requirements for Biocides—Guidance Document Update

- Coming into force (CIF) of the *Biocides Regulations* occurred on May 31, 2025
  - Includes post-market requirements

- New: Notify Health Canada of a significant safety issue without delay using the appropriate form (to be published in guidance document)
  - Use NSSI-PV

Agile Regulatory Provisions—Risk Management Plans

Agile Regulations (Effective April 1, 2027)—
Risk Management Plan (RMP) Reminders

- RMP regulatory requirement is based on significant uncertainties or serious risks warranting measures
- Moving from a product-based to a risk-based approach
- RMP package must include Canadian context and RMP summaries (in EN and FR)
- Submissions with incomplete or missing RMPs and/or summaries may face regulatory delays or negative decisions
- The review of the RMP and its summaries must be finalized and determined to be acceptable prior to issuance of Notice of Compliance (NOC)/approval

RMP Submission Requirements

Tips:

1. Engage early with Health Canada
2. Rationale for no RMP should be clearly documented in the general note to reviewer

New RMPs

- Significant degree of uncertainty respecting the risks
- Serious risk of injury that warrants measures beyond labeling

Updates to existing RMPs

- Risks or uncertainties are significantly different
- Measures are significantly different

Generics and Biosimilars

- Verify the following in the Drug Product Database (DPD) for the Canadian Reference Product (CRP) / Canadian Reference Biologic Drug (CRBD):
  - Existing RMP
  - Additional pharmacovigilance activities
  - Additional risk minimization measures
- Reference the RMP summary when available
- Engage in early discussions with Health Canada

Note:

Health Canada is no longer systematically requiring RMPs for all biosimilar submissions.

RMP Package

1	2	3	4	5
RMP note to reviewer	RMP with Canadian context	RMP summaries	Accompanying materials	RMP summary attestation form
Module 1.0.7	**Module 1.3.8.2**	**Module 1.3.8.2**	**Module 1.3.8.2**	**Module 1.2.3**

Reminders:

- ✓ Use appropriate templates
- ✓ Include location and details of submitted documents in the RMP note to reviewer
- ✓ Provide updates as tracked change(s) to the latest documents approved by Health Canada (if applicable)

RMP Summaries

- Goal: To support transparency and increase access to information on drugs
- Required whenever an RMP is provided (introduced through guidance in 2025)
- Review of RMP summaries in English and French to be finalized and found acceptable prior to NOC/approval
- Health Canada is exploring options to make RMP summaries publicly available
- MAHs are encouraged to post Health Canada-approved RMP summaries on their Canadian website

Submission Requirements

- Follow template included in RMP guidance
  - Don’t include a cover page on the RMP summary
- Submit as a stand-alone document in Word format
- Provide in at least one official language at time of initial filing (requirement)
  - Second language to be requested towards end of review
  - Early preparation of second language RMP summary is encouraged
- Include a tracked change version when updating previously approved version
- Include revised copy if RMP updates during review have an impact on RMP summary

RMP Screening—Goals

Identify significant submission issues early

Identify necessary review streams

Prevent review delays

Verify completeness of RMP package and relevance to Canadian context

Potential Screening Deficiency Scenarios

Submission-based scenario:

- No RMP provided:
  - with an NDS-NAS
  - for combination or co-packaged products where one component is a drug that includes an RMP with additional measures
  - for biosimilars and generics when reference product has an RMP with additional measures in place
  - with an EUNDS
  - after agreement during pre-submission meeting/consultation

Content-based scenarios:

- No Canadian context provided (no Canadian RMP, Canadian addendum to a reference RMP or relevance to Canadian context addressed in the RMP note to reviewer)
- No RMP summary provided in at least one language at time of initial filing

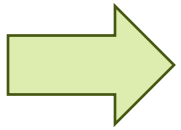
Potential Screening Clarification Request Scenarios

- No RMP note to reviewer
- No tracked change versions (RMP and RMP summary)*
- No RMP summary provided as a stand-alone document
- No supporting document(s) for aPVs and aRMMs*
- No latest version (RMP and RMP summary)*
- No reference RMP provided that is being reviewed in another jurisdiction*

*when applicable

Unsolicited RMPs

Health Canada may request clarification for the reason for an RMP submission if not clearly identified



In cases where an RMP is deemed out of scope or voluntary, Health Canada may request withdrawal of the RMP component from a submission

Tips and Tricks - Provided by Reviewers

For RMPs with additional PV activities or RM measures: The RMP summary should describe the purpose of the activity/measure (e.g. what risk it aims to mitigate) and key aspects of its implementation according to complexity. For example, it is not sufficient to state “Controlled Distribution Program” as an additional risk minimization measure in the RMP summary.

For RMP updates: Proposed RMP changes should be accompanied by a well-supported rationale. This can be done in Q&A format (if in response to previous HC correspondence), or directly in annotated RMP document (tracked changes, comment boxes).

For new RMP filings (e.g. at time of NDS): Sponsors should notify HC and submit foreign RMP review reports as they become available during submission review. This is not considered unsolicited data from the standpoint of the RMP review, especially when the sponsor uses a foreign RMP (e.g. EU RMP) as their core RMP.

For RMPs with materials to be made available on the web: Provide mock-ups of the website where the materials will be posted and ensure that the website link is available prior to submission approval if included within the Canadian Product Monograph as part of the dissemination strategy.

Questions and Discussion