Health Canada Santé Canada

Label Safety Assessment Update - Sponsor Attestation

Brand (Proprietary) Name of Drug Product	
Drug Substance / Medicinal Ingredient	
Manufacturer / Sponsor	
Dosage Form(s) and Strength(s)	
Is the Canadian Reference Product currently on the Patent Registry and does the Patent apply to your product? ***[that is (i.e.), Strength, dosage form, indication etc.]***	☐ Yes ☐ No If Yes, Abbreviated New Drug Submissions (ANDS) Control number:
Reason for Submission	*Response to Advisement dated: MM/DD/YYYY or as per innovator control number XXXXXX*

Summary of Product Labelling Information

Confirm that the following **required** documents are **provided**:
☐ Non-annotated Product Monograph (PM)
☐ The second language translation of the Product Monograph (PM)
☐ The Mock-up Labels and Packages Certification Form
☐ Annotated PM against most recent **Canadian Reference Product (CRP) PM** (CRP Name dated: *MM/DD/YYYY*)
- Note: Please complete Table 1 with the differences between your proposed PM and the CRP PM
☐ Annotated PM against **most recently approved PM for this product** (Product Name dated: *MM/DD/YYYY*)
- Note: Please complete Table 2 with the differences between your proposed PM and your currently approved PM.

Note:
- The annotated PMs should highlight the changes between the current proposed PM and the comparators identified above, and be provided as separate documents. - The changes identified in the annotated PMs must be summarised in the Document Compare Tables 1 and 2 *below.*
- All changes must have a justification (for example, update as per the reference product, not approved for this dosage form, level 3 change, type, etc.)

Have inner and/or outer labels and packages been updated? ☐ *No* ☐ *Yes*
(Please include annotated labels in submission)

If Yes, please provide a justification for revisions:

If labels have been updated, have the required Mock-ups of the inner and outer labels and packages been submitted?
☐ No ☐ Yes

Description of Proposed Labelling Changes

A document compare against the most recent CRP shows that the Product Monograph has been updated in the following way; please select the most appropriate option.
Note: only one option should be selected

☐ 1. There are **no differences** between our proposed PM and the CRP PM other than the product brand name and product specific sections (for example, Comparative bioavailability summary table(s), pharmaceutical information, storage and stability, non-medicinal ingredients, references). Details are provided in tables below.

☐ 2. There are **some differences** between our proposed PM and the CRP PM, such as; a difference in market authorized dosage forms, dosing and administration, strengths and/or indications, which have been previously approved. These differences are in addition to differences in product brand name and product specific sections. Details are provided in tables below.

☐ 3. The proposed PM includes revisions, **not previously approved**, that are different from the CRP PM Details are provided in tables below.

See Appendix for examples of document compare tables

Attestation

We attest that the proposed revisions to the Product Monograph for <*Insert product name* > submitted by <*Insert sponsor name* > contain only the changes outlined.

....

<*Insert name* > Date
<*Title* >
<*Company* >

Document Compare 1:
Summary of differences between proposed PM and most recent Canadian Reference Product (CRP) PM:

CRP name: _____
CRP PM Date: _____
CRP control number: _____

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information		
Indications and Clinical Use		
Contraindications		
Warnings and Precautions		
Adverse Reactions		
Drug Interactions (Precautions)		
Dosage and Administration		
Overdosage		
Action and Clinical Pharmacology		
Storage and Stability		
Dosage Forms, Composition and Packaging (availability)		
Part II: Scientific Information		
Pharmaceutical Information		
Clinical Trials		
Detailed Pharmacology		
Toxicology		
References		
Part III: Consumer Information (Patient Information Sheet) / **Patient Medication Information**		

Document Compare 2:
Summary of Differences between proposed PM and most recently approved PM:

Most recently approved PM date: _____
Most recently approved PM control number: _____

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information		
Indications and Clinical Use		
Contraindications		
Warnings and Precautions		
Adverse Reactions		
Drug Interactions (Precautions)		
Dosage and Administration		
Overdosage		
Action and Clinical Pharmacology		
Storage and Stability		
Dosage Forms, Composition and Packaging (Availability)		
Part II: Scientific Information		
Pharmaceutical Information		
Clinical Trials		
Detailed Pharmacology		
Toxicology		
References		
Part III: Consumer Information (Patient Information Sheet) **Patient Medication Information**		

APPENDIX. Examples of document compare tables. These pages should not be included in the submission.

Please note the **examples** provided below are not all inclusive, it is recognized that these tables will vary by submission

Document Compare 1:
Summary of differences between proposed Product Monograph (PM) and most recent Canadian Reference Product (CRP) PM:

CRP name: _____
CRP PM date: _____
CRP control number:_____

New Product Monograph Format	Differences	Justification for Differences
Part I: Health Professional Information		
Summary Product Information	Non-medicinal ingredients (NMIs)	First inclusion or changes to the NMIs
Indications and Clinical Use	Not all indications present, dosage forms and/or strengths are included	Indications, dosage and strengths are not all approved for this product
Contraindications	No Changes	
Warnings and Precautions	No Changes	
Adverse Reactions	No Changes	
Drug Interactions (Precautions)	No Changes	
Dosage and Administration	No Changes	
Overdosage	No Changes	
Action and Clinical Pharmacology	No Changes	
Storage and Stability	Differences in storage conditions	Product specific
Dosage Forms, Composition and Packaging (availability)	Composition and packaging differences	Product specific
Part II: Scientific Information		
Pharmaceutical Information	Differences in chemical name	Product specific
Clinical Trials	Comparative Bioavailability Studies	Product Specific
Detailed Pharmacology	No Changes	
Toxicology	No Changes	
References	Updated CRP References	Product Specific
Part III: Consumer Information (Patient Information Sheet) / **Patient Medication Information**	Different non medicinal ingredients, dosage forms and storage conditions	Product Specific

Document Compare 2:
Summary of Differences between proposed PM and most recently approved PM:

Most recently approved PM date: _____
Most recently approved PM control number: _____

New Product Monograph Format	**Differences**	**Justification for Differences**
Part I: Health Professional Information		
Summary Product Information	No Changes	
Indications and Clinical Use	No Changes	
Contraindications	Updates to Contraindications (brief summary to be included) *That is (i.e.) Contraindicated in breastfeeding or nursing women*	Changes are made to match the CRP
Warnings and Precautions	Updates to Warnings and Precautions (brief summary to be included) *i.e., Additional Warning added for hypertension*	Changes are made to match the CRP
Adverse Reactions	Updates to Adverse Reactions (brief summary to be included) *i.e., Additional Adverse Reaction added to include rash*	Changes are made to match the CRP
Drug Interactions (Precautions)	Updates to Drug Interactions (brief summary to be included) *i.e., New Drug Interaction with metformin*	Changes are made to match the CRP
Dosage and Administration	No Changes	
Overdosage	No Changes	
Action and Clinical Pharmacology	No Changes	
Storage and Stability	No Changes	
Dosage Forms, Composition and Packaging (Availability)	No Changes	
Part II: Scientific Information		
Pharmaceutical Information	No Changes	
Clinical Trials	No Changes	
Detailed Pharmacology	No Changes	
Toxicology	No Changes	
References	Updated the CRP Reference	Product Specific
Part III: Consumer Information (Patient Information Sheet) / **Patient Medication Information**	Changed “about this medication”, “warnings and precautions”, “interactions with this medication”, “proper use of this medication”, reporting suspected side effects” sections and revision date	Changes are made to match the CRP