Marketed health products directorate post-market submission guidance

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1 – Heading Classifications and Content Examples

Not all folders are required for a given submission and the classification, conditions and examples of appropriate content are presented in the table below.

Legend

- R = Required
- CR = Conditionally Required
- O = Optional
- NR = Not Required

All Classes for IVD and non-IVD (I to IV) Post-Market Request and Additional Information Responses to Post-Market Requests

Chapter 1 – Regional Administrative			
	Classification	Condition	Examples
CH1.01-Cover Letter	R	-	Cover Letter / Email response from manufacturer
CH1.03-List of Terms/Acronyms	O	-	List of terms or acronyms that are used in the transaction

Chapter 1 – Regional Administrative			
	Classification	Condition	Examples
CH1.05-Listing of Device(s)	CR	Required if submitting for Class I Class II, III, IV to be included when applicable or requested	List of devices including trade/product names, catalogue/reference numbers
CH1.09-Pre-Submission Correspondence and Previous Regulator Interactions	R	-	MHPD request letter or email

Chapter 2 – Submission Context			
	Classification	Condition	Examples
CH2.4.3-History of Development	CR	If applicable to request	E.g. in cases where design changes are requested/implemented
CH2.6-Global Market History	CR	If applicable to request	-
CH2.6.1-Global Market History	CR	If applicable to request	Countries where device is licensed and date of licensing
CH2.6.2-Global Incident Reports and Recalls	CR	If applicable to request	Global and Canadian complaints, Incident reports and summaries, Root cause analysis, Investigation Update / Report, Recall information
CH2.6.3-Sales, Incident and Recall Rates	CR	If applicable to request	Global and Canadian incident rate (including rates in relation to sales), Sales data
CH2.7-Other Submission Context Information	CR	When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the	Health Canada Requested Information (Post Market) Incident issue analysis (trending analysis) Clinical Evaluation Summary of

Chapter 2 – Submission Context		
Classification	**Condition**	**Examples**
	other headings of this Chapter.	device safety and effectiveness data including MAH sponsored, studies/clinical trials and published literature when requested by MHPD Post-market device safety issue analysis and risk/benefit analysis documents Listing or Description of previous risk mitigation measures implemented or planned to address the post-market issue.

Chapter 5 – Labelling and Promotional Material			
	Classification	**Condition**	**Examples**
CH5.02-Product/Package Labels	CR	If applicable to request	Package label
CH5.03-Package Insert/Instructions for Use	CR	If applicable to request	Current Instructions for Use, Package insert, Directions for Use
CH5.04-e-labelling	CR	If applicable to request	-
CH5.05-Physician Labelling	CR	If applicable to request	Physician labelling, Physician educational material
CH5.06-Patient Labelling	CR	If applicable to request	Patient brochure, Patient consent form, Patient educational material
CH5.07-Technical/Operators Manual	CR	If applicable to request	Maintenance manual
CH5.08-Patient File Stickers/Cards and Implant Registration Cards	CR	If applicable to request	-

Chapter 5 – Labelling and Promotional Material			
	Classification	Condition	Examples
CH5.09-Product Brochures	CR	If applicable to request	-
CH5.10-Other Labelling and Promotional Material	CR	If applicable to request	Any other documents that come with the device

2 – Resources and Tools

2.1 – Tools

The following additional tool is available to aid in creating MHPD post-market submissions:

- Folder Templates (.zip file 5 KB)

3 – Mailing Address

For filing process, physical media requirements and mailing address, refer to the main IMDRF ToC Implementation guidance.