Health Canada Santé Canada

Foreign Review Attestation and Summary of Quality Differences: Subsequent Market Entry Products (Human Drugs)

Complete parts 1, 2, and 3 for all products. Repeat part 4 for each Foreign Regulatory Authority, as applicable.

Part 1 - Canadian Product Information

Brand or Proprietary or Product Name (should be the same as the brand name on the product label):		
Sponsor Name:		
Application / Submission / Data Package Type:	Filing Date:	Control Number:

Part 2 – Foreign Product Information

List foreign regulatory authorities with which the application has been filed (and status):	☐ U.S. Food and Drug Administration (U.S. FDA): ☐ approved or recommended for approval (e.g., patent hold), ☐ under review, ☐ not approved
	☐ European Medicines Agency (EMA): ☐ approved or recommended for approval (e.g., patent hold), ☐ under review, ☐ not approved
	☐ Switzerland's Swiss Medic: ☐ approved or recommended for approval (e.g., patent hold), ☐ under review, ☐ not approved
	☐ Singapore's Health Sciences Authority (HSA) : ☐ approved or recommended for approval (e.g., patent hold), ☐ under review, ☐ not approved
	☐ Australia's Therapeutic Goods Agency (TGA): ☐ approved or recommended for approval (e.g., patent hold), ☐ under review, ☐ not approved
	☐ Other (specify): ☐ approved or recommended for approval (e.g., patent hold), ☐ under review, ☐ not approved
Foreign Product Information for generic application identified for participating in this Review Pilot (repeat rows as necessary)	
Foreign Regulatory Authority granting approval/authorisation:	☐ U.S. FDA, ☐ EMA, ☐ SwissMedic, ☐ Singapore's HSA, or ☐ Australia's TGA
If European Union, specify procedure used for granting authorisation:	☐ Centralised, ☐ Decentralised, ☐ Mutual Recognition, or ☐ National
Product Name:	
Date of Filing:	
Date of Approval/Authorisation:	
Approval letter or letter of authorisation provided:	☐ Yes, ☐ No
Foreign Review(s) provided:	☐ Electronic, ☐ Paper, ☐ None
Are the Test and Reference products in the generic applications filed with Health Canada and with the foreign regulator for products that contain *identical amounts of identical medicinal ingredients in comparable dosage forms*?	☐ Yes, ☐ No

Part 3 – Signed Attestation		
I, the undersigned, certify that: 1. the information and material included in this attestation is accurate and complete; 2. the foreign review(s) provided is (are) the complete and unaltered review(s) provided to us by the foreign regulator; 3. all differences between the data packages filed with Health Canada and the foreign regulator(s) (upon which the foreign review(s) and marketing authorization decision(s) was (were) based) have been identified.		
Name of Authorized Signing Official:	Signature:	Date:
Title, Company:	Email Address:	Telephone Number:

Part 4 – Summary of Quality Differences (between the applications filed with Health Canada and the Foreign Regulatory Authority)

Modules where there are no differences between the applications filed with Health Canada and with the Foreign Regulatory Authority should be reported as "No differences".

Foreign Regulatory Authority (specify):

Documents provided (see Appendix II of the draft *Guidance Document: The Use of Foreign Reviews by Health Canada*):

Module	Data Package filed with Health Canada	Data Package filed with Foreign Regulatory Authority	Discussion of Noted Differences
3.2.S Drug Substance			
3.2.S.1 General Information			
3.2.S.2 Manufacture			
3.2.S.3 Characterisation			
3.2.S.4 Control of the Drug Substance			
3.2.S.5 Reference Standard or Materials			
3.2.S.6 Container Closure System			
3.2.S.7 Stability			
3.2.P Drug Product			
3.2.P.1 Description and Composition of the Drug Product			
3.2.P.2 Pharmaceutical Development			
3.2.P.3 Manufacture			

Part 4 – Summary of Quality Differences (between the applications filed with Health Canada and the Foreign Regulatory Authority)

Modules where there are no differences between the applications filed with Health Canada and with the Foreign Regulatory Authority should be reported as "No differences".

Foreign Regulatory Authority (specify):

Documents provided (see Appendix II of the draft *Guidance Document: The Use of Foreign Reviews by Health Canada*):

Module	Data Package filed with Health Canada	Data Package filed with Foreign Regulatory Authority	Discussion of Noted Differences
3.2.P.4 Control of Excipients			
3.2.P.5 Control of Drug Product			
3.2.P.6 Reference Standard or Materials			
3.2.P.7 Container Closure System			
3.2.P.8 Stability			

Component	Data Package filed with Health Canada	Data Package filed with Foreign Regulatory Authority	Discussion of Noted Differences
Post-Approval/Authorisation Commitments (include data commitment was fulfilled, if applicable)			
Known differences between Reference Products (e.g., descriptions)			