Health Canada Santé Canada

Annual Summary Report Checklist (including PSUR and PBRER)

Checklist to be completed and accompany an annual summary report which may be provided in PSUR or PBRER format:

	Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report (PBRER) Checklist	Descriptions	Status
1	**Submitted to:**		
1.1	Biologics, Radiopharmaceuticals and Genetic Therapies (PSUR-C/PBRER-C only)		☐
1.2	Therapeutic Products Directorate (PSUR-C/PBRER-C only)		☐
1.3	Marketed Health Products Directorate		☐
2	**Reason for PSUR/PBRER Submission:**		
2.1	Significant change in what is known about the risks and benefits (C.01.018(4) Notification)		☐
2.2	PSUR-C/ PBRER-C		☐
2.3	Requested Periodic		☐
2.4	Requested Ad-Hoc		☐
2.5	Voluntary	List reasons (for example, new safety information):	☐
3	**Status in Canada:**		
3.1	Not Marketed		☐
3.2	Marketed (since)		☐
4	**PSUR/PBRER Information:**		
4.1	International Birth Date		
4.2	PSUR/PBRER #		
4.3	Period covered by the present PSUR/PBRER		
4.4	Period covered by the previous PSUR/PBRER		
5	**Appendices (indicate if included in the submission):**		
5.1	Reference Information		☐
5.2	Cumulative Summary Tabulation of Serious Adverse Events from Clinical trials and Interval/Cumulative Summary Tabulations from Marketed Experience		☐
5.3	Tabular Summary of Safety Signals		☐
5.4	Listing of Interventional and Non-Interventional Studies with a Primary Objective of Post-Authorization Safety Monitoring		☐
5.5	List of the Sources of Information Used to Prepare the PSUR/PBRER		☐