Appendix 1 Periodic Drug Safety Update Report

(Please prepare the report and provide information following the format given below; do not delete items freely or simply indicate "Refer to the Attachment".)

1. Drug Profile (if multiple drugs are reported together, please list the names of all drugs.)

(1) License number :
(2) Product Name in Chinese:
(3) Product Name in English:
(4) Active Ingredient (Please write out the complete prescription for Chinese medicine)
(5) Dosage form and contents:
(6) Indication (Please also provide the efficacy of the Chinese medicine if any is approved):
(7) License holder:
(8) Manufacturer:
(9) Country of manufacturer:

2. Period of safety surveillance

Start/End date of data reported for the first time: MM/DD/YYYY ~ MM/DD/YYYY	Submission deadline: MM/DD/YYYY
Start/End date of data reported for the second time: MM/DD/YYYY ~ MM/DD/YYYY	Submission deadline: MM/DD/YYYY
Start/End date of data reported for the third time: MM/DD/YYYY ~ MM/DD/YYYY	Submission deadline: MM/DD/YYYY
Start/End date of data reported for the fourth time: MM/DD/YYYY ~ MM/DD/YYYY	Submission deadline: MM/DD/YYYY

* If you need more space, please add additional fields.

3. Text of Periodic Safety Update Report

(The format and requirements in ICH E2C (R2) Periodic Benefit-Risk Evaluation Report (PBRER) 3. Guidance on Contents of the PBRER shall be adopted.)

4. Number of users domestically and internationally

(If the statistical period for the international data differs from the domestic monitoring period, it shall be noted additionally.)

Data range	Inferred number of users (or use frequency)	
	Domestically	Internationally
Report #1		
Report #2		
Report #3		
Report #4		
Total number of people		

* If you need more space, please add additional fields.

5. Number of domestic/international adverse events

Data range	Serious adverse events		Non-serious adverse events	
	Domestically	Internationally	Domestically	Internationally
Report #1				
Report #2				
Report #3				
Report #4				
Total				

* If you need more space, please add additional fields.

6. Distribution of domestic sales data

(Please provide the sales distribution data among domestic hospitals, clinics, and pharmacies each year after the drug is introduced onto the market and please the sales unit, such as pill, box, vial, etc.)

Year / Healthcare Level			
Hospital			
Clinic			
Pharmacy			
Total			

7. Package Insert Information

(including the latest approved Chinese package insert; for an imported drug, please provide the international package insert or CCDS of the latest version referred to by the Chinese package insert. If the change to the Chinese package insert is currently applied for, please provide the revised draft package insert.)
(Please indicate the data title and date of approval on top of the package insert or the CCDS document, such as the "latest approved Chinese package insert, approved on MM/DD/YYYY", the "latest international package insert/CCDS referred to, approved on MM/DD/YYYY", and the "revised draft Chinese package insert, prepared on MM/DD/YYYY".)

8. Domestic Safety Analysis Report

(Please analyze cases of adverse reactions reported domestically of the drug during the data period of the current report and accumulated so far in an exclusive chapter and explain if there are additional safety signals and provide the evaluation findings and if a further monitoring plan or risk control measures are adopted and provide information on related plans or measures.)