Appendix 2 Drug Safety Summary 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**

3. **Summary of Implementation of Monitored Items**
   (Including and limited to statistical and analytical summaries of domestic sales and serious and non-serious adverse events during the monitoring period and reflect upon related causes)

4. **Global Marketing Update**
   (Including, without limitation, statistical and analytical summaries of the countries where the product is sold and the sales distribution and serious and non-serious adverse events, etc.)

5. **Action adopted by domestic and international competent health authorities or the pharmaceutical dealer on drug safety**
   (including, without limitation, removing the drug from the market or termination, not renewing the Permit, restrictions over the distribution of the drug, termination of the clinical trial for safety concern, modification of the dosage level, change of the indication or the indicated population, change of the formulation, release of safety, or recall of information, etc.)

6. Change of safety information in each country

(including, without limitation, change of drug safety-related information on the package insert or related information on a significant increase in the frequency or severity of adverse reactions or known side effects of the drug, etc.)

7. Clinical Trial

(Including publications on post-marketing clinical studies of drug safety or analysis results and safety clinical studies; if no related publications are available, please provide the publication inquiry date, the database searched, and the search criteria)

8. Benefit-Risk Analysis Results and Risk Management Plan

9. Overall Safety Evaluation

10. Summary

11. Annex/Appendix

(1) Adverse Reaction Summary and Analysis Report:

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

(ii) The reporting of adverse reactions domestically and internationally shall be provided according to the form below and analyze and explain if there are additional safety signals and provide the evaluation findings in a devoted chapter and explain if a further monitoring plan or risk control measures are adopted and provide information on related plans or measures.

Number of cases / Nature of case	Domestically	Internationally
Serious adverse reaction		
Non-serious adverse reaction		
Total		

(2) 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			

(3) 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”.)