Appendix 3 Items to be specified in the Drug Risk Assessment and Control Plan

1. General information	
1.1	**Version and date of Protocol**
1.2	**Revision History**
2. Product profile	
2.1	**License number**
2.2	**Product Name in Chinese**
2.3	**Product Name in English**
2.4	**Active Ingredient (Please write out the complete prescription for Chinese medicine)**
2.5	**Indication (Please also provide the efficacy of the Chinese medicine if any is approved)**
2.6	**Pharmacological class**
2.7	**Dosage form and contents**
2.8	**License holder**
3. Information about the Plan	
3.1	**Background of safety surveillance**
3.2	**Purpose of safety surveillance**
3.3	**Period of safety surveillance (Start date and end date of the period and of data collection for each stage)**
3.4	**Subjects of safety surveillance or research h (Please explain if there are inclusion/exclusion criteria)**
3.5	**Endpoints (reporting of adverse reactions and case evaluation, cognitive, attitude, or behavioral evaluations of target populations, evaluation of differences in risk incidence, subsequent countermeasures)**
3.6	**Implementation method (implementation staff, data evaluation, recording, analysis, statistical methods and time points; if after-use follow-up descriptions are included, please also specify the follow-up period, follow-up timeframe, and its evaluation and descriptions)**
4. Annex/Appendix	
4.1	**Item and format of data collection**
4.2	**Implementation Efficacy Evaluation Report**
4.3	**Other supporting materials**