Annex I ： Submit of patent information of new drug & third person review

This column is filled in by the Central Health Authority	
Drug permit license number	Receipt date of drug permit license

I Basic information of new drugs

The holder of a drug permit license	Name	
	Address	
	Telephone number	
	Email	
Name of drug product	Chinese	
	English	
Active ingredients of the drugs and dose		
Indication		
Dosage form		
Designated delivery recipient	Name	
	Address	

II Event

Event	Reporting period starting date
Submit patent information in accordance with Article 48-21 of Pharmaceutical Affairs Act	within 3 months after the enforcement of the amended provisions
□Submit patent information of new drug registration approval	
□The Company(the holder of a drug permit license) submits patent information in accordance with Article 48-3 of Pharmaceutical Affairs Act.	Receipt date of drug permit license： ROC___Year___Month___ Day

□There are no relevant patents that claim the new drug determined by Article 48-3 of Pharmaceutical Affairs Act	
□Submit patent information for post approval changes.	Receipt date of drug permit license filling post approval change registration： ROC___Year___Month___ Day
□ Submit patent information for patent grant after new drug permit license is obtained	Issued date of the Patent Gazette ： ROC___Year___Month___ Day
Deletion or change of patent information reported：	
□Delete the published patent information	Revocation date/ Extinction date： ROC___Year___Month___ Day
□Extension of patent term	Extension date： ROC___Year___Month___ Day
□Post-grant amendment to patent claim	Amendment date ROC___Year___Month___ Day
□Amendment of the patent information of the patentee, the exclusive authorized person, its representative or agent.	Amendment date： ROC___Year___Month___ Day
□Reply to the third person's notification in accordance with Article 7.	Receipt date of notification of the Central Competent

	Health Authority： ROC___Year___Month___ Day

III Patent Information on Drug Patent Rights

1. Basic data on invention patents

Patent Certificate number	Title of invention
Upload Information (Patent Certificate or Publication of the Patent Gazette of the Patent of the Drug)	
The filing date of patent application	ROC___Year___Month___Day
The expiration date of the patent	ROC___Year___Month___Day

The relationship between the holder of a drug permit license and the patent right(Choose one)：

☐ The holder of a drug permit license is the patentee.

☐ The holder of a drug permit license is an exclusive authorized person and has been registered in accordance with patent law.
Upload Information(documents for exclusive authorization)

☐ The holder of a drug permit license is not a patentee or an exclusive licensee, but has obtained the patentee or the consent of the exclusive authorized person has been registered in accordance with the patent law.
Upload Information(documents for consent)

Patentee	☐Legal person ☐Natural person	
	Name	
	Representative of a legal person	
	Nationality	
	Business	

	office/ Residence	□Business office/ Residence not located in the Republic of China (The "Agent" field below must be renewed) Zip code：_____ _____
	Telephone number	
	Email	
Exclusive Authorized Person registered by the Competent Patent Authority □Same as the holder of a drug permit license	□Legal person □Natural person	
	Name	
	Representative of a legal person	
	Nationality	
	Business office/ Residence	□Business office/ Residence not located in the Republic of China (The "Agent" field below must be renewed) Zip code：_____
	Telephone number	
	Email	
Agent Upload Information (power of attorney)	Name	
	Business office/ Residence	Zip code：_____ _____
	Telephone number	
	Email	

2. Detailed data on invention patents

□Substance inventions □The substance claimed in this patent is the same as the active

ingredient of the drug preparation, and that is a different polymorph of the active ingredient, in the registration, the test data demonstrating that a drug preparation containing the polymorph will perform the same as the drug preparation.
□Composition or formula invention
□Inventions for medical use Please list the number of claims of the invention for the medical use and the corresponding indications recorded in the drug permit license;

The number of claims：	Corresponding indications recorded in the drug permit license：

3. Third person to view notification reply message

Third person to review the contents of the notification	Upload Information
Reasons for reviewing notifications and handling of notifications for third persons(Please outline the response focus and upload the full file data for the reply)：Upload Information	

IX Statement

The owner of the drug permit license confirms that the contents of the statement and the data examined are correct, that the patent information has not been reported, changed or deleted by means of fraud or falsehood, and that the person who is suspected of criminal responsibility shall be transferred to the judicial authorities.