

Annex II Declaration form of the status of pharmaceutical patents

I. Basic data for the filler(Drug permit license applicants)

Drug permit license applicant	Name	
	Address	
	Telephone number	
	Email	
Proposed name of the drug	Chinese	
	English	
Active ingredients of the drugs and dose of the application		
Indications of the application		
Dosage form of the application		

II. Basic data of reference new drugs

Drug permit license number of reference new drugs		
The holder of reference new drugs	Name	
	Address	
	Telephone number	
	Email	
Name of the reference new drug	Chinese	
	English	
Active ingredients of the drugs and dose		
Indications		
Dosage form		
Designated delivery recipient	Name	
	Address	

III. Declaration of patent status

1. ☐ Exempt declaration of patent status

- ☐ (1) The applicant for this application is the same as the holder of a drug permit license for the reference new drug
- evidence
- ☐ (2) Authorized by the patentee or exclusive authorized person of the new drug.
- evidence
- ☐ (3) Revocation, revocation or cancellation of reference new drug permit licenses
- evidence

2. ☐ Declaration of Article 48-9 of the various matters

- ☐ (1) Declaration of Item 1 of Article 48-9 of the matter.
- ☐ (2) Article 48-9 Item 2 to 4 shall be updated one by one of the following patent information and patent declaration in accordance with the number of the patent certificate number listing in the Registration system.

(A) Substance

Patent Certificate number	The expiration date of the patent	Declaration of patent status
	ROC ___ Year ___ Month ___ Day	<input type="checkbox"/> Declaration of Item 2 of Article 48-9 <input type="checkbox"/> Declaration of Item 3 of Article 48-9 <input type="checkbox"/> Declaration of Item 4 of Article 48-9

(B) Composition or Formulation

Patent	The expiration date of	Declaration of patent
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Certificate number	the patent	status
	ROC ____ Year ____ Month ____ Day	<input type="checkbox"/> Declaration of Item 2 of Article 48-9 <input type="checkbox"/> Declaration of Item 3 of Article 48-9 <input type="checkbox"/> Declaration of Item 4 of Article 48-9

(C) Medical use

Patent Certificate number	The expiration date of the patent	The number of claims and indications	Declaration of patent status
	ROC ____ Year ____ Month ____ Day	The number of claims : _____ Corresponding indications recorded in drug licenses : _____	<input type="checkbox"/> Declaration of Item 2 of Article 48-9 <input type="checkbox"/> Declaration of Item 3 of Article 48-9 <input type="checkbox"/> Declaration of Item 4 of Article 48-9

3. Declaration of Indications Exclusion

(A) Substance

Patent Certificate number	The expiration date of the patent	Declaration of patent status
	ROC ____ Year ____ Month ____ Day	<input type="checkbox"/> Declaration of Item 2 of Article 48-9

(B) Composition or Formulation

Patent Certificate number	The expiration date of the patent	Declaration of patent status
	ROC ____ Year ____ Month ____ Day	<input type="checkbox"/> Declaration of Item 2 of Article 48-9

(C) Medical use

Patent Certificate number	The expiration date of the patent	The number of claims and indications	Declaration of patent status
	ROC____ Year____ Month____ Day	The number of claims : _____ Corresponding indications recorded in drug licenses : _____	<input type="checkbox"/> Declaration of Item 2 of Article 48-9 <input type="checkbox"/> Drugs to be licensed do not contain this indication
<input type="checkbox"/> The Company declares that the drug application does not infringe the patent right of the new drug permit license published in the Registration system.			

IV. Statement

- ☐ The above-mentioned contents are true; if there is any hypocrisy or false, the person who made the statement is willing to bear all legal responsibility

Drug dealer of Drug license (signature) Person in charge of drug dealer(signature)

Fill in form date

_____Year_____Month_____Day