

**PHARMACY AND POISONS ORDINANCE (CHAPTER 138)**

**APPLICATION FOR CERTIFICATE FOR CLINICAL TRIAL/MEDICINAL TEST**

*(This form is used for application for a clinical trial submitted under the Listed Scheme)*

<b>PART A: STUDY INFORMATION</b>				
A1.	Protocol title		Protocol no.	
			Protocol date	
A2.	Name of applicant			
A3.	Business address of applicant		Tel. no.	
			Fax no.	
A4.	Name of principal investigator			
A5.	Name and address of institution conducting the study			
A6.	Is this a study in which a certificate was issued previously and will soon expire? <input type="checkbox"/> Yes (CTC no. _____ and valid until _____) <input type="checkbox"/> No			

<b>PART B: STUDY DESCRIPTION</b>		
B1.	The study is	<input type="checkbox"/> single centre <input type="checkbox"/> multi-centre
B2.	No. of study centres in Hong Kong	Total no. of centres _____ Centre name(s) _____
B3.	Study centres outside Hong Kong (if any)	No. of centres in each country (e.g. Mainland China – 2 centres, Singapore – 2 centres) _____
B4.	Sponsor of the study	Name of sponsor: _____ Address of sponsor: _____ <i>(Remarks: As this study is initiated and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)</i>
B5.	Recruitment size	Planned no. of subjects in Hong Kong _____ Total planned no. of subjects world-wide _____
B6.	Study period	Planned start date _____ and planned end date _____
B7.	The study is	<input type="checkbox"/> phase I                      (first-in-man? <input type="checkbox"/> Yes <input type="checkbox"/> No) <input type="checkbox"/> phase II <input type="checkbox"/> phase III <input type="checkbox"/> phase IV Describe if necessary: _____
B8.	The study is	<input type="checkbox"/> open label <input type="checkbox"/> single blind <input type="checkbox"/> double blind <input type="checkbox"/> other (please specify) _____)
B9.	The study is	<input type="checkbox"/> non-randomized <input type="checkbox"/> randomized
B10.	Therapeutic area	(e.g. Oncology, Endocrinology)
B11.	Disease/Disease type	(e.g. Nasopharyngeal cancer, Diabetes mellitus)

<b>PART C: STUDY DRUG</b>		
C1.	Study drug to be investigated	
C2.	The study involves concurrent use of	<input type="checkbox"/> placebo <input type="checkbox"/> comparator drug <input type="checkbox"/> concomitant drug <input type="checkbox"/> none of the above
C3.	Comparator drug used (if any)	
C4.	Concomitant drug used (if any)	

<b>PART D: DECLARATION OF THE APPLICANT</b>	
I/We* hereby declare that, if the application is approved and the study proceeds:	
D1.	Agree to submit local drug related safety reports, yearly progress reports and final study report of the study as stated in “Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial” (Appendix 3).
D2.	This study will be conducted in accordance with the principles established in Good Clinical Practice.
D3.	The information given in this application is true and correct.

\* Delete as appropriate

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Company stamp (if the applicant is a company)

\_\_\_\_\_  
Signatory’s name in block letters

\_\_\_\_\_  
Date (DD/MM/YY)

<b>PART E: FOR OFFICE USE ONLY</b>	
Date Received	Fee Paid

**Checklist for Clinical Trial Application Submitted under the Listed Scheme**

<u>For all studies:</u>	Yes	No
1. A completed application form and this checklist.	<input type="checkbox"/>	<input type="checkbox"/>
2. A cover letter listing all the submitted documents.	<input type="checkbox"/>	<input type="checkbox"/>
3. A completed clinical trial risk assessment form.	<input type="checkbox"/>	<input type="checkbox"/>
4. Documentary evidence that the clinical trial has been approved by the Ethics Committee of the institution in which it is to be conducted (this may be submitted when available at a later date).	<input type="checkbox"/>	<input type="checkbox"/>
5. The proposed patient information and patient consent form, in both English and Chinese, or in Chinese only.	<input type="checkbox"/>	<input type="checkbox"/>
6. A copy of the proposed protocol.	<input type="checkbox"/>	<input type="checkbox"/>
7. Application fee (HK\$1,420)	<input type="checkbox"/>	<input type="checkbox"/>

For studies in which a certificate was issued previously and will expire, the following additional documents:

8. A copy of the previous certificate.	<input type="checkbox"/>	<input type="checkbox"/>
9. Clinical trial progress report(s) (if not available, please provide justification; if the trial has not been started, please also provide justification).	<input type="checkbox"/>	<input type="checkbox"/>

<b>Risk Assessment Form for Clinical Trial Submitted under the Listed Scheme</b>			
<b>PART A: DRUG INFORMATION</b>			
		Trial drug 1	Trial drug 2 (this column is used only when >1 trial drug; additional columns may be used if applicable)
A1.	Name of trial drug		
A2.	Is the trial drug registered in Hong Kong?	<input type="checkbox"/> Yes (registration no: HK-_____) <input type="checkbox"/> No	<input type="checkbox"/> Yes (registration no: HK-_____) <input type="checkbox"/> No
A3.	Approved indication, dosage and route of administration	Indication:	Indication:
		Dosage:	Dosage:
		Route of administration:	Route of administration:
<b>PART B: TRIAL INFORMATION</b>			
B1.	Protocol title and no.:		
B2.	Is the trial initiated and conducted by a sponsor-investigator?	<input type="checkbox"/> Yes <input type="checkbox"/> No (the Listed Scheme is <u>not applicable</u> ; please submit under the Standard Scheme)	
B3.	Targeted disease or condition:		
B4.	Trial regimen, including dosage and route of administration:		

## PART C: RATIONALE FOR SUBMITTING THE TRIAL UNDER THE LISTED SCHEME

Please tick one of the following rationales and provide explanation of the risk assessment:

- C1.  The trial is a Type A\* because the trial drug is registered in Hong Kong and used in accordance with the approved indication, dosage and form (see 4.1.1 of the guidance notes).  
*Local package insert or other reputable drug references, e.g. Martindale, should be provided as supporting evidence.*
- C2.  The trial is a Type A\* because the trial drug is registered in Hong Kong. Although it is not used in accordance with the approved indication, dosage and form, the use in the trial is an established practice (see 4.1.1 of the guidance notes).  
*Published evidence such as reputable clinical guidelines or institutional guidelines should be provided as supporting evidence.*
- C3.  The trial is a Type B\*\*. However, there is extensive clinical experience with the trial drug and no reason to suspect a different safety profile in the trial population, Therefore, a grading of Type A is justified (see 4.2.1 of the guidance notes).  
*Other documents, when applicable, should be provided to support the risk assessment.*

**If the trial is submitted under the Listed Scheme with the following rationales, i.e. C4 and C5, it needs to be considered by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee of the Pharmacy and Poisons Board of Hong Kong. The final decision on whether the trial can be proceeded under the Listed Scheme will be made by the committee.**

- C4.  The trial is a Type B\*\*. There is no extensive clinical experience with the trial drug. However, the sponsor-investigator is of the view that submission under the Listed Scheme is felt to be justified (see 4.2.2 of the guidance notes).  
*Other documents, when applicable, should be provided to support the risk assessment.*
- C5.  The trial is a Type B\*\*. Although the trial drug is not registered in Hong Kong, there is extensive class data or pre-clinical and clinical evidence of the drug (see 4.2.3 of the guidance notes).  
*Other documents, when applicable, should be provided to support the risk assessment.*

Explanation of the risk assessment:

Remarks:       \*     Type A trial has risk no higher than the risk of standard medical care.  
                 \*\*     Type B trial has risk somewhat higher than the risk of standard medical care.

**DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**

**Notice of requirement on reporting of local drug related safety report,  
progress report and final study report in clinical trial**

All certificate holders of clinical trial/medicinal test are required to report to this office the following:

1. All local drug-related safety reports i.e. reports on adverse drug reactions (ADRs).
  - (a) For adverse drug reactions that are both serious\* and unexpected\*\* as soon as possible. (The attached CIOMS form [Appendix 4] may be used for reporting.)
    - (i) Fatal or life-threatening unexpected ADRs should be reported as soon as possible but no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days. This report must include an assessment of the importance and implication of the findings, including relevant previous experience with the same or similar medicinal products.
    - (ii) Other serious, unexpected ADRs that are not fatal or life-threatening, it should be reported as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.
  - (b) For non-serious adverse reactions and serious adverse reactions that are expected, it should be reported in a brief summary at the conclusion of the trial.

\* Serious Adverse Drug Reaction or Adverse Event :

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse.

\*\* Unexpected Adverse Drug Reaction:

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational medicinal product).

2. Progress report on yearly basis and a final study report at the end of the study. The attached forms (Appendix 5 & 6 respectively) may be used for reporting.
3. Please forward all reports to the following address:

Drug Registration and Import/Export Control Division  
Drug Office  
Department of Health  
3/F, Public Health Laboratory Centre  
382 Nam Cheong Street  
Shek Kip Mei, Kowloon  
Hong Kong

Fax no.: 2803 4962  
Email: [ct@dh.gov.hk](mailto:ct@dh.gov.hk)

SUSPECT ADVERSE REACTION REPORT	

**I. REACTION INFORMATION**

1. PATIENT INITIALS (first. last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab date)										<input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING  <input type="checkbox"/> CONGENITAL ANOMALY

**II. SUSPECT DRUG(S) INFORMATION**

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

**III. CONCOMITANT DRUG(S) AND HISTORY**

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period. etc.)

**IV. MANUFACTURER INFORMATION**

24a. NAME AND ADDRESS OF MANUFACTURER		
		24b. MFR CONTROL NO.
24c. DATE RECEIVED BY MANUFACTURER		24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL
DATE OF THIS REPORT		25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP

**DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**

**Clinical Trial Yearly Progress Report**

Report period \_\_\_\_\_ to \_\_\_\_\_

Date of this report \_\_\_\_\_

CT cert no.:	
Protocol no.:	
Protocol title:	

Start date: _____	Anticipated end date: _____
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Target no. of patient (as stated in protocol)	_____
No. of patient intend to recruit (per centre)	_____
No. of patient recruited (per centre)	_____
No. of patient completed the trial (per centre)	_____
No. of patient drop-out from study (per centre)	_____
Reasons for drop-out:	

Any changes for principal investigator?	(If yes please give details)
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Summary of amendments during report period (if any)
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Summary of Serious Adverse Events (if any)
Does SAE affect the study? How and what action has been taken?

Summary of complaints about the study (if any)
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Summary of recent findings (especially information about risks associated with the research)
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Progress of study:
<input type="checkbox"/> According to plan
<input type="checkbox"/> Extend study period (reason _____)
<input type="checkbox"/> Premature termination (reason _____)

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Posting: \_\_\_\_\_

Date: \_\_\_\_\_

**DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**

**Clinical Trial Final Report**

Report period \_\_\_\_\_ to \_\_\_\_\_

Date of this report \_\_\_\_\_

CT cert no.:	
Protocol no.:	
Protocol title:	

Start date: _____	End date: _____
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Target no. of patient (as stated in protocol)	_____
No. of patient intend to recruit (per centre)	_____
No. of patient recruited (per centre)	_____
No. of patient completed the trial (per centre)	_____
No. of patient drop-out from study (per centre)	_____
Reasons for drop-out:	

Summary of Serious Adverse Events (if any)
Does SAE affect the study? How and what action has been taken?

Summary of complaints about the study (if any)

Study duration:
<input type="checkbox"/> According to plan
<input type="checkbox"/> Extend study period (reason _____)
<input type="checkbox"/> Premature termination (reason _____)

Summary of study outcome

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Posting: \_\_\_\_\_

Date: \_\_\_\_\_