

## Amendment

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## 4. Amendment

### I. Amendment Submission

#### i. Create, Preview and Submit Amendment

1. Go to menu “CTC” → “Amendment”
2. Select the applicable CTC for amendment submission

Drug Office  
Department of Health  
The Government of the Hong Kong Special Administrative Region

Dash Board | CTC | Profile | 中 | Logout

Amendment - Select

Logon as: TEST HONG KONG LTD (Doctor Two)  
Date: 28.06.2022 16:38:49

1. Amendment >>> 2. Preview >>> 3. Submit

CTC No.	Protocol Title
<input type="checkbox"/>	

Add CTC Remove CTC Select from all CTC

2

3. Select the the Particulars Proposed to Change  
(Multiple selection is supported if needed)

Please tick the appropriate change category and state the nature of the change.

Particulars Proposed to Change	Brief Description of Change and Reason
+ 1 For Category 1 amendments that involve change of particulars on the Certificate, please submit the original CTC to Drug Office.	
+ 2 Protocol title	
+ 3 Protocol	
+ 4 Consent form	
+ 5 Investigator's brochure	
+ 6 Safety	
+ 7 Trial status report	
+ 8 Other (please specify)	

4. Tick the appropriate change category and state the nature of the change. State the Brief Description of Change and Reason and Click “Next”  
Multiple selection is supported if needed, for example:

Please tick the appropriate change category and state the nature of the change.

Particulars Proposed to Change	Brief Description of Change and Reason
+ 1 For Category 1 amendments that involve change of particulars on the Certificate, please submit the original CTC to Drug Office.	
+ 1.1) Change of certificate holder	<input checked="" type="checkbox"/>
+ 1.2) Change of certificate holder address	<input checked="" type="checkbox"/>
+ 1.3) Change of principal investigator	<input type="checkbox"/>
+ 1.4) Change of study drug	<input type="checkbox"/>
+ 1.5) Change of trial site/ address	<input type="checkbox"/>
+ 2 Protocol title	
+ 2.1) Change of protocol title	<input checked="" type="checkbox"/>
+ 3 Protocol	
+ 4 Consent form	
+ 5 Investigator's brochure	
+ 6 Safety	
+ 7 Trial status report	
+ 8 Other (please specify)	<input type="checkbox"/>

Next Cancel

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5. Fill-in / Edit Particulars to be changed and Click “Next”, for example:

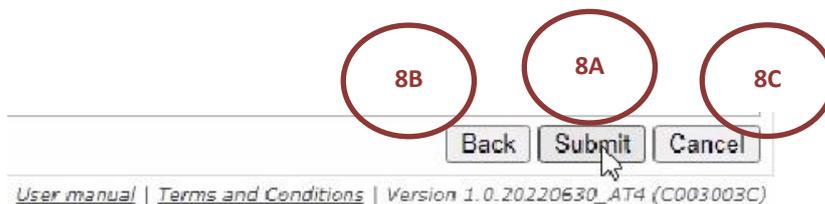
6. Upload required Supporting Documents and Click “Preview”, for example:

7. A Preview page will list out the details of the clinical trial/medicinal test and highlight amended information and/or supporting document(s)

8. A) User can click “Submit” button to submit the amendment to DHDO or

B) Click “Back” button to re-edit the form or

C) Click “Cancel” button to leave the form and back to search page.



- 8A i) Click “Choose E-cert” button, Select the corresponding E-cert,
- ii) Input the corresponding Passphrase of the login user account and
- iii) Click “Submit” button to submit the amendment to DHDO

Verify user information	
e-Cert:	<input type="text"/> <b>8A i</b> <input type="button" value="Choose e-Cert"/>
Passphrase:	<input type="text"/> <b>8A ii</b>
<input type="button" value="Submit"/> <b>8A iii</b> <input type="button" value="Cancel"/>	

- The successful message of the application will be shown.

**Link for another application**

CTC No.: CTSCR303/2022 is submitted successfully, please wait for DH approval , click [here](#) for another application.

ii. Delete a Saved Draft

Only draft record can be deleted, the steps show as follows.

1. Select menu “CTC” → “CTC Search” or redirect from Dash Board
2. Select application with the status as “Draft”
3. Click “Search” button
4. Click “Delete” button on related record

Drug Office  
Department of Health  
The Government of the Hong Kong Special Administrative Region

Dash Board | CTC | Profile | 中 | Logout

CTC Search

Logon as: TEST HONG KONG LTD (Doctor Two)  
Date: 23.06.2022 16:47:42

1

Prepared by: [Dropdown]  
Protocol Title: [Text]  
Protocol Number: [Text]  
Ref No.: [Text] ⓘ  
Application Type: [Dropdown]  
CTC Type: [Dropdown]  
Status:  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  Rejected  Expired  
Application date: (dd.mm.yyyy) [Text] to [Text] [Clear date field]

Search 3

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
AMD202250264	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	14.06.2022	Delete
AMD202250262	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	14.06.2022	Delete
AMD202250258	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete
AMD202250256	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete
AMD202250254	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete
AMD202250250	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete
AMD202250248	0050	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete

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5. Click “OK” button on the popup box

Confirm delete draft? Click [OK/確定] to continue or click [Cancel/取消] to return page

5 OK Cancel

iii. Application Status

Status name	Status description
Draft	Applications are open for edit and delete.
DH replied	Applications are replied by DHDO, user need to follow DHDO officer's instruction before re-submit them.
Follow up (DH replied)	Follow up application are replied by DHDO.
Completed Draft	Applications are completed by normal users / supervisors and are ready to submit.
Pending Payment	Applications are pending for payment by applicant.
DH Pending	Applications are under screening or evaluation in DHDO.
Approved	Applications are approved by DHDO.
Rejected	Applications are rejected by DHDO.
Expired	CTCs are expired.

## II. Payment

For amendments that will change the particulars of the CTC, a payment of HKD\$155 is required before approval. In order to complete payment, user can select menu “CTC” → “CTC Search” and search with following criteria:

1. Select Prepared by and/or
2. Input Protocol Title and/or
3. Input Protocol Number and/or
4. Input Ref No. (support partial match) and/or
5. Select Application Type and/or
6. Select CTC Type and
7. Select “Pending Payment” as Status and/or
8. Select Application date range

Drug Office  
Department of Health  
The Government of the Hong Kong Special Administrative Region

Dash Board | CTC | Profile | 中 | Logout

Logon as: TEST HONG KONG LTD (Doctor Two)  
Date: 23.06.2022 17:22:59

CTC Search

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Prepared by: [dropdown]  
Protocol Title: [text]  
Protocol Number: [text]  
Ref No.: [text] P  
Application Type: [dropdown]  
CTC Type: [dropdown]  
Status:  All  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  Rejected  Expired  
Application date: (dd.mm.yyyy) [text] to [text] Clear date field Search

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
CTSCR261/2022		New Application	10.05.2022	Standard	Protocol Title	1234	Doctor Two	Pending Application Payment	10.05.2022	Pay Now Pay by Cash/Cheque

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9. Click “Search” button, result will be displayed in the result table

Status:  All  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  Rejected  Expired  
Application date: (dd.mm.yyyy) [text] to [text] Clear date field Search

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
CTSCR261/2022		New Application	10.05.2022	Standard	Protocol Title	1234	Doctor Two	Pending Application Payment	10.05.2022	Pay Now Pay by Cash/Cheque

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## 10. Select pay method

A Click “Pay Now” button for making on-line payment or

B Click “Pay by Cash/Cheque” button

All  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  
 Rejected  Expired

Application date: (dd.mm.yyyy)  to

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
CTSCR261/2022		New Application	10.05.2022	Standard	Protocol Title	1234	Doctor Two	Pending Application Payment	10.05.2022	<input type="button" value="Pay Now"/> <b>10A</b> <input type="button" value="Pay by Cash/Cheque"/> <b>10B</b>

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### 10 A. On-line payment

i. Select Payment Method and

ii. Click “Pay” button

## GovHK 香港政府一站通

Online Payment Service

**Help**

General Customer Service Hotline (852) 183 5500

Email enquiry@1835500.gov.hk

**Please select the payment method :**

Type of Service: DH Drug Office Drug Clinical Trials  
 Merchant Name: DH Drug Office  
 Transaction Date: 09-06-2022  
 Transaction Reference Number: DHC TC-202206091810-95558  
 Total Amount: HK\$ 1,420.00  
 Payment Method:

10A i











**10A ii**

- Please take note of the transaction reference number or **PRINT** this page for making enquiry on the payment status when necessary.
- After pressing the 'Pay' button, please **DO NOT** leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful.
- Merchant Name is applicable to credit card payment method only.
- PPS Shop&Buy (PPS) does not support payment via browsers of mobile devices (including mobile phones and tablets) at the moment. If you wish to pay by PPS, please change to use desktop computer.**
- Under exceptional conditions, a refund may need to be arranged. If the payment is made by Credit Card, the refund can normally be made to the Credit Card account that is used for the payment.
- Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use other available payment methods. We apologise for any inconvenience caused.
- Different credit card issuers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please contact your card issuer if you want to learn more about the J/Secure, Mastercard SecureCode and Verified by Visa service.



- iii. Fill-in the details of the selected payment method
- iv. Click “Pay now” button

Secure payment

Card number \*

Expiry month ^ Expiry year ^

MM ^ YY ^

Cardholder name \*

Security code ^

3 digits on back of your card

10A iii

TOTAL HKD: 1420.00

The next screen you see may be payment card verification through your card issuer.

[Cancel](#)
Pay now

10A iv

- v. Successful payment message will be shown



Date	Type	Message
14.06.2022	Amendment	<a href="#">AMD202250266</a> was submitted.
10.06.2022	Amendment	<a href="#">AMD202250252</a> was submitted.
02.06.2022	New Application	Payment is pending for <a href="#">CTSCR261/2022</a> .
30.05.2022	Amendment	<a href="#">AMD202250238</a> was submitted.
30.05.2022	New Application	<a href="#">CTSCR284/2022</a> certificate fee was paid.

10 B. Pay by Cash/Cheque

- i. Click “Pay by Cash/Cheque” button to download the payment notification
- ii. The payment details are listed in the notification (Note: The fee for certificate amendment is HKD\$155)

PHARMACY AND POISONS ORDINANCE  
(CHAPTER 138)

香港法例第138章藥劑業及毒藥條例

Ref: 檔號	CTSCR 288/2022	Date: 日期	09 June 2022
<b>NOTIFICATION</b> <b>通知書</b>			
This is to notify you to pay for the following application(s)/certificate(s): 現通知閣下繳交下列申請/註冊之費用:			
		Number 數量	Fee 費用
Clinical Trial Application Fee	<b>10B ii</b>	<u>1</u>	<u>1420</u>
Clinical Trial Certificate Fee		<u>          </u>	<u>          </u>
Amendment Certificate Fee		<u>          </u>	<u>          </u>
			(W.K. NG)
			For Chief Pharmacist
			總藥劑師 (高級藥劑師代行)

- iii. Bring along the notification to Drug office to complete the payment

### III. Certificate Download / Printing

In order to print the Amended Certificate(s), user can select menu “CTC” → “CTC Search” and search with following criteria:

1. Select Prepared by and/or
2. Input Protocol Title and/or
3. Input Protocol Number and/or
4. Input Ref No. (support partial match) and/or
5. Select Application Type and/or
6. Select CTC Type and
7. Select “Approved” as Status and/or
8. Select Application date range

Drug Office  
Department of Health  
The Government of the Hong Kong Special Administrative Region

Dash Board | CTC | Profile | 中 | Logout

Logon as: TEST HONG KONG LTD (Doctor Two)  
Date: 24.06.2022 12:20:56

CTC Search

Prepared by: [Dropdown]  
 Protocol Title: [Text Field]  
 Protocol Number: [Text Field]  
 Ref No.: [Text Field] ⓘ  
 Application Type: [Dropdown]  
 CTC Type: [Dropdown]  
 Status:  All  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  
 Rejected  Expired  
 Application date: (dd.mm.yyyy) [Text Field] to [Text Field] [Clear date field] [Search]

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
PR/CT00254/2022	0051	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	
PR/CT00253/2022	0050	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	

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9. Click “Search” button, result will be displayed in the result table

Status:  All  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  
 Rejected  Expired  
 Application date: (dd.mm.yyyy) [Text Field] to [Text Field] [Clear date field] [Search]

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
PR/CT00254/2022	0051	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	
PR/CT00253/2022	0050	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	

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10. Click link on related Ref No. to Download / Print the certificate

► Status:  All  Draft  DH replied  Follow up (DH replied)  Completed draft  Pending Payment  DH Pending  Approved  
 Rejected  Expired

► Application date: (dd.mm.yyyy)  to

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Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
PR/CT00254/2022	0051	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	
PR/CT00253/2022	0050	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	

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11. Click “Print CTC” button to Download / Print the certificate

**11**

Remarks: The “Print CTC” button would be disappeared after clicking once.