# **New Application**

- I. <u>Certificate Application</u>
  - i. <u>Certificate Search</u>
  - ii. <u>Create, Preview and Submit New Application</u>
  - iii. <u>Delete a Saved Draft</u>
  - iv. <u>Application Status</u>
- II. <u>Payment</u>
- III. <u>Certificate Download / Printing</u>

# 3. New Application

- I. Certificate Application
- i. Certificate Search

In order to search specific record, user can select menu "CTC"  $\rightarrow$  "CTC Search" or redirect from Dash Board and then:

- 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/or
- 7. Select Status and/or
- 8. Select Application date range

Prug Office Department of Health The Government of the Hong Kong Special Administrative Region								
Dash Board CTC Profile (p logo								
CTC Search								
<ul> <li>Prepared by:</li> <li>Protocol Title:</li> <li>Protocol Number:</li> <li>Ref No.:</li> <li>Application Type:</li> <li>CTC Type:</li> <li>Status:</li> <li>Application date: (dd.mm.yyyy)</li> </ul>	Prepared by:   Protocol Title:   Protocol Number:   Protocol Number:   Ref No.:   Application Type:   V   CTC Type:   Status:   All O Draft O DH replied O Follow up (DH replied) O Completed draft O Pending Payment O DH Pending Approved Rejected O Expired   Application date:   (d.mm.yyyy)     to     Ctear date field							
				(e) (e) (e)	age 2 / 2 😕 🖲			
Ref No.	<pre>Application date</pre>	TC Type + Protocol Title	Protocol Number Prepared by \$	Status Status update date \$ (dd.mm.yyyy)	Action			
PR/CT00254/2022 0051 New Applica	tion 30.05.2022 Sta	andard Title	Test123 Doctor Two	Approved 30.05.2022				
AMD202250234 0050 Amend	ment 30.05.2022 Sta	andard Title	Test123 Doctor Two	30.05.2022				
AMD202250232 0050 Amend	ment 30.05.2022 Sta	andard Title	Test123 Doctor Two	Pending DH 30.05.2022				
PR/CT00253/2022 0050 New Applica	tion 30.05.2022 Sta	andard Title	Test123 Doctor Two	Approved 30.05.2022				

# 9. Click "Search" button, result will be displayed in the result table

Status:			All O Draft O Rejected O Expir	DH replied C	Follow up (DH replied)	Completed dr	aft 🔿 Pending P	ayment O	DH Pending 🔿 /	Approved
Application date: (dd.mm.yyyy)				to		Clear date field				9 Search
									🔘 🥶 P.	age 🙎 / 🙎 😕 😕
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	
AMD202250234	0050	Amendment	30.05.2022	Standard	Title	Test123	Doctor Two		30.05.2022	
AMD202250232	0050	Amendment	30.05.2022	Standard	Title	Test123	Doctor Two	Pending DH	30.05.2022	
PR/CT00253/2022	0050	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	

# 10. Click link on related Ref No. to view / edit the certificate application

Ð	Status: <ul> <li>All O Draft O DH replied O Follow up (DH replied) O Completed draft O Pending Payment O DH Pending O Approved</li> <li>Rejected O Expired</li> </ul>				pproved						
<ul> <li>Application date: (dd.mm.yyyy)</li> </ul>			to			Clear date field				Search	
_										🖲 📵 Pa	age 🛛 / 💈 🛞 🖲
Re	f 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
<u>PR</u>	/ <u>CT00254/2022</u>	0051	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	
<u>AM</u>	D202250234	0050	Amendment	30.05.2022	Standard	Title	Test123	Doctor Two		30.05.2022	
<u>AM</u>	D202250232	0050	Amendment	30.05.2022	Standard	Title	Test123	Doctor Two	Pending DH	30.05.2022	
<u>PR</u>	/ <u>CT00253/2022</u>	0050	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	

# ii. Create, Preview and Submit New Application

- A. Standard Scheme
- 1. Go to menu "CTC"  $\rightarrow$  "CTC Application"
- 2. Select "Standard Scheme" as the CTC Type and click "Continue"

Department of Health The Government of the Hong Kong Special Administrative Region	Kane
Dash Board CTC Profile	中 Logout
CTC Application - Select	Logon as: TEST HONG KONG LTD (Doctor Two) Date: 23.06.2022 11:52:18
1. Select     >>>     2. New     >>>     3. Preview     >>>>     4. Submit	
Select CTC Type:	

3. Select the type of study in Section I of the application form

CTC - New	Date: 23.06.2022 11:52:18
1. Select >>>> 2. New >>>> 3. Preview >>>> 4. Submit	
	Mandatory ^Need original copy
Section I - Type of Study	
Please tick one of the following:*	
<ul> <li>○ This is an application for a clinical trial submitted under the Standard Scheme.</li> <li>○ This is an application for a medicinal test.</li> </ul>	

# 4. Fill-in Section II of the application form

Sec	Section II - Study Information							
1.	Protocol Title*							
2.	Protocol No.*							
з.	Name of Applicant*	TEST HONG KONG LTD						
4.	Business Address of Applicant*	SHOP 2, G/F, QUEEN ST, SHEUNG WAN						
	Contact Person*							
5.	Tel. No.*	Fax No.*						
	Email*	ctc.system.user9@gmail.com						
6.	Name of Principal Investigator*	Medical Council Registration Number*						
7.	Name of Institution Conducting the Study*	<b>4</b> . •						
	Address of Institution Conducting the Study*							
8.	Is this a study in which a certificate was	issued previously and will soon expire?*						
	O Yes (CTC No.	and valid until )						
	ONO							
9.	Is this study also the subject of an applic	ation for approval by National Medical Products Administration (NMPA)?*						
	O Yes (if available, the acceptance num and date of approval	ber of Drug Clinical Trial Approval Document (奠初館林試驗通知書) ])						
	ONO							

### Remarks:

- Name of Applicant and Business Address of Applicant will be filled-in automatically by the system and cannot be revised
- Address of Institution Conducting the Study will be filled-in automatically after selecting the Name of Institution Conducting the Study

# 5. Fill-in Section III of the application form

Se	ction III - Study Description	
1.	⊖ Single Centre ⊖ Multi-Centre	
2.	$\bigcirc$ Phase I (First in Human: $\bigcirc$ Yes $\bigcirc$ No )	
	○ Phase II ○ Phase III ○ Phase IV	
	Remark	
з.	Open Label OSingle Blind ODouble Blind	1
	Describe if necessary	
4.	O Non-Randomized O Randomized	
5.	Total Number of Centres in Hong Kong"	
	Name of Other Participating Centre(s)	
6.	Total Number of Centre outside Hong Kong (if any)	
	Other Participating Region(s) (e.g. USA, China etc.)	
7.	Sponsor of the Study"	O The sponsor is a pharmaceutical company or research organization / institution
		Name of Sponsor
		Address of Sponsor
		$\bigcirc$ The sponsor is initiated and conducted by a sponsor-investigator
		Name of Sponsor
		Address of Sponsor
		(Remarks: As this study is initiated and conducted and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)
8.	Recruitment Size	
	Planned Number of Subjects in Hong Kong*	
	Total Planned Number of Subjects World-wide*	
9.	Study Period"	Planned start date and planned end date
10.	Therapeutic Area (e.g. Oncology, Endocrinology)*	<b>v</b>
11.	Disease / Disease Type (e.g. Breast Cancer)*	

- 6. Fill-in Section IV of the application form, select if Advanced Therapy Products (ATP) is/are involved in the study
- 7. Select applicable type of study drug(s) and fill-in the drug name, dosage form, strength and source of supply as applicable (Note: Please only provide name and address of <u>final product</u> manufacturer(s))

Section IV - Study Drug							
Advanced Therapy Products (ATP) Yes	No						
The clinical trial will involve							
1. Investigational Drug Name							
Dosage Form	<b></b>						
Strength	•						
Supply	<b></b>						
Add Investigational Drug							
1. Placebo Drug							
Dosage Form	<b>```</b>						
Supply							
Add Placebo Drug	6 – 7						
1. Comparator Drug Name							
Dosage Form	<b></b>						
Strength	•						
Supply	<b></b>						
Add Comparator Drug							
1. Concomitant Drug Name							
Dosage Form	<b>v</b>						
Strength	3						
Supply	<b>~</b>						
Add Concomitant Drug							

8. Upload related Supporting Document(s), fill-in File Name, Version and Date (Multiple upload is supported if needed)

Supp	orting Document(s)						
No.	Document Description	File Name	Version / Date			Action	
1 *	Cover letter			/		Upload	
2 *	Letter from the principal investigator confirming his involvement in the clinical trial or medicinal test			/		Upload	Add
3 *	Curriculum Vitae of the principal investigator			/		Upload	Add
4	Documentary evidence that the clinical trial has been approved by the Ethics Committee of the institution in which it is to be conducted			/		Upload	Add
5 *	Proposed patient information and patient consent form			/		Upload	Add
6 #	Tracked change of patient information and patient consent form						
7 *	Copy of the proposed protocol			/		Upload	Add
8 #	Summary of changes of protocol						
9 *	Information of the drug (e.g. investigator's brochure, package insert, other information if applicable, etc.)			/		Upload	Add
10 #	Summary of changes of investigator's brochure						
11 *	Sample certificate of analysis of the drug and/ or placebo			/		Upload	Add
12 *	Evidence that the drug and/ or placebo are manufactured in accordance with Good Manufacturing Practices (GMP)			/	•	Upload	Add
13	Copy of the previous certificate			/	۲	Upload	
14	Clinical trial progress report			/		Upload	
15	Drug clinical trial approval document (葉杓語林試驗通知書) issued by NMPA			/		Upload	Add
16	Copy of the protocol submitted to NMPA			/		Upload	Add
17 #	Cover letter issued by original certificate holder						
18 #	Letter issued by new certificate holder confirming acceptance of the CTC						
19 *	Copy of Wholesale Dealer Licence of the new certificate holder						
20 #	Copy of Wholesale Dealer Licence with new address						
21 #	Safety update documents						
22	Others			/		Upload	Add

#### 9. Put a tick in the declaration boxes

9
Section V - Declaration of Applicant \*
I/We hereby declare that, if the application is approved:

I/We hereby declare that, if the application is approved:
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".

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.
D4. By submitting this application, consent is given to the Pharmacy & Poisons Board of Hong Kong to arrange any information provided in this application to be displayed on the website of the Board.

Save as draft Preview Cancel



10. A) After all information is filled, user can click "Preview" button to view the filled details <u>in</u> the Preview page.



- i) Click "Back" button to re-edit the form or
- ii) Click "Submit" button to submit the new application to DHDO
  - Click "Choose E-cert" button,
  - Select the corresponding E-cert,
  - Input the corresponding Passphrase of the login user account and
  - Click "Submit" button to submit the new application to DHDO

Verify user information					
e-Cert:	Choose e-Cert				
Passphrase:					
	Submit Cancel				

- The successful message of the application will be shown.



- B) Or click "Save as draft" button for future editing.
  - The successful message will be shown.

Saved as draft. (Ref No.: TS03975)

C) Or click "Cancel" button to leave the form and back to search page.

- B. Listed Scheme
- 1. Go to menu "CTC"  $\rightarrow$  "CTC Application"
- 2. Select "Listed Scheme" as the CTC Type and click "Continue"

Drug Office Department of Health The Government of the Hong Kong Special Adminis	trative Region	A Contraction of the second se
Dash Board CTC Profile		ф Logout
CTC Application - Select		Logon as: TEST HONG KONG LTD (Doctor Two) Date: 23.06.2022 14:02:07
1. Select >>>> 2. New >>>>	3. Preview 3. Submit	
Select CTC Type: Standard Scheme	2	
		Continue
		User manual   Terms and Conditions   Version 1.0.20220630. AT4 (C003002

3. Fill-in Part A of the Risk Assessment Form

CTC - New		Logon as: TEST HONG KONG LTD (Doctor Two) Date: 23.06.2022 14:02:07
1. Select >>>> 2. New >>>> 3. Preview >>>> 4. Submit		
		Mandatory Need original copy
Risk Assessment Form for Clinical Trial Submitted under the Listed Scheme	2	
Part A: Drug Information		
1. Name of trial drug		8
Is the trial drug registered in Hong Kong?	○Yes(registration no: HK)	
	ONo	
Approved indication, dosage and route of administration		
Indication		
Dosage		
Route of administration		
		Add trial drug

Remarks: Applicant can add trial drug(s) if needed.

# 4. Fill-in Part B of the Risk Assessment Form

Pa	rt B: Trial Information	
1.	Protocol no.*	
	Protocol title*	
2.	Is the trial initiated and conducted by a sponsor- investigator?*	O Yes O No (the Listed Scheme is not <u>applicable</u> ; please submit under the Standard Scheme)
з.	Targeted disease or condition*	
4.	Trial regimen, including dosage and route of administration*	

# 5. Select the Rationale for Submitting the Trial under the Listed Scheme

<ul> <li>Please tick one of the following rationales and provide explanation of the risk assessment:</li> <li>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 the guidance notes).             Local package insert or other reputable drug references e.g. Martindale, should be provided as supporting evidence.      </li> <li>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, (see 4.1.1 of the guidance notes).             Local package evidence such as reputable drug references e.g. Martindale, should be provided as supporting evidence.         </li> <li>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.         </li> <li>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 on Q Type A is justified (see 4.2.1 of the evidance notes).      </li> </ul>	Part	Part C: Rationale for Submitting the Trial under the Listed Scheme*									
<ul> <li>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 the guidance notes). Local package insert or other reputable drug references e.g. Martindale, should be provided as supporting evidence.</li> <li>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.</li> <li>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).</li> </ul>	Please	Please tick one of the following rationales and provide explanation of the risk assessment:									
<ul> <li>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.</li> <li>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).</li> </ul>	C1.	0	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.								
C3. O 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).	C2.	0	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.								
Other documents, when applicable, should be provided to support the risk assessment.	С3.	0	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 rationale, 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 Poisions Boar of Hong Kong. The final decision on whether the trial can be proceeded under the Listed Scheme will be made by the committee.	<u>If the</u> ( <u>Regi</u> of Ho										
C4. O 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.	C4.	0	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. O The trial is a Type B**. Although the trial drug is not registered in Hong Kong, there is extensive class data or pre-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.	C5.	0	The trial is a Type B**. Although the trial drug is not registered in Hong Kong, there is extensive class data or pre-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.								

# 6. Fill-in Part D of the Risk Assessment Form

Part D: Explanation of the risk assessment*		
	6	

7. Fill-in Section I of the application form

Se	ction I - Study Information	
1.	Protocol Title*	
2.	Protocol No.*	
з.	Name of Applicant*	TEST HONG KONG LTD
4.	Business Address of Applicant*	SHOP 2, G/F, QUEEN ST, SHEUNG WAN
5.	Contact Person" Tel. No."	Fax No.
	Email*	ctc.system.user9@gmail.com
6.	Name of Principal Investigator*	Medical Council Registration Number*
7.	Name of Institution Conducting the Study*	✓
	Address of Institution Conducting the Study $\ensuremath{^{st}}$	
8.	Is this a study in which a certificate was issued pre-	viously and will soon expire?*
	O Yes (CTC No. and	valid until )
	ONO	

Remarks:

- Name of Applicant and Business Address of Applicant will be filled-in automatically by the system and cannot be revised
- Address of Institution Conducting the Study will be filled-in automatically after selecting the Name of Institution Conducting the Study

### 8. Fill-in Section II of the application form

Se	ction II - Study Description	
1.	⊖ Single Centre ⊖ Multi-Centre	
2.	$\bigcirc$ Phase I (First in Human: $\bigcirc$ Yes $\bigcirc$ No )	
	$\bigcirc$ Phase II $\bigcirc$ Phase III $\bigcirc$ Phase IV	
	Remark	
з.	$\bigcirc$ Open Label $\bigcirc$ Single Blind $\bigcirc$ Double Blind	
	Describe if necessary	
4.	$\bigcirc$ Non-Randomized $\bigcirc$ Randomized	
5.	Total Number of Centres in Hong Kong*	
	Name of Other Participating Centre(s)	
6.	Total Number of Centre outside Hong Kong (if any)	
	Other Participating Region(s) (e.g. USA, China etc.)	
7.	Sponsor of the Study"	Name of Sponsor
		Address of Sponsor
		(Remarks: As this study is initiated and conducted and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)
8.	Recruitment Size	
	Planned Number of Subjects in Hong Kong*	
	Total Planned Number of Subjects World-wide*	
9.	Study Period*	Planned start date
10.	Therapeutic Area (e.g. Oncology, Endocrinology)*	<b>v</b>
11.	Disease / Disease Type (e.g. Breast Cancer)*	

- 9. Fill-in Section III of the application form, select if Advanced Therapy Products (ATP) is/are involved in the study
- 10. Select applicable type of study drug(s) and fill-in the drug name, dosage form, strength and source of supply as applicable (Note: Please only provide name and address of <u>final product</u> manufacturer(s))

Section III - Study Drug		
Advanced Therapy Products (ATP) $\bigcirc$ Yes	s O No	
The clinical trial will involve		
✓Investigational Drug(s)	ebo 🗹 Comparator Drug(s)	✓ Concomitant Drug(s)
1. Investigational Drug Name		
Dosage Form		~
Strength		3
Supply		~
Add Investigational Drug		
1. Placebo Drug		
Dosage Form		~
Supply		~
Add Placebo Drug	9 - 10	
1. Comparator Drug Name		
Dosage Form		✓
Strength		(?)
Supply		~
Add Comparator Drug		
1. Concomitant Drug Name		
Dosage Form		~
Strength		(?)
Supply		~
Add Concomitant Drug		

 Upload related Supporting Document(s), fill-in File Name, Version and Date (Multiple upload is supported if needed)

۷o.	Document Description	File Name	Version / D	ste	Action	
-	Cover letter			/	Upload	
	Documentary evidence that the clinical trial has been approved by the Ethics Committee of the institution in which it is to be conducted			/	Upload	Ad
×	Proposed patient information and patient consent form	(		/	Upload	Ad
×.	Tracked change of patient information and patient consent form					
-	Copy of the proposed protocol	1		/	Upload	Ad
*	Summary of changes of protocol	_				
	Copy of the previous certificate			/	Upload	
	Clinical trial progress report			1/	Upload	
5	Cover letter leaved by original certificate holder					
e.	Letter issued by new certificate holder confirming acceptance of the CTC					
1	Others	[		/	Uplead	Ad

## 12. Put a tick in the declaration boxes



13. A) After all information is filled, user can click "Preview" button to view the filled details in the Preview page.



- i) Click "Back" button to re-edit the form or
- ii) Click "Submit" button to submit the new application to DHDO
  - Click "Choose E-cert" button,
  - Select the corresponding E-cert,
  - Input the corresponding Passphrase of the login user account and

- Click "Submit" button to submit the new application to DHDO

Verify user information								
e-Cert:	Choose e-Cert							
Passphrase:								
	Submit Cancel							

- The successful message of the application will be shown.



- B) Or click "Save as draft" button for future editing.
  - The successful message will be shown.

Saved as draft. (Ref No.: TS03975)

C) Or click "Cancel" button to leave the form and back to search page.

#### iii. Delete a Saved Draft

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

- 1. Select menu "CTC"  $\rightarrow$  "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

Dru Dep. The	i <b>g Off</b> artment Govern	ice t of Health ment of the H	long Kong Speci	al Administrative Regio	on					~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
Dash Board		стс	Pr	ofile							中 Logou	Jt
्र ctc s	earch	1	$\left( \right)$						Logon as: Date:	TEST HONG KONG LTI 23.06.2022 16:47:42	D (Doctor Tv	vo)
<ul> <li>Prepared by:</li> <li>Protocol Title:</li> <li>Protocol Number:</li> <li>Protocol Number:</li> <li>Ref No.:</li> <li>Application Type:</li> <li>CTC Type:</li> <li>Status:</li> <li>Application date:</li> <li>Implication date:<th>Search 3</th><th></th></li></ul>									Search 3			
									•	3 Page 1 /	1 🕑 🗷	
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	
AMD20225	<u>50264</u>	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	14.06.2022	Delete	
AMD20225	<u>50262</u>	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	14.06.2022	Delete	
AMD20225	50258	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete	
AMD20225	<u>50256</u>	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete	J
AMD20225	502 <u>54</u>	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete	
AMD20225	50250	0051	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete	
AMD20225	<u>50248</u>	0050	Amendment		Standard	Title	Test123	Doctor Two	Draft	10.06.2022	Delete	

User manual | Terms and Conditions | Version 1.0.20220630\_AT4 (C003001)

# 5. Click "OK" button on the popup box



# iv. 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
	onneer's instruction before re-subinit them.
Follow up (DH	Follow up application are replied by DHDO.
replied)	
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

In order to complete payment, user can select menu "CTC"  $\rightarrow$  "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         Construction												
Dash B	Board	стс		Profile								ф Logout
Q, c	TC Searc	1								Logon as: TES Date: 23.0	T HONG KONG LTI 16.2022 17:22:59	D (Doctor Two)
0 0 0 0	Prepared by Protocol Tit Protocol Nu Ref No.: Application CTC Type: Status:	: e: mber: Type:		✓ ✓ All O Draft O	DH replied (	<b>1-8</b>	Completed d	raft 💿 Pending P	Payment 〇	DH Pending 〇	Approved	
Ð	Application (dd.mm.yy	date: ry)		C Rejected C Ex	to		Clear date field					Search
(8) (8) Page 1 / 1 (9) (8)												
Ref	f 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	
<u>CTS</u>	CR261/2022		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

ID       Status: <ul> <li>All</li> <li>Draft</li> <li>D H replied</li> <li>Follow up (DH replied)</li> <li>Completed draft</li> <li>Pending Payment</li> <li>D</li> </ul> Application date: (dd.mm.yyyy)       to       Clear date field						DH Pending O A	Appro red 9 Search
Ref No. + CTC No Type	Application ¢ date ¢ CTC Ty (dd musee)	rpe 🕈 Protocol Title	Protocol Number	Prepared by \$	Status	(K) (K) P. Status update date \$	age 1 / 1 😕 🖲
CTSCR261/2022 New Applicat	ion 10.05.2022 Standa	rd 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

Status:			(	) All ○ Draft ○ ) Rejected ○ Ex	DH replied (	○ Follow up (DH replied) ○ Completed draft ● Pending Payment ○ DH Pendin					g 🔿 Approved		
<ul><li>Application date: (dd.mm.yyyy)</li></ul>					to		Clear date field				Search		
_				4						8 % F	Page 1 / 1 🕨 🖲		
Ref	No. 🕈	CTC No	Type 💠	Application date \$ (dd.mm.yyyy)	CTC Type 🗢	Protocol Title	Protocol Number	Prepared by \$	Status	date (dd.mm.yyyy)	Action		
<u>CTSC</u>	CR261/2022	1	New Application	10.05.2022	Standard	Protocol Title	1234	Doctor Two	Pending Application Payment	10.05.2022	Pay Now Pay by Cash/Cheque		
								<u>User ma</u>	anual   <u>Terms a</u>	n <u>d Conditions</u>   Versi	<b>10B</b> n 1.0.20220630_AT4 (C003001)		

- 10 A. On-line payment
  - i. Select Payment Method and
  - ii. Click "Pay" button

GOV <mark>HK</mark> 香	港政府 <b>一站通</b>	
or	nline Payment Service	
Help	Please select the payment method :	
General Customer Service Hotline (852) 183 5500 Email enquiry@ 1835500.gov.hk	Type of Service       DH Drug Office Drug Clinical         Merchant Name       DH Drug Office         Transaction Date       09-06-2022         Transaction Reference       DH CTC-202206091810-95558         Number       HK\$ 1,420.00         Payment M       10A i         Please take note of the transaction reference number or         • Please take note of the transaction reference number or         • Merchant Name is applicable to credit card payment mett         • PPS Shop&Buy (PPS) does not support payment via you wish to pay the PS plase change to use desktor	trials 58 <b>Cancel Paymen</b> <b>Cancel Paymen</b> <b>Pay</b> or <b>PRINT</b> this page for making enquiry on the payment status when necessary. this e-service until you receive the acknowledgement page, otherwise your transaction may nethod only. ia browsers of mobile devices (including mobile phones and tablets) at the moment. If ktop computer
	<ul> <li>Under exceptional conditions, a refund may need to be a Credit Card account that is used for the payment.</li> <li>Some users may receive an error page or have to wait fo experience such a problem, please wait a moment and re caused.</li> <li>Different credit card issuers may have implemented differ contact your card issuer if you want to learn more about to</li> </ul>	e arranged. If the payment is made by Credit Gard, the refund can normally be made to the t for several minutes before they get a response from the credit card payment gateway. If you d retry, or change to use other available payment methods. We apologise for any inconvenien fferent mechanisms to authenticate the cardholder's identity during online payment. Please ut 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 *         10A iii         Cardhaldar page *	
Caronolder name -	
Security code *	
	TO TAL HKD: 1420.00
	The next screen you see may be payment card verification through your card issuer.
	Cancel Pay now

### v. Successful payment message will be shown



- 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

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

香港法例領	第138章藥劑業及毒藥	條例	
Ref.:		Date:	
CTSCR 288/2022 檔號		日期	09 June 2022
,	NOTIFICATION		
	通知書		
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	Fee
		數量	費用
Clinical Trial Application Fee	10B ii	1	1420
Clinical Trial Certificate Fee			
Amendment Certificate Fee			
		_	(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 Approved Certificate(s), user can select menu "CTC"  $\rightarrow$  "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 8	Board	стс	Pro	file							4	þ Logout
Q, 0	TC Search									Logon as: T Date: 2	EST HONG KONG LTD 4.06.2022 12:20:56	(Doctor Two)
Ð	Prepared by			~								
Ð	Protocol Title	:										
Ð	Protocol Nun	nber:										
Ð	Ref No.:											
Ð	Application T	ype:		<u> </u>								
Ð	CTC Type:			~		<b>T-0</b>						
Ð	Status:		0 <i>4</i> 0 f	ll ○ Draft ○ DH Reiected ○ Expired	replied O Fol	low up (DH replied)	O Completed	draft 🔿 Pen	ding Payment 🔿 Di	H Pending 🤇	Approved	
Ð	Application of (dd.mm.yyy	ate: v)			to		Clear date field				(	Search
											) Page 1 / 1	<b>)</b> (H)
Ref	No.	CTC No	o Type 🕈	Application date (dd.mm.yyyy)	CTC Type 🔶	Protocol Title		Protocol Number	Prepared by 🔶	Status	Status update date (dd.mm.yyyy)	Action
PR/0	CT00254/202	2 0051	New Application	30.05.2022	Standard	Title		Test123	Doctor Two	Approved	30.05.2022	
<u>PR/0</u>	<u>CT00253/202</u>	<u>2</u> 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

<ul> <li>Status:</li> <li>Application date: (dd.mm.yyyy)</li> </ul>		O AI	II O Draft O DH ejected O Expired	I replied O Foll	low up (DH replied)	Completed Clear date field	draft () Pend	ding Payment 🔿 D	H Pending (	Approved	Search
									в е	Page 1 / 1	<b>B H</b>
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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Status:	Status:		Ⅱ ○ Draft ○ DH ejected ○ Expired	replied O Foll	ow up (DH replied) O C	ompleted draft 🔿 Pen	draft $\bigcirc$ Pending Payment $\bigcirc$ DH Pending $ extbf{  extbf  $			
<ul> <li>Application dat (dd.mm.yyyy)</li> </ul>	ie:			to	Clear	Clear date field				
								<b>R</b> (	Page 1 / 1	<b>B B</b>
Ref No. 🔶	CTC No	Туре 🔶	Application date \$ (dd.mm.yyyy)	CTC Type 💠	Protocol Title	Protocol Number	Prepared by 🔶	Status	Status update date ¢ (dd.mm.yyyy)	Action
PR/C102 4/2022	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	
							Isos manual   Torms and	Conditions   Ve	reion 1.0.20220620.	TA (C00200

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

11. Click "Print CTC" button to Download / Print the certificate



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