

APPLICATION USER MANUAL

FOR THE

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

(PRS 2.0)

OF THE

DEPARTMENT OF HEALTH

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1. SYSTEM REQUIREMENT

You have to install and configure the following software to access the PRS2.0 online services.

- Web browser: Internet Explorer11.0 or Chrome
- Web browser settings: Accept cookies and enable JavaScript
- TLS1.0, TLS1.1 and TLS1.2 are enabled

1.1.1 For PRS2.0 Online Services that Require e-Cert

1.1.2 New Operating Systems and Browsers

When a new operating system or browser is released to the public, the Government needs to conduct compatibility tests to ensure proper function of the online services on the new operating system or browser. When compatibility issues arise, we may need to modify the online services. The whole process of modification and testing may take a few months to complete.

1.1.3 File Upload Size Limitation

The file upload size limitation for all modules is shown in the following table.

Application	Application Type	Scope	Single File Max. Size	Total File Size Max. Size	
	Comoria (Dialogiaal)	Module 1	50MB	300MB	
	Generic (Biological)	Module 2-5	Submit b	y CD/DVD	
Now Application	Generic (Others)	Module 1	50MB	100MB	
New Application		Module 2-5	Submit b	y CD/DVD	
		Module 1	50MB	300MB	
	NCL	Module 2-5	Submit by CD/DVD		
CORP Application	All Case	All scope	5MB	100MB	
Renewal Application	All Case	All scope	No File	e Upload	
End of Life	All Case	All scope	5MB	100MB	

1.1.4 Enquiries

If you encounter problems in using a PRS2.0 online services, please contact PRS2.0 help desk at (852) 3974 4195 during office hours (Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to 'prs2_info@dh.gov.hk'.

2. USER PROCEDURES (EXTERNAL)

2.1 USER REGISTRATION

2.1.1 New User Registration

Step 1:

• Type the following link into the web browser and click the button "Request for New Account".

https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp

electronic form for applications for ini For details, please visit	macy and Poisons Board will only issue certi tial registration, renewal of registration and c en/popup launch of electronic certificate of	change of registered particulars.	
	Welcome to Pharma	aceuticals Registration Syste	em (PRS2.0)
	Username: *		
	Organizational e-Cert File Location:*	Choose File No file chosen	
	e-Cert PIN:*	Please select the e-Cert file, e.g. C:\cert.p12	
	System Password:*		
	Login Reset		Request for New Account
	Cert Validation * mandatory field		Reset Password
	For support service, please contact PRS 09:00-13:00 and 14:00-17:45) or via e-m	\$2.0 help desk at (852) 3974 4195 during of nail to 'prs2_info@dh.goy.hk'	ffice hours (Monday-Friday:
	Points to note:		
	 Install and configure the required soft Web browser: Google Chrome Web browser settings: Accept cool Ensure TLS1.2 are enabled 		
		-Cert will not be transmitted during the trans	
	You should be alert to your surroundin see your personal particulars and e-Ce	ngs before entering any personal informatior ert password.	n. Make sure that no one can
	4. You should disable options on your be computer.	rowser to avoid storing or retaining your e-C	ert password on the personal
		, it is case-insensitive in Windows platform.	

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Step 2:

- Read the "TERMS AND CONDITIONS FOR THE USE OF PHARMACEUTICALS REGISTRATION SYSTEM 2.0 (PRS2.0)" and select the checkbox "I have read and agree to be legally bound by the above Terms" if you agree with the terms.
- Click "Continue" to proceed.

New User Registration	USER REG 01 USR					
Step 1: Agreement on the Terms and Conditions ("Terms") for the Use of the Pharmaceuticals Registration System 2.0 ("PR\$2.0") Terms for the Use of PR\$2.0						
TERMS AND CONDITIONS FOR THE USE OF PHARMACEUTICALS REGISTRATION SYSTEM 2.0 (PRS2.0)						
1. Introduction						
The following are the terms and conditions (" Terms ") for the use of the Pharmaceuticals Registration System 2.0 (" PRS2.0 ") operated by the Department of Health (" DH ") of the Government (" Government ") of the Hong Kong Special Administrative Region of the People's Republic of China (" Hong Kong "). The Government agrees to provide the Services (as defined in Clause 3 below) and you, as the user of PRS2.0 (" User "), agree to use the Services in accordance with the Terms.						
2. Acceptance of Terms of Use						
Your accessing and using PRS2.0 is taken as your agreement to be legally bound by these Terms as may be modified and/or supplemented from time to time by the Government without prior notice to any User. Please check the website at https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp regularly for any modification and/or supplement which may be made.	Ŧ					
You need to read the complete content of the Terms before you are able to click the check box below.						
I have read and agree to be legally bound by the above Terms.						
Continue						

Step 3:

- Type the user name under the "Login Information" section. Please note the username only allows alphabets (a-z, A-Z), numbers (0-9), underscores (_) and hyphens (-) and must be 5-20 characters long.
- Type the full path of the e-cert file location for the organizational e-cert and enter the e-cert PIN.
- Enter the section on "Information on e-cert". The items with asterisks (*) are mandatory fields.
- Enter the Contact Phone Number
- Click "Continue" to proceed.

	New User Registration			
T	Step 2: Provide User / Organization Information	1		
	Please provide the following information to cre	ate your account. Field with* are mandator	ry	INT-USER_REG_02 USR
	Login Information			
	* Username userna	me	Username only allows alphabets (a-z, A-Z), numbers (0-9), underscores (_) and Hyphens(-) and must be 5-20 characters long.	
	Note: Password would be automatically genera	ted by the system and sent to the authoriz	ed user through email.	
	e-Cert (Organizational)			
	* Organizational e-Cert File Location	C:\cert.p12 瀏覽		
	* e-Cert PIN	Please select the e-Cert file, e.g. C:\cert.p12		
	event in	*****		
	Information on e-Cert (Click Ocheck e-Cert Information in Hongkong Post			
	* Email address	eCert@emailAddress.com	(Case Sensitive)	
	* Name of Organization	Name of Organization of e-Cert		
	* Business Registration Certificate Number	12345678-000	(e.g. 12345678-123)	
	* Name of Authorized User	Name of Authorized User of e-Cert		
	*Contact Phone Number (852)	2319-8414		
	Position	Position		
	*Company Address			
	Unit:	Room 111		
	Floor:	11/F	7	
	Block:			
	Building:	Building		
	Street No.:	11		
	Street Name:	Street		
	Sub-district:		-	
	Area:			
	E-cert Register:			
	E-Cert Token:			
		Back Continue Cancel		

Note: The user may click the question mark to open new windows to access the Hong Kong Post website check the e-Cert file content for input in PRS2.0 system.

そ Hongkong Post e-Cert 香港郵政電子核證	The solution for e-Security			
•≥=::::::::::::::::::::::::::::::::::::			cate - e-Cert (Organisational)	
CERTIZEN	Please input either on English Name in Certifi Email Address in Certifi	Surname	Given Name	
The operator of Hungloog Post + Cert services 奇法的双電子板證證書之留重用	Subscriber Reference N			
CHongkong Post 香港都政 Unking people Delivering business	Warning: Any informat signatures and encryp	ion and certificates downloaded from th tion.	is web site shall only be used for lawful purpose	es relevant to the use of digital
傳心意 建商機	eknowledge that	I have read the above warning message ar	d will abide by the purposes and limitations on use	stated therein.
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Handward Andread Anti-Schurden Hangkrang Post Bill Bill Hangkrang Post	Note - The Certificate status displayed above locating its serial number in the latest the Certificate has been suspended or http://crifi.new.htcri/cr	imail Address in Certificate : irganisation Name in English : irganisation Name in Chinese : iranch Name in Chinese : IR Number : RICI : Whers : ubscriber Reference Number : yee of Certificate : ssued by : certificate Serial Number : certificate Serial Number : certificate Serial Number : certificate Status : aldidty Period (dd/mm/yyyy) : Dow is for information only. Before you rely on 1 Certificaton Revocation List (CRL) issued b	Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha1RSA Active	I number of the Certificate is found in a CRL, then ertificate at
Handward Andread Anti-Schurden Hangkrang Post Bill Bill Hangkrang Post	Note - The Certificate status displayed above locating its serial number in the latest the Certificate has been suspended or http://crifi.new.htcri/cr	imail Address in Certificate : Jrganisation Name in English : Jrganisation Name in Chinese : Jrganisation Name in Chinese : Itanch Name in Chinese : IR Number : RNC1 : Uthers : ubscriber Reference Number : ype of Certificate : ssued by : certificate Signature Algorithm : certificate	Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha TRSA Active Inload the Certificate the Certificate displayed above, you should verify if y Hongkong Post Certification Authority. If the series may download the latest cartitioned CRL of the C	I number of the Certificate is found in a CRL, then ertificate at
Handward Andread Anti-Schurden Hangkrang Post Bill Bill Hangkrang Post	Note - The Certificate status displayed above locating its serial number in the latest the Certificate has been suspended or http://crifi.new.htcri/cr	imail Address in Certificate : Jrganisation Name in English : Jrganisation Name in Chinese : Jrganisation Name in Chinese : Itanch Name in Chinese : IR Number : RNC1 : Uthers : ubscriber Reference Number : ype of Certificate : ssued by : certificate Signature Algorithm : certificate	Hongkong Post e-Cert CA 1 - 10 32 d 32 sha TRSA Active Inload the Certificate the Certificate displayed above, you should verify if y Hongkong Post Certification Authority. If the series nay download the latest participed CRL of the C jownload the latest full CRL at http://crl1.hongkong	I number of the Certificate is found in a CRL, then ertificate at
Hongkong Post Birth R 2 A Will B A 2 Will B Hongkong Post Birth Bolt Birth Bo	Note - The Certificate status displayed above locating its serial number in the latest the Certificate has been suspended or http://crifi.new.htcri/cr	imail Address in Certificate : Irganisation Name in English : Irganisation Name in Chinese : Iranch Name in Chinese : IR Number : RNC1 : Uthers : Subscriber Reference Number : ye of Certificate : ssued by : Fertificate Serial Number : Fertificate Signature Algorithm : Fertificate Sig	Hongkong Post e-Cert CA 1 - 10 32 d 32 sha TRSA Active Inload the Certificate the Certificate displayed above, you should verify if y Hongkong Post Certification Authority. If the series nay download the latest participed CRL of the C jownload the latest full CRL at http://crl1.hongkong	I number of the Certificate is found in a CRL, then ertificate at

Note: If Branch Name in English is exist, please fill the Branch Name in English into Name of Organization

Step 4:

- The user will then be redirected to the summary page.
- Click "Submit" to confirm the information to be sent to Drug Office and proceed to the next step.
- Click "Print" to print the summary screen.
- Click "Edit" to edit the information.
- Click "Cancel" to cancel the registration.

Ť	New User Registration Step 3: Review and confirm the account details Please check your account details before submi	ssion.	INT-USER_REG_03 USR
	* Username	username	
	* Email address	org1@testing.com	
	* Name of Organization	TESTING LIMITED	
	* Business Registration Certificate Number	11223344-000	
	* Name of Authorized User	ORG Trial One	
	Contact Phone Number	23198414	
	Position	Position	
	*Company Address		
	Unit:	Room 111	
	Block:		
	Building:	Building	
	Street No.:	11	
	Street Name: Sub-district:	Street	
	Area:		
	Alea.		
		Print Edit Submit Cancel	
	2015 copyright In	nportant notices Last Revision Date: 09 August 2018 Version: 1.0.76	

Step 5:

- An email notification of new user registration will be sent to the applicant.
- User need to complete and send the Application form to drug office using the URL.

Ť	New User Registration					
	Thank you for your registration					
	Your registration request has been submitted to Drug Office successfully.					
	Your Reference Number is: D0201808-001					
	You must complete and send the "Application form for new on-line user account registration for PRS2.0" to Drug Office.					
	For enquiries, please call our office at (852) 3974 4175 or email to prs2_info@dh.gov.hk :					
	Monday to Friday:					
	9:00 am - 1:00 pm					
	2:00 pm - 5:45 pm					
	(up to 6:00 pm on Monday)					
	(Closed on Saturdays, Sundays & Public Holidays)					
	Print Close					
	2015 copyright Important notices Last Revision Date: 12 July 2018 Version: 1.0.75					

New User Registration Inbox x

Drug Office <prs_info@dh.gov.hk>
to me
 Your registration request has been submitted to Drug Office successfully.
Your Reference Number is DO201412-002

2.1.2 Received Registration Approved Email

Step 1:

• Upon approval of new account registration, a one-time password will be sent to the registered user via email by the Drug Office. Type the following link into the web browser and fill in the username, full path of the e-cert file location, e-cert PIN and the user password (sent via email). Click "Login" to proceed.

https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp



Step 2:

- For first time login, user will be redirected to the change password page. Input the onetime password as current password and a new password according to the format (8-20 characters containing alphabet(s) alphabets (a-z, A-Z), numbers (0-9), underscores (_) and hyphens (-)).
- Click "Save" to proceed.

						類1篇
Ť		due to security reason and you	need to change password befor abet(s) in lower case and non-all			Save
You are login as FONG Winnis DEF COMPANY Login date and time 13.01.2015 20.46 - System	Current Password : New Password : Confirm New Password :	••••••• ••••••				
- System	 After you have saved the 	paseword, you will be logged of	ot automatically and need to logi	n again.		
Change Password						Save
Logout						
	201	5 copyright important notices	Last Revision Date: 09 JAN 20	115 Version: 0.2.46	SVN Version: 12079	

Step 3:

- User will then be redirected to login page again. Fill in the username, full path of the e-cert file location, e-cert PIN and the new user password.
- For forgot password, please follow the steps states in the following link to reset your password and regain access to your account.

https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/forget_password.html

• Click "Login" to proceed.

With effect from 1 July 2023, the Pharmac electronic form for applications for initial For details, please visit https://www.drugoffice.gov.hk/eps/do/en/p	registration, renewal of registration an	d change of registered particulars.	
	Welcome to Pharm	naceuticals Registration Syster	n (PRS2.0)
Use	rname: *	username	
	anizational e-Cert File Location:*	Choose File prs20-prod-test-2022.p12	
e-C	ert PIN:" tem Password:"	Please select the e-Cert file, e.g. C:\cert.p12	
Lo	ogin Reset		Request for New Account
	ert Validation andatory field		Reset Password
Fo		RS2.0 help desk at (852) 3974 4195 during offic e-mail to ' <u>prs2_info@dh.gov.hk</u> '.	e hours (Monday-Friday:
Ро	ints to note:		
1.	Install and configure the required s a. Web browser: Internet Explorer b. Web browser settings: Accept c c. Ensure TLS1.0, TLS1.1 and TL	r 11.0 or Chrome ookies and enable JavaScript	
		ar e-Cert will not be transmitted during the transa	
3.	You should be alert to your surrour see your personal particulars and e	ndings before entering any personal information. -Cert password.	Make sure that no one can
4.		r browser to avoid storing or retaining your e-Cer	t password on the personal
5.	For organizational e-Cert file locat	ion, it is case-insensitive in Windows platform.	

Step 4:

• User will be redirected to the main screen. The first representative of the company to log-in to the system would automatically be assigned as administrator of that company, who has the right for granting privileges to other colleagues or subordinates under his /her organization for rights to access various system functions. The individual functions will be introduced in other sections.

		ne Notification	ONL	INE_NOTIFIC	ATION_VIEV	N_01					
	New P	roduct Registration	n						Archiv	ved Notificat	ions
		Notification Date	\$	Subject		\$	Propose	d Name of Product 🛛 🔶	PL No. 🜩	Payment St	atu s
ou are login as ORG RIAL ONF	Open	21.01.2021 17:25:14		Application Payment Request			FACE CF	REAM	PL0001/2021	Paid	
ESTING LIMITED (TEST)	Open	21.01.2021 17:14:03		Screening Application			FACE CF	REAM	PL0001/2021	N/A	
0.02.2021 14:33	Open	06.11.2019 11:52:34		Application Payment Request			TEST OF	PEN FILE CASE 3	PL0024/2019	Paid	
	Open	05.09.2019 16:10:27		Screening Application			TEST OF	EN FILE CASE 3	PL0024/2019	N/A	
Online Notification	Open	04.09.2019 11:17:16		Evaluation Application			TEST 20	17022401	PL0030/2017	N/A	
My Product Search	CORP								Arabia	ed Notificati	ione
New Registration	0014								Archiv	eu Noulicau	
			Subject		\$		\$	Name of Product			\$
Change of Registered Particulars	Open	28.01.2021 04:00:12	Application Effe			HK63536		DEMO ON 2017-01-19			
	<u>Open</u>				HK63668						
Renewal of Registration	Open	20.01.2021 11:50:56	Application Sub	nitted Notification		HK63536		DEMO ON 2017-01-19			
Request to change name and/or address	Renew	val of Registration							Archiv	ed Notificati	ions
of the certificate holder		Notification Date \$	Subject		\$	Name of Proc	duct		\$ No. o	f Renewals	\$
Request to Cancel	Open	28.09.2019 02:06:59	Expired Product	Notice		DEMO ON 20	017-		1		
Product Registration	Open	20.07.2019 02:05:10	Expired Product	Expired Product Notice		TEST OPEN FILE CASE			1		
Payment	Open	08.07.2019 04:00:11	Renewal Final F	eminder		DEMO ON 20	017-		1		
	Cancel	lation Request									
Application History						HK No.	\$	Name of Product			\$
		Notification Date \$	Subject								
	Open	Notification Date ♦ 21.01.2021 15:49:10		stration Request Submitted Notification		HK63517		WALKTRHOUGH			
User Profile	<u>Open</u>			stration Request Submitted Notification		HK63517		WALKTRHOUGH			
Application History User Profile Printing Service System	Non Ph		Cancellation Reg	stration Request Submitted Notification		HK63517		WALKTRHOUGH			

2.1.2.1 Request Reset Password

Step 1: Click Reset Password to request reset password

electronic form for application for details, please visit	the Pharmacy and Poisons Board will only issue certificates of drug/ product registration in ons for initial registration, nenewal of registration and change of registered particulars. https://www.initiality.com for an initiality.
	Welcome to Pharmaceuticals Registration System (PRS2.0)
	Username: *
	Organizational e-Cert File Location:* Choose File No file chosen
	e-Cert PIN."
	System Password:*
	Login Reset Request for New Account
	Cert Validation * mandatory field
	For support service, please contact PRS2.0 help desk at (852) 3974 4195 during office hours (Monday-Friday; 09:00-13:00 and 14:00-17:45) or via e-mail to ' <u>prs2_info@dh.gov.hk</u> '.
	Points to note:
	 Install and configure the required software: Web browser: Google Chrome Web browser settings: Accept cookies and enable JavaScript Ensure TL\$1.2 are enabled
	2. The private key and the PIN of your e-Cert will not be transmitted during the transaction.
	You should be alert to your surroundings before entering any personal information. Make sure that no one can see your personal particulars and e-Cert password.
	4. You should disable options on your browser to avoid storing or retaining your e-Cert password on the personal computer.
	 For organizational e-Cert file location, it is case-insensitive in Windows platform.

Step 2: Fill-in the username, email address, organization e-Cert file location and e-Cert PIN and click Submit

•	Reset Password			
	Please provide the following information to reset the password.	Field with * are mandatory	INT-USER_REQ_RESET_PW_01 USR	
	User Information			
	* Username	username		
	* Email address (User)	useraccount@email.com		
	* Organizational e-Cert File Location	C:\cert.p12 瀏覽		
		Please select the e-Cert file, e.g. C:\cert.p12		
	* e-Cert PIN	•••••		
	(C	Submit		
	Canc			

Step 3: A reset password email will be sent to your registered email

eset Password	
	INT-USER_REQ_RESET_PW_02 USR
An email has been sent to you for password reset, please reset your password with the	the link provided in the email within 15 minutes.
For support service, please call our office at (852) 3974 4195 or email to prs2_info@dh.gov.hk during office hours	s :
Monday to Friday:	
9:00 am - 1:00 pm	
2:00 pm - 5:45 pm	
(up to 6:00 pm on Monday)	
(Closed on Saturdays, Sundays & Public Holidays)	

2.1.3 Reset Password Step 1: Open the reset password email and click here

PRS2.0 System Password Reset Inbox ×

Drug Office <prs2_info@dh.gov.hk> to me 💌

Dear The Dame,

Your PRS 2.0 system password reset request was accepted.

Please click here to reset your password

This password reset is only valid for the next 15 minutes.

Please don't reply this auto sent mail by PRS 2.0 system.

Step 2: Input the new password and confirm new password and click submit

	Reset Password							
T	(8-20 characters containing at least one alphabet in upper case, one alphabet in lower case and one numeric)	INT-USER_RESET_PW_01 USR						
	New Password							
	Confirm New Password							
	Submit							

Step 3: Click Login Now to go to login page and use the new password to login

	Reset Password	
÷		INT-USER_RESET_PW_02 USR
	Your password have been reset successfully.	
	(Login Now)	
	Lugin Now	

2.1.4 Product E-Cert Validation Step1: Click the Cert Validation button.

electronic form for applications for initial For details, please visit	cy and Poisons Board will only issue certifi I registration, renewal of registration and ch /popup launch of electronic certificate of	hange of registered particulars.	
	Welcome to Pharma	ceuticals Registration System	n (PRS2.0)
Us	ername: *		
Org	ganizational e-Cert File Location:*	Choose File No file chosen	
	Cert PIN:" stem Password:"	Please select the e-Cert file, e.g. C:\cert.p12	
	ogin Reset		Request for New Account
C	Cert Validation mandatory field		Reset Password
FO	or support service, please contact PRS/ 9:00-13:00 and 14:00-17:45) or via e-ma	2.0 help desk at (852) 3974 4195 during offic ail to ' <u>prs2_info@dh.gov.hk</u> '.	e hours (Monday-Friday:
	oints to note: Install and configure the required softv a. Web browser: Google Chrome b. Web browser settings: Accept cook c. Ensure TLS1.2 are enabled		
		Cert will not be transmitted during the transac gs before entering any personal information. I t password	
4.	· · ·	owser to avoid storing or retaining your e-Cert	t password on the personal
5.	. For organizational e-Cert file location,	it is case-insensitive in Windows platform.	
	2015 convrict Limportant	notices Last Revision Date: 5 July2023 Version	. 1.0.1216

Step2: Enter the Serial No. of the Product e-cert (right hand corner) Step3: Upload the E-cert file Step4: Click the 'Verify' button

Verification System for Electronic Certificate of Drug/ Product Registration
Please enter the serial number printed on the upper right-hand corner of the electronic Certificate of Drug/ Product Registration ("electronic certificate").
* Serial no.
* Electronic certificate UPLOAD Please upload the PDF file of the electronic certificate. No File Chosen
Verify Clear Cancel
For support service, please contact PRS2.0 help desk at (852) 3974 4195 during office hours (Monday-Enday: 06:00-13:00 and 14:00-17:45) or via e-mail to prs2_into@dh.gov.hk.
(Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.hk.
2015 copyright Important notices Last Revision Date: 5 July2023 Version: 1.0.131c
If the E-Cert is Valid
Verification System for Electronic Certificate of Drug/ Product Registration
Please enter the serial number printed on the upper right-hand corner of the electronic Certificate of Drug/ Product Registration ("electronic certificate").
* Serial no.
* Electronic certificate UPLOAD Please upload the PDF file of the electronic certificate.
No File Chosen
Verify Clear Cancel
Result
This electronic certificate is valid. (at HKT 12:37, on 27/07/2023)
Excessionant sendes inlesse contact DDS2 0 hals dark at (852) 2074 4495 during office house
For support service, please contact PRS2.0 help desk at (852) 3974 4198 during office hours (Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.hk.
2015 copyright Important notices Last Revision Date: 14 July2023 Version: 1.0.131e
If the E-Cert is not Valid
Verification System for Electronic Certificate of Drug/ Product Registration
Please enter the serial number printed on the upper right-hand corner of the electronic Certificate of Drug/ Product Registration ("electronic certificate").
* Serial no.
* Electronic certificate UPLOAD Please upload the PDF file of the electronic certificate. No File Chosen
(Verify) Clear Cancel
Result The uploaded PDF file is NOT the same as the valid electronic certificate on record. (at HKT 10:10, on 10/07/2023)
For support service, please contact PRS2.0 help desk at (852) 3974 4195 during office hours (Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.hk.

2.2 USER PROFILE

The company administrator and the supervisor can access the "User Profile" function. There are three sub-functions, namely (i) "Maintain Company's User Accounts" (only accessed by company administrator); (ii) "Add Access Right"; and (iii) "Remove/Transfer Access Right".

2.2.1 Maintain Company's User Accounts

- Click the menu item "Maintain Company's User Accounts" under "User Profile" in the menu on the left.
- "Position" describes the position of the users in the company.
- "Supervisor Name" indicates the supervisor of a particular user.
- "New App.", "CORP" and "Renewal" indicate the application submission privileges for applications for registration for pharmaceutical products, change of registered particulars and registered pharmaceutical product renewal of a particular user respectively.
- Indicator "Y" indicates the user has the specific right and "N" indicates the user does not have the specific right under the specific functions or roles.
- "All Product" indicates the user has the right to access all products of its company.
- "User Admin." indicates whether the user is the company administrator in PRS2.0.
- "Supervisor" indicates the user is the supervisor in PRS2.0 system which he has right to grant staff under his supervision to have access rights of products in the company.
- "Status" indicates the right to log in to PRS2.0. Inactive user is prohibited from logging into PRS2.0.
- Click "Edit" to edit the company user account profile (Section Error! Reference source not found.)



2.2.1.1 Edit user account profile

Step 1:

• Click "Edit" to edit a company user account profile.

		Login User Name 🔶	User Name	ŧ	Position	Phone Number	Supervisor Name	New App.	CORP	Renewal	All Product	User Admin.	Supervisor	Status	
	1	irenechu	Irene Chu		Company Administrator	26482518		Y	Y	γ	Y	Y	N	Activ	Ed
are login as Irene Chu COMPANY	2	issaclee	Issac Lee		Supervisor	26482522		N	N	Y	N	N	Y	Active	E
in date and time		winniefong	FONG Winnie		Company Staff	24925648		N	Y	N	N	N	N	Active	E
5.2015 11.51	4	edwintsang	Edwin Tsang		Senior Staff	26482520	Issac Lee	Y	Y	N	N	N	N	Active	E
Inline Notification															
ly Product Search															
lew Registration															
Change of Registered Particulars															
Renewal of Registration															
Submission of Other															
Post-registration															
Post-registration Supplement															
Post-registration Supplement Interview															
Post-registration Supplement nterview Request to Cancel Product Registration															
Post-registration Supplement Interview Request to Cancel Product Registration															
Post-registration supplement Request to Cancel Product Registration Payment Application History															
Post-registration Post-registration Request to Cancel Product Registration Payment Application History Jser Profile Kaintain Company's Ser Accounts															
ost-registration upplement terview equest to Cancel roduct Registration ayment pplication History ser Profile taintain Company's															

Step 2:

• Administrator can maintain the basic information of the staff or assign a supervisor to the user.

	User Account Detail			INT-USE	R_PROFILE_UPD	DATE_01
T	View Details information on e-Cert					
You are login as Irene Chu DEF COMPANY	* Email Address of Authorized User	prs.winnie.fong@gmail.co	n			
Login date and time 17.03.2015 11:31	* Organization Name	DEF COMPANY				
	* Business Registration Certificate Numb	er 00781432-000				
Online Notification	* Authorized User Name	FONG Winnie				
My Product Search	Position	Company Staff				
+ New Registration	Contact Phone Number	24925648				
+ Change of Registered Particulars	Company Address	04 11/F BLK A DEF B 1 DEF Street 10067 KOWLOON	uilding *			
+ Renewal of Registration			*			
+ Submission of Other Post-registration Supplement	Active Status Privileges Control	Active Inactive				
+ Interview	Supervisor	(Only applic	able for non-supervisor)			
+ Request to Cancel Product Registration	Product Information Application Submission					
+ Payment	New Product Registration	Allow Oeny				
Application History	Change of Registered Particulars	Allow O Deny	Senior Privileges User Administrator	⊖Yes No		
- User Profile	Renewal of Registration	Allow Deny 	Access All products	OYes ●No		
Maintain Company's User Accounts	Cancel Product Registration	Allow Oeny	Supervisor	⊖Yes ●No		
A 44 A Dista					Save	Cancel

Scenario 1:

Administrator can edit the basic information of the staff, including the position, contact phone number and the active status of the user. (Note that the phone number cannot be blank) The privileges on accessing new application, CORP, and renewal senior privileges functions of his staff can also be amended.

	User Account Detail			INT-U	SER_PROFILE_UPDATE_01
T	View Details				
You are login as Irene Chu DEF COMPANY	* Email Address of Authorized User	prs.winnie.fong@gmail.com			
Login date and time	* Organization Name	DEF COMPANY			
	* Business Registration Certificate Numl	per 00781432-000			
Online Notification	* Authorized User Name	FONG Winnie			
My Product Search	Position	Company Staff			
+ New Registration	Contact Phone Number	24925648			
+ Change of Registered Particulars	Company Address	04 11/F BLK A DEF Build 1 DEF Street 10067 KOWLOON	ing		
+ Renewal of Registration			-		
+ Submission of Other Post-registration Supplement	Active Status	Active Inactive			
Supplement	Privileges Control				
+ Interview	Supervisor	 (Only applicable f 	or non-supervisor)		
+ Request to Cancel	Product Information				
Product Registration	Application Submission				
+ Payment	New Product Registration	Allow Deny 			
Application History	Change of Registered Particulars Application 	Allow O Deny	Senior Privileges User Administrator	○Yes No	
- User Profile	Renewal of Registration	Allow Deny 	Access All products	⊖Yes No	
Maintain Company's User Accounts	Cancel Product Registration	Allow Deny	Supervisor	⊖Yes ●No	
Add Assess Disks					Save Cancel

Scenario 2:

Administrator can assign supervisor to a particular staff. The "Supervisor" privilege allows user to control access rights of products of staff under his supervision in the company. (Assign Issac Lee as the supervisor of Winnie Fong in the following example)

Issac's access rights of products before assignment:

	Application ID	PL No.	PR No.	HK No.	Name of Product		User Account
		PL0321/1987	PR0426/1987	HK29705	WARTEX	issaclee	prs.issac.lee@gmail.co
		PL0330/1987	PR0428/1987	HK29707	VERRUGON	issaclee	prs.issac.lee@gmail.co
٥		PL0253/1994	PR0558/1994	HK40985	CPC VITAMIN B1	issaclee	prs.issac.lee@gmail.co
		PL0531/1994	PR0392/1994	HK41132	VITAMIN B6 (CPC)	iceaclea	prs.issac.lee@gmail.co

Winnie's access rights of products before assignment: • User Account: FONG Winnie----prs.winnie.fong@gmail.com • Add

Application ID	PL No.	PR No.	HK No.	Name of Product		User Account	\$
	PL0121/2000	PR0301/2000	HK46915	OYSTER CALCIUM W/ VIT D	winniefong	prs.winnie.fong@gmail.co	om

Issac's access rights of products after assignment: • User Account: Issac Lee----prs.issac.lee@gmail.com

Application ID	PL No.	PR No.	HK No.	Name of Product		User Account \$
	PL0321/1987	PR0426/1987	HK29705	WARTEX	issaclee	prs.issac.lee@gmail.com
	PL0330/1987	PR0428/1987	HK29707	VERRUGON	issaclee	prs.issac.lee@gmail.com
	PL0253/1994	PR0558/1994	HK40985	CPC VITAMIN B1	issaclee	prs.issac.lee@gmail.com
	PL0531/1994	PR0392/1994	HK41132	VITAMIN B6 (CPC)	issaclee	prs.issac.lee@gmail.com
	PL0121/2000	PR0301/2000	HK46915	OYSTER CALCIUM W/ VIT D	issaclee	prs.issac.lee@gmail.com

	User Account Detail			INT-USE	R_PROFILE_UP	DATE_01
T	View Details information on e-Cert					
You are login as Irene Chu	* Email Address of Authorized User	prs.winnie.fong@gmail.co	m			
DEF COMPANY Login date and time 17.03.2015 11:31	* Organization Name	DEF COMPANY				
7.03.2015 11.31	* Business Registration Certificate Number	er 00781432-000				
Online Notification	* Authorized User Name	FONG Winnie				
My Product Search	Position	Company Staff				
+ New Registration	Contact Phone Number	24925648				
+ Change of Registered Particulars + Renewal of	Company Address	04 11/F BLK A DEF B 1 DEF Street 10067 KOWLOON	uilding 🔺			
Registration + Submission of Other	Active Status	Active Inactive	Ŧ			
Post-registration Supplement	Privileges Control					
+ Interview	Supervisor	Issac Lee 💌 (Only applic	able for non-supervisor)			
 Request to Cancel Product Registration 	Product Information Application Submission					
+ Payment	New Product Registration	Allow Deny				
Application History	Change of Registered Particulars Application	Allow O Deny	Senior Privileges User Administrator	⊖Yes No		
- User Profile	Renewal of Registration	Allow Oeny	Access All products	OYes ●No		
Maintain Company's User Accounts	Cancel Product Registration	Allow Deny	Supervisor	⊖Yes ●No		
Add Assess Dista					Save	Cancel

Step 3:

• Click "Save" to save the updated profile or click "Cancel" to revoke the changes and go back to the user account list.

	User Account Detail				INT-USER_PRO	OFILE_UPDATE_01
T	View Details information on e-Cert					
You are login as Irene Chu DEF COMPANY	* Email Address of Authorized User	prs.winnie.fong@gmai	il.com			
Login date and time 17.03.2015 11:31	* Organization Name	DEF COMPANY				
Online Notification	* Business Registration Certificate Numb	per 00781432-000				
Childe Wouldation	* Authorized User Name	FONG Winnie				
My Product Search	Position	Company Staff				
+ New Registration	Contact Phone Number	24925648				
+ Change of Registered Particulars	Company Address	04 11/F BLK A DE 1 DEF Street 10067 KOWLOON	F Building	*		
+ Renewal of Registration				-		
+ Submission of Other Post-registration Supplement	Active Status Privileges Control	 Active Inactive 				
+ Interview	Supervisor	Issac Lee 💌 (Only ap	plicable for non-supervisor)			
+ Request to Cancel Product Registration	Product Information Application Submission					
+ Payment	New Product Registration	Allow O Deny				
Application History	Change of Registered Particulars Application 	Allow O Deny	Senior Privile User Admini		○Yes ●No	
- User Profile	Renewal of Registration	Allow Deny	Access All p	roducts	OYes ●No	
Maintain Company's User Accounts	Cancel Product Registration	Allow Deny	Supervisor		⊖Yes ●No	
A 44 A Diska						Save Cancel

2.2.2 Add Access Right

The company administrator and supervisor can access the "Add Access Right" function. This function allows the addition or assigning the access right of product(s) to staff.

Step 1:

• Click the menu item "Add Access Right" under "User Profile" in the menu on the left.

•			E			Add Access Right	Clear
T	Add Access Right						
	All Products Add						
You are login as Irene Chu DEF COMPANY Login date and time 17.03.2015 12:27	Application ID/PL No./PR N	Io./HK No.	Ac	_			
Online Notification	O User Account:		- Add				
My Product Search	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account	\$
+ New Registration	Add Access Right to						
-	All Accessible Staff User Account:		- Add				
+ Change of Registered Particulars							
+ Renewal of Registration						Add Access Right	Clear
+ Submission of Other Post-registration Supplement							
+ Interview							
+ Request to Cancel Product Registration							
+ Payment							
Application History							
- User Profile							
Maintain Company's User Accounts							
Add Access Right							
Remove/Transfer Access Right							

Step 2:

- Select the product list by (i) choosing all products; (ii) specify a product with application ID (e.g. ANP20149000153) / PL no.(e.g. PL0012/2015) /PR no. (e.g. PR0012/2015) / HK no. (e.g. HK12345); or (iii) selecting user account.
- Click 'Add' to generate the product list.
- Under 'Add Access Right to..', select the user account from the dropdown for a specific staff or click 'all accessible staff' for all staff under his supervision.
- After that, click "Add Access Right" to update the changes or click "Clear" to reload the page.

							Add Access Right	Clea
T	Add Ac	cess Right						
ou are login as WONG avid BC COMPANY LIMITED ogin date and time 7.08.2018 14:15	● All Prod ○ Applicat ○ User Ac	tion ID/PL No./PR No.	/HK No.	Add V Ad				
Online Notification		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account	
My Product Search	Add Acces	s Right to						
New Registration	All Access	sible Staff						
F Change of Registered Particulars	User Accou	unt:		► Add				
F Renewal of Registration							Add Access Right	Clea
Interview								
Request to Cancel Product Registration								
Payment								
Application History								
User Profile								
Maintain Company's User Accounts								
Add Access Right								
Remove/Transfer Access Right								
System								
Logout								

Scenario 1:

Select from all product(s) and access right of product(s) to a particular user (in this scenario assigning product HK-63516 and HK-63525 to staff Susan Cheung):

• Select All Products and click the "Add" button.

							Add Access Right	Clea
T	Add Acces							
ou are login as WONG avid BC COMPANY LIMITED ogin date and time 7.08.2018 14:15	○ Application I		./HK No.	Add				
Online Notification	A	application ID	PL No.	PR No.	HK No.	Name of Product	User Account	¢
My Product Search	Add Access Rig	ht to						
New Registration	All Accessible	Staff						
Change of Registered Particulars	User Account:			✓ Add				
Renewal of Registration							Add Access Right	Clear
Interview								
Request to Cancel Product Registration								
Payment								
Application History								
User Profile								
Maintain Company's User Accounts								
Add Access Right								
Remove/Transfer Access Right								
System								
Logout								

• Select the product(s) and the accessible staff.

							Add Access Right	Cleur
	Add	Access Right						
		Products Add						
u are login as WONG	() All							
vid C COMPANY LIMITED gin date and time		plication ID/PL No./PR	No./HK No.		Add			
D8.2018 14:34	OUse	er Account:			✓ Add			
Online Notification		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account	¢
y Product Search		ANP20169000012	PL0010/2016	PR0012/2016	HK63516	PAYMENT TEST	david_wong prs.david.wong@gmail.com	
ew Registration		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	kenny_liu prs.kenny.liu@gmail.com	
Change of Registered							david_wong prs.david.wong@gmail.com	m
Renewal of							susan_cheung_1 prs.susan.cheung@gmail.	com
Registration		ANP20179000064	PL0087/2017	PR0055/2017	HK63565	MY 20170512 1612	david_wong prs.david.wong@gmail.com	
nterview	Add A	ccess Right to						_
Request to Cancel Product Registration		ccessible Staff						
Payment	User A	Account: Susan CHEU	NGprs.susan.che	ung@gmail.com	Ard			
Application History							Add Access Right	Clear
User Profile								
/laintain Company's Jser Accounts								
Add Access Right								
Remove/Transfer Access Right								
System								

Scenario 2:

Assign access right of product(s) to a particular user (in this scenario assigning product HK-63516 to staff Kenny Liu):

• Select "Application ID /PL No. /HK No.".

• Select the user account from the dropdown list (staff Kenny Liu).

Ť		Access Right					Add Access Right Clear
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 14:34	·	cation ID/PL No./PR No	o./HK No. HK63516		d		
Online Notification		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account 🔶
My Product Search	Б	ANP20169000012	PL0010/2016	PR0012/2016	HK63516	PAYMENT TEST	david_wong prs.david.wong@gmail.com
+ New Registration	Add Acc	ess Right to					
+ Change of Registered Particulars	All Acce	essible Staff					
+ Renewal of Registration	Jser Aco	count: LIU Kennyprs	.kenny.liu@gmail.cor	m V (Ad	d		Add Access Right Clear
+ Interview							Add Access Right Clear
+ Request to Cancel Product Registration							
+ Payment							
Application History							
- User Profile							
Maintain Company's User Accounts							
Add Access Right							
Remove/Transfer Access Right							
+ System							
Logout							

Scenario 3:

Assign access right of product(s) to all users (in this scenario assigning product HK-63516 to all staff):

- Select "Application ID /PL No. /HK No.".
- Click "All Accessible Staff", then all active staff will be added to the accessible staff list.

You are login as WONG		Access Right					Add Access Right) (Clear
David ABC COMPANY LIMITED Login date and time	Applic	cation ID/PL No./PR No	o./HK No. HK63516	Ad	d		
17.08.2018 14:34	⊖User A	Account:		~	Add		
Online Notification		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account 🔶
My Product Search		ANP20169000012	PL0010/2016	PR0012/2016	HK63516	PAYMENT TEST	david_wong prs.david.wong@gmail.com
+ New Registration	Add Acce	ess Right to					
+ Change of Registered Particulars	All Acce	ssible Staff					
+ Renewal of Registration	User Acc	ount: WONG David count: LIU Kennyprs.	kenny.liu@gmail.con	n V Rei	rove		
+ Interview	User Acc	ount: Susan CHEUNG-	prs.susan.cheung(@gmail.com ✔ Rei	rove		
+ Request to Cancel							Add Access Right Clear

Scenario 4:

Assign access right of product(s) from a user account to another user account (in this scenario assigning product HK-63489 from Kenny Liu to Susan Cheung):

- Select User Account and specify a user account.
- Click the "Add" button.
- Select the product(s) and user account to add access right.
- Click the "Add Access Right" button.

yu are login as WONG ivid 3C COMPANY LIMITED gin date and time 08.2018 14:34	⊖ All Pr ⊖ Applie	Access Right roducts Add cation ID/PL No./PR No Account: LIU Kenny		Add)	d		
Online Notification		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
My Product Search		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	kenny_liu prs.kenny.liu@gmail.
New Registration		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	kenny_liu prs.kenny.liu@gmail.
Change of Registered Particulars		ANP20159000238	PL0183/2015	PR0001/2016		HP Test Generic 1005	kenny_liu prs.kenny.liu@gmail.
Renewal of Registration		ANP20159000242	PL0019/2016	PR0017/2016		TEST 20160803	kenny_liu prs.kenny.liu@gmail.
Interview		ANP20159000245	PL0190/2015	PR0003/2016		HP test 20151222	kenny_liu prs.kenny.liu@gmail.
Request to Cancel Product Registration		ANP20159000246	PL0001/2016	PR0004/2016		ABC TABLES	kenny_liu prs.kenny.liu@gmail.
Payment	✓	ANP20159000217	PL0141/2015	PR0083/2015	HK63489	HP TEST MANUAL 0417	kenny_liu prs.kenny.liu@gmail.
Application History		ANP20169000052				TEST ABC	kenny_liu prs.kenny.liu@gmail.
User Profile		ANP20169000053				TEST 20161216	kenny_liu prs.kenny.liu@gmail.
Maintain Company's User Accounts	Add Acc	ess Right to					
Add Access Right		essible Staff					
Remove/Transfer Access Right	l ser Acc	count: Susan CHEUNG	prs.susan.cheung@)gmail.com 🗸 🗚			
System							Add Access Right

Step 3:

• After clicking the "Add Access Right" button to update the changes or click "Clear" to reload the page, the following dialogue box will come up.



2.2.3 Remove/Transfer Access Right

The company administrator and the supervisor can access the "Remove/Transfer Access Right" function. This function allows the revoke or transfer of access right of product(s) between staff.

Step 1:

• Click the menu item "Remove/Transfer Access Right" under "User Profile" in the menu on the left.

								Remove/Tr	ansfer
Ť	Add A	Access Right							
	Transfer	Revoke From: Susan	CHEUNGprs.sus	an.cheung@gmail.con	n 🗸				
You are login as WONG David ABC COMPANY LIMITED	To: < <re< th=""><th>evoke from User>></th><th></th><th>\checkmark</th><th></th><th></th><th></th><th></th><th></th></re<>	evoke from User>>		\checkmark					
Login date and time 04.05.2016 10:53		Application ID	PL No.	PR No.	HK No.	Name of Product		User Account	\$
Online Notification		ANP20159000243	PL0185/2015	PR0116/2015	HK63505	TEST 1127	susan_cheung	prs.susan.cheung@gn	nail.com
My Product Search								Remove/Tr	ansfer
► New Registration									
 Change of Registered Particulars 									
Renewal of Registration									
Interview									
Request to Cancel Product Registration									
Payment									
Application History									
User Profile									
Maintain Company's User Accounts									
Add Access Right									
Add Access Right Remove/Transfer Access Right									
Remove/Transfer									

Step 2:

• Select the user (i) revoke the access right of the product from the user; (ii) to transfer the access right of the product to another user.

For users who are "Company Admin" and "Supervisor", the user role would be displayed next to the email address

Ť		Access Right /Revoke From: Susar	CHEUNGprs.su	san.cheung@gmail.c	om(Supervisor) 🗸		(Remove/Transfer
You are login as WONG David ABC COMPANY LIMITED	0: < <re< th=""><th>evoke from User>></th><th></th><th>~</th><th></th><th></th><th></th></re<>	evoke from User>>		~			
Login date and time 17.08.2018 14:34		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account 🔶
Online Notification		ANP20169000032	PL0029/2016	PR0024/2016	HK63517	WALKTRHOUGH	susan_cheung_1 prs.susan.cheung@gmail.com
My Product Search		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	susan_cheung_1 prs.susan.cheung@gmail.com
+ New Registration		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com
-		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com
+ Change of Registered Particulars							Remove/Transfer
+ Renewal of Registration							



• Click the checkbox of the product(s) and select a specific user account to transfer the access right of product(s) or select "<<Revoke from User>>" to revoke the access right of product(s).

Scenario 1:

To revoke product access right from particular user (in this scenario revoke the access right of the selected product from staff Susan CHEUNG).

• Select staff Winnie Fong from the "Transfer/Revoke From" dropdown list and select "<<Revoke from User>>"option under the "To" dropdown list.

	A	A see a Diskt					Remove/Tra	nsfer
		Access Right						
	Transfe	er/Revoke From: Susar	n CHEUNGprs.su	san.cheung@gmail.c	om(Supervisor) 🗸			
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 14:34	LIU	Revoke from User>> Kennyprs.kenny.liu@ an CHEUNGprs.susa		m(Supervisor)	HK No.	Name of Product	User Account	÷
17.08.2018 14:34		ANP20169000032	PL0029/2016	PR0024/2016	HK63517	WALKTRHOUGH	susan_cheung_1 prs.susan.cheung@gma	
Online Notification		ANF20109000032	FL0028/2010	FR0024/2010	HR03317			
My Product Search		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	susan_cheung_1 prs.susan.cheung@gma	ail.com
+ New Registration		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gma	ail.com
-		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gma	ail.com
+ Change of Registered Particulars							Remove/Tra	nsfer
+ Renewal of Registration								
Interview								
+ Request to Cancel								

Scenario 2:

To transfer the access right of the product between staff (in this scenario transfer the access right of the selected product from staff Susan CHEUNG to Kenny LIU).

• Select staff Winnie Fong from the "Transfer/Revoke From" dropdown list and select staff Edwin Tsang under the "To" dropdown list.

							Remove/Transfer					
	Add	Add Access Right										
	Transfe	r/Revoke From: Susan	CHEUNGprs.su	an.cheung@gmail.co	om Supervisor) 🗸							
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 14:34	10.	Rennyprs kenny liu@		m(Supervisor)	HK No.	Name of Product	User Account ▲					
17.00.2010 14.34		ANP20169000032	PL0029/2016	PR0024/2016	HK63517	WALKTRHOUGH	susan_cheung_1 prs.susan.cheung@gmail.com					
Online Notification												
My Product Search		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	susan_cheung_1 prs.susan.cheung@gmail.com					
+ New Registration		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com					
		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com					
+ Change of Registered Particulars							Remove/Transfer					
+ Renewal of Registration												
+ Interview												
+ Request to Cancel												

Step 3:

- Select the product(s).
- Click "Remove/Transfer" to update the changes.

÷	Add A	Access Right					(Remove/Transfer
	Transfer	r/Revoke From: Susan	CHEUNGprs.sus	san.cheung@gmail.c	om(Supervisor) 🗸		
You are login as WONG David ABC COMPANY LIMITED	To: LIU I	Kennyprs.kenny.liu@	gmail.com	~			
Login date and time 17.08.2018 14:34		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
Online Notification		ANP20169000032	PL0029/2016	PR0024/2016	HK63517	WALKTRHOUGH	susan_cheung_1 prs.susan.cheung@gmail.com
My Product Search		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	susan_cheung_1 prs.susan.cheung@gmail.com
New Registration		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com
•		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com
+ Change of Registered Particulars 網頁訊息	×						Remove/Transfe
Updated success	fully.						
	確定						

2.3 ONLINE NOTIFICATION

Online Notification is the default landing page after the user has logged in to PRS2.0 successfully. User can view all the important messages sent by the Drug Office in this page.

The online notification is divided into 7 different modules, namely (i) "New Product Registration"; (ii) "On Going"; (iii) "CORP" (change of registered particulars); (iv) "Renewal of Registration"; (v) "Cancellation Request"; (vi) "Interview"; and (vii) "Non Pharmaceutical Product Alert". And New Product Registration, CORP, Renewal of Registration modules have an 'Archived Notifications' button. When the application is completed, its notification will be archived and will not be shown in online notification page. Click 'Archived Notifications' of that three modules will show the archived notification of that three modules.

	New P	roduct Registratior	ו						Archiv	ed Notification
		Notification Date		Subject		\$	Propose	d Name of Product	\$ PL No. 🜩	Payment Statu
i are login as ORG IAL ONE	Open	21.01.2021 17:25:14		Application Payment Request			FACE CR	EAM	PL0001/2021	Paid
STING LIMITED (TEST)	Open	21.01.2021 17:14:03		Screening Application		FACE CREAM			PL0001/2021	N/A
and time	Open	06.11.2019 11:52:34		Application Payment Request		TEST OPEN FILE CASE 3			PL0024/2019	Paid
	Open	05.09.2019 16:10:27		Screening Application			TEST OP	EN FILE CASE 3	PL0024/2019	N/A
Online Notification	Open	04.09.2019 11:17:16		Evaluation Application		TEST 2017022401			PL0030/2017	N/A
Ay Product Search	CORP	-							Archive	d Notification
New Registration		Notification Date 🗢	Subject		•	HK No.		Name of Product	(
Change of Registered	Open	28.01.2021 04:00:12		ffective Reminder	•	HK63536	•	DEMO ON 2017-01-19		
Particulars	Open	22.01.2021 09:47:20		Submitted Notification		HK63668		TEST 20145		
Renewal of	Open	20.01.2021 11:50:56		Submitted Notification		HK63536		DEMO ON 2017-01-19		
Registration Request to change	Renew	al of Registration	٦						Archive	ed Notification
name and/or address			-							
			Subject		\$	Name of Proc			No. of	Renewals 4
Request to Cancel	<u>Open</u>	28.09.2019 02:06:59	Expired Proc			DEMO ON 20			1	
Product Registration	<u>Open</u>	20.07.2019 02:05:10	Expired Proc			TEST OPEN F			1	
ayment	Open	08.07.2019 04:00:11	Renewal Fin	al Reminder		DEMO ON 20	17-		1	
pplication History	Cancell	ation Request								
Jser Profile		Notification Date \$	Subject		\$	HK No.	\$	Name of Product		\$
	<u>Open</u>	21.01.2021 15:49:10	Cancellation F	Registration Request Submitted Notification		HK63517		WALKTRHOUGH		
Printing Service										

Online	e Notification		-	•	ONLINE_NOTIFICATION_VIEW_01
Filter by	y Notification Date O Filt	er by HK No.			Back
From 23	8.08.2018 to 01.1	0.2018 Search			
	Notification Date \$	Subject	\$ HK No. 🜲	Name of Product	\$
Open	14.09.2018 15:34:32	Application Approval Notification	HK63517	WALKTRHOUGH	
Open	14.09.2018 15:02:02	Application Screening Notification	HK63517	WALKTRHOUGH	
Open	13.09.2018 11:59:48	Application Submitted Notification	HK63517	WALKTRHOUGH	

The online notifications for different modules will be shown in the respective section in this manual.

The user can have the two options for filtering the data below:-

(i) Filter by Notification Date: Input the date range, for example from 29.07.2020 to 29.01.2021. Then click "Search" button.

Online	e Notification			ONLINE_NOTIFICATION_	VIEW_01
<u> </u>	y Notification Date O Filte				Back
JORF	Notification Date \$	Subject	\$ HK No.	\$ Name of Product	÷
Open	12.01.2021 17:37:19	Application Clarification Notification	HK42660	CALCIUM UNISON TAB SUUMG	
			111012000	CALCION DIVISOR TAD SUMIO	
Open	12.01.2021 17:34:49	Application Screening Notification	HK42660	CALCIUM UNISON TAD S00MG	
	12.01.2021 17:34:49 27.11.2020 04:00:10	Application Screening Notification Application Effective Reminder			
Open Open Open			HK42660	CALORUM UNISON TAD SOOMO	

(ii) Filter by HK No.: Input a HK no., for example 41190. Then click "Search" button.

Online	Notification			ONLINE_NOTIFICATION_	VIEW_01
O Filter by M	Notification Date Filte 	r by HK No.			Back
HK 41190	Search				
CORP					
	Notification Date \$	Subject	\$ HK No.	\$ Name of Product	\$
Open	21.08.2018 18:35:21	Application Approval Notification	HK41190	PRODUCT NAME XXXXX XXXX	
Open	21.08.2018 18:34:10	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX	
Open	21.08.2018 18:33:18	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX	

The "Archived Notification" function in CORP is similar to those in "New Product Registration" and "Renewal of Registration".

2.3.1 New Product Registration Online Notification

Users can view the basic application information such as the product information and the notification letter:

Step 1:

• Click the menu item "Online Notification" in the menu on the left.

• Click the hyperlink "Open" to view the notification.

	New Pr	New Product Registration Archived Not									
		Notification Date	÷ \$	Subject		¢	Pro	oposed Name of Product	♦ PL No. ♦	Payment Statu	
u are login as	Open	12.01.2021 10:34:23		Certificate Payment Request				500 TABLETS 500MO	PL0975/2016	Paid	
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA 8	START	PL0004/2020	Paid	
gin date and time 01.2021 15:06	Open	20.11.2020 16:45:42		Screening Application			BOURB	ON POWDER	PL0002/2020	N/A	
Online Notification	CORP								Archi	ved Notificatio	
My Product Search		Notification Date \$		Subject	¢	HK	No.	\$ N	ame of Product	rou nounoute	
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification		HK42660		CALCION ONISON TAX	300MG		
New Registration	Open	12.01.2021 17:38:55	Application Su	bmitted Notification		HK42660		GALOUM UNISON THE			
Change of Registered	Open	12.01.2021 17:38:55	Application Sc	n Screening Notification HK42660				CALCIUM UNICON THE			
Particulars Renewal of	Renew	al of Registration							Archi	ved Notificatio	
Registration		Notification Date \$		Subject	¢			Name of Product	¢ 1	No. of Renewals	
Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notif	ication		DRUG NAM	Е ХХХХХ Т.	AB 50MG	1		
Payment	Cance	llation Request									
Application History		Notification Date \$		Subject	\$	НК	No.	\$ N	ame of Product		
	Open	26.01.2021 15:07:50	Cancellation F	Registration Request Submitted Notification		HK31199		EFILIM FREEZE-DRIE	PDR FOR IV INJ	400MG	
Jser Profile	Non B	harmaceutical Produ	int Alart								
System	NOTE										
_ogout		Notification Date		Subject			K No. 🗢		me of Product		
	Open	11.02.2016 04:00:00	Renewal P	ending Reminder		HK6	J464	COTFOLIN COD CVL COON			

Step 2:

- Click the hyperlink "Notification Detail" to view the notification letter in detail.
- Click the "Go" button to redirect to the corresponding page.

Online Notification		ONLINE_NOTIFICATION_VIEW_01
New Product Registration		
Notification Date :	12.01.2021 10:34:23	
PL No. :	PL0975/2016	
PR No. :	PR0012/2017	
HK No. :	HK65261	
Proposed Name of Product (English) :	VOCIN 500 TABLETS 500MG	
Notification Detail :		
Attachment(s) :		
1. Go To Certificate Payment :	Go	
2. In alternative to (1), you may send the	putstanding information by post or in person to the Drug Office:	
Drug Evaluation and Import / Export Co Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong	ntrol Division	
For enquiries, please call our hotline at (8 under the process of new product registra	52) 3974 4175 or email to prs2_info@dh.gov.hk quoting the reference number of th tion.	is application or the PL number of PR number of your product



The system will redirect to the new application payment pool.

•	New	Application Pa	yment					
							Print	eady to Pa
		Application Received Date	PL No.	φ	PR No.	\$ Proposed Name of Product	Payment Status	φ.
You are login as WONG David		31.05.2017 16:16	PL0070/2017			MY 20170531 1559	Ready for Application Payment	
ABC COMPANY LIMITED Login date and time 17.08.2018 15:08		25.10.2017 14:34	PL0086/2017			MY 20170928 1652	Ready for Application Payment	
Online Notification								
My Product Search								
+ New Registration								
+ Change of Registered Particulars								
Renewal of Registration								
+ Interview								
+ Request to Cancel Product Registration								
+ Payment								
Application History								
+ User Profile								
+ System								
Logout								

Version. : 1.1.18
2.3.2 CORP Online Notification

Users can view basic CORP application information such as product information and application details:

Step 1:

- Click the menu item "Online Notification" in the menu on the left.
- Click the hyperlink "Open" to view the notification.

•	Onlir	ne Notification						0	NLINE_NOTIFIC	ATION_VIEW_
T	New P	roduct Registration							Archiv	ed Notification
		Notification Date	\$	Subject		\$	Pr	oposed Name of Product		Payment Statu
u are login as	Open	12.01.2021 10:34:23		Certificate Payment Request			VOOIN	500 TABLETO 500MO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA 8	START	PL0004/2020	Paid
in date and time 11.2021 15:06	Open	20.11.2020 16:45:42		Screening Application			BOURE	ON POWDER	PL0002/2020	N/A
Inline Notification	CORF	0							Archi	ved Notificatio
My Product Search		Notification Date 💠		Subject	÷	iik	No.	•	iame of Product	
New Registration	<u>Open</u>			hdrawal Rejected Notification		HK42660		CALCION UNISON TA	B 300MG	
iew registration	<u>Open</u>			bmitted Notification		HK42660		OALOIUM UNISON TA	B SEEMO	
Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sci	eening Notification		HK42660		CALCIUM UNISON TA	B-909MC	
Renewal of	Rene	wal of Registration							Archi	ved Netificatio
Registration		Notification Date \$		Subject	¢			Name of Product	¢ 1	to. of Renewals
tequest to Cancel roduct Registration	Open	27.01.2021 04:00:14	Renewal Notif	cation		DRUG NAM	E XXXX T	AB 50MG	1	
ayment	Cance	ellation Request								
pplication History		Notification Date \$		Subject	\$	HK	No.	\$	Name of Product	
pplication mistory	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification		HK31199		EFILIM FREEZE-DRIE	D FDR FOR IV INJ	400MG
Jser Profile	N	Diaman (1 - 1 D - 1								
ystem	Non	Pharmaceutical Produ								
		Notification Date		Subject			K No. 🗢		ame of Product	
ogout	Open	11.02.2016 04:00:00	Renewal P	ending Reminder		HK6	0464	OCTECTIN 500 CAP 500		
	Open	12.01.2016 04:00:02	D	ending Notification		HK6	0.4.0.4	OCTEOTIAL FOR CAD FOR		

Step 2:

• Click the "View Detail" button to view the application in detail.

Ť	Online Notificati	on					CORP_NOTIFICATION
You are login as FONG							View Detail Back
Winnie DEFG COMPANY Login date and time 17.08.2018 15:38	Application Clarifica	tion Notific	ation				
Online Notification	Notification Date: 24.08.20 Notification Letter: Clarifica						
My Product Search	Dear Certificate Holder,						
+ New Registration	We want to inform you followi	ing application(s) have been evaluation failed. Please	e follow up attached clarificatio	n letter required information to reply	y appl	ication as soon as possible.
+ Change of Registered	Application Ref. No.	HK No	. Name of Product	Change Catego	ries Application Status	\$	Application Payment Status \$
Particulars	CORP-HK63554-201750673	HK63554	TEST 20170221001	2,3	Application Evaluated		Not Necessary
+ Renewal of Registration							View Detail Back

• The system will redirect to the CORP application page.

						6.		N (
	Summary e-Product File (e-PF) Change	DO Req. Clarification	1 attas) . Aats	Letter CORP Change	Minton Dad		Clarification L	.etter) Withdraw A	pplication
are login as FONG	Application Reference No.:	CORP-HK63554-2017		Letter CORP Change Application St			same Batch		
ie COMPANY	Application Batch No.:	CORP-HK63554-2017 CORP-HK63554-2017		Application St Application Ty				nitiated - New CORF	application
adate and time	HK No.:	HK63554		Previous App.	Reference No.				
line Notification	Product Name: Application Received Date:	TEST 20170221001 18.08.2017		DO Request F Client Date:	Reference No.:	10 (08.2017		
_	Proposed Effective Date:	10.00.2017		Application Fo	orm Image:		File Chosen		
Product Search	Hard Copy Received Date:			Justification (I	Jrgent Applicati	on):			
w Registration	Submission Acknowledgement: Applicant Username:	Submission Acknowled winnie_fong	<u>igement</u>						
ange of Registered rticulars	Category 2 - Label Under	Evaluation —							
newal of gistration	Particulars Proposed to Change		Recall C Required	ert. Reprint Required	Evaluation Co	omment and	l Result		
erview			Required		·				
quest to Cancel oduct Registration	2.Label				,				
yment	2.1-Change in label		Yes 🗸 I	Not Required					
plication History	Brief Description of Change and Reason:	lewSI			Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
er Profile	Supporting Documents:								
stem	2.1 Change in label								
gout	i. Proposed label with the change(s) up	nderlined or highlighted	1*						
	Documents File Name	Remark	s	creening Comment	E	Evaluation C	omment		
					ſ				
	test3.pdf The same file has already been uploaded in another								
	location in this submission								
		lment:							
	location in this submission Change Categories Allowed for Amend		etter Sent	t					
	location in this submission			t	Evaluation Co	omment and	d Result		_
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse				Evaluation Co	omment and	d Result		
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse		Recall C		Evaluation Co	omment and	d Result		
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse		Recall C			omment and	d Result		_
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change		Recall C Required			omment and	d Result		
	Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert	rt Clarification L	Recall C Required	Cert. Reprint Required		omment and	d Result		
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert	rt Clarification L	Recall C Required	Cert. Reprint Required				Acknowledged	Withdrawn
	Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert	rt Clarification L	Recall C Required	Cert. Reprint Required	test 1234			Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Insee Particulars Proposed to Change 3.Package Insert 3.1-Change in package Insert Brief Description of Change and Reason	rt Clarification L	Recall C Required	Cert. Reprint Required	test 1234			Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert	rt Clarification L	Recall C Required	Cert. Reprint Required	test 1234			Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert with the ch	rt Clarification L test	Recall C Required	Cert. Reprint Required	test 1234 Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert with the ch	rt Clarification L	Recall C Required	Cert. Reprint Required	test 1234 Satisfactor		tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert with the ch	rt Clarification L test	Recall C Required	Cert. Reprint Required	test 1234 Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert I. Proposed package insert with the ch Documents File Name	rt Clarification L test	Recall C Required	Cert. Reprint Required	test 1234 Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert with the ch	rt Clarification L test	Recall C Required	Cert. Reprint Required	test 1234 Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Insee Particulars Proposed to Change 3.Package Insert 3.1-Change in package Insert Brief Dacciption of Change and Reason Supporting Documents: 3.1 Change in package Insert with the ch Documents File Name I Proposed package Insert with the ch Documents File Name	rt Clarification L test	Recall C Required	Cert. Reprint Required	test 1234 Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Insee Particulars Proposed to Change 3.Package Insert 3.1-Change in package Insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package Insert I. Proposed package Insert I. Proposed package Insert I. Proposed package Insert I. Proposed package Insert with the ct Documents File Name Itsti forf The same file has already been uploaded in another	rt Clarification L test ange(s) underlined and Remark	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inser Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert I. Proposed package insert I. Proposed package insert with the ct Documents File Name Instal and the submission II. Documents substantiating the prop	rt Clarification L test ange(s) underlined and Remark	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory Comment	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inser Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert I. Proposed package insert I. Proposed package insert with the ct Documents File Name Instance of the same file has already been uploaded in another location in this submission II. Documents substantiating the prop	test ange(s) underlined and Remark osed change(s) with th	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory Comment	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inser Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert I. Proposed package insert I. Proposed package insert with the ct Documents File Name Instance of the same file has already been uploaded in another location in this submission II. Documents substantiating the prop	test ange(s) underlined and Remark osed change(s) with th	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory Comment	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inser Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert I. Proposed package insert I. Proposed package insert I. Proposed package insert with the ct Documents File Name Instance of the same file has already been uploaded in another location in this submission II. Documents substantiating the prop	test ange(s) underlined and Remark osed change(s) with th	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory Comment	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert 3.1 Change in package insert 4.1 Change in package insert 4.1 Change in package insert 4.2 Change in package insert 4.2 Change in package insert 4.2 Change in package insert 4.3 Change in package insert 4.2 Change in package insert 4.3 Change in package insert 4.4 Change in package insert 4.4 Change in package insert 4.5 Change insert 5.5 Change insert	test ange(s) underlined and Remark osed change(s) with th	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory Comment	Acknowledged	Withdrawn
	Iocation in this submission Change Categories Allowed for Amend Category 3 - Package Insee Particulars Proposed to Change 3.Package Insert 3.1-Change in package insert Brief Daccuments: 3.1 Change in package insert with the ch Documents File Name Lest3.pdf The same file has already been uploaded in another location in this submission III. Documents File Name Lest3.pdf The same file has already been uploaded in another location in this submission	test ange(s) underlined and Remark osed change(s) with th	Recall C Required C Yes Y 1	Not Required	test 1234 Satisfactor	y Unsa	tisfactory Comment	Acknowledged	Withdrawn

2.3.3 Renewal of Registration Online Notification

Users can view the basic application information such as the product information and the application detail:

Step 1:

- Click the menu item "Online Notification" in the menu on the left.
- Click the hyperlink "Open" to view the notification.

	Online	e Notification						ONLIN	E_NOTIFIC	ATION_VIEW_0
T	New Pro	oduct Registration							Archive	ed Notification
		Notification Date	e \$	Subject		\$	Proposed Name of Pro	oduct 🜲	PL No. 🗢	Payment Statu
ou are login as	Open	12.01.2021 10:34:23	Certificate Payment	Request		Vee	IN 500 TABLETO 500M		PL0975/2016	Paid
	Open 2	20.11.2020 17:13:29	Certificate Payment	Request		JAVA	8 START		PL0004/2020	Paid
gin date and time	Open 2	20.11.2020 16:45:42	Screening Application	n		BOU	RBON POWDER		PL0002/2020	N/A
Online Notification	CORP								Archiv	ved Notificatio
My Product Search		Notification Date \$	Su	bject	\$	HK No.	\$	Name	of Product	
New Registration	<u>Open</u>	12.01.2021 17:40:32	Applicaton Withdrawal Rejected Not	ification		K42660	CALCIONI UNIS	ON TAB 300	MG	
New Registration	Open	12.01.2021 17:38:55	Application Submitted Notification		Н	K42660	GALOUM UNIO	ON TAD 300	M0 -	
 Change of Registered Particulars 	<u>Open</u>	12.01.2021 17:38:55	Application Screening Notification		Н	K42660	CALCIUM UNIO	ON TAD 389	MO	
Particulars -		12.01.2021 17:38:55	Application Screening Notification		н	K42660	CALCIUM UNIO	ON TAB 369		ved Notificatio
Particulars				ıbject	HI ¢	K42660	CALCIUM UNIO	ION TAD 389	Archiv	
Particulars Renewal of Registration		al of Registration		ıbject	¢	K42660 RUG NAME XXXX	Name of Product	ION TAB 309	Archiv	
Particulars Renewal of Registration Request to Cancel Product Registration	Renew:	al of Registration	Si	ıbject	¢		Name of Product	ON TAB 369	Archiv	
Particulars Renewal of Registration Request to Cancel Product Registration Payment	Renew:	Al of Registration Notification Date \$ 27.01.2021 04:00:14	St Renewal Notification	ubject ubject	¢		Name of Product		Archiv	ved Notificatio
Particulars Renewal of Registration Product Registration Payment Application History	Renew:	al of Registration Notification Date \$ 27.01.2021 04:00:14	St Renewal Notification	ıbject	¢ D	RUG NAME XXX	Name of Product	Name	Archiv Archiv N 1 of Product	lo. of Renewals
Particulars Renewal of Registration Request to Cancel Product Registration Payment Application History	Renewa Open Cancel	al of Registration Notification Date \$ 27.01.2021 04:00:14 Iation Request Notification Date \$ 26.01.2021 15:07:50	St Renewal Notification St Cancellation Registration Request S	ıbject	¢ D	RUG NAME XXXX Hk No.	Name of Product CTAB 50MG	Name	Archiv Archiv N 1 of Product	lo. of Renewals
Particulars Renewal of Registration Request to Cancel Product Registration Payment Application History User Profile	Renewa Open Cancel	al of Registration Notification Date 27.01.2021 04.00.14 Internation Request Notification Date	St Renewal Notification St Cancellation Registration Request S	ıbject	¢ D	RUG NAME XXXX Hk No.	Name of Product CTAB 50MG	Name	Archiv Archiv N 1 of Product	lo. of Renewals
Particulars Renewal of Registration Request to Cancel Product Registration Payment Application History User Profile System	Renewa Open Cancel	al of Registration Notification Date \$ 27.01.2021 04:00:14 Iation Request Notification Date \$ 26.01.2021 15:07:50	Si Renewal Notification Si Cancellation Registration Request S uct Alert	ıbject	¢ D	RUG NAME XXXX Hk No.	Name of Product TAB 50MG CPILIM TRECZ	Name E-DRIED FD	Archiv Archiv N 1 of Product	lo. of Renewals
Particulars Renewal of Registration Request to Cancel	Renewa Open Cancel	al of Registration Notification Date 27.01.2021 04:00:14 Internation Request Notification Date 26.01.2021 15:07:50 narmaceutical Prod	Si Renewal Notification Si Cancellation Registration Request S uct Alert	ibject Submitted Notification	¢ D	RUG NAME XXXX HK No. K31199	Name of Product TAB 50MG CPILIM TRECZ	Name C- DAIED PD Name c P 669MO —	Archiv Archiv N 1	lo. of Renewals

Step 2:

• Click the hyperlink "View Renewal Application Status" to view the application in detail.

Ť	Renew	al of	f Regis	tra	tion			RENEWAL_NOTIF	ICATION
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 15:44	Renewal I	Final	Reminde	er				Print Product Lis	t Back
Online Notification My Product Search	Notification I Notification I		<u>Renewal Fi</u>	nal R					
+ New Registration	HK No. HK61844		PR No. PR0664/2012		PRODUCT NAME XXXX	Name of Product	\$	Required information	¢
+ Change of Registered	HK61840	P	PR0659/2012		PRODUCT NAME XXXX				
Particulars	HK36789	P	PR0830/1992		PRODUCT NAME XXXX		BABE Requirement		
+ Renewal of Registration	View Renewa	al Applic	cation Status	È					
+ Interview								Print Product Lis	t Back

• The system will redirect to the Renewal Application Status page.

ł	Renew	val of R	egistr	ration						RE	NEWAL_STATU:
Lare login as WONG vid C COMPANY LIMITED jin date and time	Please com transaction	plete the rene at least 5 wor	wal proce king days	wal of Registration	ə. İl						evant payment
07.2023 10:04	Note: Work	ing days do no	t include	saturday / Sunday / holiday(s).	ase contact our rr c	oneagues of this	52.0 help desk a	3574 4153 00	any once nours		
Online Notification										Renew	
ly Product Search	\$	HK No.	\$	Name of Product			Notify E		Expiry Date		
ew Registration		HK37027		CEDAX CAP 400MG			15.09.2	22	12.09.2023	Batcl	h Five
nange of Registered articulars	Paymen	t Complet	ed								
	HK No.	\$ N	ame of Pr	roduct	¢ F	Payment Date 🔶	Last Expiry Dat	e⇔ Expiry Da	te \$ Cert Co Date	ollection 🔶 I	Batch No. 🔶
egistration pplication Status		-Certifica		of the or Cadificate is eachied for any li	ime une Glasse ke		o Codificato for		- developeding		
egistration pplication Status Reply and Pay for enewal of Registration Payment Completed Troduct Confinemed Not to enew Solvey Es further Action drive Product Renewal ubmission of Other ost-registration	When relea HK No.	sed, the down \$ N	load link (ame of Pro	of the e-Certificate is enabled for one-ti roduct to Renew		ep a copy of the e Payment Date ✦				ficate 💠 I	
tenewal of tegistration pelication Status Reply and Pay for newal of Registration newal of Registration newal of Registration newal of Registration to Product Remewal submission of Other ost-registration upplement terview	When relea HK No. Product	sed, the down \$ N	load link (ame of Pri d Not t	roduct				🗢 Expiry Da		ficate \$ i \$ Batcl	Reinstate
egistration pplication Status Registration and Cognitication and Cognitication and Cognitication area Registration area Registration activity of the state of the	When relea HK No. Product \$ Require: Please com transaction In case cert	sed, the down \$ N Confirme HK No. s Further . plete the rene at least 5 wor lifecate holder(load link (ame of Pri d Not t ¢ Action wal proce king days b) cannot	roduct to Renew Name of Product Before Product Renewal edure at least 10 working days before th before the expiry date of the certificate to new certificate(s) in due cortificate	the expiry date of the second se	e certificate. If yo	tast Expiry Dar Reply D	e¢ Expiry Da	te \$ e-Certi Expiry Date S 2.0, please con	Batch mplete the relevant	(Reinstate h No. \$
egistration pplication Status Rep/ and Pay for serval of Capitolead Product Continued Not to enew Requires Further Action effore Product Renewal ubmission of Other ost-registration upplement	When relea HK No. Product \$ Require: Please com transaction In case cert	sed, the down \$ N Confirme HK No. s Further . plete the rene at least 5 wor lifecate holder(load link (ame of Pri d Not t ¢ Action wal proce king days b) cannot	roduct to Renew Name of Product Before Product Renewal edure at least 10 working days before it before the conflictate	the expiry date of the second se	e certificate. If yo	tast Expiry Dar Reply D	e¢ Expiry Da	te \$ e-Certi Expiry Date S 2.0, please con	Batch mplete the relevant	(Reinstate h No. \$
egistration pplication Status Reyard Power of Registration states and Paylow States and Paylow Regulars Further Adden there Product Registration bere Product Registration publication Charge sch-registration equest to Cancel oduct Registration agyment oplication History	When relea HK No. Product * Require: Please contransaction In case cert Note: Work	sed, the down \$ N Confirme HK No. s Further . plete the rene at least 5 wor lifecate holder(load link (ame of Pr d Not t ¢ Action wal proce (sing days s) cannot t include	roduct to Renew Name of Product Before Product Renewal edure at least 10 working days before th before the expiry date of the certificate to new certificate(s) in due cortificate	the expiry date of the second se	e certificate. If yo	tast Expiry Dar Reply D	tte ¢ 1974 4195 du	te \$ e-Certi Expiry Date S 2.0, please con	Batch mplete the relevant	(Reinstate h No. ¢ evant payment (Not to Renew
spistration pplication Status reveal of Registration reveal of Registration reveal Continues the Photosuc Renewal between the State Renewal between t	When relea HK No. Product * Require: Please contransaction In case cert Note: Work	sed, the dowr	load link (ame of Pr d Not t ¢ Action wal proce (sing days s) cannot t include	roduct to Renew Name of Product Before Product Renewal edure at least 10 working days before th sefore the expirit date of the estilicate t renew certificate(s) in due course, plea Sawrday / Sunday / holiday(s).	the expiry date of the second se	e certificate. If yo	Last Expiry Dat A Reply D w make online p S2.0 help desk a	te ¢ Annu de terre de la constante de la cons	te ¢ e-Certi Expiry Date S 2.0, please con rring office hours	 Batcl mplete the relation Batcl 	(Reinstate h No. ↓ evant payment (Not to Renew
egistration pplication Status Keyl and Paye Reyard Company Service Company Heyer Compa	When relea HK No. Product * Require: Please contransaction In case cert Note: Work	sed, the dowr ¢ N Confirme HK No. s Further plete the renet at least 5 wor dicat by the renet at least 5 wor dicat by the renet the renet	load link (ame of Pr d Not t \$ Action wal proce (sing days s) cannot t include	roduct to Renew Name of Product Before Product Renewal edure at least 10 working days before th before the expiry date of the certificate Saturday / Sunday / Holiday(6). Name of Product	the expiry date of the second se	e certificate. If yo	keply D keply D	te ¢ Annu de terre de la constante de la cons	te ¢ e-Certi Expiry Date S 2.0, please con rring office hours Expiry Date	Batcl mplete the rel Batcl Batcl Batcl Batcl	(Reinstate h No. ♀ evant payment (Not to Renew h No. ♀

2.3.4 Cancellation Request Online Notification

Users can view the basic application information such as the product information:

Step 1:

- Click the menu item "Online Notification" in the menu on the left.
- Click the hyperlink "Open" to view the notification.

	Onlir	ne Notification					0	NLINE_NOTIFIC	ATION_VIEW_01
T	New P	roduct Registration						Archiv	ved Notifications
		Notification Dat	e 🜩	Subject	4	Pr	oposed Name of Product	♦ PL No. ♦	Payment Status
u are login as	Open	12.01.2021 10:34:23		Certificate Payment Request		VOOIN	500 TABLETS SOOMO	PL0975/2010	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8	START	PL0004/2020	Paid
in date and time 11.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application		BOURE	ON POWDER	PL0002/2020	N/A
Online Notification	CORF	•						Archi	ved Notifications
My Product Search		Notification Date \$		Subject	\$ НК	No.	\$ 1	Name of Product	÷
In Deviatenties	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification	HK42660		CALCION UNISON TA	B 300MG	
lew Registration	<u>Open</u>	12.01.2021 17:38:55	Application Su	bmitted Notification	HK42660		CALCIUM UNICON TA	B 300MO	
hange of Registered	Open	12.01.2021 17:38:55	Application Sc	reening Notification	HK42660		CALCIUM UNISON TA	B-309MG	
Renewal of	Rene	wal of Registration						Arch	ived Notification
Registration		Notification Date \$		Subject	\$		Name of Product	¢	No. of Renewals
equest to Cancel roduct Registration	Open	27.01.2021 04:00:14	Renewal Notif	ication	DRUG NAM	IE XXXX T	AB 50MG	1	
Payment	Cance	ellation Request							
Application History		Notification Date \$		Subject	\$ H	No.	\$	Name of Product	4
	Open	26.01.2021 15:07:50	Cancellation F	tegistration Request Submitted Notification	HK31199		EFILIM FREEZE-DRIE	D FOR FOR IV IN	1400MG
Jser Profile	Non	Pharmaceutical Prod							
System	NOILI			0				() () ()	
ogout	Onen	Notification Date 11.02.2016 04:00:00		Subject ending Reminder		HK No. \$		ame of Product	:
- 3	Open	12.01.2016 04:00:02	renewal P	enang Reminaer		50464 50464	OSTECTINI 500 CAD 500		

Step 2:

• View the notification detail.

Ť	Online Notificat	ion				END_OF_PRODUCT_LIFE_NOTIFICA	TION Back
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 15:51	Notification Date : 07.08.20 Cancellation Reque			n			
Online Notification My Product Search	Dear Sirs/Madams, Cancellation of Drug/Prod	-					
+ New Registration	НК No. НК63533	¢ PR	PR No.	\$	TEST 20161208	Name of Product	•
+ Change of Registered Particulars	Thank you for your online ap providing professional and e	plication date xecutive sup	ed 07.08.2018 for canc port to the Pharmacy a	ellation of o	drug/product registration. F Board and its Committee.	Please return the original certificate to the Drug Office. The Department of Health is	;
+ Renewal of Registration	We acknowledge the receipt	of your appli	cation and it is now bei	ng process	sed.		
+ Interview + Request to Cancel						E	Back

2.3.5 Non Pharmaceutical Product Alert Online Notification

Users can view the basic application information such as the product information and the alert detail:

Step 1:

- Click the menu item "Online Notification" in the menu on the left.
- Click the hyperlink "Open" to view the notification.

•	Onlir	ne Notification						O	ILINE_NOTIFIC	ATION_VIEW_0
T	New P	roduct Registration							Archiv	ed Notifications
		Notification Dat	e \$	Subject		¢	Pro	oposed Name of Product	♦ PL No. ♦	Payment Statut
ou are login as	Open	12.01.2021 10:34:23		Certificate Payment Request			VOOIN	500 TABLETS 500MO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA 8	START	PL0004/2020	Paid
gin date and time	Open	20.11.2020 16:45:42		Screening Application			BOURB	ON POWDER	PL0002/2020	N/A
Online Notification	CORF								Archi	ved Notification
My Product Search		Notification Date \$		Subject	\$	НК	No.	\$ N	ame of Product	\$
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification		HK42660		CALCIUM UNISON TAE	SUOMG	
New Registration	Open	12.01.2021 17:38:55	Application Su	bmitted Notification		HK42660		OALOUM UNISON THE	- OM000	
Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sci	eening Notification		HK42660		CALCIUM UNISON TAE		
Renewal of	Rene	wal of Registration							Archi	ved Notification
Registration		Notification Date \$		Subject	φ.			Name of Product	¢ 1	lo. of Renewals
Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notif	cation		DRUG NAM	E XXXX T.	AB 50MG	1	
Payment	Canc	ellation Request								
Application History		Notification Date \$		Subject	¢	HK	No.	\$ N	ame of Product	4
	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification		HK31199		CFILIM FREEZE-DRIED	PERFORINING	400MG
User Profile	Non	Pharmaceutical Prod	uct Alert							
System	Non	Notification Date		Subject		♦ H	K No. 🗢	Na	me of Product	
Logout	<u>Open</u>	11.02.2016 04:00:00		ending Reminder			0464			
	Open	12.01.2016 04:00:02		ending Notification			0464	OSTECTIN 500 CAR 500M	-	

Step 2:

• View the notification detail.

Ť	Online Notifi	ication	Detail			
						Back
You are login as WONG David ABC COMPANY LIMITED Login date and time	Renewal Pendir	ng Notifi	cation			
17.08.2018 16:00	Notification Date: 21.	03.2016 16	:43:10			
Online Notification	Please be informed that	at the belov	v product(s) does	not fal	II within the meaning of pharmaceutical product and, for this reason, is exempt from registration control under the Pharmac	/ and
My Product Search	Poisons Ordinance and Poisons Board and its	d its regula Committee	tions. Registration s.	of the	Il within the meaning of pharmaceutical product and, for this reason, is exempt from registration control under the Pharmac a product is therefore not renewed. The Department of Health is providing professional and executive support to the Pharm	acy and
+ New Registration	As the product is not p diseases. Otherwise, the regulations.	harmaceuti he product	cal product, I wish will fall within the	n to re meani	mind you that no promotional or advertising materials should carry any implication on the product for treating or preventing ing of pharmaceutical product and the sale of unregistered pharmaceutical product is an offence under the above Ordinanc	e and its
+ Change of Registered Particulars	regulations.					
Falticulars	HK No.	\$	PR No.	\$	Name of Product	\$
+ Renewal of Registration	HK47678	PR1	402/2000		PRODUCT NAME XXXX	
+ Interview	L					
+ Request to Cancel Product Registration						Back

2.4 MY PRODUCT SEARCH

My Product Search function allows user to search four categories of information under his access control base on different searching criteria:

- registered product
- product under new application
- product under change of registration product
- product under renewal application

Step 1:

- Click the menu item "My Product Search" in the menu on the left.
- Input the searching criteria, including range of HK No., range of PR No. (e.g. PR 0060/2015), range of PL No. (e.g. PL 0001/2015), the keyword of product name or the active ingredient(s) of the product (any of these).

	My F	roduct	Search														
T	_															Searc	ch Clear
	HK No).		нк	- Hł	<											
'ou are login as ORG Trial)ne	PR No).		PR	1	- PR		1									
ESTING LIMITED ogin date and time 8.01.2021 09:10	PL No			PL	/	- PL		/									
Online Notification		ict Name e Ingredien	t(e)		ntains All 🔿 (Contains Fith	er One (Evert Mat									
My Product Search	Active	mgreuten	43)) Exact mate									
+ New Registration					-												
+ Change of Registered Particulars																Searc	ch Clear
+ Renewal of									uct Infor	mation							
Registration	Seq.	HK No.		Pr	oduct Name		No. of Ingre	Active lient			Active Ing	redient(s)			Status	PI	R No.
 Request to Cancel Product Registration 	R (1 to 1 of	1 rows		10 🗸											
+ Payment							lew Applic	ation for Reg	istration	of Pharmace	utical Produ	ict					
Application History	Seq.	Application Ref. Number	PL No.	PR No.	Proc	luct Name		No. of Active predient		Activ	ve Ingredient	t(s)		Status	Submission Date	Last Updated By	Last Update Date
+ User Profile																	
+ System	•		1 to 1 of	1 rows	() ()	10 🗸											
Logout								ered Particula			armaceutical						
Logour	Seq.	HK No. 4	Application Ref. Number		Product Name	Ac	o. of ctive redient		Active Ing	redient(s)		Application Type	Category	Status	Submission Date	Last Updated By	Last Update Date
			1 to 1 of	1 rows	• •	10 🗸											
								Pr	duct Ren	newal							
	Seq.	HK No.		Produc	ct Name	No. of Ingr	f Active edient		Ad	ctive Ingredie	ent(s)		Status	Expir Date	y Last Up B	odated /	Last Update Date
	R (1 to 1 of	1 rows	•	10 🗸											
				2015 c	opyright Impo	rtant notices	Last R	evision Date	02 Sep	2020 Ver	sion: 1.0.99	(PP)					

Step 2:

- There are 3 options for the searching criteria of active ingredient, including "Contains All", "Contains Either One" and "Exact Match".
- The active ingredient name preferably be the full name of the ingredient (except Exact Match). System provides auto-complete function for the active ingredient(s) input field.
 - If the ingredient is a poison, enter the keyword as the name appears in Poison List.
 - If the ingredient is not a poison but in any of the monographs, enter the keyword as the name appears in monographs of British Pharmacopeia, British Pharmaceutical Codex or British Veterinary Codex / name appears in International Nonproprietary Names (INN).
 - In any other case the accepted scientific name.

Active Ingredient(s)	💿 Contains All 💿 Contains Either One 💿 Exact Match
Haemophilus	
Haemophilus influe	enzae type b

- For "Contains All", system will only search the product(s) which contains all of the below ingredient(s) (maximum 3 ingredients).
- For "Contains Either One", system will only search the product(s) which contains either one of the below ingredient(s) (maximum 3 ingredients).
- For "Exact Match", system will only search the product(s) which is exact match with the keyword entered and exact match to the combination of ingredient(s) entered (no more or less).

Step 3:

• Click the button "Search" to search, based on the searching criteria, or click the button "Clear" to remove all the searching criteria.

	My F	Product	Search											
Y													Sear	ch (Clear)
	HK N	0.		нк	- HK									
You are login as Irene Chu DEF COMPANY	PR No	D.		PR	1	- PR	Ĩ							
Login date and time 17.03.2015 18:10	PL No) .		PL 0000	/ 1994	- PL 333	33 / 20	15						
Online Notification	1.1.1.1.1.1.1.1	uct Name e Ingredie	n#(a)	© 000	taina All 🗢 Cante	aiaa Fithar Oa	a 🗢 Event Mi	ntah						
My Product Search	Active	e ingreaie	nu(s)	0.00	tains All 💿 Conta	ans Einer On	e O Exact Ma	aton						
+ New Registration														
+ Change of Registered Particulars													Sear	ch Clear
+ Renewal of								er Product Information						contract.
Registration	Seq.	HK No.		Pro	duct Name	Ne	o. of Active ngredient	Active	Ingredient(s)			Status	F	R No.
+ Submission of Other Post-registration Supplement	•	0	1 to 1 of	1 rows	ю ю 1	0 -								
+ Interview							New	Application Information						
+ Request to Cancel Product Registration	Seq.	Application Ref. Number	n PL No.	PR No.	Product	t Name	No. of Active Ingredient	Active Ingre	dient(s)		Status	Submit Date	Last Update By	Last Update Date
+ Payment	•	0	1 to 1 of	1 rows	• • • 1	0 💌								
Application History							Change of R	egistered Product Information						
+ User Profile	Seq.	HK No.	Application Ref. Number	F	roduct Name	No. of Active Ingredie		Active Ingredient(s)	Application Type	Category	Status	Submit Date	Last Update By	Last Update Date
+ System														
Logout		0	1 to 1 of	1 rows	D 🖲 🗎	0 💌								
Logoui							Produ	ct Renewal Information						
	Seq.	HK No.		Product	Name	No. of Acti Ingredier		Active Ingredient(s)		Status	Expiry Date	Last Up	date By	Last Update Date
	•	9	1 to 1 of	1 rows	• • 1	0 💌								

Step 4:

- The product(s) and application(s) are shown in different pools with basic information.
- Click the hyperlink of the "Seq." to view the detailed information.
- For "Active Registered Product Information" pool, a detailed page is shown. For "New Application Information" pool, "Change of Registered Product Information" pool and "Product Renewal Information" pool. The corresponding application detail is shown.

	My	Product	t Search	1									
Ť												Sea	rch Clea
	HK N	o.		нк - нк									
'ou are login as ORG Tria)ne	PRN	0.		PR 0060 / 199	5 - PR	8888 / 2	2019						
ESTING LIMITED ogin date and time 8.01.2021 09:10	PL N	0.		PL /	- PL	/							
Online Notification		uct Name					N-t-b						
My Product Search	Activ	e Ingredie	ent(S)	Contains All C	ontains Eith	er Une () Exact	Match						
New Registration	臣												
Change of Registered Particulars												Sea	rch Clea
Renewal of	<u> </u>						Product Information						
Registration	Seq.	HK No.		Product Name		No. of Active Ingredient		Active Ingredier	it(s)		Status		PR No.
Request to Cancel Product Registration	1	HK41190	PRODU	JCT NAME XXXXX XXXX		3	C1.1 biodiastase 25mg/1table C1.2 dried aluminium hydrox C1.3 methiosulfonium chlorid	et ide gel 192mg/1t le 25mg/1tablet	ablet		Active	PR05	52/1996
Payment	2	HK42175		DOMETHACIN 25 CAP 25M	G	1	C1.1 indomethacin 25mg/1ca	apsule			Active		22/1996
Application History	<u>3</u> 10	HK60366	DRUG 1 to 3 of	3 rows	10 🗸	1	C1.1 acarbose 50mg/1tablet				Active	PR12	11/2009
User Profile						ew Application fo	r Registration of Pharmaceuti	ical Product					
System	Seq.	Applicatio Ref. Number	n PLNo.	PR No. Prod	uct Name	No. of Active Ingredient	Active	ingredient(s)		Status	Submission Date	Last Update By	Last Update Date
Logout													
	H	9	1 to 1 of	1 rows	10 🗸								
	Seq.	HK No.	Application	Product Name	No. of Active	-	ticular(s) of Registered Pharn ctive ingredient(s)	Application		Status	Submission	Last	Last
			Ref. Number		Active Ingredier	ıt		Туре			Date	Updated By	Date
	1	HK41190	CORP- HK41190- 201857483	PRODUCT NAME XXXXX XXXX	3	192mg/1tablet	e 25mg/1tablet inium hydroxide gel onium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	5	Application Under Screening	21/08/2018	Drug Office	21/08/201
	2	HK41190	CORP- HK41190- 201857485	PRODUCT NAME XXXXX	3	192mg/1tablet	e 25mg/1tablet inium hydroxide gel onium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	4	Application Evaluated	21/08/2018	Drug Office	21/08/20
	3	HK41190	CORP- HK41190- 202050013	PRODUCT NAME XXXXX XXXX	3	192mg/1tablet	e 25mg/1tablet inium hydroxide gel onium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	3,4,7	Application Evaluated	05/06/2020	Drug Office	12/01/202
		HK42175	CORP-	APT-INDOMETHACIN 25 CAP 25MG	1	C1.1 indometha	cin 25mg/1capsule	Certificate holder initiated - Response	1,2,3,4,5,6,7,8	Application Approved	18/04/2017	ORG Trial One	27/02/201
	4		HK42175- 201753699- 02					to clarification letter					
	4		201753699-	4 rows	10 🗸			clarification					
			201753699- 02	4 rows (H) (H)	10 🗸		Product Renewal	clarification					
			201753699- 02	4 rows (8)	No. of	'Active edient	Product Renewal Active Ingredient	clarification letter	Statu	is Exp Da	lry Last U le E	pdated Sy	Last Update Date
	(1)		201753699- 02 1 to 4 of		No. of	adient		clarification letter	Statu Pending Reply	Da	10 E	sy	Last Update Date 27/01/202

Step 5:

- The detailed page shows the basic information (e.g. HK No, PR No., registration date, etc), the contact information (e.g. contact person, phone number, and email), the product detail (e.g. active ingredient, strength, dose form, route of administration) and the batch manufacturer detail (e.g name of manufacturer, country, manufacturing role, etc).
- For detail page of application, user can click the application ref. number to redirect to the corresponding application summary page.

					Close
	TEST 2017010501 (test6)		Manufacturer appeared or	product label of finished product	
You are login as WONG David	HK No. :	HK63532	Name of Manufacturer :	MANU NAME XXXX	
ABC COMPANY LIMITED	PR No. :	PR0001/2017	Manufacturer Address :	MANU ADDRESS XXXXX XXXXX XXXXX	
17.08.2018 16:16	PL No. :	PL0001/2017	Place/Region :	ICELAND	
Online Notification	Application Ref. Number :	CORP-HK63532-201750110	Manufacturing activities/role	: Manufacturer of Dosage Form	
My Product Search	Application Type :	Human chemical pharmaceutical product			
+ New Registration	Registration Date :	06/01/2017			
+ Change of Registered	Expiry Date :	05/01/2022			
Particulars	Legal Classification :	Part 1 Poison			
+ Renewal of Registration	Contact Person :	fdasf			
+ Interview	Phone No. :	12345678			
+ Request to Cancel Product Registration	Email :	gafdg@fda.com			
+ Payment	Active Ingredient Populus tremula extract	Strength 1 % / 1 L			
Application History	Dose Form				
+ User Profile	Pills Route of Administration				
+ System	Intrabursal				
Logout					Close

• The system will redirect to the corresponding application detail page.

										C
	Summary	e-Product File (e-PF) Change	DO Req.	Clarification Letter	Ack. Letter	CORP Change History	Ref. Material	Same Batch		
e login as WONG		Reference No.:		K63532-201750110		Application Status:		Certificate Fee F		_
OMPANY LIMITED date and time 018 16:16	Application E HK No.:		HK63532	-		Application Type: Previous App. Referen		Certificate holde	r initiated - New CORF	^o application
ne Notification		Received Date:	TEST 20 13.03.20	17010501 (test6) 17		DO Request Reference Client Date:		13.03.2017		
Product Search	Proposed Ef Hard Copy F	fective Date: Received Date:				Application Form Imag Justification (Urgent A	~	No File Chosen		
Registration	Submission	Acknowledgement:	Submiss	ion Acknowledgemer	<u>ut</u>					
nge of Registered iculars	Cate	gory 5 - Registration	Certifica	te Holder Ap	olied —					
ewal of stration	Particular	s Proposed to Change		Recal Requi		print Required Evalua	tion Comment	t and Result		
view	5.Registra	ation Certificate Holder								
uest to Cancel luct Registration	5.1-Chang	e in name and / or address of	the current	registration	Require	d V				
nent		ription of Change and Reason	sadsa		- Roquire					
ication History		Date: 14.03.2017				Sati	sfactory L	Insatisfactory	Acknowledged	Withdrawn
Profile	Supportin	g Documents:								
em	5.1 Chang	je in name and / or address	of the curre	ent registration cert	ficate holder					
om										

2.5 NEW REGISTRATION

2.5.1 Initiate New Product Registration

Step 1: Click the menu item "Initiate New Product Registration Application" under "New Registration" in the menu on the left.

	Online	Notification						ONLINE		ICATION_VI	EW_0
Ť	New Pro	duct Registration							Arc	hived Notific	ations
	No relate	ed notifications									
ou are login as ORG Trial											
ne ESTING LIMITED ogin date and time	CORP								Arc	hived Notific	ation
7.01.2021 09:43		Notification Date \$		Subject	\$	HK No.	\$	Name of	Produc	t	¢
Online Notification	Open	12.01.2021 17:44:04	Application Screening Notificat	ion		HK41190		PRODUCT NAME XXXXX XXXX	x		
	Open	05.06.2020 11:00:01	Application Submitted Notifical	ion		HK41190		PRODUCT NAME XXXXX XXXX	x		
My Product Search	Open	03.10.2019 11:55:37	Application Submitted Notificat	ion		HK37565		PRODUCT NAME XXXXX			
New Degistration	Open	04.03.2019 11:33:13	Application Approval Notification	n		HK31199		EPILIM FREEZE-DRIED PDR F	OR IV I	VJ 400MG	
New Registration	Open	27.02.2019 11:52:23	Certificate Fee Notification			HK65135		CELECOXIB FARMOZ			
Initiate New Product	Open	26.02.2019 15:12:46	Application Approval Notification	n		HK42175		APT-INDOMETHACIN 25 CAP	25MG		
Registration Application	Open	21.08.2018 18:25:53	Application Clarification Notific	ation		HK41190		PRODUCT NAME XXXXX XXXX	x		
	Open	21.08.2018 18:20:50	Application Screening Notification	ion		HK41190		PRODUCT NAME XXXXX XXXX	x		
Application Status - Action Required	Open	21.08.2018 18:19:47	Application Submitted Notifical	ion		HK41190		PRODUCT NAME XXXXX XXXX	x		
 Not Submitted Application Submitted 	Open	21.08.2018 18:07:37	Application Submitted Notificat	ion		HK37565		PRODUCT NAME XXXXX			
Withdraw application	Renewal	of Registration							Arc	hived Notific	ation
Change of Registered Particulars		Notification Date \$		Subject	\$		Nar	ne of Product	\$	No. of Renew	wals 4
	Open	27.01.2021 04:00:14	Renewal Notification			DRUG NAME XXX	х тав	50MG	1		
Renewal of Registration	Cancella	tion Request									
Request to Cancel Product Registration		Notification Date \$		Subject	¢	HK No.	\$	Name of	Produc	t	:
Payment	Open	26.01.2021 15:07:50	Cancellation Registration Requ	uest Submitted Notification		HK31199		EPILIM FREEZE-DRIED PDR F	OR IV I	NJ 400MG	
Application History	Non Pha	rmaceutical Produ	uct Alert								
User Profile	No relate	ed notifications									
System											

Step 2: The page is redirected to new application module in CTD format. It contains 5 modules:

- Module 1: Regional administrative information
- Module 2: Quality overall summary, non-clinical overview, non-clinical summary, clinical overview, clinical study.
- Module 3: Quality
- Module 4: Non-clinical study reports
- Module 5: Clinical study reports
- Filling in CTD Module 1 Page 1 and click the "Next" button. The current page will be saved and then will be directed to next page.
- •
- Click the button "Save" to save the content in the current page.
- Click the button "Save and Exit" to save the content and redirect to the application list.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.
- You cannot save or go to next page if you have not completed the mandatory fields.
- Select the application form (generic or NCE).
- Enter the proposed name of product. (in Capital letters)
- Input the name / proposed name used in other place and select the place.
- Select the no of component (Maximum: 5) and select the active ingredient, at least one component with 1 active ingredient is required.

• Select the application type.

10000 - 10000	Guidance										Save Save and Ex	xit Next
	New Pro	duct Red	istration							NEW_PR	ODUCT_REGISTRATION_V	/IEW_01
	The maximum File upload is				ile the ma	ximum total (ipload size pe	application	n is 100 MB.			
You are login as ORG Trial), please s	submit the	files to Drug	Office via CD			00 No. 1		
One TESTING LIMITED	Proposed Nan	ne of Product (English):					PL N	10.:	PR No.:	HK No.:	
Login date and time 26.01.2021 11:20	Module 1	Module 2	Module 3	Mo	dule 4	Module 5						
Online Notification												
Mu Des durt Count	Page 1	Page 2	Page 3 P	age 4	Page 5	Page 6	Page 7	Page 8	Page 9	Application Form		
My Product Search	Priority A	Application										
- New Registration	For priori	ity application	is, the followi	ng suppo	rting docu	iments are n	equired:	of currond	or original rad	istration upon		
Initiate New Product	appro	oval of registra	ation of the a	pplied pr	oduct and	I the original	registration of	ertificate o	of the existing	sistration upon product; or		
Registration Application		change of proc					nutacturer to	r the chang	e.			
Application Status	1.0 Application	on Form*	Generic 💿 N	ew Cherni	ical Entity	(NCE)						
 Action Required Not Submitted Application Submitted 	1.0.1 Name o	of Drug / Pharm	naceutical Proc	luct / Sub	stance							
Withdraw application	1.0.1.1 Prope	osed Name of P	Product / Subst	ance								
· Change of Registered	a. P	roposed Name	of Product (i	English):*		PRODUCT N	IAME	2				
+ Change of Registered Particulars	b. P	roposed Name	of Product (Chinese),	if any:							
+ Renewal of	c. N	lames / Propo	sed Names Us	ed in Oth	er Places							
Registration	Na	ame: PRODUC	T NAME			Place:	GERMANY		~			
+ Request to Cancel Product Registration	N	ame: PRODUC	T NAME			Place:	UNITED KING	DOM	~			
+ Payment	Na	ame:				Place:	Please Select		~			
								Add Mo	re			
Application History	1.0.1.2 Name	e of Active Sub	stance(s) / Ing	redient(s)	(Please lis	st below)						
+ User Profile	No.	. of Compone	nt(s)* 1 🗸									
+ System					Active	e Ingredient			Active Ing Appeared o	redient Product		
Logout									Lab	el		
	Con	mponent 11. *	bisbentiami	ne				~	bisbentiamin	e label		
		2.	None of the					~	New Ingredie	nt Name		
		3.	New Ingredi Please Sele		2							
		4.	Please Sele					~				
			- rease setter					Add More	•			
	1.0.1.3 Appli	ication Type: (please select o	ne) *								
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	-	Human chemic										
	-	Human vaccine										
		Pharmaceutica Veterinary bio		aceutical	product							
	01	Veterinary che	mical pharma									
		Veterinary vac ATP - gene the										
		ATP - gene une ATP - somatic										
	-	ATP - tissue er										
	Guidance										Save Save and Exit	Next
	Culdance		1	2015 copyr	right Impo	rtant notices	Last Revision	Date: 02 Se	ep 2020 Vers	ion: 1.0.99 (PP)	(Jare) (Jare and Exit	

Step 3: Filling in CTD Module 1 Page 2 and click the "Next" button.

- Select the dose form of product, route of administration of each component from the pull down menu.
- Enter the proposed indication(s) and corresponding dosage(s).
- Select the no of product pack size, maximum 10
- For each pack size, input the product pack size description
- For each component, input the packaging material, type of container, proposed shelf life and select the proposed storage conditions. Upload the stability report, in-use stability report and input the duration and the start date of real-time stability report.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

Page 1 Page 2 Page 3 Page 4 Page 5 Page 6 Page 7 Page 8 Page 9 Application Form 0.2 Dose Form (Applicable to Drug/Pharmaceutical Product Only) Component Dose Form of product:* 1 Cream ✓ Add 0.3 Indication, Route(s) of Administration and Dosage Indication:* Dosage:* Dosage of the Drug	Application	History Guida	nce							Back Save Save and Exi
page Name of Product (English): PROUNT NAME PLANE THE NET OF THE N	lew Proc	duct Reg	istration						NEW_PR	ODUCT_REGISTRATION_VIEW_
Abcdule 1 Module 2 Module 3 Module 4 Module 5 Page 1 Page 4 Page 5 Page 6 Page 7 Page 8 Page 9 Application Form 0.2 Obse form (Applicable to Drug/Pharmacultical Product Only) Component Dose form of product:* I ream I Add Osage of the Drug I ream I Add Osage of the Drug I dication:* I dication:* I dication:* Add 0.3 Indication: Dose for of product:* Add 0.4 Component: Route of administration* Apply for Data Exclusivity/Description 1 Module 7 2/12/ bitter/box Osage:* 0.4 Container. Counce and Administrative Device(), Including description of material from which it is constructed No. of Product Pack Size():* I with bitter box; I with bitter box; I with bitter box; 0.4 Conduct Pack Size(): I with bitter box; I with bitter bitter, box; I with bitter bitter, box; I with bitter, box; I wit	he maximum i ile upload is n	upload size of allowed for	single file is 1ME modules 2 - 5, p	3, while the n lease submit	naximum total u the files to Dru	pload size per g Office via CD	application is /DVD if neces	10MB. sary.		
Page 1 Page 2 Page 3 Page 4 Page 5 Page 6 Page 7 Page 8 Page 9 Application Form 0.2 Once Form (Applicable to Durg/Pharmacutcleal Product Day) Component Dose Form of product: 1 Cream Add 0.3 Indications. Nature(s) of Administration and Doseps Indications. 1 Minocillaneous: 1 Minocillaneous: 1 Minocillaneous: 1 Minocillaneous: 1 Minocillaneous: 1 Product Pack Size 2 X 125 bilister/box. 1 Product Pack Size 2 X 145 bilister/box. 1 Product Pack Size 2 Y 145 bilister/box. 1 Product Pac	oposed Nam	e of Product (E	nglish): PRODU	CT NAME			PL No		PR No.:	HK No.:
2.2 Does Form (Applicable to Drug/Pharmaceutical Product Only) Component: Does Form of product: 1 Cream V Add 3.3 Indication, Recuted of Administration and Desge Indication: 1 Docage of the Drug Doca	Module 1	Module 2	Module 3	Module 4	Module 5					
2.2 Does Form (Applicable to Drug/Pharmaceutical Product Only) Component: Does Form of product: 1 Cream V Add 3.3 Indication, Recuted of Administration and Desge Indication: 1 Docage of the Drug Doca	Page 1	Page 2 P	age 3 Page	4 Page	5 Page 6	Page 7	Page 8	Page 9	Application Form	
Component Does Form of product:* 1					1					
0.3 Indication, Route(s) of Administration and Bosge Indication of the Drug Decage:* Decage of the Drug Decage Decage of the Drug Decage D										
Indication:** Docage:* Indication of the Drug	1	Cream		Add						
Indication of the Drug Dosage of the Drug Image: Component Route of administration* Apply for Data Exclusivity/Description 1 /Miscellaneous Add 0.4 Container, Closure and Administrative Device(s), including description of material from which it is constructed No. of Product Pack Size* 2 x 175 bitster/box 0.4. One of Container, Closure and Administrative Device(s), including description of material from which it is constructed No. of Product Pack Size* 2 x 175 bitster/box 0.4. One of Contact with the product) If (months) If if end contact with the product) If (months) Forgoosed storage conditions* Stability Report* Image: Contract with the product) If (months) Forgoosed storage conditions* Stability Report* Image: Contract with the product) If (e.g., vial, hDPC) Evaluation Do not store over 25°C Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact with the product) Image: Contact w			Administration a							
Image: state of administration Apply for Data Exclusivity/Description Image: state of administration Apply for Data Exclusivity/Description Image: state of administration Image: state of administration I						ug				
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Component Route of administration* Apply for Data Exclusivity/Description 1 Miscellaneous Add 0.4 Container, Closure and Administrative Device(s), including description of material from which it is constructed No. of Product Pack Size(s):* 2 1. Primary Container (container that is in Proposed Storage conditions* Stability Report* 1. Au De not store over 25'C 24 24 Do not store over 25'C 24 In-Use Stability Report* 1. Au Delster/box, 15g tube/box) Upload 2. Product Pack Size* 2 x 48's bilister/box, 100's bottle/box, 15g tube/box) Value 2. Product Pack Size* 2 x 48's bilister/box, 100's bottle/box, 15g tube/box) Value In-Use Stability Report* In-Use Stability Report* 2. Product Pack Size* 2 x 48's bilister/box, 100's bottle/box, 15g tube/box) Stability Report* In-Use Stability Report* 2. Product Pack Size* 2 x 48's bilister/box, 15g tube/box) In-Use Stability Report* In-Use Stability Repor				\sim			~	(bbA)		
1 Miscellaneous Add 0.4 Container, Closure and Administrative Device(s), including description of material from which it is constructed No. of Product Pack Size(s)* 2 1 Product Pack Size(s)* 2 1. Product Pack Size(s)* 2 1. Product Pack Size(s)* 2 0. of Primary Container (container that is in Proposed storage conditions* Stability Report* 0. primary Container (container that is in Proposed storage conditions* Stability Report* 0. primary Container (container that is in Proposed storage conditions* Stability Report* 0. primary Container (container that is in Proposed storage conditions*) In-Use Stability Report* 0. primary Container (container that is in Proposed storage conditions*) Watch Mut, HUPE) 0. do of File(s): 1 Upload 1 Au Wister/box, 1000's bottle/box, 15g tube/box) 1 Component Primary Container (container that is in Proposed shelf Proposed storage conditions* 1 Au Wister/box, 1000's bottle/box, 15g tube/box) 1 Au Wister/box, 100's bottle/box, 15g tube/box) 24 Do not store over 25'C 24 10.05.2015 24 Do not store over 25'C <td< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>										
0.4 Container, Closure and Administrative Device(s), including description of material from which it is constructed No. of Product Pack Size(s): 1. Product Pack Size(s): 2. X 14's blister/box (e.g.: 2 X 14's blister/box, 100's bottle/box, 15g tube/box) Component Packaging Material Type of container (e.g. dbss (e.g.: 2 X 14's blister/box, 100's bottle/box, 15g tube/box) 1. Alu Do not store over 25'C ✓ 2. Product Pack Size" 2. X 14's blister/box, 100's bottle/box, 15g tube/box) Component Primary Container (container that is in Proposed shelf Proposed storage conditions* (e.g. dbss (e.g. 2 X 14's blister/box, 15g tube/box) 2. Product Pack Size" 2. X 14's blister/box, 100's bottle/box, 15g tube/box) Component Primary Container (container that is in Proposed shelf Proposed storage conditions* (e.g. 2 X 14's blister/box, 100's bottle/box, 15g tube/box) Component Primary Container (container that is in Proposed shelf Proposed storage conditions* (e.g. 2 X 14's blister/box, 100's bottle/box, 15g tube/box) Component Packaging Material Type of container 1. Alu De not store over 25'C ✓ 2.4 10.05.2015 Upload No of File(s): 1 Upload No of File(s): 0 Upload No of File(f administratior				a Exclusivity/	Description		
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Step 4: Filling in CTD Module 1 Page 3 and click the "Next" button.

- Verify the information under the sections applicant information and proposed registration certificate holder
- Input the contact person information including contact person name, phone number, position, email and fax no.
- Select the business type.
- Input the information of person responsible for pharmacovigilance if applicable.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

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Page 1	Page 2	Page 3 Pa	ge 4 Pag	e 5 Page 6	Page 7	Page 8	Page 9	Application Form		
.0.5 Legal St	itatus									
.0.6 Applica	ant Information	1								
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Step 5: Filling in CTD Module 1 Page 4 and click the "Next" button.

- Input the information of manufacturer appeared on product label of finished product, including: place/region, name of manufacturer and address.
- The Chinese name of manufacturer and its address is mandatory if the region is "China" or "Taiwan".
- Upload GMP certificate and manufacturer licence, and input its certificate or licence number and expiry date.
- Select the manufacturing activities / role, Manufacturer role "batch release manufacturer of finished product" should be specified to at least one manufacturer.
- Input other manufacturer information if more than one manufacturer involved in the preparation of the product / substance.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

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Page 1	Page 2	Page 3 P	age 4 Pa	ge 5 Page 6	Page 7	Page 8	Page 9	Application Form	
.0.7 Manufa									
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Step 6: Filling in CTD Module 1 Page 5 and click the "Next" button.

- Input the qualitative and quantitative composition in terms of the all active ingredient(s) and all the excipient(s), including the name, strength value and unit, dose value and unit, as stated in the master formula. (Note: synonyms should be considered before entering new names)
- User can now export the Excipient as CSV so that they can import the CSV next time and do no need to input Excipient again.
- Select the reference / monograph standard if applicable.
- Input additional information for the active ingredient if any.
- Fill in 1.0.8.2 or/and 1.0.8.3 if the product contains animal or human origin materials.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

New Product Registration New_PRODUCT_REGISTRATION_VI The maximum upload size of single file is MB, while the maximum total upload size per application is 10MB. Proposed Name of Product (English): ONLINE 2017012 PL No: PR No: HK No: Module 1 Module 3 Module 4 Module 5 P. ge a Page 3 Page 4 Page 6 Page 7 Page 8 Page 9 Application Form 1.0.8.0 qualitative and Quantitative composition 1 1.0.8.1 qualitative and Quantitative composition in Terms of the Active Ingredient(s) and the Excipient(s) Image 2 1.0.8.1 qualitative and Quantitative composition in Terms of the Active Ingredient(s) and the Excipient(s) Image 2 1.0.8.2 qualitative and Quantitative composition in Terms of the Active Ingredient(s) and the Excipient(s) Image 2 1.0.8.2 qualitative and Quantitative composition in Terms of the Active Ingredient(s) and the Excipient(s) Image 2 Please select those excipient suitable to use the "Export" function to export the inputted excipient list. Image 2 Vene input is complete, you are advised to use the "Export" function to export the input de excipient list. Image 2 Vene input is complete, you are advised to use the "Export" function to export the input de excipient list. Image 2 Image 2 Input is the active ingredient(s)* Quantity Unit	Guidance										Back Save Sa	ve and Exit
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Module 1 Module 2 Module 4 Module 5 Page 1 Page 2 Page 4 Page 5 Page 6 Page 7 Page 9 Application Form 1.0.8.Qualitative and Quantitative composition Interms of the Active Ingredient(s) and the Excipient(s) © Page 1 Page 2 Page 4 Page 5 Page 6 Page 7 Page 9 Application Form 1.0.8.1 Qualitative and Quantitative composition Interms of the Active Ingredient(s) and the Excipient(s) © Page 1 Page 4 Page 4 Page 6 Page 7 Page 9 Application Form 1.0.8.1 Qualitative and Quantitative composition Interms of the Active Ingredient(s) and the Excipient Iist, you computer in .csv file format. Nettime when you have to amend the content of excipient Iist, you can use the "Input" function to retrieve the saved excipient Iist. Please Iist the active Ingredient(s) and the excipient(s) as stated in the Master Formula: Component1 Tomport1 Quantity Unit (Strength Unit)* Dose Value* Dose Unit* Reference / Monograph Stand: 1 Bordetella pertussis Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Monograph Mo	The maximum	upload size of	single file is 1	MB, while t								
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 1.0.8 Qualitative and Quantitative Composition 1.0.8.1 Qualitative and Quantitative Composition in Terms of the Active Ingredient(s) and the Excipient(s) Please select those excipients available under the drop down list When input is complete, you are advised to use the "Export" function to export the inputted excipient list and save in your computer in .esv file format. Next time when you have to amend the content of excipient list, you can use the "Import" function to retrieve the saved excipient list. Please list the active ingredient(s) and the excipient(s) as stated in the Master Formula: Component: Name of Active Ingredient(s)* Quantity (Strength Value)* Unit (Strength Unit)* Dose Value* Dose Unit* Reference / Monograph Stand: (Strength Value)* Additional Information Lest Excipient* Quantity (Strength Value)* Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add Monograph Add This component does not have any excipient. Import CSY Export as CSY Clean all D Excipient* Quantity (Strength Value)* Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add Monograph Add TEST ▼ Please Selix \@ monoir and and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicin product? No Yes, please fill in the following. 	Module 1	Module 2	Module 3	Modu	ile 4	Module 5						
 1.0.8.1 Qualitative and Quantitative Composition in Terms of the Active Ingredient(s) and the Excipient(s) Please select those excipients available under the drop down list When input is complete, you are advised to use the "Export" function to export the inputted excipient list and save in your computer in .esv file format. Next time when you have to amend the content of excipient list, you can use the "Import" function to retrieve the saved excipient list. Please Ist the active ingredient(s) and the excipient list, you can use the "Import" function to retrieve the saved excipient list. Please Ist the active ingredient(s) and the excipient list, you can use the "Import" function to retrieve the saved excipient list. Please Ist the active ingredient(s) and the excipient list, you can use the "Import" function to retrieve the saved excipient list. Please Ist the active ingredient(s) and the excipient list, you can use the "Import" function to retrieve the saved excipient list. Please Ist the active ingredient(s) and the excipient(s) as stated in the Master Formula: Component1 Name of Active Ingredient(s) Additional Information Lest Additional Information Lest Additional Information Lest Quantity Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add Nonograph Standard Lexcipient* Quantity Value,* Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add Nonograph Standard Lest Remo 1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicie product?	Page 1	Page 2	Page 3 Pa	nge 4	Page 5	Page 6	Page 7	Page 8	Page 9	Application Form		
1 Bordetella pertussis test % v/w 1 PRLS Data Conversion ∨ USP ∨ Additional Information test Add This component does not have any excipient. Add Excipient* Quantity Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add adipic acid 0.5 AHU 1 TEST Please Selk ∨ Remo 1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicir product? • • No ○ Yes 1.0.8.3 Does the product contain human plasma-derived ingredients? • • No ○ Yes, please fill in the following.	When Next t Pleas	input is comp time when you se list the act Component1—	lete, you are a 1 have to amer tive ingredier	dvised to u d the conte it(s) and th	ise the "Ex ent of exc he excipi	port" functio ipient list, yo ent(s) as sta	u can use th ted in the I	e "Import" fu Aaster Form	nction to ret ula:	rieve the saved excipie	nt list.	
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Add This component does not have any excipient. Excipient* Quantity Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add adipic acid 0.5 AHU 1 TEST Please Sele Remo 1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicir product? • • No Yes 1.0.8.3 Does the product contain human plasma-derived ingredients? • • No Yes, please fill in the following.					onal Infor						0.51	
Import CSV Export as CSV Clean all D Excipient* Quantity Unit (Strength Unit)* Dose Value* Dose Unit* Function Reference / Add adipic acid V 0.5 AHU V 1 TEST V Please Sele V Remo 1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicir product? • • No O Yes 1.0.8.3 Does the product contain human plasma-derived ingredients? • • No O Yes, please fill in the following.										$\hat{}$	Add	
(Strength Value)*				· ·			(+) * D	so Value	Doco Uni		~ · _ ~	
 1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicir product? • • • No O Yes 1.0.8.3 Does the product contain human plasma-derived ingredients? • • • No O Yes, please fill in the following.		cipienc				strength on	it) Di	Jse value	Dose offi	runction	Monograph	Add
product? • ● No ○ Yes 1.0.8.3 Does the product contain human plasma-derived ingredients? • ● No ○ Yes, please fill in the following.	ac	dipic acid	~	0.5	AHU		~	1	TEST	✓	Please Sele	Remove
	produ • • 1.0.8.3 Does t	No Yes	ntain human p	lasma-deriv	ved ingred		an plasma-d	erived materi	als) containe	d or used in the manuf	facturing process of t	he medicinal
Guidance Back Save and Exit	• •	No 🔿 Yes, pl	lease fill in th	e following	g.							
	Guidance										Back Save Save	and Exit Ne

Step 7: Filling in CTD Module 1 Page 6 and click the "Next" button.

- Select and fill in the marketing authorization application of the product in other countries (1.0.9.1 to 1.0.9.3).
- For NCE application, please upload free sale certificates with approved/conditional approval status for two or more of the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK, USA or European Union.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

e maximum up e upload is not	uct Regist								Duck	Save Save and Exit
e upload is not		ration						1	NEW_PRODUCT	
oposed Name o	load size of sing t allowed for mo	gle file is 1MB, v dules 2 - 5, plea	vhile the max se submit the	imum total uploa files to Drug Off	d size per appl ice via CD/DVI	ication is) if neces	10MB. sary.			
	of Product (Engl	ish): PRODUCT	NAME			PL No	.:	PR No.:		HK No.:
Module 1	Module 2	Module 3	Module 4	Module 5						
Page 1 Pa	age 2 Page	e 3 Page 4	Page 5	Page 6	Page 7 P	age 8	Page 9	Application F	orm	
.0.9 Other Mark	keting Authoriza	tion Application	IS							
.0.9.1 Is there	another country	/region where a	n authorizati	on is granted for	the same prod	uct?				
* () No	D () Yes									
		re any differen	es which hav	e therapeutic ind	ications, dosag	e. contra	indication	or side effects be	tween this appli	cation and authorization
				pecified in 1.0.9.		c, contra	marcation		cheen and appli-	
* 💿 No	D 🔿 Yes									
0.9.3 Is there	another countrie	es/regions wher	e an authoriz	ation was refused	l / suspended /	revoked	by the con	petent authorities	for the same pr	oduct?
* 💿 No	D 🔿 Yes									
.0.9.4 Please li	ist marketing aut	thorization appl	ication(s) for	the same product	t in other coun	try/regior	here :			
Country	y/Region	Status		Date of Author	ization Produc	t Name		Free Sale Certificate(FSC) attached	Authorization Number	Expire Date of FSC
GERMA	ANY	✓ Appro	ved 🗸	01.08.2018	PROD	JCT NAM	E	Upload No of File(s): 1		
UNITE	D KINGDOM	✓ Appro	ved 🗸	01.08.2018	PROD	JCT NAM	E	Upload No of File(s): 1		
					Rer	nove	Add More)		

Step 8: Filling in CTD Module 1 Page 7 and click the "Next" button.

- Upload the requested file(s) accordingly. For each file list, multiple files can be uploaded.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

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					, while the max	imum total upl	oad size per	application	is 10MB.			
					, while the max ease submit th	e files to Drug	Office via CE					
oposed	Name	of Product (I	English): F	PRODUC	CT NAME			PL N	lo.:	PF	8 No.:	HK No.:
Module	1	Module 2	Modu	ile 3	Module 4	Module 5						
Page 1		Page 2	Page 3	Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Applica	tion Form	
1.0 An	nexed	Documents/ii	formatio	n/sample	Ð							
* Pi	rototy	pe sales pacl	k/outer a	nd inner	r container lat	els (Reference	e for 1.0.4 o	f Page 2)			Prototyp	e Sale Pack(s) List
.* Pa	ackage	e insert (Refe	erence for	r 1.0.3 c	of Page 2)							ge Insert(s) List
		rmaceutical r scanned im			e provide a sa oct samples	mple for inspe	ction. <mark>(</mark> Refe	rence for 1.	0.1.3 of Pag	e 1)	Upload No of File(] (<u>s): 0</u>
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pi fo	ackage or 1.0.	e insert, e.g. 4 of Page 2)	, measuri	ing cups	ponent(s) incl /spoons, syrin	ge, connectors					9 Upload No of File(] (s): 0
. In	forma	tion on the d	overseas l	egal sta	itus of the pro	duct.					Upload No of File(] <u>s): 0</u>
.* C	opy of	business reg	istration	certifica	ate. <mark>(</mark> Referenc	e for 1.0.6.1 o	of Page 3)				Upload No of File(] (<u>s): 1</u>
. A	uthori: elated	zation letter to this appli	from the cation) (i	applica f applica	ant authorizing able)	a person/com	npany to dea	al with the c	communicati	on matters	Upload No of File(<u>]</u> (s): 0
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0.* A di	n unde ocume	ertaking, give ents relating	en by the to the pro	applica oduct/si	nt to provide, ubstance upon	at any stage o request withi	of registration n the prescr	on, any infor ibed timefra	mation and/ ame	or	Upload No of File(<u>s): 1</u>
b	e show	/n on the lab	el issued	by com	compliance wit petent authori copy(ies) is re	ties.				ifacturer to	<u>Manufa</u>	<u>icturer(s) List</u>
m in	anufa specte	ctured, and t ed by or on b	the opera ehalf of t	itions ca the Phar	cturer(s) of th arried on or to rmacy and Poi nal Test) Comr	be carried on sons (Registrat	in the cours	e of manufa	acturing it, to	o be	Upload] s): 0
th	e pro	duct/substar	ice any re	auirem	turer of the pr ents imposed omplied with.						Upload No of File(] <u>s): 0</u>
4. Fl in	ow ch cludin	art indicatin ng testing site	g sequence. (Refere	ce and a ence for	activities of th 1.0.7 of Page	e different site 4)	es involved i	in the manu	facturing pro	ocess,	Upload No of File(] (s): 0

Step 9: Filling in CTD Module 1 Page 8 and click the "Next" button.

- Upload the requested file(s) accordingly. For each file list, multiple files can be uploaded.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

Application	History Gui	dance									Back Save Save and Ext
ew Pro	duct Re	gistrat	ion							NEW_F	PRODUCT_REGISTRATION_VIEW
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oposed Nan	ne of Product	(English):	PRODUCT	T NAME			PL N	o.:	PR N	b.:	HK No.:
Module 1	Module 2	Modu	ule 3	Module 4	Module 5						
Page 1	Page 2	Page 3	Page 4	Page 5	5 Page 6	Page 7	Page 8	Page 9	Application	n Form	
1.0 Annexe	d Documents	/informatio	n/sample								
					respect of its	manufactur	ing and quali	ty control fa			
personn	el. (Referend	ce for 1.0.	/ OF Page	4)						Jpload of File(s): 0
5.*Master I	Formula (con	nplete gua	litative ar	nd quantitat	ive compositio	on of the dru	g product iss	ued by the			<u> </u>
manufa	cturer) (Refe	rence for 1	1.0.8 of P	age 5)						Jpload of File(s): 1
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process,			/ith one o	r more of th	ie safety meas iuman, includi	ures taken t		he risk of	o for 1 0 s an	imals and	of the source of I/or human origin
									<u>1116</u>	aterials	
							aceutical pro	ducts. (Refe	rence for		
9. An unde	rtaking from	the manu	facturer o	of the produ	ct to inform t	ne applicanț	in case of ar	ly change in	nature or		
(s) or ex	of materials (ccipient(s)du 8 of Page 5)	(e.g., from ring the ap	plication	process or a	ed to animal/ after approval	human origi of registrat	n or vice-ver ion has been	granted. (Re	eference	Jpload of File(s	<u>): 0</u>
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excipier	nt(s) đường t	he applica	tion proce	ess or after a	nal/human ori approval of re	gistration ha	as been grant	ed. (Referer	nce for	Jpload of File(s). 0
	Page 5)				cts of plasma-					or rite(s	<u></u>
but not					ctivation proceed of products. (F				s taken to		
	submission of				untry of origin (ies) is require		nce for 1.0.9	of Page 6)			
Òfficial	evidence of	registratio	n approva	al of the pro	duct (e.g. orig es: Australia,	inal or certi	fied true cop	ies of free s	ale <u>L</u>	<u>ist showi</u> arket(s)	ng free sale certificate in othe
Czech R Latvia,	epublic, Den Lithuania, Lu	mark, Esto xembourg	onia, Finla , Malta, P	and, France, Ioland, Portu	Germany, Gro Igal, Romania	eece, Hollar	d, Hungary,	reland, Italy	v. Japan.		
4.* (For NC	and, UK and E)	ota (nele	rence for	1.0.9.4 01 P	age 0)						
Ċlinical	and non-clin	ical overvi	ews and o	quality overa	all summary					Jpload). <i>4</i>
5 Informa	tion on clinic	al trial(s)	performe	d in Hong Ko	ong (Please pro	vide clinica	l trial certifi	rate no /ap		of File(s	<u>): 1</u>
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Step 10: Filling in CTD Module 1 Page 9 and click the "Module 2" tab. Modules 2 to 5 are specific modules and are not mandatory for a generic product.

- Upload the requested file(s) accordingly. For each file list, multiple files can be uploaded.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.



Step 11: Filling in CTD Module 2 and click the "Next" button.

- Input the remarks if any.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

101111,	
Guidance	Back Save Save and Exit Next
New Product Registration	NEW_PRODUCT_REGISTRATION_VIEW_MODULE_02
The maximum upload size of single file is 50MB, while the maximum total upload size per application File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necr	n is 100MB. essary.
Proposed Name of Product (English): Indapamide-Trial Prolonged Release Tablets 1.5mg (AP6) PL N (CH3)	
Module 1 Module 2 Module 3 Module 4 Module 5	
2.1 Overall CTD Table of Contents of Modules 2-5	
Remarks:	
2.2 Introduction to Summary	
Remarks:	
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2.3 Quality Overall Summary	
Remarks:	
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2.3.S Drug Substance (name, manufacturer)	
Remarks:	
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2.3.P Drug Product (name, dosage form)	
Remarks:	
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2.3.A Appendices	
Remarks:	
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2.3.R Regional Information	
Remarks:	
2.4 Nonclinical Overview	
Remarks:	
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2.5 Clinical Overview	
Remarks:	
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2.6.1 Introduction	
Remarks:	
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2.6.2 Pharmacology Written Summary	
Remarks:	
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2.6.3 Pharmacology Tabulated Summary	
Remarks:	
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2.6.4 Pharmacokinetic Written Summary	
Remarks:	
2.6.5 Pharmacokinetic Tabulated Summary	
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2.6.6 Toxicology Written Summary	
Remarks:	
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2.6.7 Toxicology Tabulated Summary	
Remarks:	
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2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Method	
Remarks:	
A	
2.7.2 Summary of Clinical Pharmacology Studies	
Remarks:	
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2.7.3 Summary of Clinical Efficacy [indication]	
Remarks:	
✓	
2.7.4 Summary of Clinical Safety	
Remarks:	
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2.7.5 References	
Remarks:	
2.7.6 Synopses of individual studies	
Remarks:	
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Guidance	Back Save Save and Exit Next

Step 12: Filling in CTD Module 3 and click the "Next" button.

- Input the remarks if any.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

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Guidance	Ba	ick Save Save and Exit Nex
New Product Registration	NEW_PRODUCT_REG	ISTRATION_VIEW_MODULE_0
The maximum upload size of single file is 50MB, while the maximum total upload size per application is File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necess	100MB. arv.	
Proposed Name of Product (English): Indapamide-Trial Prolonged Release Tablets 1.5mg (AP6) PL No.: (CH3)		HK No.:
Module 1 Module 2 Module 3 Module 4 Module 5		
3.1 Module 3 Table of Contents		
Remarks:		
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3.2.S.1 General Information		
Remarks:		
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3.2.S.1.1 Nomenclature		
Remarks:		
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3.2.S.1.2 Structure		
Remarks:		
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3.2.S.1.3 General Properties		
Remarks:		
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3.2.S.2.1 Manufacturer(s)		
Remarks:		
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3.2.S.2.2 Description of Manufacturing Process and Process Controls		
Remarks:		
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3.2.S.2.3 Control of Materials		
Remarks:		
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3.2.S.2.4 Controls of Critical Steps and Intermediates Remarks:		
V		
3.2.S.2.5 Process Validation and/or Evaluation		
Remarks:		
V		
3.2.S.2.6 Manufacturing Process Development		
Remarks:		
\Box		
3.2.S.3.1 Elucidation of Structure and other Characteristics		
Remarks:		
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3.2.S.3.2 Impurities		
Remarks:		
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3.2.5.4.1 Specification	
Remarks:	
3.2.S.4.2 Analytical Procedures Remarks:	
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3.2.S.4.3 Validation of Analytical Procedures	
Remarks:	
✓	
3.2.S.4.4 Batch Analyses Remarks:	
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3.2.S.4.5 Justification of Specification	
Remarks:	
3.2.5.6 Container Closure Systems	
Remarks:	
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3.2.S.7.1 Stability Summary and Conclusions Remarks:	
3.2.S.7.2 Post Approval Stability Protocal and Stability Commitment	
Remarks:	
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3.2.S.7.3 Stability Data	
Remarks:	
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3.2.P.1 Description and Composition of the Drug Product Remarks:	
3.2.P.2 Pharmaceutical Development	
Remarks:	
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3.2.P.3 Manufacture	
Remarks:	
3.2.P.3.1 Manufacturer(s) Remarks:	
Remarks:	
3.2.P.3.2 Batch Formula	
Remarks:	
3.2.P.3.3 Description of Manufacturing Process and Process Controls	
Remarks:	
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3.2.P.3.4 Controls of Critical Steps and Intermediates	
Remarks:	

3.2.P.3.5 Process Validation and/or Evalution	
Remarks:	
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3.2.P.4 Control of Excipitents [name]	
Remarks:	
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3.2.P.4.1 Specification(s)	
Remarks:	
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3.2.P.4.2 Analytical Procedures	
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3.2.P.4.3 Validation of Analytical Procedures	
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3.2.P.4.4 Justification of Specifications Remarks:	
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3.2.P.4.5 Excipients of Human or Animal Origin	
Remarks:	
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3.2.P.4.6 Novel Excipients	
Remarks:	
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3.2.P.5.1 Specification(s)	
Remarks:	
3.2.P.5.2 Analytical Procedures	
Remarks:	
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3.2.P.5.3 Validation of Analytical Procedures	
Remarks:	
3.2.P.5.4 Batch Analyses	
Remarks:	
3.2.P.5.5 Characterization of Impurities	
Remarks:	
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3.2.P.5.6 Justification of Specification(s)	
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3.2.P.6 Reference Standards or Materialstermediates	
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3.2.P.7 Container Closure System	
Remarks:	
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3.2.P.8 Stability	
Remarks:	
3.2.P.8.1 Stability Summary and Conclusion	
Remarks:	
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3.2.P.8.2 Post-approval Stability Protocal and Stability Commitment	
Remarks:	
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3.2.P.8.3 Stability Data	
Remarks:	
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3.2.A.1 Facilities and Equipment [name,manufacturer]	
Remarks:	
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3.2.A.2 Adventitious Agents Safety Evaluation [name,dosage,form,manufacturer]	
Remarks:	
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2.2.A.2.Nevel Evolution	
3.2.A.3 Novel Excipients	
Remarks:	
3.2.R Regional Information	
Remarks:	
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3.3 Literature references	
Remarks:	
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Step 13: Filling in CTD Module 4 and click the "Next" button.

- Input the remarks if any.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

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Guidance		Back Save Save and Exit
New Product Registration	NEW_PRODUCT_R	REGISTRATION_VIEW_MODULE
The maximum upload size of single file is 50MB, while the maximum total upload size per application is 100MB. File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necessary.		
Proposed Name of Product (English): Indapamide-Trial Prolonged Release Tablets 1.5mg (AP6) PL No.: (CH3)	PR No.:	HK No.:
Module 1 Module 2 Module 3 Module 4 Module 5		
4.1 Module 4 Table of Contents		
Remarks:		
4.2.1.1 Primary Pharmacodynamics		
Remarks:		
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4.2.1.2 Secondary Pharmacodynamics		
Remarks:		
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4.2.1.3 Safety Pharmacology		
Remarks:		
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4.2.1.4 Pharmacodynamic Drug Interactions		
Remarks:		
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4.2.2.1 Analytical Methods and Validation Reports (if separate reports are available)		
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4.2.2.2 Absorption		
Remarks:		
4.2.2.3 Distribution		
Remarks:		
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4.2.2.4 Metabolism		
Remarks:		
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4.2.2.5 Excretion		
Remarks:		
4.2.2.6 Pharmacokinetic drug interactions (nonclinical)		
Remarks:		
Remarks:		
Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks: 4.2.3.1 Single-Dose Toxicity (in order by species, by route) Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks: 4.2.3.1 Single-Dose Toxicity (in order by species, by route) Remarks:		
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks: 4.2.3.1 Single-Dose Toxicity (in order by species, by route) Remarks: 4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive toxicokinetics evaluation)	ons)	
Remarks: 4.2.2.7 Other pharmacokinetics studies Remarks: 4.2.3.1 Single-Dose Toxicity (in order by species, by route) Remarks:	ons)	

4.2.3.3 Genotoxicity
Remarks:
4.2.3.3.1 In vitro
Remarks:
4.2.3.3.2 In vivo (including supportive toxicokinetics evaluations)
Remarks:
<u> </u>
4.2.3.4.1 Long-term studies (in order by species; including range-finding studies that cannot appropriately be included under repeat-dose toxicity or pharmacokinetics)
Remarks:
4.2.3.4.2 Short- or medium-term studies (including range-finding studies that cannot appropriately be included under repeat-dose toxicity or pharmacokinetics)
Remarks:
4.2.3.4.3 Other studies
Remarks:
4.2.3.5 Reproductive and Development Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the followir sub-headings should be modified accordingly.)
Remarks:
4.2.3.5.1 Fertility and early embryonic development
Remarks:
4.2.3.5.2 Embryo-fetal development
Remarks:
Antifar AS.
4.2.3.5.3 Prenatal and postnatal development, including maternal function
Remarks:
4.2.3.5.4 Studies in which the offspring (juvenile animals) are dosed and/or further evaluated
Remarks:
4.2.3.6 Local tolerance
Remarks:
4.2.3.7 Other Toxicity Studies (if available)
Remarks:
4.2.3.7.1 Antigenicity
Remarks:

4.2.3.7.2 Immunotoxicity	
Remarks:	
×	
4.2.3.7.3 Mechanistic Studies (if not included elsewhere)	
Remarks:	
4.2.3.7.4 Dependence	
Remarks:	
4.2.3.7.5 Metabolites	
Remarks:	
4.2.3.7.7 Other	
Remarks:	
0	
4.3 Literature References	
Remarks:	
Application History Guidance	Back Next Prin

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Step 14: Filling in CTD Module 5 and click the "Module 1" tab.

- Input the remarks if any.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

Guidance	Back	Save Save and Exit
New Product Registration	NEW_PRODUCT_REGISTRATION	VIEW_MODULE_05
The maximum upload size of single file is 50MB, while the maximum total upload size per application is 10 File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necessary	юмв. /.	
Proposed Name of Product (English): Indapamide-Trial Prolonged Release Tablets 1.5mg (AP6) PL No.: (CH3)	PR No.: HK M	No.:
Module 1 Module 2 Module 3 Module 4 Module 5		
5.1 Module 5 Table of Contents		
Remarks:		
\Diamond		
5.2 Tabular Listing of All Clinical Studies		
Remarks:		
\Box		
5.3.1.1 Bioavailiability (BA) Study Reports		
Remarks:		
\bigcirc		
5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports		
Remarks:		
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5.3.1.3 In Vitro - In Vivo Correlation Study Reports		
Remarks:		
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5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies		
Remarks:		
5.3.2.1 Plasma Protein Binding Study Reports and Related Information		
Remarks:		
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E 2 2 2 Provide of Harvelle Hotels live and Deve laboration Studies		
5.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies Remarks:		
^		
5.3.2.3 Reports of Studies Using Other Human Biomaterials		
Remarks:		
<u> </u>		
5.3.3 Reports of Human Pharmacokinetics (PK) Studies		
Remarks:		
<u> </u>		
5.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports and Related Information		
Remarks:		
\bigcirc		
5.3.3.2 Patient PK and Initial Tolerability Study Reports and Related Information		
Remarks:		
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5.3.3.3 Intrinsic Factor PK Study Reports and Related Information		
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Remarks:		
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5.3.3.4 Extrinsic Factor PK Study Reports and Related Information		
Remarks:		
5.3.3.5 Population PK Study Reports and Related Information		
Remarks:		
5.3.4.1 Healthy Subject PD and PK/PD Study Reports		
Remarks:		
5.3.4.2 Patient PD and PK/PD Study Reports		
Remarks:		
5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication and Related Information		
Remarks:		
5.3.5.2 Study Reports of Uncontrolled Clinical Studies and Related Information		
Remarks:		
<u>₩</u>		
5.3.5.3 Reports of Analyses of Data from More Than One Study (Integrated Summary of Safety Report)		
Remarks:		
5.3.5.4 Other Study Reports and Related Information (Special Pathogens and Immune Modulator Reports, Antiviral Reports)		
Remarks:		
5.3.6 Reports of Postmarketing Experience		
Remarks:		
5.3.7 Case Report Forms and Individual Patient Listings		
Remarks:		
5.4 Literature References		
Remarks:		
Application History Guidance		
2015 convrint Limonitant notices Last Revision Date: 02 Sen 2020 Version: 1.0.99 (PP)		

Step 15: Click the "Application Form" tab. Data on the application form is mapped from the corresponding data in Module 1. You can view the form and choose 'back' to revise the data, 'print' to print the form or 'proceed to submit' to submit the application.

	Guidance									Save	Save and Ex	tit Next
Ť	New Proc	duct Reg	istratior						NEW_PRO	DDUCT_REC	SISTRATION_V	IEW_01
	The maximum u File upload is n	upload size of ot allowed for	single file is modules 2 -	50MB, while the r 5, please submit	naximum tota the files to Dr	l upload size p Jg Office via Cl	er applicatio D/DVD if neo	n is 100 MB. essary.				
You are login as ORG Trial One	Proposed Name					-	PL		PR No.:	нк	No.:	
TESTING LIMITED Login date and time 26.01.2021 11:20	Module 1	Module 2	Module	Module 4	Module !							
Online Notification	Page 1	Page 2	Page 3 P	age 4 Page	5 Page 6	Page 7	Page 8	Page 9	Application Form	1		
My Product Search										-		
- New Registration	Priority Ap For priorit	y application	s, the followi	ng supporting de	ocuments are	required:						
Initiate New Product Registration Application	approv	val of registra	ition of the a	m or active ingre pplied product a e holder, a state	and the origin	al registration	certificate	of the existi	egistration upon ng product; or			
Application Status - Action Required - Not Submitted - Application Submitted				ew Chemical Enti luct / Substance	ty (NCE)							
Withdraw application	1.0.1.1 Propos	sed Name of P	roduct / Subs	ance								
+ Change of Registered Particulars		oposed Name oposed Name		English):* Ehinese), if any:	PRODUCT	NAME] ?) 1					
+ Renewal of Registration	c. Na	mes / Propos	ed Names Us	ed in Other Plac	es]					
+ Request to Cancel Product Registration		me: PRODUC				GERMANY	GDOM	~				
-	Nai	me:			Place	: Please Sele	ct	~				
+ Payment							Add Mo	ore				
Application History	1.0.1.2 Name	of Active Subs	tance(s) / Ing	redient(s) (Please	list below)							
+ User Profile	No.	of Componer	nt(s)* 1 🗸									
+ System				Act	ive Ingredie	it		Appeared	ngredient on Product			
Logout								La	bel			
	Com	ponent 11. *	bisbentiami	ne			~	bisbentiami	ne label			
		2.	None of the	above			×	New Ingred	ient Name			
		_	New Ingredi					1				
		3. 4.	Please Sele					1				
		4.	Please Sele	.t			Add Mor	e				
	1.0.1.3 Applica	ation Type: (p	lease select o	ne) *								
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	Guidance									Save	Save and Exit	Next
			:	015 copyright In	portant notice:	Last Revisio	n Date: 02 S	ep 2020 Ve	rsion: 1.0.99 (PP)			

Step 16: Click the "Proceed to Submit" button.

 ile upload is not allowed for Proposed Name of Product (E ofe: A specimen sales pack of d supporting documents issue ame of the Drug / Product / S ame of the Drug / Product / S Dose Form / Package Size(s) : Dose Form / Component 1 Package Size(s): etailed Qualitative and Quant omponent 1 Name of Active Ingredient 1. bisbentiamine 2. New Ingredient Name dications: 1. Indication of the Drug 	modules 2 - 5, please submit nglish): PRODUCT NAME PHARM/ APPLICATION FO APPLICATION FO be drug/product or sample of th by the health authority in the c ubstance ² , * (*(*Delete as ap PRODUCT NAME Cream Product Pack Size - 2 Product Pack Size - 2 Product Pack Size - 2 itative Composition : (s) Quantity (Strength Value) 1.5	ACY AND PO RM FOR REG PROI re substance and th propriate))	Control of the constant of the	PR No.: HAPTER 138)	HK No.: FORM6_VIE
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Name of Active Ingredient bisbentiamine New Ingredient Name dications: 1. Indication of the Drug	Value) 1.5				
New Ingredient Name dications: . Indication of the Drug	1.5	Unit (Strength Un	it) Dose Value	Dose Unit Reference / Monogr	raph Standard
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1. Indication of the Drug	200	mcg	1	tablet	
egistered and Marketed in W	nich Countries/Places : GEF UNI	RMANY TED KINGDOM			
ame of Applicant:	A	BC COMPANY LI	AITED		
usiness Registration No.:	0	0671890-000			
What Capacity the Applican	Makes This Application: In	nporter			
usiness Address of Applicar	t: 382, 3, A, CHA KWO LING	KOWLOON			
el No.:	23198414 (Contact Person				
	12345678 (Submitted By:W	VONG David)			
acsimile No.:					
	23198414 (Contact Person				
mail Address:	prs.david.wong@gmail.con prs.david.wong@gmail.con				
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	ne preparation of the product				
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			RATION OF APPLICAN		
the information given in thi	stration of the said pharmaceuti a application is correct.	cal products under	the Pharmacy and Poisons Ordi	nance. I hereby declare that, to the be	st of my knowledge and belief,
Name: WONG David				Position held:	
		e-Cert Authentic	ation		
			e-Cert file, e.g. C:\cert.p12		
		e-Cer	t PIN:		
		F	or Office Use Only		
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					%

Version. : 1.1.18

Step 17:

- Review the page information again by clicking the tab of different pages if necessary.
- Click 'Edit Application' to edit the data if necessary.
- Click "Print" to print the current page with browser printing function.

• Click the "Application Form" tab directly again to proceed the application.

	Guidance									Save	Save and Ex	it Next
—	New Produ	uct Rea	istration						NEW_PRO	DUCT_REG	STRATION_V	IEW_01
	The maximum up File upload is not			B, while the max	ximum total u	pload size pe	application	n is 100 MB.				
You are login as ORG Trial				ease submit the	files to Drug	Office via CD						
One TESTING LIMITED	Proposed Name of	of Product (B	English):				PLN	ło.:	PR No.:	нк	No.:	
Login date and time 26.01.2021 11:20	Module 1	Module 2	Module 3	Module 4	Module 5							
Online Notification	Page 1 P	age 2 F	Page 3 Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form	1		
My Product Search	U so Z seco U	-		_								
- New Registration	Priority App For priority	applications	s, the following s e, dosage form or	upporting docu	iments are re	quired:	of surrend	er original re	eistration upon			
Initiate New Product Registration Application	approva	l of registra	ition of the appli uct certificate ho	ed product and	the original	registration of	ertificate (of the existin	ig product; or			
Application Status - Action Required - Not Submitted			Generic		(NCE)							
- Application Submitted Withdraw application	1.0.1.1 Proposed	d Name of Pi	roduct / Substance	e			_					
+ Change of Registered Particulars			of Product (Engl		PRODUCT N	AME	9					
+ Renewal of Registration		es / Propos	ed Names Used in T NAME	n Other Places	Place:	GERMANY		~				
+ Request to Cancel Product Registration	Nam	e: PRODUC			Place:	UNITED KING		~				
+ Payment	Name	e:			Place:	Please Select	Add Mo	re				
Application History	1.0.1.2 Name of	Active Subs	tance(s) / Ingredi	ent(s) (Please lis	t below)							
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	Guidance									(Pauro)	Save and Exit	Next
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Step 18:

- Tick the checkbox of "I hereby declare that to the best of my knowledge and belief the information given in this application is correct" and input the full path of e-certificate information and the e-certificate PIN
- Then click the "Submit Application" button.

he maximum upload size of single ile upload is not allowed for modu	file is 1MB, while the n les 2 - 5, please submit	naximum total up the files to Drug	load size per application is Office via CD/DVD if neces	10MB. sary.		ack Submit Application
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1. bisbentiamine	Value) 1.5	mg	1	tablet	EP	
2. New Ingredient Name	200	mcg	1	tablet		
dications:						
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ame of Applicant:	A	BC COMPANY LI	MITED			
usiness Registration No.:	0	0671890-000				
What Capacity the Applicant Make	s This Application: Ir	mporter				
usiness Address of Applicant: 38	32, 3, A, CHA KWO LING	, KOWLOON				
el No.: 23	3198414 (Contact Person	:David Wong)				
	2345678 (Submitted By:V	VONG David)				
acsimile No.: 2'	3198414 (Contact Person	David Wong)				
	s.david.wong@gmail.cor		David Wong)			
pr	s.david.wong@gmail.cor	n (Submitted By:W	ONG David)			
ame of Manufacturer:						
Name of manufacturer appeared on	product label of finished	product: MANU	NAME xxxxxx			
ddress of Manufacturer:						
Address of manufacturer appeared of	on product label of finishe	ed product: MAN	U ADDR XXXXXX XXXXXX	XXXXXX		
Il Company(ies) involved in the pre		substance				
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1. MAINO NAME XXXXXX MANC	ADDR AAAAAA AAAAA	~ ~~~~				
		DECLA	RATION OF APPLIC	ANT		
wish to apply for registration the information given in this applied) of the said pharmaceuti cation is correct.	cal products under	the Pharmacy and Poisons	Ordinance. I hereb	y declare that, to the bes	t of my knowledge and bel
Name: WONG David					Position held:	
		e-Cert Authentica C:\cert.p12	ation: 刻覽…			
		Please select the	e-Cert file, e.g. C:\cert.p12			
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Date Received Legal	Classification		Registration App	proved Cer	tificate Issued	Registration
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Date Received Legal	Classification			proved Cei	tificate Issued	
Date Received Legal	Classification			proved Cen	tificate Issued	

Version. : 1.1.18

The page is redirected to the acknowledgement summary page with application ID, submission date, product name and PL No.

Submission Date: 2018.08	189000154 8.17		
Pro	posed Nam	ne of Product (English)	PL No.
PRO		ME	PL0023/2018
The Drug Office acknowledg will provide response as soo	ges your on- on as possib	line submission for application le.	of new product registration. We will process your reques
or enquiries, please call us qu	uoting this re	eference number.	
General enquiries:			
	e Hours::	Monday to Friday	
	e Hours::	Monday to Friday 9:00 am - 1:00 pm	
	e Hours::		
	e Hours::	9:00 am - 1:00 pm	
	e Hours::	9:00 am - 1:00 pm 2:00 pm - 5:45 pm	ays & Public Holidays)
	e Hours::	9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on Monday)	ays & Public Holidays)

2.5.2 Application Status

• Click the menu item "Application Status" under "New Registration" in the menu on the left.

There are 3 pools:

- Action Required
- Not Submitted
- Application Submitted
- Under each pool, applicant can find the detailed application status e.g. "Request for outstanding information" under "Action Required"

1	New	Pro	duct Reg	istration	ı						N	EW_PRODUCT	_REGISTRA	TION_STA
	New Su	ubmi	ssion											
ou are login as	InitiateN	ew Pr	oduct Registrat	ion										
ogin date and time 8.01.2021 15:13	Action	Req	uired											
		φ	Application Date	Application	ID _¢	PL No. 💠	F	PR No.	Proposed Name of Pro	duct (English) _‡	No. of submission	Application Status	Status ¢	Payment Status*
Online Notification My Product Search	1		17.07.2018	ANP20189000	0108 PL00	10/2018			TEST ECERT CASE1		1	Request for Outstanding Information	24.07.2018	No
New Registration	2		31.07.2017	ANP20179000	0079 PL00	82/2017			TEST LOGIN2		1	Request for Outstanding Information	22.06.2018	No
Initiate New Product Registration Application	3		31.07.2017	ANP20179000	0078 PL00	81/2017			TEST USER LOGIN 2		1	Request for Outstanding Information	14.11.2017	No
Application Status	Not Su	bmit	ted											
Application Status - Action Required - Not Submitted - Application Submitted		φ.	Latest Draf	t Date 🗢	Арр	lication ID	φ		Proposed Nan	ne of Product (E	nglish)	φ	Application !	Status 🔶
Withdraw application	1		10.08.2018		ANP201890			TEST N				Pen	-	
	2		18.07.2018	4	ANP201890	00132		TEST C	PEN FILE CASE 3			Pen	ding	
 Change of Registered Particulars 	Applica	ation	Submitted	Application		PL No.		PR No.	Proposed Name of Pro	duct (Englieh)	No. of	Application	Status .	Payment
Renewal of	1	•	Date •	ANP20189000	•	22/2018			TEST NCE CASE	aact (English)	submission *	Application	Date 👻	Status No
Registration												Submitted		
 Request to Cancel Product Registration 	2		06.08.2018	ANP20189000	0133 PL00	19/2018			TEST 2015		1	Screening	10.08.2018	No
+ Payment														
Application History														
- User Profile														
- System														
Logout														
New list ad	ded fo	or	new ve	rsion:										

 Application Date
 Application ID
 PL No.
 PR No.
 PR No.
 Proposed Name of Product (English)
 Status Date
 Download
 Download
 Download

 The download link of the e-Certificate is enabled for one-time use.
 Please keep a copy of the e-Certificate for your record after downloading.
 Image: Certificate is enabled for one-time use.
 Please keep a copy of the e-Certificate for your record after downloading.
 Image: Certificate is enabled for one-time use.

2.5.2.1 Not Submitted:

Step 1: Click the application under "Not Submitted" section, and then continue the "Initiate New Product Registration" flow. The page is redirected to new application CTD module.

+	Ne	w Pro	oduct R	Registratio	n							N	EW_PRC	DUCT_R	EGISTRA	TION_S	TAT
	New	Subm	ission														
ou are login as ORG Trial ne	Initia	teNew P	roduct Regi	stration													
ESTING LIMITED ogin date and time 7.01.2021 10:22		on Red	·														
	÷		ation Date	Application IB	PL No‡	PR No‡	Propos	ed Name	of Product (En	glish) 🗢	No. of submission	Application S	tatus‡	Status Date	Payn	nent Statu	us¢
Online Notification	Not	Submi	tted														
My Product Search		\$	Lates	t Draft Date 🛛 🜲		Application I	D 🕯			Proposed	Name of Product (Er	nglish)	\$: Ap	plication	Status	\$
	1		27.01.2021		ANP20	219000005		FACE C	CREAM					Pending			
New Registration	2		26.01.2021		ANP20	219000001		PRODU	JCT NAME					Pending			
Initiate New Product	3		01.03.2019		ANP20	199000002		TEST D	RUG 20190301	L				Pending			
Registration Application	App	icatio	n Submit	ted													
		\$	Applicatio Date	Applicatio	on ID _‡	PL No.	\$	PR No.	Propose	d Name of	Product (English)	No. of submission	Applic Stat	ation. us ♥	Status Date ≑	Payme Status	ent s
Application Status - Action Required - Not Submitted - Application Submitted	1		26.01.2021	ANP202190	00004	PL0001/2021			PRODUCT	NAME		1	Applicati Submitte	on 27	.01.2021	No	
Withdraw application																	
Change of Registered Particulars																	
Renewal of Registration																	
Request to Cancel Product Registration																	
Payment																	
Application History																	
User Profile																	
System																	
Logout																	
				2015 copyrig	ht Imp	ortant notices	Last	Revision	Date: 02 Sep	2020 V	ersion: 1.0.99 (PP)						

New list added for new version:

Issued E-Certificate

Application Date	Application	ion ID	♦ PL No. ♦	PR No. 🜩	HK No.	Proposed I	Name of Pro	duct (Englis	h) 🗘	Status Date	Download
The download link of the	e e-Certificate is er	nabled for	one-time use.	Please keep a	a copy of th	e e-Certificat	te for your r	ecord after o	downloading.		
	Guidance									Save	Save and Exit
Ť	New Produ	ct Reg	jistration						NEW	_PRODUCT_REG	ISTRATION_VIEW
	The maximum uple File upload is not a	oad size of allowed for	single file is 50N modules 2 - 5, p	IB, while the ma lease submit th	aximum tota e files to Dri	l upload size p ug Office via Cl	er application D/DVD if nece	n is 100 MB. essary.			
You are login as ORG Trial One	Proposed Name of						PL N		PR No.:	нк	No.:
TESTING LIMITED Login date and time 28.01.2021 11:20	Module 1	Module 2	Module 3	Module 4	Module !	•					
Online Notification	Page 1 Pa	ge 2	Page 3 Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form		
My Product Search											
- New Registration	Priority Appl For priority a		s, the following	supporting doc	uments are	required:					
Initiate New Product Registration Application	a. for chang approval	ge of name of registra	e, dosage form o ation of the appl luct certificate h	or active ingred ied product an	lient, letter d the origin	from applican al registration	certificate (of the existin	egistration upon 1g product; or		
Application Status - Action Required - Not Submitted	1.0 Application Fo	-			(NCE)						
Application Submitted Withdraw application	1.0.1.1 Proposed	-									
+ Change of Registered	a. Propo	ised Name	of Product (Eng	lish):*	PRODUCT	NAME	0				
Particulars	b. Propo	ised Name	of Product (Chi	nese), if any:]				
+ Renewal of Registration		s / Propos	ed Names Used	in Other Places		GERMANY		~			
+ Request to Cancel Product Registration		PRODUC				UNITED KIN	GDOM	~			
+ Payment	Name	:			Place	: Please Sele	ct	~			
							Add Mo	re			
Application History	1.0.1.2 Name of A		stance(s) / Ingred	ient(s) (Please l	ist below)						
+ User Profile	10.01	componer	ic(s).					4 - til 1 -			
+ System				ACTIV	e Ingredier	IC .		Appeared La	igredient on Product hel		
Logout								La	bet		
	Compor	nent 11. *	bisbentiamine				~	bisbentiami	ne label		
		2.	None of the ab				~	New Ingredi	ent Name		
		3.	New Ingredient Please Select	: Name							
		4.	Please Select				~				
							Add More	•			
	1.0.1.3 Applicatio	on Type: (p	lease select one)	•							
		-	cal pharmaceuti								
		an chemic an vaccine	al pharmaceutic	al product							
	O Phar	maceutica	l substance								
			ogical pharmace mical pharmace								
		rinary vac		acreat product							
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			cell therapy pro gineered produc								
	Guidance									Save	Save and Exit Ne
	annande		201	5 copyright Imp	ortant notices	Last Revisio	in Date: 02 Se	ap 2020 Ver	rsion: 1.0.99 (PP)	Jave	

2.5.2.2 Application Submitted:Step 1: Click the application under "Application Submitted" section. Then the page will be redirected to view CTD information page.

•	Ne	N Pr	oduct I	Registra	ation							N	EW_PRO	DUCT_RE	GISTRA	FION_STAT
	New	Subm	nission													
You are login as ORG Trial	Initia	teNew F	roduct Re	gistration												
One TESTING LIMITED Login date and time 27.01.2021 10:22	Actio		quired	Application	ID¢ PI	LNoc	PR Not	Propos	ed Nar	ne of Product (English) \$	No. of submission¢	Application St	tatus\$ S	tatus Dat e	Paym	ent Status
Online Notification	Not	Subm	itted		_											
My Product Search		\$	Late	est Draft Date	\$	A	pplication I	D ¢		Proposed	I Name of Product (En	ıglish)	\$	App	lication \$	Status 🗢
ini, i roudor o daron	1		27.01.2021		A	NP2021	9000005		FAC	E CREAM				Pending		
- New Registration	2		26.01.2021		A	NP2021	9000001		PRO	DUCT NAME				Pending		
Initiate New Product	3		01.03.2019)	A	NP2019	9000002		TES	T DRUG 20190301				Pending		
Registration Application	Appl	icatio	n Submi													
Application Status		\$	Applica Date	tion & Appl	ication I	₽	PL No.	¢	PR No	 Proposed Name of 	f Product (English)	No. of submission [♠]	Applica Statu	tion S Is I	tatus Date \$	Payment Status
- Action Required - Not Submitted - Application Submitted	1		26.01.202	1 ANP20	2190000	004 PL	L0001/2021			PRODUCT NAME		1	Application Submittee	in 27.0	01.2021	No
Withdraw application																
+ Change of Registered Particulars																
+ Renewal of Registration																
+ Request to Cancel Product Registration																
+ Payment																
Application History																
+ User Profile																
+ System																
Logout																

New list added for new version:

Issued E-Certificate

Application Date	Application ID	♦ PL No. ♦	PR No. 🔶	HK No. 🔶	Proposed N	ame of Pro	duct (Englis	h) 🗢	Status Date	Download	ad 🗢
The download link of the	e e-Certificate is enabled fo	or one-time use. P	lease keep a	a copy of the	e e-Certificat	e for your r	ecord after (downloading.			
10000 - 10000	Guidance								Save	Save and Ex	it Next
*	New Product Re	aistration						NEW	_PRODUCT_REG	ISTRATION_V	IEW_01
	The maximum upload size of File upload is not allowed for	-	, while the ma	ximum total	upload size pe	er applicatio	n is 100 MB.				
You are login as ORG Trial			ase submit the	e files to Drug	g Office via CL	J/DVD if nec PL N		PR No.:	112	No.:	
One TESTING LIMITED	Proposed Name of Product	(English).				FLI	NO	FR NO	пк	NO	
Login date and time 26.01.2021 11:20	Module 1 Module 2	Module 3	Module 4	Module 5							
Online Notification	Page 1 Page 2	Page 3 Page 4	Page 5	Page 6	Page 7	Page 8	Page 9	Application Form			
My Product Search	d			1							
- New Registration	Priority Application For priority applicatio	ns the following su	poorting doc	uments are r	equired:						
Initiate New Product	 a. for change of nan 	ne, dosage form or a ration of the applied	active ingredi	ient, letter f	rom applican	t of surrend	ler original re	egistration upon			
Registration Application	b. for change of pro	duct certificate hol	der, a statem	ent from ma	nufacturer fo	or the chang	ge.	.s product, or			
Application Status	1.0 Application Form*	Generic New Ch	emical Entity	(NCE)							
- Action Required - Not Submitted - Application Submitted	1.0.1 Name of Drug / Pharr	maceutical Product /	Substance								
Withdraw application	1.0.1.1 Proposed Name of	Product / Substance									
+ Change of Registered	a. Proposed Nam	e of Product (Englis	h):*	PRODUCT I	NAME	0					
Particulars	b. Proposed Nam	e of Product (Chine	se), if any:								
+ Renewal of Registration		osed Names Used in	Other Places	Diama			~				
+ Request to Cancel	Name: PRODU				GERMANY	5004					
Product Registration	Name:	CT NAME			Please Selec		~				
+ Payment					110050 5000	Add Mo	are				
Application History	1.0.1.2 Name of Active Sub	bstance(s) / Ingredier	nt(s) (Please li	st below)							
+ User Profile	No. of Compone	ent(s)* 1 🗸									
+ System			Activ	e Ingredient			Active In	gredient on Product			
Logout								on Product bel			
208001											
	Component 11.						bisbentiami				
	2.	None of the abov New Ingredient N				ĭ	New Ingredi	ent Name			
	3.	Please Select				~					
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	1.0.1.3 Application Type: (
	-	ical pharmaceutical ical pharmaceutical									
	O Human vaccin	ne	product								
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	 Veterinary value ATP - gene th 										
	O ATP - somatic	cell therapy produ	ct								
	⊖ ATP - tissue e	engineered product									
	Guidance								Save	Save and Exit	Next
		2015 -	onwright Linner	atant antines	Last Devision	- Dete: 02.C.	2020 1/-	cion: 1.0.00 (PP)			

Step 2: View the application history by clicking the "Application History", the "Application History" will allow to view once the application has been submitted. You can choose the version no. from the drop-down list of 'application version'

and Draduct Date	ance						(Next) (F
ew Product Reg	istration					NEW_P	RODUCT_REGISTRATION_VIEW_
e maximum upload size of e upload is not allowed for	single file is 1MB, while the max modules 2 - 5, please submit the	mum total u files to Drug	pload size per applica g Office via CD/DVD if	ion is 10M necessary	IB.		
oposed Name of Product (E					.0023/2018	PR No.:	HK No.:
Module 1 Module 2	Module 3 Module 4	Module 5					
Page 1 Page 2 F	Page 3 Page 4 Page 5	Page 6	Page 7 Page	8 Pa	ige 9 App	lication Form	
a. for change of name approval of registra b. for change of prod	b, the following supporting doct e, dosage form or active ingredi- tion of the applied product and uct certificate holder, a statem Generic New Chemical Entity	ent, letter f I the origina ent from ma	rom applicant of surr l registration certifica	te of the	ginal registrat existing prod	ion upon .ct; or	
0.1 Name of Drug / Pharm	aceutical Product / Substance						
0.1.1 Proposed Name of Pi							
	of Product (English):*	DRODUCT					
		PRODUCT	NAME 🕑				
-	of Product (Chinese), if any:						
· ·	ed Names Used in Other Places						
Name: PRODUC	T NAME	Place:	GERMANY	×	~		
Name: PRODUC	TNAME	Place:	UNITED KINGDOM	×	 Image: A set of the /li>		
Name:		Place:	Please Select	×	 Image: A start of the start of		
0.1.2 Name of Active Subs	tance(s) / Ingredient(s) (Please lis	st below)					
No. of Componen	it(s)* 1 🗸						
	Active	e Ingredient	:	Act Appe	tive Ingredien ared on Prod	t uct	
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Component 11. *					ntiamine Labe		
	None of the above			✓ New I	ngredient Nar	ne	
2.	New Ingredient Name						
	D1 C 1 .			~			
3.	Please Select						
	Please Select Please Select			~			
3. 4.	Please Select			~			
3. 4. 0.1.3 Application Type: (pl O Human biologic	Please Select lease select one) * al pharmaceutical product			~			
3. 4. 0.1.3 Application Type: (pl Human biologic I Human chemica	Please Select lease select one) *			~			
3. 4. 0.1.3 Application Type: (pl Human biologic Human chemica Human vaccine	Please Select lease select one) * al pharmaceutical product al pharmaceutical product			~			
3. 4. 0.1.3 Application Type: (pl Human biologic Human chemica Human vaccine Pharmaceutical	Please Select lease select one) * al pharmaceutical product al pharmaceutical product			~			
3. 4. 0.1.3 Application Type: (p Human biologic Human vaccine Pharmaceutical Veterinary biolo	Please Select lease select one) * al pharmaceutical product al pharmaceutical product substance			~			

Application Version 1	$\overline{}$	
CTD in PDF format Application Submitted: Application History.p	odf	
Document List		
Page 2 1. Product Pack Size: 6x10's blister/pack		
ComponentDuration (Month) Start dat 1 24 08.01.2C	eport e	In-Use Stability Report
Stability Report.pdf		
2. Product Pack Size: 3x10's blister/pack Stability R	eport	
ComponentDuration (Month) Start date 1 24 08.01.20	0	In-Use Stability Report
Stability Report.pdf		
Page 4		
1.0.7.1.a Manufacturer appeared on product label of finished product GMP Certificate of Manufacturer Appeared on		
Product Label	GMP.pdf	
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label		
1.0.7.1.b All Other Company(ies) involved in the preparation of the product/substance	<u>ML.pdf</u>	
GMP Certificate of Other Manufacturer 1	GMP.pdf	
ML of Other Manufacturer 1		
Page 6	<u>ML.pdf</u>	
1.0.9.4 Please list marketing authorization application(s) for the same product in other		
country/region here : Other Country/Region 1		
Page 7	Free Sales Certificate.pdf	
Prototype Sales Pack Product Pack Size:		
1. 6x10's blister/pack	Prototype Sales Pack.pdf	
2. 3x10's blister/pack	Prototype Sales Pack.pdf	
Package Insert File Product Pack Size:		
1. 6x10's blister/pack	Package Insert.pdf	
2. 3x10's blister/pack	Package Insert.pdf	
Photo or scanned image of the product samples	Product Sample.pdf	
Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)	BRC.pdf	
Authorization letter from the manufacturer/marketing authorization holder		
authorizing the applicant to apply registration for its product.		
An undertaking, given by the applicant to provide	Manufacturer Authorization	<u>a Letter.pdf</u>
at any stage of registration, any information and/or documents relating to the product/substance upon request within the prescribed timeframe	r	
GMP Certificate of Manufacturer Appeared on Product Label	Product Information.pdf	
GMP Certificate of Other Manufacturer 1	<u>GMP.pdf</u>	
Page 8	<u>GMP.pdf</u>	
Other Country/Region 1	Free Sales Certificate.pdf	
Page 9 Specification of the product (showing compliance		
with pharmacopoeias listed in the Guidance Notes on Registration of Pharmaceutical		
Products) (Reference for 1.0.8 of Page 5)	Product Specification.pdf	
Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)		
Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)		
Reputable documentary evidence to substantiate	Certificate of Analysis.pdf	
the content of package insert. Cross-referencing to documents should be made by referring to		
page number of the reference and the relevant parts of the reference document(s) shall be clearly	,	
highlighted. Please refer to the list of reputable references in the Guidance Notes on Registration of Pharmaceutical Products		
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label	Evidence Document.pdf	
ML of Other Manufacturer 1	ML.pdf	
version. : 1.1.10	ML.pdf	

Step 3: Click the Application_History.pdf can view the whole CTD content in pdf format.

New Product Registration Module 1 Page 1 - Submitted Application
Application Reference no.: ANP20169000003
PL no.: PL0004/2016 PR no.:
Version no.: 1
Submission Date: 07.03.2016
Priority Application No
For Priority applications, the following supporting docuements are required:
a. for change of name, dosage form or active ingredient, letter from applicant of surrender original registration upon approval of registration of the applied product and the original registration certificate of the existing
product; or
b. for change of product certificate holder, a statement from manufacturer for the change.
1.0 Application Form Generic
1.0.1 Name Of Drug / Pharmaceutical Product / Substance
1.0.1.1 Proposed Name of Product / Substance
a. Proposed Name of Product (English): ONLINE 20160307
b. Proposed Name of Product (Chinese), if any:
c. Names / Proposed names used in other places
Name: Place:
1.0.1.2 Name of Active Substance(s) / Ingredient (s)
No. of Component(s): 1
Ingredient Labelled Ingredient
Component 1 a. CARDAMOM OIL CARDAMOM OIL
1.0.1.3 Application Type: Human chemical pharmaceutical product

Step 4: Click the pdf hyperlink to view every corresponding pdf uploaded in the particular version.

Application Version 1	~	
CTD in PDF format Application Submitted: Application History.p	df	
Document List	-	
Page 2 1. Product Pack Size: 6x10's blister/pack		
Stability R		In-Use Stability Report
ComponentDuration (Month) Start date 1 24 08.01.20		
Stability Report.pdf		
2. Product Pack Size: 3x10's blister/pack		
ComponentDuration (Month) Start date		In-Use Stability Report
1 24 08.01.20	15	
Stability Report.pdf		
Baar 4		
Page 4 1.0.7.1.a Manufacturer appeared on product		
label of finished product GMP Certificate of Manufacturer Appeared on Department Label		
Product Label	GMP.pdf	
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label		
1.0.7.1.b All Other Company(ies) involved in the	ML pdf	
preparation of the product/substance GMP Certificate of Other Manufacturer 1		
ML of Other Manufacturer 1	<u>GMP.pdf</u>	
	ML.pdf	
Page 6 1.0.9.4 Please list marketing authorization		
application(s) for the same product in other country/region here :		
Other Country/Region 1	Free Sales Certificate.pdf	
Page 7 Prototype Sales Pack		
Product Pack Size:	Destatung Salas Deals adf	7
1. 6x10's blister/pack 2. 3x10's blister/pack	Prototype Sales Pack.pdf Prototype Sales Pack.pdf	
Package Insert File Product Pack Size:		
1. 6x10's blister/pack	Package Insert.pdf	
2. 3x10's blister/pack Photo or scanned image of the product samples	Package Insert.pdf	
	Product Sample.pdf	
Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)	DD.G. 14	
Authorization letter from the	BRC.pdf	
manufacturer/marketing authorization holder authorizing the applicant to apply registration for		
its product.	Manufacturer Authorization	a Letter.pdf
An undertaking, given by the applicant to provide, at any stage of registration, any information and/or		
documents relating to the product/substance upon request within the prescribed timeframe		
GMP Certificate of Manufacturer Appeared on	Product Information.pdf	
Product Label	GMP.pdf	
GMP Certificate of Other Manufacturer 1	GMP pdf	
Page 8	GiviP.bdf	
Other Country/Region 1	Free Sales Certificate.pdf	
Page 9 Specification of the product (showing compliance		
with pharmacopoeias listed in the Guidance Notes on Registration of Pharmaceutical		
Products) (Reference for 1.0.8 of Page 5)	Product Specification.pdf	
Method of analysis (detailed method of analysis for all tests per finished product specifications)		
(Reference for 1.0.8 of Page 5)	Method of Analysis.pdf	
Certificate of analysis (showing results for all tests		
per finished product specifications) (Reference for 1.0.8 of Page 5)		1
Reputable documentary evidence to substantiate	Certificate of Analysis.pdf	1
the content of package insert. Cross-referencing to documents should be made by referring to		
page number of the reference and the relevant parts of the reference document(s) shall be clearly		
highlighted. Please refer to the list of reputable references in the Guidance Notes on Registration of Pharmaceutical Products		
	Evidence Document.pdf	
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label		
ML of Other Manufacturer 1	<u>ML.pdf</u>	
version. : 1.1.10	ML.pdf	

2.5.2.3 Action Required (If the application requires outstanding information requested by pharmacist, the application will be under the "Action Required" section).

- For application which is "Action Required", applicant will also receive a notification about the required information or comments for the application.
- Applicant needs to update his/her application information and resubmit through online system by the link in the notification or new application pool.

Method 1: 'New Product Registration' of 'Online Notification':

Step 1: Click the menu item "Online Notification" in the menu on the left.

	Onli	ne Notification					0	NLINE_NOTIFIC	ATION_VIEW_0
T	New F	Product Registration						Archiv	ed Notifications
		Notification Date	• •	Subject	\$	Pro	posed Name of Product	♦ PL No. ♦	Payment Statu
ou are login as	Open	12.01.2021 10:34:23		Certificate Payment Request		VOOINS	00 TABLETS 500MO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8	START	PL0004/2020	Paid
gin date and time 01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application		BOURB	ON POWDER	PL0002/2020	N/A
Online Notification	COR	•						Archi	ved Notification
My Product Search		Notification Date \$		Subject	\$ нк	No.	¢ I	ame of Product	4
	Open	12.01.2021 17:40:32	Applicaton With	drawal Rejected Notification	HK42660		CALCIUM UNISON TA	D 300MG	
New Registration	<u>Open</u>	12.01.2021 17:38:55	Application Sub	mitted Notification	HK42660		OALOUM UNISON TA	D SOOMO	
Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Scr	eening Notification	HK42660		CALCIUM UNISON TA	D 389MO	
Renewal of Registration	Rene	wal of Registration						Archi	ved Notificatior
rtegistration		Notification Date \$		Subject	\$	N	lame of Product	÷ 1	lo. of Renewals
Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notific	cation	DRUG NAME	E XXXX TA	B 50MG	1	
Payment	Canc	ellation Request							
Application History		Notification Date \$		Subject	\$ HK	No.	¢ I	Name of Product	
, approximent motory	Open	26.01.2021 15:07:50	Cancellation Re	egistration Request Submitted Notification	HK31199		CHILIM FREEZE-DRIE	D FDR FOR IV INJ	400MG
User Profile									
System	Non	Pharmaceutical Prod	uct Alert						
		Notification Date		Subject		K No. 🗢		ame of Product	
Logout	<u>Open</u>	11.02.2016 04:00:00	Renewal Pe	nding Reminder	HK6	0464	OCTECTIN 500 CAP 500	40 -	
	Open	12.01.2016 04:00:02		nding Notification	HK6		OCTEOTINI FOO CAD FOOL		

Step 2: Click a notification which subject is "Screening Application" or "Evaluation Application".

	New F	roduct Registration						Archiv	red Notifications
		Notification Dat	e \$	Subject	\$	Pr	oposed Name of Product	♦ PL No. ♦	Payment Statut
'ou are login as	Open	12.01.2021 10:34:23		Certificate Payment Request		VOOIN	500 TABLETS SOOMO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8	START	PL0004/2020	Paid
ogin date and time 8.01.2021 15:06	Open	20.11.2020 16:45:42		Screening Application		PRODU	JCT NAME	PL0023/2018	N/A
Online Notification	CORF							Archi	ved Notification
My Product Search		Notification Date \$		Subject	\$ НК	No.	\$ Na	ame of Product	4
	Open	12.01.2021 17:40:32	Applicaton Wit	drawal Rejected Notification	HK42660		CALCIUM UNISON TAB	300MG	
+ New Registration	Open	12.01.2021 17:38:55	Application Su	mitted Notification	HK42660		GALCIUM UNISON TAB		
 Change of Registered Particulars 	Open	12.01.2021 17:38:55	Application Sc	eening Notification	HK42660		CALCIUM UNISON TAB		
 Renewal of Registration 	Rene	wal of Registration						Archi	ved Notification
registration		Notification Date \$		Subject	\$		Name of Product	÷ 1	No. of Renewals 🗧
 Request to Cancel Product Registration 	<u>Open</u>	27.01.2021 04:00:14	Renewal Notif	cation	DRUG NAME	E XXXXX T	AB 50MG	1	
+ Payment	Canc	ellation Request							
Application History		Notification Date \$		Subject	\$ HK	No.	\$ N	ame of Product	4
Application History	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification	HK31199		EPILIM FREEZE-DRIED	POR FOR IV INJ	400MG
+ User Profile									
+ System	Non	Pharmaceutical Prod							
		Notification Date		Subject	\$ H	K No. 🗢		ne of Product	
Logout	Open	11.02.2016 04:00:00		ending Reminder	HK60		OCTECTIN 500 CAP 500M	-	
	Open	12.01.2016 04:00:02	Renewal P	ending Notification	HK60)464	OSTECTIN 500 CAD 500M	<u> </u>	

New Product Registration

-	
Notification Date :	17.08.2018 18:05:14
PL No. :	PL0023/2018
PR No. :	-
HK No. :	-
Proposed Name of Product (English) :	PRODUCT NAME
Notification Detail :	NOTIFICATION_PRINT.pdf
Attachment(s) :	
1. Back To Application :	Go

2. In alternative to (1), you may send the outstanding information by post or in person to the Drug Office: L. In supermative to (1), you may send the outstanding info Drug Registration and Import / Export Control Division 3/F, Public Health Laboratory Centre 382 Nam Cheong Street Shek Kip Mei Kowloon Hong Kong

For enquiries, please call our hotline at (852) 2319 8458 or email to prs2_info@dh.gov.hk quoting the reference number of this application or the PL number of PR number of your product under the process of new product registration.

Step 3: Click the "NOTIFICATION_PRINT.pdf" to view the notification in PDF format. ONLINE_NOTIFICATION_VIEW_01 **Online Notification**

New Product Registration

Notification Date :	17.08.2018 18:05:14
PL No. :	PL0023/2018
PR No. :	-
HK No. :	-
Proposed Name of Product (English) :	PRODUCT NAME
Notification Detail :	NOTIFICATION PRINT.pdf
Attachment(s) :	
1. Back To Application :	Go

2. In alternative to (1), you may send the outstanding information by post or in person to the Drug Office: Drug Registration and Import / Export Control Division 3/F, Public Health Laboratory Centre 382 Nam Cheong Street Shek Kip Mei Kowloon Hong Kong

For enquiries, please call our hotline at (852) 2319 8458 or email to prs2_info@dh.gov.hk quoting the reference number of this application or the PL number of PR number of your product under the process of new product registration.





DEPARTMENT OF HEALTH DRUG OFFICE DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION 3/F., Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, Hong Kong

電話號碼 Tel. No: 23198414 詢問處 Enquiries: (852) 23198458 傳真號碼 Faxline No: (852) 28034962 本署檔號 Our Ref.: PL0023/2018 (來屆前發明比檔案號碼) (IN REPLY PLASE QUOTE THIS FILE REF.)

> ABC COMPANY LIMITED 382, 3, A CHA KWO LING, KOWLOON

Proposed Name of Product:	PRODUCT NAME
Application Reference No.	ANP20189000154
PL No.	PL0023/2018
Applicant:	ABC COMPANY LIMITED
Date of Assessment:	2018-08-17

Dear Sirs,

Application for Registration of Pharmaceutical Products/Substances (Screening)

Thank you for your application dated 17.08.2018 for registration of pharmaceutical products/substances. The Department of Health is providing professional and executive support to the Pharmacy and Poisons Board and its Committee.

Please provide the items (stated in the attached page) for our consideration before application could be accepted. For enquiries, please contact the undersigned at .

Yours faithfully, Screen Officer

Page1 of 2

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority

Application for Registration of Pharmaceutical Products/Substances

Date: 2018-08-17

PL Number: PL0023/2018

Product Name: PRODUCT NAME

Screened by: Screen Officer

Comments/Outstanding Information: Section 1.0.1.1: Please update the proposed names used in ohter places

Section 1.0.8.1: Screening Comment

Assessment made By:

Screen Officer

Signature of Assessment Officer: Name (in BLOCK letters): Post Title: Date:

Screen Officer

2018-08-17

Page2 of 2

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority Step 4: Click the "Go" button will redirect the application to the CTD page for outstanding information. Pharmacist's comment for every section can be viewed at the same time.

Online Notification	0	NLINE_NOTIFICATION_VIEW_01
New Product Registration		
Notification Date :	17.08.2018 18:05:14	
PL No. :	PL0023/2018	
PR No. :	-	
HK No. :		
Proposed Name of Product (English) :	PRODUCT NAME	
Notification Detail :	NOTIFICATION_PRINT.pdf	
Attachment(s) :		
1. Back To Application :	Go	

2. In alternative to (1), you may send the outstanding information by post or in person to the Drug Office: Drug Registration and Import / Export Control Division 3/F Public Health Laboratory Centre 382 Nam Cheong Street Shek Kip Mei Kowloon Hong Kong

For enquiries, please call our hotline at (852) 2319 8458 or email to prs2_info@dh.gov.hk quoting the reference number of this application or the PL number of PR number of your product under the process of new product registration.

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Page 1	Page 2	Page 3	Page 4	Page 5	Page 6	Page 7	Page 8	Page 9	Application Form	
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Method 2: 'Action Required' under 'Application status' of 'New Registration' (Resubmit application).

Step 1: Click the application under "Action Required" section will be redirected to view CTD information page with pharmacist comments.

New Product Registration

NEW_PRODUCT_REGISTRATION_STATUS

You are login as	28

New Submission

.01.2021 11:02	\$	Application \$	Application ID	PL No. 💠	PR No. 💠	Proposed Name of Product (English)	No. of submission \$	Application Status	Status Date ≑	Paymen Status
Online Notification	1	06.04.2020	ANP20209000002	PL0023/2018		PRODUCT NAME	1	Request for Outstanding Information	20.11.2020	No
My Product Search	2	29.11.2019	ANP20199000004	PL0005/2019		CALMING RELIFE	2	Pending for Application Fee	04.12.2019	No
New Registration	Not Submi	tted								
Initiate New Product	\$	Latest Dra	ft Date 💠	Application ID	\$	Proposed Name of Product (E	nglish)	\$	Application	Status
Registration Application	1	20.11.2020	ANP	20209000006	TESTAA	A		Pend	ling	
Application Status	2	09.10.2020	ANP	20209000005	OCTOBE	RUAT		Pend	ling	
- Action Required - Not Submitted	Applicatio	n Submitted								
- Application Submitted	¢	Application Date	Application ID _{\$}	PL No. 💠	PR No. 💠	Proposed Name of Product (English)	No. of submission \$	Application Status	Status Date ♥	Paymen Status
Withdraw application	1	16.12.2016	ANP20169000348	PL0975/2016	PR0012/2017	VOCIN 500 TABLETS 500MG	5	Issue Certificate	12.01.2021	Yes
Change of Registered Particulars	2	24.10.2019	ANP20199000003	PL0003/2019	PR0005/2019	ADVANCE TYPE PRODUCT	4	Evaluation	12.01.2021	Yes
Renewal of	3	05.06.2020	ANP20209000004	PL0004/2020	PR0004/2020	JAVA 8 START	1	Issue Certificate	21.11.2020	Yes
Registration Request to Cancel	4	03.11.2016	ANP20169000317	PL0886/2016	PR0717/2016	CETIZAL TABLETS 5MG	4	Withdraw Application Request	20.11.2020	Yes
Product Registration Payment	5	23.06.2017	ANP20179000747	PL0270/2017	PR0260/2017	CILOSOL 100 TABLETS 100MG	2	Withdraw Application Request	20.11.2020	Yes
Application History	6	09.01.2019	ANP20179000769	PL0001/2019		SULSA 500 TABLETS 500MG	3	Screening	09.10.2020	No
	7	12.05.2020	ANP20209000003	PL0003/2020	PR0003/2020	TEST2020	1	Issue Certificate	05.06.2020	Yes
User Profile	8	09.03.2020	ANP20209000001	PL0001/2020	PR0002/2020	PURHEART PILL	2	Issue Certificate	06.04.2020	Yes
System	9	20.12.2019	ANP20169000308	PL0006/2019	PR0001/2020	LECETAM 250	3	Issue Certificate	31.01.2020	Yes
Logout	10	17.12.2018	ANP20179000740	PL0005/2018	PR0002/2019	VIVIR CREAM	3	Evaluation	14.06.2019	Yes
	11	28.06.2017	ANP20169000306	PL0283/2017	PR0002/2018	MONTULAR 10 TABLETS 10MG	2	Issue Certificate	17.12.2018	
	12	16.12.2016	ANP20169000346	PL0974/2016	PR0011/2017	VOCIN 250 TABLETS 250MG	4	Evaluation	27.06.2017	Yes

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Page 1 Page 2	. P	Page 3	Page 4	Page 5	Page 6	Page 7	Page 8	Page 9	Application Form	
Priority Applicat For priority applicat a. for change o approval of ro b. for change o 0 Application Form*	cations f name egistra f produ	e, dosage t tion of the uct certifi	form or ac e applied p cate holde	tive ingred roduct and	ient, letter fr I the original Ient from mar	om applicant registration o	of surrende ertificate o r the change	er original re f the existir e.	gistration upon g product; or	Comments for page Page 1 Section 1.0
).1 Name of Drug /	_	-			(102)					• S ()
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a. Proposed	Name	of Produc	t (English)	*	PRODUCT N	AME 🔮				Please update the
b. Proposed	Name	of Produc	t (Chinese), if any:						proposed names used
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Step2: Update the information according to the comments (if any) given by pharmacist officer or any changes.

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Page 1 Page 2	Page 3 Page 4 Page	5 Page 6	Page 7 Page	e 8 Page 9	Application Form	
Priority Application						Comments for page Page 1
Priority Application For priority application	s, the following supporting d	ocuments are re	quired:			Section 1.0
a. for change of nam	e, dosage form or active ing ation of the applied product	edient, letter fr	om applicant of sur	render original re	egistration upon	
b. for change of prod	luct certificate holder, a stat	ement from mar	ufacturer for the c	hange.	ig product, or	^
Application Form*	Generic New Chemical Ent	ity (NCE)				
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.1.1 Proposed Name of P	roduct / Substance					Section 1.0.1.1
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Step3: Click the "Next" button or click the tab to redirect to other page.

Applicant can also proactively update the information in the CTD. For example, applicant can update the person responsible for Pharmacovigilance information in Page 3.

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Page 1	Page 2	Page 3	Page 4	Page 5	Page 6	Page 7	Page	B Page 9	Application Form		
.0.5 Legal S	itatus									Comment	s for page Page 3
.0.6 Applica	ant Informatio	on								Section 1.	.0.5
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fe	or this applic	ation*: Joh			none No*:	23192319		Position*: A	dministrator		^
E	mail*: testir	ig@hk.com	Fax N	0.*: 35234	4534						~
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.0.6.2 Perso	on responsibl	e for Pharma	covigilance								
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Step 4: After finish updating the application, click the "Application Form" tab.

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Module 1	Module 2	Module 3	Module 4	Module 5						
Page 1	Page 2	Page 3 Pa	ge 4 Page	5 Page 6	Page 7	Page 8	Page 9	Application Form		
.0.5 Legal S	tatus								Comments fo	r page Page 3
0.6 Applica	ant Information								Section 1.0.5	
a. L	Jsername :	CH6_ADMIN								~
b. E	Email Address	charles.lee	@ch6.com.hk							
0.6.1 Prop	osed Registrati	on Certificate H	lolder							× ×
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	ontact Person or this applicat	tion*: John Ho		Phone No*:	23192319	F	osition*:	dministrator		~
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b. (HK Telephone	No. : 852 23	192319	Position	Supervise	or	Email :		
	ting@hk.com									
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Step 5: Click the "Proceed to Submit" button.

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usiness Address of Appli	cant: 382	3, A, CHA KWO LING	, KOWLOON						
el No.:		98414 (Contact Persor							
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acsimile No.:									
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Il Company(ies) involved									
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1. MANU NAME xxxxxx		DDR XXXXXX XXXX							
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I wish to apply for the information given in			ical products under	r the Pharmacy and	Poisons Ordinance.	I hereby declare that	t, to the best of i	my <mark>kn</mark> owledge an	d belief,
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Version.: 1.1.18

Step 6: Review the page information by clicking the tab if necessary, otherwise click the "Application Form" tab directly.

Application History Guid	ance								Next Pr
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roposed Name of Product (I			Thes to Drug			No.: PL0023/2	018 PR No.:	HK No.:	
roposed Name of Froduct (Englishij. Trobo					NO 1 20023/2		int no	
Module 1 Module 2	Module 3	Module 4	Module 5						
Page 1 Page 2 I	Page 3 Pag	e 4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form		
1.0.1 Name of Drug / Pharm 1.0.1.1 Proposed Name of P a. Proposed Name b. Proposed Name c. Names / Propos Name: PRODUC Name: PRODUC	e, dosage form. ation of the app luct certificate I Generic New aceutical Product roduct / Substan of Product (Eng of Product (Chi sed Names Used T NAME	or active ingredi lied product and holder, a statem r Chemical Entity ct / Substance ace glish):* inese), if any:	PRODUCT N PRODUCT N PROCE: G Place: G Place: U	Tegistration cert registration cert nufacturer for th	surrenc ificate e chan	ler original re of the existir ge.	gistration upon ig product; or		
Name:			Place: P	lease Select		\sim			
1.0.1.2 Name of Active Subs	stance(s) / Ingred	lient(s) (Please lis	st below)						
No. of Componer	nt(s)* 1 🗸								
		Active	e Ingredient			Active Ins Appeared o Lab	n Product		
Component 11. *	bisbentiamine				~	bisbentiamir			
2.	None of the at				~	New Ingredi	ent Name		
3.	New Ingredien Please Select	t Name			~				
3.	Please Select				Ť				
					*				
1.0.1.3 Application Type: (p		·							
Human biologic Human chemic Human vaccine Pharmaceutica Veterinary biol Veterinary vacc	al pharmaceutic disubstance ogical pharmace mical pharmace	cal product eutical product							
Guidance								Edit Application	Noxt Dr
Juluance								Eult Application	Hext Pr

Step 7:

Tick the checkbox of "I hereby declare that to the best of my knowledge and belief the information given in this application is correct" and input the certificate information. Then click the "Submit Application" button.

					6	
Application History Gu		ter in over me			E	Back Print Proceed To Sub
he maximum upload size ile upload is not allowed t	of single file is 1MB, while the m for modules 2 - 5, please submit	aximum total up the files to Drug	load size per application is Office via CD/DVD if neces	10MB. sary.		
roposed Name of Produc	t (English): PRODUCT NAME		PL No	.: PL0023/2018	PR No.:	HK No.:
						FORM6_VIE
		ACY AND PO	SONS ORDINANCE		R 138)	
	APPLICATION FC	RM FOR REC	GISTRATION OF A D	RUG / PHA	RMACEUTICAL	
		PRO	DUCT / SUBSTANCE			
ate: A sussimus cales and		ha aukatanan and	the relevant literature privat b	a submitted to set	ather with the prolonition (
nd supporting documents is	solution of the drug/product or sample of t sound by the health authority in the	country of origin sl	hould be submitted if require	d.	jeuler with the application. C	applementary documentation
ame of the Drug / Produc	t / Substance *: * (*(*Delete as a _l	opropriate))				
	PRODUCT NAME					
ose Form / Package Size('s) :					
Dose Form						
Component 1	Cream					
Package Size(s):	Cieam					
	Product Pack Size : Product Pack Size :	2 x 12's blister/box 2 x 48's blister/box				
etailed Qualitative and Qu omponent 1	uantitative Composition :					
Name of Active Ingred	lient(s) Quantity (Strength	Unit (Strength U	nit) Dose Value	Dose Un	it Reference / Monog	raph Standard
1. bisbentiamine	Value) 1.5	mg	1	tablet	EP	
2. New Ingredient Name	200	mcg	1	tablet		
idications:						
1. Indication of the Drug						
agistarad and Markets 1	Which Countries/Plasses	PMANY				
egistered and marketed in	n Which Countries/Places : GE UN	RMANY ITED KINGDOM				
ame of Applicant:	ł	ABC COMPANY LI	IMITED			
usiness Registration No.:	: (0671890-000				
What Capacity the Appli	cant Makes This Application:	mporter				
usiness Address of Appli						
el No.:	23198414 (Contact Persor					
	12345678 (Submitted By:V	WONG David)				
acsimile No.:						
	23198414 (Contact Persor	n:David Wong)				
mail Address:	prs.david.wong@gmail.com					
	prs.david.wong@gmail.com	m (Submitted By:V	VONG David)			
lame of Manufacturer:						
	peared on product label of finished	product: MANU	NAME xxxxxx			
ddress of Manufacturer:						
Address of manufacturer a	appeared on product label of finish	ed product: MAN	IU ADDR XXXXXX XXXXXX	XXXXXX		
II Company(ies) involved	in the preparation of the produc	t/substance				
Name of Manufacture	er Address of Manufacturer					
1. MANU NAME xxxxxxx	MANU ADDR XXXXXX XXXX	XX XXXXXX				
		DECLA	RATION OF APPLIC	ANT		
	registration of the said pharmaceut	ical products unde	r the Pharmacy and Poisons	Ordinance. I he	ereby declare that, to the be	st of my knowledge and belief,
he information given in	this application is correct.					
Name: WONG David					Position held:	
		C:\cert.p12	ation. 瀏覽.			
		Please coloct the	Out file, e.g. Oilert.p12			
		e-Cer	rt PIN			
		F	or Office Use Only			
Date Received	Legal Classification	Fees Paid	Registration Ap	proved C	Certificate Issued	Registration
						%
				1		
Guidance					В	act Submit Application Pr

Version. : 1.1.18

The page is redirected to the acknowledgement summary page with submission date, product name and PL No.

Submission Date: 2018.0	0189000154 08.17		
Pro	oposed Nan	ne of Product (English)	PL No.
PR		ME	PL0023/2018
The Drug Office acknowledg will provide response as soc	ges your on- on as possib	line submission for application le.	of new product registration. We will process your request an
⁼ or enquiries, please call us q G eneral enquiries:	quoting this r	eference number.	
Offic	e Hours::	Monday to Friday	
		9:00 am - 1:00 pm	
		9:00 am - 1:00 pm 2:00 pm - 5:45 pm	
		2:00 pm - 5:45 pm	ys & Public Holidays)
Tel:		2:00 pm - 5:45 pm (up to 6:00 pm on Monday)	ys & Public Holidays)

2.5.2.4 Application Payment (For Application which is screening accepted by Drug Office)

Step 1: Click the menu item "Online Notification" in the menu on the left.

	Onli	ne Notification						ONLI	NE_NOTIFIC	ATION_VIEW_01
T	New F	roduct Registration							Archiv	ed Notifications
		Notification Date	\$	Subject	\$	Pro	oposed Name of F	roduct ≑	PL No. \$	Payment Statuts
u are login as	Open	12.01.2021 10:34:23		Application Payment Request		VOOIN	500 TADLETO 500	MO -	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8	START		PL0004/2020	Paid
in date and time 1.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application		PRODU	ICT NAME		PL0023/2018	N/A
Online Notification	CORF	5							Archiv	ved Notifications
My Product Search		Notification Date 🗢		Subject	\$ НК М	lo.	\$	Nam	e of Product	¢
	Open	12.01.2021 17:40:32	Applicaton With	ndrawal Rejected Notification	HK42660		CALCIUM UN	SUN TAB 30	UWG	
lew Registration	<u>Open</u>	12.01.2021 17:38:55	Application Sub	pritted Notification	HK42660		OALOIUM UN	SON TAD S	omo -	
change of Registered	Open	12.01.2021 17:38:55	Application Scr	eening Notification	HK42660		CALCIUM UN	SON TAD SI		
Renewal of	Rene	wal of Registration							Archi	ved Notifications
Registration		Notification Date \$		Subject	\$		Name of Product		¢ N	lo. of Renewals 💠
Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notifi	cation	DRUG NAME	XXXX T	AB 50MG		1	
Payment	Canc	ellation Request								
opplication History		Notification Date 🗢		Subject	\$ HKN	lo.	\$	Nam	e of Product	¢
phonon motory	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification	HK31199		CPILIM FREE	ZE-DRIED P	DR FOR IV INJ	400MG
lser Profile										
System	Non	Pharmaceutical Produ								
		Notification Date \$		Subject		(No. 🗢			of Product	+
ogout	<u>Open</u>	11.02.2016 04:00:00		ending Reminder	HK60		OCTECTIN 500 (•	
	Open	12.01.2016 04:00:02		ending Notification	HK60-	464	OCTEOTINI EDD (

Step 2: Click the "Open" button of notification which subject is "Application Payment Request" under "New Product Registration".

	Onlir	ne Notification						O	ILINE_NOTI	FICATION_VIEW_01
T	New P	roduct Registration							Arc	hived Notifications
		Notification Da	te \$	Subject		\$	Pro	posed Name of Product	PL No	. Payment Statuts
You are login as	Open	12.01.2021 10:34:23		Application Payment Request			VOOIN	500 TABLETS 500MO	PL0975/2	016 Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA 8	START	PL0004/2	020 Paid
Login date and time 28.01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application			PRODU	ICT NAME	PL0023/2	018 N/A
Online Notification	CORF								Ar	chived Notifications
My Product Search		Notification Date \$		Subject	¢	НК	No.	\$ N	ame of Produ	t \$
	Open	12.01.2021 17:40:32	Applicaton Wit	ndrawal Rejected Notification		HK42660		CALCIUM UNISON TAD	SOOMG	
+ New Registration	Open	12.01.2021 17:38:55	Application Su	omitted Notification		HK42660		OALOUM UNISON THE	- OM000	
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sc	eening Notification		HK42660		CALCIUM UNISON TAE		
+ Renewal of Registration	Rene	wal of Registration							A	chived Notifications
Registration		Notification Date 🗢		Subject	\$		1	Name of Product	¢	No. of Renewals 🜲
+ Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notif	cation		DRUG NAME	XXXXX TA	AB 50MG	1	
+ Payment	Cance	ellation Request								
Application History		Notification Date \$		Subject	\$	HK	No.	\$ N	ame of Produ	ct 🗢
	Open	26.01.2021 15:07:50	Cancellation F	egistration Request Submitted Notification		HK31199		EPILIM FREEZE-DRIE	PERFORIN	114J 400MG
+ User Profile										
+ System	Non I	Pharmaceutical Proc								
Logout		Notification Date		Subject			K No. 🗢	Na	me of Produc	¢ (
Logoui	Open	11.02.2016 04:00:00		ending Reminder		HK60		OSTECTIN 500 CAD 500M		
	Open	12.01.2016 04:00:02	Renewal P	ending Notification		HK60	1464	OVIED HIN 600 CAD 500M	<u> </u>	

Step 2: Click the "NOTIFICATION_PRINT.pdf" button to view the application payment notification.

Online Notification		ONLINE_NOTIFICATION_VIEW_0
New Product Registration		
Notification Date :	26.04.2018 14:11:15	
PL No. :	PL0086/2017	
PR No. :	-	
HK No. :	-	
Proposed Name of Product (English) :	MY 20170928 1652	
Notification Detail :	NOTIFICATION_PRINT.pdf	
Attachment(s) :		
1. Go To Application Payment :	Go	

2. In alternative to (1), you may send the outstanding information by post or in person to the Drug Office:

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

For enquiries, please call our hotline at (852) 2319 8458 or email to prs2_info@dh.gov.hk quoting the reference number of this application or the PL number of PR number of your product under the process of new product registration.

PHARMACY AND POISONS ORDINANCE (CHAPTER 138) 香港法例第138章藥劑業及毒藥條例

Date 日期: 30/01/2015

NOTIFICATION OF PAYMENT 繳費通知書

A. Payment Particulars 甲:繳費詳情

This is to notify you to pay for the following application(s)/registration(s): 現通知 閣下繳交下列申請/註冊之費用:

	Number 數量	Total Fee 總費用
XApplication(s) for Product Registration 藥劑製品註冊申請 (HK\$1,100)	1	HK\$1,100
Ref. 檔號:		
PL1052/2015		

Drug Office Department of Health

CERT HOLDER 6 044, 11, A ABC BUILDING, 1, ABC STREET SHEK KIP MEI, KOWLOON B. Payment Instructions 乙:繳費辦法

Please proceed to arrange payment of the prescribed fee within 10 working days from the date of this notification via the following means: 請於本通知書發出日期起10工作天內透過以下途徑繳交所須費用: For application(s) made via paper mode, please arrange payment by Method 1 - 2; for application(s) made via electronic mode (i.e., PRS 2.0), please arrangement payment by Method 1 - 4: 如以硬本形式遞交申請,請以方法1 - 2繳費;如以電子形式(即PRS 2.0)遞交申請,請以方法1 -4繳費: 1. By post with payment cheque and this notification letter addressed to "Shroff Office, Drug Office of Department of Health" at Suite 2002-05, 20/F, AIA Kowloon Tower Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong. Please note that crossed cheques should be made payable to "The Government of the Hong Kong Special Administrative Region". 用支票連同本通知書郵寄衛生署藥物辦公室繳款處收。地址為香港九龍觀塘巧明街100號 Landmark East友邦九龍大棲20樓2002-05室。劃線支票抬頭寫上「香港特別行政區政府」 2. In person with payment cheque or cash and this notification letter at the above address. Hours of operation: Monday to Friday: 9:00 a.m. to 1:00 p.m. 2:00 p.m. to 5:30 p.m. (up to 5:45 p.m. on Monday) 攜同本通知書到上述辦事處以支票或現金繳交。辦事處收款時間: 星期一至星期五:上午九時至下午一時 下午二時至下午五時三十分 (星期一至下午五時四十五分) (Note: CASH should NOT be sent through post 注意:請勿郵寄現金) 3. By online credit card (Visa/MasterCard) payment via EGIS in PRS 2.0 透過PRS2.0的電子政府基建服務以信用卡繳費 (Link / 網址: https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp) 4. By online PPS payment via EGIS in PRS 2.0 透過PRS2.0的電子政府基建服務以繳費靈繳費

Step 3: Click the "GO" button for application payment.

(Link / 網址: <https://www.drugoffice.gov.hk/prs2-ext/login internet.jsp>)

Online Notification		ONLINE_NOTIFICATION_VIEW_01
New Product Registration		
Notification Date :	30.01.2015 01:05:14	
PL No. :	PL1052/2015	
PR No. :		
HK No. :		
Proposed Name of Product (English) :	Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6)	
Notification Detail :	NOTIFICATION PRINT.pdf	
Attachment(s) :		
1. Go To Application Payment :	Go	
2. In alternative to (1), Send the outstand Drug Registration and Import / Export (3/F, Public Health Laboratory Centre 382 Nam Cheong Street Shek Kip Mei Kowloon Hong Kong	ing information by post or in person to the drug office: Control Division	
For enquiries, please call our hotline at (a product under the process of new product	352) 2319 8458 or email to prs_enquiry@dh.gov.hk quoting the reference number of this application or the PL t registration.	. number of PR number of your

Step 4: Select a single/multiple applications and click "Ready to Pay" button. Select an application and click 'print' if you want to print the payment details.

ame of Product
Print Ready
ame of Product 💠 Payment Status 💠
ame of Product

Step 5: Click "Yes" and the page will be redirected to the payment gateway.



Step 6: Select a payment method, then click "Pay" button, or click 'Cancel Payment' to cancel the payment and the page is back to new application payment page. GovHK香港政府一站通

or	nline Payment Service	9			
Help Customer Service Hotline 2319 8461 Email pharmweb@ dh.gov.hk	Please select the payment method :				
	Type of Service Transaction Date Transaction Reference Number Total Amount Payment Method*	DH Drug Office 29-03-2023 DHPRS-202303291025-94191 HKD\$ 1,370.00			
	Please take note of the	Cancel Payment Pay			
	 Prease take note of the transaction reference number of PKINT this page for making enduity on the payment status when hecessary. 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. 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. Merchant Name is applicable to credit card payment method only. 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. 				
	experience such a prob caused.Different credit card issu	ie an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you lem, please wait a moment and retry, or change to use other available payment methods. We apologise for any inconvenience uers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please r if you want to learn more about the J/Secure, Mastercard SecureCode and Verified by Visa service.			
		HONG			

Step 6: When the payment is successful, it will be redirected to the payment summary page with payment reference no, PR No., payment amount, etc. Click "Print Receipt" button to view the payment receipt in pdf format.

New Produ							
Payment Referen	ice No.: DHPF	RS-201907261629-14197					
Payment Method	: Cash						
Type of Payment:	: Applic	ation Fee					
Transaction Time	e: 16.01	16.01.2020 11:20:30					
Application Re	eceived Date	Reference No.	PR No.	Product Name			
25 07 201	0 15-22	ANP20199000015	PR0014/2019	TESTBBC			
	acknowledges			the above product(s). We will process you	r application and will provide		
The Drug Office response as soc Please kindly qu	acknowledges on as possible. lote the above F		00.00 for certificate fee regarding		application and will provide		
The Drug Office response as soo Please kindly qu General Enquirie:	acknowledges on as possible. lote the above F	the receipt of your payment of HK\$1,1	00.00 for certificate fee regarding		r application and will provide		
The Drug Office response as soc Please kindly qu	acknowledges on as possible. Jote the above F s: Monday to Frid	the receipt of your payment of HK\$1,1 'ayment Reference Number for enquir	00.00 for certificate fee regarding		r application and will provide		
The Drug Office response as soo Please kindly qu General Enquirie:	acknowledges on as possible. Jote the above F s: Monday to Frid 9:00 am - 1:00	the receipt of your payment of HK\$1, 1 Payment Reference Number for enquir	00.00 for certificate fee regarding		r application and will provide		
The Drug Office response as soo Please kindly qu General Enquirie:	acknowledges on as possible. Jote the above F s: Monday to Frid 9:00 am - 1:00 2:00 pm - 5:45	the receipt of your payment of HK\$1,1 Payment Reference Number for enquir Jay .pm .pm	00.00 for certificate fee regarding		r application and will provide		
The Drug Office response as soo Please kindly qu General Enquirie:	acknowledges on as possible. Iote the above F s: Monday to Fri 9:00 am - 1:00 2:00 pm - 5:45 (up to 6:00 pm	the receipt of your payment of HK\$1,1 Payment Reference Number for enquir lay .pm .pm on Monday)	00.00 for certificate fee regarding		r application and will provide		
The Drug Office response as soc Please kindly qu General Enquirie Office Hours:	acknowledges on as possible. Jote the above F s: Monday to Frid 9:00 am - 1:00 2:00 pm - 5:45 (up to 6:00 pm (Closed on Sa	the receipt of your payment of HK\$1,1 Payment Reference Number for enquir tay pm pm on Monday) turdays, Sundays & Public Holidays)	00.00 for certificate fee regarding		r application and will provide		
The Drug Office response as soc Please kindly qu General Enquirie	acknowledges on as possible. Iote the above F s: Monday to Fri 9:00 am - 1:00 2:00 pm - 5:45 (up to 6:00 pm	the receipt of your payment of HK\$1,1 'ayment Reference Number for enquir fay pm pm on Monday) turdays, Sundays & Public Holidays) 75	00.00 for certificate fee regarding		r application and will provide		

Print Receipt Close
Name of Company		Payment Date
公司名稱		繳費日期
CERT HOLDER 6		30.1.2015
Payment Reference No: 付款编號:	DHPRS-201501300213-90574	
EGIS Reference No: EGIS編號:	A201501300000043	
Payment Method: 付款方法:	PPS	
Payment Amount: 付款金額:	HK\$1,100.00	

Payment Reference No: 付款编號:	DHPRS-20	1501300213-90	574		
Name of Product 製品/物質名稱		PL No. PL 號碼	PR No. PR 號碼	Reference No. 参考編號	
Indapamide-Trial Prolonged Relea mg (AP8)(CH6)	ase Tablets 1.5	PL1052/2015	PR0002/2015	ANP20159000003	
	第2	頁(共2頁)			

2.5.2.5 Certificate Payment (For Application which is approved by Drug Office and ready for registration certificate payment)

Step 1: Click the menu item "Online Notification" under "New Product Registration" in the menu on the left.

	Onli	Online Notification ONLINE_NOTIFICATION_VIEW_01												
T	New F	Product Registration								Archive	ed Notifications			
		Notification Dat	te 🗢	Subject		¢	Pro	posed Name of Product	\$	PL No. 🗢	Payment Status			
You are login as	Open	12.01.2021 10:34:23		Application Payment Request			VOOINS	500 TABLETS 500MO		PL0975/2016	Paid			
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA 8	START		PL0004/2020	Paid			
Login date and time	<u>Open</u>	20.11.2020 16:45:42		Screening Application			PRODU	CT NAME		PL0023/2018	N/A			
Online Notification	COR	Þ								Archiv	ed Notifications			
My Product Search		Notification Date \$		Subject	¢	HK	lo.	¢ N	lame	of Product	\$			
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification		HK42660		CALCION UNISON TA	5 30	UMG				
+ New Registration	Open	12.01.2021 17:38:55	Application Su	bmitted Notification		HK42660		OALOUM UNISON TA	B 90					
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sc	reening Notification		HK42660		CALCIUM UNISON TA	3 90 1	9MO				
+ Renewal of Registration	Rene	wal of Registration								Archiv	ved Notifications			
-		Notification Date \$		Subject	\$			lame of Product		\$ N	o. of Renewals 🜲			
+ Request to Cancel Product Registration	<u>Open</u>	27.01.2021 04:00:14	Renewal Notif	ication		DRUG NAME	XXXXX TA	AB 50MG		1				
+ Payment	Canc	ellation Request												
Application History		Notification Date \$		Subject	\$	HK	lo.	÷ !	lame	e of Product	\$			
, approximit instally	Open	26.01.2021 15:07:50	Cancellation F	Registration Request Submitted Notification		HK31199		EPILIM FREEZE-DRIE	DPC	OR FOR IV INJ	400MG			
+ User Profile														
+ System	Non	Pharmaceutical Prod	uct Alert											
		Notification Date	φ	Subject		¢ H	(No. 💠	Na	me	of Product	\$			
Logout	Open	11.02.2016 04:00:00	Renewal P	ending Reminder		HK60	464	OCTECTIN 500 CAP 500M	10	•				
	<u>Open</u>	12.01.2016 04:00:02	Renewal P	ending Notification		HK60	464	OSTECTIN 500 CAP 500M	AC.	-				

Step 2: Click the "Open" button of notification which subject is "Certificate Payment Request".

	Online	e Notification						ON	ILINE_NOTIFIC	ATION_VIEW_01	
T	New Pr	New Product Registration									
		Notification Dat	e \$	Subject		\$	Pro	posed Name of Product		Payment Statuts	
ou are login as	Open	12.01.2021 10:34:23		Application Payment Request			VOOINS	00 TABLETS SOOMO	PL0975/2016	Paid	
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA 8	START	PL0004/2020	Paid	
gin date and time .01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application			PRODU	CT NAME	PL0023/2018	N/A	
Online Notification	CORP								Archiv	ed Notifications	
My Product Search		Notification Date \$		Subject	\$	HK	lo. a	► Na	ame of Product	\$	
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification		HK42660		CALCIUM UNISON TAB	SUDING		
New Registration	Open	12.01.2021 17:38:55	Application Sul	bmitted Notification		HK42660		OALOUM UNISON TAB	B SSEMO		
Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sci	reening Notification		HK42660		CALCIUM UNISON TAB			
Renewal of	Renew	al of Registration							Archi	ved Notification	
Registration		Notification Date \$		Subject		♦ Name of Product		lame of Product	No. of F		
Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notifi	cation		DRUG NAME	XXXXX TA	B 50MG	1		
Payment	Cancel	llation Request									
Application History		Notification Date \$		Subject	\$	HK	lo.	¢ N	ame of Product	\$	
(pproducent noter)	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification		HK31199		CPILIM FREEZE-DRIED	PDR FOR IV INJ	400MG	
User Profile											
	Non P	harmaceutical Prod	uct Alert								
System						¢ HI	(No. 🗢	Mar			
		Notification Date		Subject		÷	(HO. +	Nai	ne of Product	4	
System Logout	Open	Notification Date 11.02.2016 04:00:00	Renewal P	Subject ending Reminder ending Notification		• нк60		OCTECTIN 500 CAP 500M	-	4	

Step 3: Click the "Cert_Payment_Notification.pdf" to view the certificate payment notification in pdf format.

	Online Notification	ONLINE	_NOTIFICATION_VIEW_01
T	New Product Registration		
	Notification Date :	17.08.2018 15:01:28	
You are login as WONG David	PL No. :	PL0031/2017	
ABC COMPANY LIMITED	PR No. :	PR0038/2017	
Login date and time 16.01.2020 11:13	HK No. :	HK63573	
Online Notification	Proposed Name of Product (English) : Notification Detail :	TEST 2016022701 Cert Payment Notification.pd	
My Product Search	Attachment(s) :		
+ New Registration	1. Go To Certificate Payment :	Go	
+ Change of Registered Particulars	2. In alternative to (1), you may send the	outstanding information by post or in person to the Drug Office:	
+ Renewal of Registration	Drug Evaluation and Import / Export C Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East,	ontrol Division	
Request to change name and/or address of the certificate holder	100 How Ming Street, Kwun Tong, Kowloon, Hong Kong	352) 3974 4175 or email to prs2_info@dh.gov.hk quoting the reference number of this application or the PL number of F	PR number of your product
+ Request to Cancel Product Registration	under the process of new product registr	ation.	
+ Payment			
Application History			
+ User Profile			
+ Printing Service			
+ System			
Logout			

PHARMACY AND POISONS ((CHAPTER 138)		
香港法例第138章藥劑業及	毒藥條例	
		Date 日期: 30/01/2015
NOTIFICATION OF PAY 徽費通知書	(MENT	
A. Payment Particulars 甲:繳費詳情		
This is to notify you to pay for the following application(s)/ 現通知 閣下繳交下列申請/註冊之費用:	registration(s):	
光道/山 南千藏大千万千亩/正间之夏用,		
	Number 數量	Total Fee 總費用
X Certificate(s) of Product Registration	1	UV\$1 270
藥劑製品註冊證明書 (HK\$1,370)	1	HK\$1,370
Ref. 檔號:		
PR0002/2015		
		Drug Office Department of Health
		Department of fream
CERT HOLDER 6 044, 11, A		

B. Payment Instructions 乙:繳費辦法

Please proceed to arrange payment of the prescribed fee within 10 working days from the date of this notification via the following means:

請於本通知書發出日期起10工作天內透過以下途徑繳交所須費用:

For application(s) made via paper mode, please arrange payment by Method 1 - 2; for application(s) made via electronic mode (i.e., PRS 2.0), please arrangement payment by Method 1 - 4: 如以硬本形式遞交申請,請以方法1 - 2繳費;如以電子形式(即PRS 2.0)遞交申請,請以方法1 - 4繳費;

- By post with payment cheque and this notification letter addressed to "Shroff Office, Drug Office of Department of Health" at 3/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, Hong Kong. Please note that crossed cheques should be made payable to "The Government of the Hong Kong Special Administrative Region". 用支票連同本通知書郵寄衞生署藥物辦公室繳款處收。地址為香港九龍南昌街382號公共衞
- 生檢測中心3樓。劃線支票抬頭寫上「香港特別行政區政府」。 2. In person with payment cheque or cash and this notification letter at the above address. Hours of operation:

Monday to Friday: 9:00 a.m. to 1:00 p.m. 2:00 p.m. to 5:30 p.m. (up to 5:45 p.m. on Monday) 攜同本通知書到上述辦事處以支票或現金繳交。辦事處收款時間: 星期一至星期五: 上午九時至下午一時 下午二時至下午五時三十分 (星期一至下午五時四十五分) (Note: CASH should NOT be sent through post 注意: 請勿郵寄現金) 3. By online credit card (Visa/MasterCard) payment via EGIS in PRS 2.0

- By online credit card (Visa/MasterCard) payment via EGIS in PRS 2.0 透過PRS2.0的電子政府基建服務以信用卡繳費 (Link / 網址: <<u>https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp></u>)
- By online PPS payment via EGIS in PRS 2.0 透過PRS2.0的電子政府基建服務以繳費靈繳費 (Link / 網址: <<u>https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp></u>)

第2頁(共3頁)

For "Certificate(s) of Product Registration", "Duplicate of Certificate(s)", "Change(s) of Registered Particulars", "Certificate(s) for Clinical Trial / Medicinal Test" and "Photocopy Service", please fill in Part C •

有關「藥劑製品註冊證明書」、「證明書的複本」、「更改註冊詳情」、「臨床試驗/藥 物測試證明書」及「影印服務」[,]請填妥<u>丙部</u>。

C. Certificate(s) Collection Method 丙: 領取證明書方法

Or或

I/we would like to collect the Certificate(s) of Product Registration in person at the above address from at least 5 working days from the date of payment made or effective date, whichever is later

我/我等欲在繳交費用或生效日期(以較遲者為準)後最少5個工作天起親自前往上述地址 領取證明書

> Company Stamp: 公司印鑑:

第3頁(共3頁)

Step 4: Click the "Go" button to the payment page if the fee is paid online.

	Online Notification	ONLINE_NOTIFICATION_VIEW_01
T	New Product Registration	
	Notification Date :	17.08.2018 15:01:28
You are login as WONG David	PL No. :	PL0031/2017
ABC COMPANY LIMITED	PR No. :	PR0038/2017
Login date and time 20.08.2018 14:04	HK No. :	
	Proposed Name of Product (English) :	TEST 2016022701
Online Notification	Notification Detail :	Cert_Payment_Notification.pdf
My Product Search	Attachment(s) :	
+ New Registration	1. Go To Certificate Payment :	Go
+ Change of Registered Particulars	2. In alternative to (1), you may send the	outstanding information by post or in person to the Drug Office:
+ Renewal of Registration	Drug Registration and Import / Export 0 3/F, Public Health Laboratory Centre 382 Nam Cheong Street Shek Kip Mei Kowloon	Control Division
+ Interview	Shek Kip Mei Kowloon Hong Kong	
+ Request to Cancel Product Registration	For enquiries, please call our hotline at (under the process of new product registra	352) 2319 8458 or email to prs2_info@dh.gov.hk quoting the reference number of this application or the PL number of PR number of your product ation.
+ Payment		
Application History		
+ User Profile		
+ System		
Logout		

Step 5: Select single/multiple application, then choose the certificate collection method (received by post or collect in person in Drug Office), and then click the "Ready to Pay" button.

New	Application Ce	rtificate Payment	t		
					Ready to Pay
	Application Received Date	PR No. 🗢	PL No. 💠	Proposed Name of Product \$	Payment Status 💠
	19.01.2017 10:52	PL0004/2017	PR0006/2017	TEST 2017011901	Ready for Certificate Payment
Certific	ate Collection: OReceive	ed By Post ⊜ Collect in Perso	n in Drug Office		

Step 6: Click "Yes" and the page will be redirected to payment gateway.





Step 7: Select a payment method, and then click the "Pay" button. GovHK香港政府一站通

or 📷	nline Payment Service	9			
Help	Please select the paym	ent method :			
Customer Service Hotline 2319 8461 Email	Type of Service Transaction Date Transaction Reference Number	DH Drug Office 29-03-2023 DHPRS-202303291025-94191			
pharmweb@ dh.gov.hk	Total Amount Payment Method*				
		Cancel Payment Pay			
	 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 r be successful. PPS Shop&Buy (PPS) does not support payment via browsers of mobile devices (including mobile phones and tablets) at the moment. If you pay by PPS, please change to use desktop computer. Merchant Name is applicable to credit card payment method only. 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 payment get or wait for several minutes before they get a response from the credit card payment gateway. I experience such a problem, please wait a moment and retry, or change to use other available payment methods. We apologise for any incomv caused. 				
		uers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please r if you want to learn more about the J/Secure, Mastercard SecureCode and Verified by Visa service.			
		HONG			

Step 8: A payment summary page is shown after payment is succeeded. Click the "Print Receipt" to view the payment receipt in pdf format.

NEW FIOU	uct Registration			Print Receipt Clos
Payment Refere	ence No.: DHPRS-201501	300534-90575		
EGIS Reference	No.: A201501300000	026		
Payment Metho	d: PPS			
Type of Paymer	nt: Certificate Fee			
Transaction Tim	ne: 30.01.2015 05:3	6:24		
Delivery Method	d: Collect in Persor	n in Drug Office		
Certificate Colle	ection Date: 06.02.2015			
Application Received Date 29.01.2015 14:02		Reference No. ANP20159000003	PR No. PR0002/2015	Product Name Indapamide-Trial Prolonged Release Tablets 1.5mg
				(AP8)(CH6)
response as so	e acknowledges the receipt of oon as possible. quote the above Payment Refe		tion fee regarding the above prod	(AP8)(CH6) luct(s). We will process your application and will provide
response as so Please kindly o	oon as possible. quote the above Payment Refe		tion fee regarding the above prod	
responsē as so Please kindly o General Enquirio Office Hours:	oon as possible. quote the above Payment Refe es: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on Monday) (Closed on Saturdays, Sund	rence Number for enquiries.	tion fee regarding the above prod	
response as so Please kindly o General Enquirio	oon as possible. quote the above Payment Refe es: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on Monday)	rence Number for enquiries.	tion fee regarding the above prod	

Name of Company 公司名稱 CERT HOLDER 6		Payment Date 繳費日期 30.1.2015
Payment Reference No: 付款編號: EGIS Reference No: EGIS編號:	DHPRS-201501300534-90575 A201501300000026	
Payment Method: 付款方法:	PPS	
Payment Amount: 付款金額:	HK\$1,370.00	

For Office use

certificate(s) collected on _____

Company Stamp:

公司印鑑:

Certificate(s) Collection Method

領取證明書方法

Please tick your preferred collection method: 請選擇領取證明書方法並在適當的空格內剔:

I/we would like to collect the Certificate(s) by post ;

我/我等欲以郵遞方式領取證明書

Or或

X I/we would like to collect the Certificate(s) of Product Registration in person at the above address from at least 5 working days from the date of payment made or effective date, whichever is later

我/我等欲在繳交費用或生效日期(以較遲者為準)後最少5個工作天起親自前往上述地址領取證 明書

2.5.2.6 Withdraw application

Step 1: Click the menu item "Withdraw application" under "New Product Registration" in the menu on the left.

•	Online	Notification						ONLIN	IE_NO	TIFICATION_VIE	EW_01
	New Pro	duct Registration							(Archived Notifica	ations
	No relat	ed notifications									
ou are login as ORG Trial ine ESTING LIMITED	CORP								(Archived Notifica	ations
ogin date and time 7.01.2021 09:43		Notification Date \$		Subject	¢	HK No.	¢	Name	of Pro	luct	¢
Online Notification	Open	12.01.2021 17:44:04	Application Screening Notificati	- on		HK41190		PRODUCT NAME XXXXX XX	oox		
Offinite Nouncation	Open	05.06.2020 11:00:01	Application Submitted Notificati	on		HK41190		PRODUCT NAME XXXXX XX	XXX		
My Product Search	Open	03.10.2019 11:55:37	Application Submitted Notificati	on		HK37565		PRODUCT NAME XXXXX			
	Open	04.03.2019 11:33:13	Application Approval Notification	1		HK31199		EPILIM FREEZE-DRIED PDF	RFOR	IV INJ 400MG	
New Registration	Open	27.02.2019 11:52:23	Certificate Fee Notification			HK65135		CELECOXIB FARMOZ			
Initiate New Product	Open	26.02.2019 15:12:46	Application Approval Notification	1		HK42175		APT-INDOMETHACIN 25 CA	P 25M	G	
Registration Application	Open	21.08.2018 18:25:53	Application Clarification Notifica	tion		HK41190		PRODUCT NAME XXXXX XX	oox		
	Open	21.08.2018 18:20:50	Application Screening Notificati	on		HK41190		PRODUCT NAME XXXXX XX	00X		
Application Status - Action Required	Open	21.08.2018 18:19:47	Application Submitted Notificati	Application Submitted Notification		HK41190 PRODUCT NAME XXXXX X			00X		
 Not Submitted Application Submitted 	Open	21.08.2018 18:07:37	Application Submitted Notificati	on		HK37565		PRODUCT NAME XXXXX			
Withdraw application	Renewa	l of Registration							(Archived Notifica	ations
Change of Registered Particulars		Notification Date \$		Subject	¢		Na	me of Product	ф	No. of Renewa	als ¢
Renewal of	Open	27.01.2021 04:00:14	Renewal Notification			DRUG NAME XXX	X TAB	50MG		1	
Registration	Cancella	ation Request									
Request to Cancel Product Registration		Notification Date \$		Subject	\$	HK No.	\$	Name	of Pro	luct	¢
	Open	26.01.2021 15:07:50	Cancellation Registration Requ	est Submitted Notification		HK31199		EPILIM FREEZE-DRIED PDF	RFOR	IV INJ 400MG	
Payment											
Application History		armaceutical Prod	uct Alert								
User Profile	No relat	ed notifications									
System											

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Step 2: Select a single/multiple application and click the "Withdraw application" button.

	New	Product	t Registration Withdr	awal			
							Withdraw application
You are login as ORG Trial			Application Date \$	PL No. 💠	PR No. 💠	Proposed Name of Product (English) \$	Application Status \$
One TESTING LIMITED Login date and time		2021.01.26		PL0001/2021		PRODUCT NAME	Application Submitted
27.01.2021 10:22		2021.01.26				PRODUCT NAME	Pending
Online Notification		2019.03.01				TEST DRUG 20190301	Pending
My Product Search							Withdraw application
- New Registration		-					
Initiate New Product Registration Application							
Application Status - Action Required - Not Submitted - Application Submitted							
Withdraw application							
+ Change of Registered Particulars							
+ Renewal of Registration							
+ Request to Cancel Product Registration							
+ Payment							
Application History							
+ User Profile							
+ System							
Logout							_

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Step 3: Input the reason (s) of withdrawal and click "Save" button to proceed the withdrawal request. Click 'Cancel' to cancel the withdrawal request.

Application Date	PL No.	÷	PR No.	÷	Proposed Name of Product (English) 💠	Ap	plication Status	¢
2018.07.18	PL0019/2018	•		•	TEST 2015	Screening		•
Date of Withdrawal Request :	20.08.2018							
Reason(s) of Withdrawal :					^ ~			
							Save	Cancel
Application Date	PL No.	\$	PR No.	\$	Proposed Name of Product (English)	A A	plication Status	\$
2018.07.18	PL0019/2018				TEST 2015	Screening		
Date of Withdrawal Request :	20.08.2018							
Reason(s) of Withdrawal :	The withdraw reason	state he	ere		~			

Step 4: Click the menu item "Application Status" under "New Application" in the menu on the left, the application status is changed to "Withdraw Application Request" under "Application Submitted".

								Withdraw application
are login as ORG Trial		Application Date	\$ PL No.	¢	PR No.	¢	Proposed Name of Product (English)	\$ Application Status
TING LIMITED	2021.01.2	6	PL0001/2021				PRODUCT NAME	Application Submitted
n date and time 1.2021 10:22	2021.01.2	6					PRODUCT NAME	Pending
nline Notification	2019.03.0	1					TEST DRUG 20190301	Pending
y Product Search								Withdraw applicati
ew Registration								
tiate New Product								
gistration plication								
blication Status tion Required tf Submitted piloation Submitted								
Indraw application								
ange of Registered rticulars newal of								
ange of Registered rticulars newal of gistration								
ange of Registered irticulars enewal of gistration equest to Cancel oduct Registration								
thdraw application nange of Registered rifticulars enewal of equest to Cancel oduct Registration syment upplication History								
ange of Registered inticulars gistration rquest to Cancel oduct Registration yment								
ange of Registered riticulars gistration quest to Caistration duct Registration yment plication History								

+	New	Pro	oduct Reg	jistratio	n								
	New S	ubm	ission										
u are login as ORG Tria	I InitiateN	lew P	roduct Registrat	ion									
sting LIMITED gin date and time .08.2018 14:24	Action	Rec	•										
Online Notification		\$	Application Date	Applicatio	on ID _‡	PL No. 💠	F	PR No. 💠	Proposed Name of Product (English)	No. of submission [‡]	Application Status	Status Date ≑	Paymen Status
	1		17.07.2018	ANP201890	00108	PL0010/2018			TEST ECERT CASE1	1	Withdraw Application Request	20.08.2018	No
My Product Search	2		31.07.2017	ANP201790	00079	PL0082/2017			TEST LOGIN2	1	Request for Outstanding	22.06.2018	No
Initiate New Product Registration Application	3		31.07.2017	ANP201790	00078	PL0081/2017			TEST USER LOGIN 2	1	Information Request for Outstanding Information	14.11.2017	No
	Not Su	bmi	tted										
Application Status - Action Required - Not Submitted - Application Submitted		\$	Latest Drat	ft Date 💠		Application ID	\$		Proposed Name of Product (E	nglish)	¢	Application !	Status 4
Application Submitted	1		10.08.2018		ANP2	0189000153		TEST NC	E2		Pen	ding	
Withdraw application	2		18.07.2018		ANP2	0189000132		TEST OP	EN FILE CASE 3		Pen	ding	
Change of Registered	Applic	atior	n Submitted										
Change of Registered Particulars		\$	Application Date	Applicatio	on ID _‡	PL No. 💠	F	PR No. 💠	Proposed Name of Product (English)	No. of submission *	Application Status	Status Date	Payment Status
Renewal of Registration	1		06.08.2018	ANP201890	00133	PL0019/2018			TEST 2015	1	Withdraw Application Request	20.08.2018	No
Interview	2		10.08.2018	ANP201890	00151	PL0022/2018			TEST NCE CASE	1	Application Submitted	15.08.2018	No
Request to Cancel Product Registration	3		24.02.2017	ANP201790	00023	PL0030/2017	PROD	36/2017	TEST 2017022401	1	Evaluation	31.07.2018	Yes
Payment													
Application History													
User Profile													
System													

After Drug Office Pharmacist reviewed and confirmed the application, the application status will be changed to "Withdraw Application Approved".

	Applicatio	n History	/								
	New Product	Registrati	on						Tota	Number of Ap	plication Records:1
You are login as	Application Date	PL No.	PR No.	♦ HK No.	\$	Name of	Product	\$	Payment Statuş	Status	Last Updated Date
Login date and time 20.08.2018 15:46	06.08.2018	PL0019/2018				TEST 2015			No	Withdraw Application Approved	06.08.2018
Online Notification	Change of R	egistered P	articulars						Total	Number of App	lication Records:1
My Product Search	Application Date	F	Ref No.	♦ HK No.	\$	Name of Product	¢	Change Categories 🕈	Payment Statuş	Status	Last Updated Date
+ New Registration	23.05.2018	CORP-HK56673	3-201851497	HK56673		VICK-CLONAZEPAM TAB 2N	IG	5	Certificate Fee Paid	Application Withdrawn	23.06.2018
+ Change of Registered Particulars	Renewal of F	Registratior	1						Total	Number of Appl	ication Records:0
+ Renewal of Registration	Expiry Date 🜲	HK No. 🧃	>			Name of Product		¢	Applicati	on Status 🕴	Last Updated Date
+ Interview	Termination	of Product	Registration						Total	Number of App	lication Records:0
+ Request to Cancel	Application Date	1	Ref No.	¢ I	HK No	φ. φ.	Name	of Product	\$	Status 🗢	Last Updated Date
Product Registration	Interview								Total	Number of App	lication Records:0
+ Payment	Applicati	on Date 🗧	>	Subject		\$		Application	¢	S	tatus 💠
Application History											
+ User Profile											
+ System											
Logout											

For application which is under evaluation process, applicant may receive an online notification "Confirmation for withdrawal".

	Onlir	ne Notification										ONL	INE_NOTIF	ICATION_VIEW_01
	New P	Product Registration	n											
		Notification [Date 🗢			Subject			\$	Prop	oosed Name of Proc	luct 💠	PL No.	Payment Statuts
You are login as	<u>Open</u>	20.08.2018 15:45:31		Confirmation for	or withdrawal					TEST 201	15		PL0019/20	018 N/A
	<u>Open</u>	14.11.2017 11:06:22		Application Pa	yment Reques	st -				TEST US	ER LOGIN 2		PL0081/20	017 Unpaid
Login date and time 17.08.2018 13:44	<u>Open</u>	03.04.2017 10:47:03		Application Pa	yment Reques	st				TEST 201	7022401		PL0030/20	17 Paid
Online Notification	CORP													
My Product Search	<u>Open</u>	Notification Date ¢ 07.08.2018 17:35:15		eening Notificati	Subject			\$	HK No HK63517). ¢	WALKTRHOUGH	Nam	e of Product	¢
	Open	07.08.2018 09:52:51		bmitted Notification					HK63517		WALKTRHOUGH			
+ New Registration														
+ Change of Registered Particulars	Renew	Notification Date			Subject			¢		Nar	ne of Product		¢	No. of Renewals 🗢
+ Renewal of	Open	29.06.2018 04:20:28	Renewal Notific	ation	Jubjeet			•	APO-LEVETIRA				1	No. of Renewards +
Registration	Open	23.06.2018 02:13:33	Expired Product						VICK-CLONAZE				1	
+ Interview	Cance	llation Request												
+ Request to Cancel Product Registration		•	tion Date	¢	5	Subject	\$		HK No.	\$		Name of	of Product	¢
+ Payment	Intervi	iew												
Application History				Notif	fication Date					¢		S	ubject	\$
+ User Profile	Non P	harmaceutical Prod	luct Alert											
+ System		Notifica	tion Date	\$	5	Subject	\$		HK No.	\$		Name o	of Product	\$
•	Onlin	ne Notification										ONLI	NE_NOTIFI	CATION_VIEW_01
		Product Registration												
		tion Date :		18 15:45:31										
You are login as	PL No. :		PL0019/2	2018										
Login date and time	PR No. HK No.		-											
20.08.2018 15:46		ed Name of Product (Englisi	h): TEST 20	15										
Online Notification		tion Detail :												
My Product Search	Attachm	nent(s) :												
+ New Registration	The with	hdrawal application has bee	n confirmed.											
+ Change of Registered Particulars	1. Back	To Application :	Go											
+ Renewal of Registration	2. In alter	mative to (1), you may send	d the outstanding	g information by	y post or in pe	erson to the	Drug Offi	ice:						
+ Interview	Drug R 3/F, Pu 382 No	Registration and Import / Exp ublic Health Laboratory Cen am Cheong Street	oort Control Divis tre	sion										
+ Request to Cancel Product Registration	Shek K Hong k													
+ Payment	For enqu under the	uiries, please call our hotline e process of new product re	at (852) 2319 8 gistration.	458 or email to	prs2_info@	dh.gov.hk q	uoting the	refer	rence number o	f this app	lication or the PL n	umber o	of PR numb	er of your product
Application History														
+ User Profile														
+ System														
Logout														

Applicant will receive the confirmation of withdrawal letter by post.



DEPARTMENT OF HEALTH DRUG OFFICE DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION 3/F., Public Health Laboratory Centre, 382 Nam Cheong Street, Kowfoon, Hong Kong

衛生署藥物辦公室 藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓

電話號碼 Tel. No: 98765432 詢問處 Enquiries: (852) 23198458 傳真號碼 Faxline No: (852) 28034962 本習檔號 Our Ref.: DH DO PRIE/8-15/2 (來函請敍明此檔案號碼) (IN REPLY PLEASE QUOTE THIS FILE REF.)

> ABC COMPANY LIMITED 382, 3, A CHA KWO LING, KOWLOON

Dear Sirs,

1. MY 20170523 1434 (ZEPATIER) (PR0002/2018)

Mfd By: My Manufacturer

Thank you for your letter dated 20.08.2018 under Ref. PR0002/2018 the content of which has been noted. The Department of Health is providing professional and executive support to the Pharmacy and Poisons Board and its Committees.

Please be informed that the Pharmacy and Poisons Board has no objection to the withdrawal of your application for registration of the above-named product(s).

Your attention is also drawn to Regulation 40 as read with Regulation 36(1) of the Pharmacy and Poisons Regulations, Cap138A, that the sale, offer for sale, distribution or possession for the purposes of sale, distribution or other use of unregistered pharmaceutical product/products is an offence under the Pharmacy and Poisons Regulations.

For enquiries, please contact prs_pp_super3 at Tel. No. .

Yours faithfully,

(H.K. CHAN) for Chief Pharmacist

c c SP (Drug IE) & SP (LC-W) File : PR0002/2018 HKC/

> We build a healthy Hong Kong and aspire to be an internationally renowned public health authority

2.6 CHANGE OF REGISTERED PARTICULARS

2.6.1 Initiate CORP Application

Step 1: Click the menu item "Initiate CORP Application" in the menu on the left.

The step 1 page of Change of Registered Particulars (CORP) Application will be displayed for input.

	Change of Registered Particulars (CORP) Application	
	Step 1: Selection of Products and Change Categories	Back Next
	Urgent Application (subject to decision by Drug Office)	
You are login as ORG Tria	Justification for urgent application Application Received 26.01.2021	
Dne Testing limited	Date: *Client Date: 26.01.2021	
Login date and time 26.01.2021 11:20	I know I have already submitted another CORP application under the same category/sub-category which is	
Online Notification	under processing. Justification for same category/sub-category application	
My Product Search		
+ New Registration	Certificate Holder Name:	
 Change of Registered Particulars 	TESTING LIMITED	
Initiate CORP	HK No. Product Name	
Application	Add Product Remove Product Select from all product	
Application Status - Action Required - Not Submitted	Please tick the appropriate change category and state the nature of the change.	
- Application Submitted	Particulars Proposed to Change Brief Description of Change and Reason	n
Withdraw application	+ 1 Specification	
DO Request Application	+ 2 Label	
+ Renewal of	+ 3 Package Insert	
Registration	+ 4 Manufacturer	
+ Request to Cancel Product Registration	+ 5 Registration Certificate Holder	
-	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)	
+ Payment	+ 7 Excipients	
Application History	+ 8 Indication / Dosage / Route of Administration	
+ User Profile	+ 9 Other	
+ System		\sim
Logout		
		Back

User can click "Add Product" button to add new row and input the product HK registration number directly. Selected product(s) can be removed by using "Remove Product" button.

	Change of Registered Particulars (CORP) Application			
-	Step 1: Selection of Products and Change Categories			Back Next
	Urgent Application (subject to decision by Drug Office) Justification for urgent application			
You are login as ORG Trial One TESTING LIMITED			*Application Received 26.01.2021 Date:	
Login date and time 26.01.2021 11:20	I know I have already submitted another CORP application under the same category/sub-c	ategory wł	*Client Date: 26.01.2021 hich is	
Online Notification	under processing. Justification for same category/sub-category application			
My Product Search	<u></u>			
+ New Registration	Certificate Holder Name:			
 Change of Registered Particulars 				
Initiate CORP Application	HK No. Product Name			
Application Status	Add Product Remove Product Select from all product			
 Action Required Not Submitted Application Submitted 	Please tick the appropriate change category and state the nature of the	change		
Withdraw application	Particulars Proposed to Change		Brief Description of Change and Reason	
	+ 1 Specification			
DO Request Application	+ 2 Label			
+ Renewal of	+ 3 Package Insert			
Registration	+ 4 Manufacturer			
+ Request to Cancel Product Registration	+ 5 Registration Certificate Holder			
-	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)			
+ Payment	+ 7 Excipients			
Application History	+ 8 Indication / Dosage / Route of Administration			
+ User Profile	+ 9 Other			
+ System				$\mathbf{\hat{v}}$
Logout				
				Back Next

User may click the "Select from all product" button to select the product which is proposed to change.

	Change of Registered Particulars (CORP) Application			
-	Step 1: Selection of Products and Change Categories			Back Next
	Urgent Application (subject to decision by Drug Office) Justification for urgent application			
You are login as ORG Trial One TESTING LIMITED			*Application Received 26.01.2021 Date:	
Login date and time 26.01.2021 11:20	I know I have already submitted another CORP application under the same category/sub-ca	tegory wh	*Client Date: 26.01.2021 nich is	
Online Notification	under processing. Justification for same category/sub-category application			
My Product Search	0			
+ New Registration	Certificate Holder Name:			
 Change of Registered Particulars 	TESTING LIMITED			
Initiate CORP Application	HK No. Product Name			
Application Status - Action Required - Not Submitted	(Add Product) Remove Product) Select from all product) Please tick the appropriate change category and state the nature of the	change	<u>.</u>	
- Application Submitted	Particulars Proposed to Change		Brief Description of Change and Reason	
Withdraw application	+ 1 Specification			
DO Request Application	+ 2 Label			
+ Renewal of	+ 3 Package Insert			
Registration	+ 4 Manufacturer			
+ Request to Cancel Product Registration	+ 5 Registration Certificate Holder			
+ Payment	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)			
	+ 7 Excipients			
Application History	+ 8 Indication / Dosage / Route of Administration			
+ User Profile	+ 9 Other			~
+ System				\sim
Logout			L	Back Next
				Back Next

By clicking the "Select from all product" button, the product list will be shown in pop up window for selection.

rod	luct List		
	HK No.	Product Name	
	HK37565	PRODUCT NAME XXXXX	
	HK41190	PRODUCT NAME XXXXX XXXX	
			Confirm Cancel

After user selects the product(s) and clicks the "Confirm" button, the selected product(s) will be shown in application step 1 page.

User may click "Urgent Application (subject to decision by Drug Office)" checkbox and provide justification for the request.

User can select one or more categories in one application, reason(s) for each change should be provided.

After input all mandatory fields, user may click "Next" button to proceed.

10001 - 10001	Change of Registered Particulars (CORP) Application		
-	Step 1: Selection of Products and Change Categories		Back Next
	Urgent Application (subject to decision by Drug Office)		
You are login as ORG Trial One TESTING LIMITED Login date and time 26.01.2021 11:20	desinction for upper application Need to use new location for our product	*Application Received 26.01.2021 Date: *Client Date: 26.01.2021	
26.01.2021 11:20	I know I have already submitted another CORP application under the same category/sub-ca under processing.	ategory which is	
Online Notification	diructi processing.		
My Product Search	0		
+ New Registration	Certificate Holder Name:		
- Change of Registered Particulars			
Initiate CORP Application	HK No. Product Name		
	HK37565 PRODUCT NAME XXXXX		
Application Status - Action Required - Not Submitted - Application Submitted	PRODUCT NAME XXXXX XXXX		
Withdraw application	Add Product) Remove Product) Select from all product		
DO Request	Please tick the appropriate change category and state the nature of the	-	
Application	Particulars Proposed to Change	Brief Description of Change and Reason	
+ Renewal of Registration	+ 1 Specification		
+ Request to Cancel	+ 2 Label		
Product Registration	+ 3 Package Insert		
+ Payment	+ 4 Manufacturer		
Application History	+ 5 Registration Certificate Holder		
+ User Profile	+ 5.1 Change in name and / or address of the current registration certificate holder	Change company location	^
+ System			~
Logout	+ 5.2 Change in new registration certificate holder		~
			\sim
	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)		
	+ 7 Excipients		
	+ 8 Indication / Dosage / Route of Administration		
	+ 9 Other		
			0
			~
			Back Next
	2015 copyright Important notices Last Revision Date: 02 Se	p 2020 Version: 1.0.99 (PP)	

Note:

- 1) Application by batch (i.e. select more than one product in one submission) is applicable for categories 3, 5 & 8 only. For remaining categories, only one product is allowed to select in one submission.
- For category "5.1 Change in name and / or address of the current registration certificate holder", user should <u>select all active product(s)</u> in one submission, otherwise the application cannot be submitted to Drug Office.

Step 2: Provide required supporting documents.

The step 2 page of Change of Registered Particulars (CORP) Application will be displayed for input.

User can propose an effective date for the application, two options are available.

10100 - 10100	Change of Register	ed Particulars (CORP) Application			
	Step 2: Uploading D	ocuments with Proposed Changes Highli	ghted, and Other Supp	orting Documents Close Back	Delete Save & Close
	For uploading Clean	Copy of Supporting Documents, please	refer to Step 3		Next
ou are login as VMG EST USER1 EAMAN COMPANY	Application Type: Application Received Dat	e: 07.12.2021	pplication		
.ogin date and time 7.12.2021 10:47	Product Selected:				
	# HK No.	Product Name		Proposed Effective Date *	
Online Notification	1 HK63722	PRODUCT_20211116		 1 week after approval 1 year after approval 	
My Product Search					
+ New Registration	*Remarks 1. For CORP application sub	mitted on or after 1 December 2021, the available options	for the effective date proposed by	v the applicant would only include 1 week or	1 vear after approval.
 Change of Registered Particulars 	 Applicants can apply for cl twice¹. 	hange of implementation date (CIMP) subsequent to the a	pproval of CORP, and for each ap	pproved CORP, the applicant can apply for C	IMP no more than
Initiate CORP Application	3. CORP shall be implement	ed within 2 years after approval [!] .			
Application Status	¹ This requirement applies to	CORP approved on or after 1 December 2021.			
Action Required Not Submitted Application Submitted		orting Documents. (Only relevant supporting docume			
Withdraw application	The recommendation resolution	Letter if no highlighed Copy ution of scanning for the supporting document is 360d	pi		
DO Request	i. Letter summarising th	e proposed changes			
Application	Remark	i i li	Dor	cuments File Name	
Change Effective Date					
+ Renewal of Registration				PLOAD File Chosen	
+ Submission of Other Post-registration	Add File Remove File				
Supplement		h the change(s) underlined or highlighted*			
+ Interview	Remark # Please	e specify the name of the Uploaded File in "Remark". (if ap		cuments File Name	
Request to change name and/or address of the certificate holder				PLOAD	
+ Request to Cancel Product Registration	Add File Demove File		No	File Chosen	

Application should submitted proposed effective date either 1 week after approval or 1 year after approval. By default, 1 year after approval is selected. (except for change in category 5 -Registration Certificate Holder).

For change in registration certificate holder, proposed effective date can be chosen from two options.

	Chang	ge of Re	egistered Pa	articu	lars	(CO	RP)	Appl	olicati	on											
T			ding Highligh Clean Copy									r to Ste	<mark>p 3</mark>				Close	Back	Delete	Save & Close	Next
You are login as CHAN Kim		ation Type ation Rece				tificate)7.2018		r initiate	ted - Ne	w COR	RP applicat	tion									
HONG KONG RED CROSS BLOOD TRANSFUSION	Product	Selected:																			
SERVICE Login date and time	#	HK No.		Pro	duct Na	ame									Propo	sed Eff	fective Da	ite			
01.08.2018 18:11 Online Notification	1	HK44456		MO	NOFIX	-VF HU	UMAN	FACTO	FOR IX	FOR IN	NJ 500IU			Г	~		d Date:	al: N		1	
Chime Notification	2	HK46073		INT	DAGAN		ODMAN				.IN INJ 6%			L	0.5	ayo an	or appro-	u.			
My Product Search	2	HK46073								LOBULI	IN INJ 6%	þ									
+ New Registration	3	HK58571					= 12.5G														
- Change of Registered Particulars	Change	Category a	nd Supporting D	Docum	nents. ((Only r	relevan			g docu	iments wil	ll be proc	essed)								
Initiate CORP Application	Please u The reco	pload Declormmendation	laration Letter if r on resolution of s	if no hig of scann	ghlighe ning for	d Cop r the s	oy support	rting do	locume	ent is 30	60dpi										
Application Status - Action Required - Not Submitted	Ŭ		Certificate H name and / o			e of	the c		nt ro	aiotra	ation co	rtificat	e holde								
Application Submitted			fication of Incorp											•							
Withdraw application			Remark											Doc	uments	File Na	ame				
DO Request Application													0		lpload File Cho]					
+ Renewal of Registration	Add Fil	e Remove	e File											NO	r në Cho	iseri					
+ Submission of Other Post-registration Supplement																	Close	Back	Delete	Save & Close	Next

One is to choose the date from the calendar box (pop-up window as shown below).

Expected Date:											
Days after appropriate	0	() Jan		▼ 20	15 💌		0				
	Su	Мо	Tu	We	Th	Fr	Sa				
					1	2	3				
	.4	5	6	7	8	9	10				
	11	12	13	14	15	16	17				
	18	19	20	21	22	23	24				
	25	26	27	28	29	30	31				

Another one is in the form of "X days after approval", X can be 1 to 60. It can be selected from the dropdown list as shown below.

Proposed Effective Date			
Expected Date:			
Oays after approval:		Ŧ	
	31 32 33 34 35 36 37 38 39 40 41 42 43 44 45	*	
cuments File Name	46		
Jpload No File Chosen	47 48 49 50 51 52 53 54 55 56 57 58 59 60	4 III	Cancel Save & Close Next

Application can be submitted without any proposed effective date. In such case, the effective date by default is 30 days after approval.

For change in registration certificate holder, signature fee is required for issuing an updated Certificate of Drug/Product Registration, the payment date will be regarded as the effective date if it is not proposed by applicant.

2 Label

2.1 Change in label i. Proposed label with the change(s) underlined or highlighted

	Remark	D	ocuments File Name	The same file has already
	# Please specify the name of the Uploaded File in "Remark". (if applicable)			been uploade in another location in this submission #
]			Upload st20170702.pdf	
ld File (Remove File			
Packag	je Insert ge in package insert			
Packag	ge Insert ge in package insert package insert with the change(s) underlined and highlighted*	n	ocuments File Name	The same file
Packag	je Insert ge in package insert	D	ocuments File Name	The same file has already been uploadd in another location in th submission #

Add File Remove File

Application can check the checkbox under the "The same file has already been uploaded in another location in this submission" and indicate the file name in Remark to avoid duplicate upload.

	Chang	ge of Re	gistered Pa	articulars (CORP) /	Applica	ation						_					
Ť			ding Highligh Clean Copy						to Step	3			Clo	se Bac	k Delete	Save &	Close	Nex
You are login as CHAN		ation Type: ation Rece			ficate holder i 7.2018	initiated - N	New CO	RP applicati	tion									
HONG KONG RED CROSS BLOOD TRANSFUSION	Product	Selected:																
SERVICE Login date and time	#	HK No.		Product Na	me							Proposed	Effective	Date				
01.08.2018 18:11 Online Notification	1	HK44456		MONOFIX-	VF HUMAN F	FACTOR I	IX FOR I	INJ 500IU				 Expe Days 			~			
Online Nouncation		1.00070										() bujo	anoi app		•			
My Product Search	2	HK46073			1 P NORMAL		GLOBUI	ILIN INJ 6%										
+ New Registration	3	HK58570			5 INF 12.5G/													
· New Neglatration	4	HK58571		ALBUMEX	20 INF 10G/5	50ML												
 Change of Registered Particulars 			nd Supporting D	•					I be proces	ssed)								
Initiate CORP Application	Please u The reco	pload Declommendation	aration Letter if on resolution of	f no highlighed f scanning for	I Copy the support	ting docun	ment is 3	360dpi										
Application Status	5 Regi	stration	Certificate H	Holder														
 Action Required Not Submitted Application Submitted 			name and / c															
Withdraw application			Remark								Docu	uments File	Name					
DO Request Application										$\hat{}$		oload ile Chosen						
+ Renewal of Registration	Add Fil	e Remove	e File								Nor	ine onosen	-					_
+ Submission of Other Post-registration Supplement													Cla	ose Bac	k Delete	Save &	Close	Next

Different supporting document(s) is/ are required depending on the change category. Some supporting documents are mandatory (denoted as "*"), and they must be provided before clicking "Next" button to proceed.

After the upload of required supporting documents (tracked copies if applicable), user can click "Next" button to proceed.

User can click "Back" button without saving and go back to step 1 page to select another product and/ or category for this application.

User can click "Cancel" button to cancel this application and go back to "Application Status" page. Please note all saved data of this application will be lost after this action.

User can click "Save & Close" button to save the application as draft version and continue the submission in the future.

Step 3: Change of related product particulars.

The step 3 page of Change of Registered Particulars (CORP) Application will be displayed for input.

	Change of Registered P	Particulars (CORP) Application			
Ť	Step 3: Change Product			Close Back Delete	Save & Close Next
	Application Type:	Certificate holder initiated - New Co	ORP application		
You are login as ORG Trial One	Application Received Date:	21.08.2018			
TESTING LIMITED Login date and time	Product Selected:			1	
21.08.2018 17:56	# HK No.	Product Name		Proposed Effective Date	
Online Notification	1 HK37565 2 HK41190	PRODUCT NAME XXXXX PRODUCT NAME XXXXX XXXX			
My Product Search					
+ New Registration	1.0.6.1 Proposed Registratio	n Certificate Holder			
 Change of Registered Particulars 	a. Name:	TESTING LIMITED			
Initiate CORP Application	b. Address: Unit:	Room 301			
Application Status - Action Required - Not Submitted	Floor:	3/F			
- Application Submitted	Block:				
Withdraw application	Building:	Public Health Laboratory Cer	ntre		
+ Renewal of Registration	Street No.:				
+ Submission of Other Post-registration Supplement	Street Name:	382 Nam Cheong Street			
+ Request to Cancel Product Registration	Sub-district: Area:	SHEK KIP MEI			
+ Payment	c. Phone Number:		Fax Number:		
			Fax Number.		
Application History	d. Contact Person for t	thin Trial	Phone No*:	23198414	
+ User Profile	Application*:		Email*:		
+ System		Trial	Email".	trial@test.com	
Logout		lesale dealer subsidiary, representative, agent or distributor lesale dealer who has entered into a contract v		ich the licensed manufacturer is required	to manufacture the
	1.0.6.2 Staff responsible for F	Pharmacovigilance			
	a. Name of Staff:	Trial One			
	b. Contact Person H	HK Telephone No.: 852 23198414	Position: Trial	Email: trial@test.com	
	(24 hours)				
	1.1.0 Annexed Documents/inf		_		
	 Copy of business registra 	ation certificate. (Reference for 1.0.6.1 of Pa	UPLOAD No of File(s): 1		
				Close Back Delete	Save & Close Next

By default the currently registered product information will be shown. User needs to modify the product particulars related to the selected categories.

All mandatory fields with "*" must be provided before clicking "Next" button to proceed to application summary.

User can click "Back" button without saving and go back to step 2 page to select another proposed effective date or provide other supporting documents for this application.

User can click "Cancel" button to cancel this application and go back to "Application Status" page. Please note all saved data of this application will be lost after this action.

User can click "Save & Close" button to save the application as draft version and continue the submission in the future.

Step 4: View application summary before submission of application

The application summary of Change of Registered Particulars (CORP) Application will be displayed for review.

	Observe of Pogistor		
	Application Summary	red Particulars (CORP) Application	Close Back Delete Save & Close Confirm & Submit
You are login as ORG Trial	Application Type: Application Received Date	Certificate holder initiated - New CORP application	
One	Product Selected:		
Login date and time 21.08.2018 17:56	# HK No.	Product Name	Proposed Effective Date
	1 HK37565	PRODUCT NAME XXXXX	1 Depresentation of a care
Online Notification	2 HK41190	PRODUCT NAME XXXXX XXXX	
My Product Search	Change Category:		
+ New Registration	Particulars Proposed to Char	ange	Brief Description of Change and Reason
 Change of Registered Particulars 	-	or address of the current registration certificate holder	change company location
Initiate CORP Application	Supporting Documen 5 Registration Certific		
		and / or address of the current registration certific of Incorporation on the Change of Name (for incorporated compan	
	Remark		Documents File Name
Withdraw application			No File Chosen
+ Renewal of Registration			
+ Submission of Other Post-registration Supplement		DECLARAT	лом
+ Request to Cancel Product Registration		BY THE APPLICANT: I hereby declare that to the best of my knowledge en identified and are being applied for the approval to change the regist	ge and belief that the information given in this application is correct and all the stered particular(s).
+ Payment			
Application History			
Application matory			
+ User Profile	The product / sub	bstance	
	is supplied to the De	Department of Health via tender or direct purchase agreements.	
+ User Profile	is supplied to the De		

If no further change is required after reviewing the application summary, user may tick the checkbox of declaration and select the product / substance is or is not supplied to the Department of Health via tender or direct purchase agreements". After that, user may click "Confirm & Submit" button to submit the application to Drug Office.

Please note that application is not allowed to change once submitted. Application can be withdrawn if the application is not yet approved by Drug Office.

User can click "Back" button without saving and go back to step 3 page for update of product particulars for this application.

User can click "Cancel" button to cancel this application and go back to "Application Status" page. Please note all saved data of this application will be lost after this action.

User can click "Save & Close" button to save the application as draft version and continue the submission in the future.

Step 5: Acknowledgement of application

The acknowledgement of Change of Registered Particulars (CORP) Application will be displayed.

	Chan	ge of Registe	red Particulars	(CORP) A	pplication					
-	Ackn	owledgement						Print Close		
	Tha	nk you for using (our service. Your ap	oplication has	been submitted to the Drug Office.					
You are login as ORG Trial One	Appl	ication submitted sh	ould be subjected to or	ur final approval	- I.					
TESTING LIMITED Login date and time	Fore	enquiries, please ca	II us quoting this refere	nce number.						
21.08.2018 17:56	Gen	eral enquiries:								
Online Notification			Office Hours:	Monday to Frid	lay					
My Product Search				9:00 am - 1:00	pm					
+ New Registration				2:00 pm - 5:45	pm					
-				(up to 6:00 pm						
 Change of Registered Particulars 				(Closed on Saturdays, Sundays & Public Holidays)						
Initiate CORP Application			Tel:	(852) 2319 8458						
			Email:	prs2_info@dh.						
Application Status - Action Required - Not Submitted - Application Submitted	Арр	lication Received [Date: 21.08.2018							
Withdraw application	Produ	ict Selected:								
+ Renewal of Registration		HK No.	PR No. F	PL No.	Product Name		Application Reference No.	Proposed Effective Date		
+ Submission of Other	1	HK37565	PR0568/1993		PRODUCT NAME XXXXX		CORP-HK37565-201857482			
Post-registration Supplement	2	HK41190	PR0552/1996		PRODUCT NAME XXXXX XXXX		CORP-HK41190-201857483			
	Chan	ge Category:								
Product Registration	Particu	ilars Proposed to Ch	nange				Brief Description of Change and Reasor	1		
+ Payment	5.1 C	hange in name and	/ or address of the curr	ent registration	certificate holder		change company location			
Application History	Supp	orting Docume	ents:							
+ User Profile	5 Reg	istration Certi	ficate Holder							
					rrent registration certificate hold Name (for incorporated company only)	ler				
Logout		Rema	rk			Docume	ents File Name			
						No File	Chosen			
								Print Close		

Once the application is submitted, the application received date and the application reference number are shown for user information.

Application reference number for each application is unique. For application by batch, the application reference number of the first product in the batch is assigned as the batch application reference number.

User may click "Print" button to print the acknowledgement letter for record.

衛生署藥物辦公室 藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓

電話號碼 Tel. No: (852) 2319 8458 詢問處 Enquiries: (852) 2319 8458

傳真號碼 Faxline No: (852) 2803 4962

TESTING LIMITED XXXXX BUILDING, 10 XXXX XXXX XXX STREET YAU TONG, KOWLOON 10/F

Dear Sirs/Madams,

Change of Registered Particulars Acknowledgment

Thank you for using our service. You application have been submitted to the Drug Office.

Application submitted should be subject to our final approval (where applicable).

For enquiries, please call us quoting this reference number.

General Enquiries:

Office Hour : Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on Monday) (Closed on Saturdays, Sundays & Public Holidays)

Email: pharmgeneral@dh.gov.hk

You application have been submitted to the Drug Office. The reference number are listed with the product for your reference.

HK No.	PR No.	PL No.	Product Name	Application Reference No.
HK-37565	PR0568/1993		PRODUCT NAME XXXXX	CORP-HK37565-201857482
HK-41190	PR0552/1996		PRODUCT NAME XXXXX XXXX	CORP-HK41190-201857483
Particulars I	Proposed to Change	,	Change R	eason

5.1 Change in name and / or address of the current registration certificate holder change company location

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User may click "Close" button and go to "Application Status" page to view status of all applications.

2.6.1.1 Application Status - Action Required - Not Submitted - Application Submitted

DEPARTMENT OF HEALTH DRUG OFFICE DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION 3/F., Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon, Hong Kong

21 August 2018

Step 1: Click the menu item "Application Status" in the menu on the left.

ou are login as ORG Tria ne	Initia	e New CORP App	plication						
ESTING LIMITED ogin date and time 5.01.2021 11:20	Actio	on Required							
Online Notification	\$	Received \$	Batch No. 💠	Ref. No. 🔶	HK No. 🔶	Product Name	Change Categories	Status 🜩	Payment Status
My Product Search	1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX	4	Application Evaluated	Not Necessary
New Registration	Not	Submitted							
-	÷	Received 🜲	Batch No. 💠	Ref. No. ♦	HK No. 🔶	Product Name 🜲	Change Categories \$	Status 💠	Payment Status
Change of Registered Particulars	1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary
Initiate CORP Application	Appl	ication Subm	nitted						
Application Status	÷	Received 🜲	Batch No. 💠	Ref. No. 🔶	HK No. 🔶	Product Name 🜲	Change Categories \$	Status 💠	Payment Status
- Action Required - Not Submitted - Application Submitted	1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX	3,4,7	Application Evaluated	Not Necessary
Withdraw application	2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
DO Request Application	3	04.03.2019	CORP-HK31199-201950013- 01	<u>СОRР-НК31199-201950013- 01</u>	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	1,5,7	Application Approved	Certificate Fee Pai
Renewal of	4	25.04.2017	CORP-HK42175-201753699- 02	CORP-HK42175-201753699- 02	HK42175	APT-INDOMETHACIN 25 CAP 25MG	1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Pai
Registration	5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
Request to Cancel Product Registration	6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
Payment	7	03.07.2017	CORP-HK31199-201757230	CORP-HK31199-201757230	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	3	Application Screening Accepted	Not Necessary
Application History									
User Profile	i								
System									
Logout									
-				rtant notices Last Revision	Date: 02 Sep 20	20 Version: 1.0.99 (PP)			

The application status page will be displayed for review.

The download link of the e-Certificate is enabled for one-time use. Please keep a copy of the e-Certificate for your record after downloading.

All applications will be listed in this page for review except those have been completed or withdrawn. Applications are categorized according to their status:

1) Action Required

ou are login as ORG Tria		Submission te New CORP Ar							
19 STING LIMITED	" (initiat	LE NEW CORP AL	pplication						
gin date and time .01.2021 11:20	Actio	on Required							
0 F 11 FF F	+	Received 🖕	Batch No. 🖕	Ref. No. 🖕	HK No. 🖕	Product Name 🖕	Change	Status 🖕	Payment Statu
Online Notification	1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX	4	Application Evaluated	Not Necessary
My Product Search									
New Registration	Not \$	Submitted							
Change of Registered	÷	Received 🔶	Batch No. 🔶	Ref. No. 🔶	HK No. 🔶	Product Name 🔶	Change Categories	Status 🔶	Payment Statu
Particulars	1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary
Initiate CORP Application	Appl	ication Subr							
Application Status	¢	Received \$	Batch No. 💠	Ref. No. 💠	HK No. 🔶	Product Name 🔶	Change Categories ≑	Status 💠	Payment Statu
- Action Required - Not Submitted - Application Submitted	1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX XXXXX	3,4,7	Application Evaluated	Not Necessary
Withdraw application	2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
DO Request Application	3	04.03.2019	CORP-HK31199-201950013- 01	CORP-HK31199-201950013- 01	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	1,5,7	Application Approved	Certificate Fee Pa
Renewal of	4	25.04.2017	CORP-HK42175-201753699- 02	CORP-HK42175-201753699- 02	HK42175	APT-INDOMETHACIN 25 CAP 25MG	1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Pa
Registration Request to Cancel	5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary
Product Registration	6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
Payment	7	03.07.2017	CORP-HK31199-201757230	CORP-HK31199-201757230	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	3	Application Screening Accepted	Not Necessary
Application History									
User Profile									
System									
Logout									

User needs to take necessary action to follow up the applications listed in this section. For example, user needs to reply deficiency / clarification letter or pay signature fee. By clicking the application reference number, related details will be shown as below:

	CORP A	pplication Status								
-								Reply Clarification	n Letter Withdraw A	Application Close
	Summary	e-Product File (e-PF) Change	DO Req.	Clarification Letter	Ack. Letter	CORP Change Hist	ory Ref. Ma	terial Same Batch		
You are login as ORG Trial One		Reference No.:		K41190-201857485		Application Status	c -	Application Eval		
TESTING LIMITED Login date and time 21.08.2018 18:26	Application E HK No.: Product Nan		HK41190	K41190-201857485) CT NAME XXXXX XX	xx	Application Type: Previous App. Ref DO Request Refe		Certificate holde	P application	
Online Notification		Received Date:	21.08.20	18		Client Date:		21.08.2018		
My Product Search	Proposed Ef Hard Copy F	fective Date: Received Date:				Application Form I Justification (Urge	-	No File Chosen		
+ New Registration	Submission Applicant Us	Acknowledgement: sername:	<u>Submiss</u> joelun	ion Acknowledgemen	t					
- Change of Registered Particulars	Cate	gory 4 - Manufacturer	Clarif	ication Letter S	ent —					
Initiate CORP Application	Particular	s Proposed to Change		Recall Reguir		print Required Eva	aluation Com	ment and Result		
Application Status - Action Required - Not Submitted - Application Submitted	4.Manufad	cturer				Pl	.ease repl	У		^
Withdraw application	4.1-Chang	e in name and / or address of	the current	manufacturer Yes	V Not Req	uired 🗸				
+ Renewal of Registration	Brief Desc	ription of Change and Reason	: test				Satisfactory	Unsatisfactory	Acknowledged	Withdrawn
+ Submission of Other Post-registration Supplement	Supportin	g Documents:					,	,	J	
+ Request to Cancel	4.1 Chang	je in name and / or address o	of the curre	ent manufacturer						
Product Registration	i. Propose	ed label with the change(s) u	nderlined	or highlighted *						
+ Payment	Documen	nts File Name	Remark		Screeni	ng Comment	Eva	aluation Comment		
Application History										_
+ User Profile	test2017(0702.pdf The same file								~
+ System	has alrea	dy been uploaded in another n this submission								
Logout		ategories Allowed for Amend	dment:							
								Reply Clarification	n Letter Withdraw A	Application Close

User can withdraw application if the application is not yet approved by Drug Office.

User may click "Reply Deficiency/ Clarification Letter" to reply screening/ evaluation officer with the requested information:

User can click "Submission Acknowledgement" to view the acknowledgement letter

	Step 1: Selection of Products and Change Categoria	ries			Back Next
	Urgent Application (subject to decision by Drug Office) Justification for urgent application				
'ou are login as ORG Trial)ne		^	Application Received Date:	21.08.2018	
ESTING LIMITED		v	Client Date:	21.08.2018	
1.08.2018 18:26	Certificate Holder Name:	J	ustification for changing the	batch :	
Online Notification	TESTING LIMITED	Γ			~
					\bigcirc
My Product Search		L			
+ New Registration	HK No. Product Name				
- Change of Registered Particulars	HK41190 PRODUCT NAME XXXX	x xxxx			
Initiate CORP	Please tick the appropriate change category and state	the nature of the chang	ge.		
Application	Particulars Proposed to Change		Brief Description of	Change and Reason	
Application Status - Action Required - Not Submitted	+ 1 Specification				
- Application Submitted	+ 2 Label				
Withdraw application	+ 3 Package Insert				
+ Renewal of	+ 4 Manufacturer				
Registration	+ 4.1 Change in name and / or address of the curre	nt manufacturer 🔽	test		
+ Submission of Other Post-registration Supplement					\sim
+ Request to Cancel Product Registration	+ 4.2 Change in new manufacturer				
-					^
+ Payment					×
Application History	+ 5 Registration Certificate Holder				
+ User Profile	+ 6 Quantity of the Dose Form in Unit Package (i.e. F	Package Size)			
+ System	+ 7 Excipients	J ,			
Logout	+ 8 Indication / Dosage / Route of Administration				
Logout	+ 9 Other				
					^
					~

In replied application, selected product(s) can be "deselected"; no new product can be added. If any product from the batch is "deselected", justification should be provided in the field "Justification for changing the batch". Unless under the direction of evaluation officer, other category cannot be selected in the replied application.

2) Not Submitted

		be reminded that Submission	for approved application(s), y	ou are required to submit app	lication(s) for	cha	ange of implementation date	e 5 working days b	efore the effective dat	e, if necessary.
ou are login as ORG Tria ne	I Initiat	e New CORP App	olication							
ESTING LIMITED ogin date and time 5.01.2021 11:20	Actic	on Required								
	\$	Received 🜲	Batch No. 💠	Ref. No. 💠	HK No.	¢	Product Name	Change Categories	Status 🔶	Payment Status
Online Notification My Product Search	1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190		PRODUCT NAME XXXXX XXXX	4	Application Evaluated	Not Necessary
New Registration	Not §	Submitted								
	¢	Received 🔶	Batch No. 🔶	Ref. No. 💠	HK No. 🗧	¢	Product Name 🝦	Change Categories	Status ¢	Payment Status
Change of Registered Particulars	1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565		PRODUCT NAME XXXXX	1	Application Saved	Not Necessary
Initiate CORP Application	Appl	ication Subm	itted							
Application Status	¢	Received 🜩	Batch No. 💠	Ref. No. 💠	HK No.	¢	Product Name	Change Categories	Status 💠	Payment Status
- Action Required - Not Submitted - Application Submitted	1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190		PRODUCT NAME XXXXX XXXX	3,4,7	Application Evaluated	Not Necessary
Withdraw application	2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565		PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
DO Request Application	3	04.03.2019	CORP-HK31199-201950013- 01	CORP-HK31199-201950013- 01	HK31199		EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	1,5,7	Application Approved	Certificate Fee Paid
Renewal of	4	25.04.2017	CORP-HK42175-201753699- 02	<u>CORP-HK42175-201753699-</u> 02	HK42175		APT-INDOMETHACIN 25 CAP 25MG	1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Pai
Registration	5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190		PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary
Request to Cancel Product Registration	6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565		PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
Payment	7	03.07.2017	CORP-HK31199-201757230	CORP-HK31199-201757230	HK31199		EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	3	Application Screening Accepted	Not Necessary
Application History										
User Profile										
System										
Logout										

The applications listed in this section has been saved but not yet submitted to Drug Office. User may click the application reference number to continue submission as shown below:

	CORP Ap	plication Status												
Ť										Continue	Application	Delete Appl	ication	Close
	Summary	e-Product File (e-PF) Change	DO Req.	Clarification	etter	Ack. Letter	CORP Change Hi	istory	Ref. Material	Same Batch				
You are login as ORG Trial One	Application R	leference No.:	CORP-H	K37565-2018	57484		Application State	us:		Application Sav	ed			
TESTING LIMITED Login date and time	Application B	atch No.:		K37565-20185 -	7484		Application Type			Certificate hold	er initiated - I	New CORP ap	plication	
21.08.2018 18:26	HK No.: Product Nam	o.	HK3756	D OT NAME XXX	vv		Previous App. R DO Request Re							
Online Notification		e. leceived Date:	21.08.20		~~		Client Date:	lerence	NO	21.08.2018				
	Proposed Eff	ective Date:					Application Forn	n Image:		No File Chosen				
My Product Search	Hard Copy R	eceived Date:					Justification (Urg	gent App	lication):					
+ New Registration	Categ	jory 3 - Package Inse	rt Initia	ated —										
- Change of Registered Particulars	Particulars	s Proposed to Change			Recall	Cert. Re	print Required E	valuatio	on Commen	t and Result				
					Require									
Initiate CORP Application														
Application Status - Action Required - Not Submitted	3.Package	Insert												\sim
- Not Submitted - Application Submitted	3.1-Chang	e in package insert			Yes	 Not Req 	uired 🗸							
Withdraw application	Brief Desci	ription of Change and Reason	: tets					_						
+ Renewal of								Satisfa	actory L	Insatisfactory	Acknow	ledged V	Withdraw	/n
Registration	Supporting	g Documents:												
+ Submission of Other Post-registration	3.1 Chang	e in package insert												
Supplement	Change Ca	tegories Allowed for Amen	dment:											
+ Request to Cancel Product Registration														
-										Continue	Application	Delete Appl	ication	Close
+ Payment														
Application History														
+ User Profile														
+ System														
Logout														

User can click "Delete Application" to delete the application as the application is not yet submitted to Drug Office.

User may click "Continue Application" to continue the submission as shown below:

	Change of Registered Particulars (CORP) Application				
	Step 1: Selection of Products and Change Categories			Back	Next
	 Urgent Application (subject to decision by Drug Office) Justification for urgent application 				
You are login as ORG Trial One		*Ap	plication Received Date: 21.08.2018		
TESTING LIMITED	\sim	*Cli	ent Date: 21.08.2018		
21.08.2018 18:26	Certificate Holder Name:				
Online Notification	TESTING LIMITED				
My Product Search	HK No. Product Name				
+ New Registration	HK37565 PRODUCT NAME XXXXX				
- Change of Registered	Add Product Remove Product Select from all product				
Particulars	Please tick the appropriate change category and state the nature of the	change			
Initiate CORP Application	Particulars Proposed to Change		Brief Description of Change and Reason		
Application Status	+ 1 Specification				
 Action Required Not Submitted Application Submitted 	+ 2 Label				
Withdraw application	+ 3 Package Insert				
+ Renewal of	+ 3.1 Change in package insert		change PI		
Registration					0
+ Submission of Other					
Post-registration Supplement	+ 3.2 Addition of package insert				
+ Request to Cancel Product Registration					\sim
+ Payment	+ 4 Manufacturer				
Application History	+ 5 Registration Certificate Holder				
	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)				
+ User Profile	+ 7 Excipients				
+ System	+ 8 Indication / Dosage / Route of Administration				
Logout	+ 9 Other				
					$\hat{\mathbf{C}}$
					~
				Back	Next

3) Application Submitted

		e be reminded that Submission	for approved application(s), y	ou are required to submit app	lication(s) for cl	hange of implementation date	5 working days be	fore the effective date	e, if necessary.
u are login as ORG Tri e	al Initia	te New CORP App	olication						
STING LIMITED gin date and time 01.2021 11:20	Actio	on Required							
Online Melification	¢	Received 🜲	Batch No. \$	Ref. No. 💠	HK No. 🗢	Product Name 🜲	Change Categories	Status 💠	Payment Status
Online Notification	1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated	Not Necessary
My Product Search New Registration	Not	Submitted							
Change of Registered	¢	Received 🔶	Batch No.	Ref. No. 💠	HK No. 🔶	Product Name 🔶	Change Categories 🗢	Status 💠	Payment Status
Particulars	1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary
Initiate CORP Application	Appl	ication Subm	itted						
Application Status	¢	Received 🔶	Batch No. 💠	Ref. No. 💠	HK No. 💠	Product Name 🔶	Change Categories \$	Status 💠	Payment Status
- Action Required - Not Submitted - Application Submitted	1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX XXXX	3,4,7	Application Evaluated	Not Necessary
Withdraw application	2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
DO Request Application	3	04.03.2019	CORP-HK31199-201950013- 01	CORP-HK31199-201950013- 01	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	1,5,7	Application Approved	Certificate Fee Pai
Renewal of	4	25.04.2017	CORP-HK42175-201753699- 02	<u>CORP-HK42175-201753699-</u> 02	HK42175	APT-INDOMETHACIN 25 CAP 25MG	1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Pai
Registration	5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXXX	5	Application Under Screening	Not Necessary
Request to Cancel Product Registration	6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
Payment	7	03.07.2017	CORP-HK31199-201757230	CORP-HK31199-201757230	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	3	Application Screening Accepted	Not Necessary
Application History									
User Profile									
System									
Logout									

The applications listed in this section are those submitted to Drug Office and under processing. The application status will be changed subjected to the progress. User may click the application reference number to view the application information:

	CORP A	pplication Status											
											Change Eff	ective Date	Close
	Summary	e-Product File (e-PF) Change	DO Req.	Clarification I	etter	Ack. Letter	CORP Change Hi	istory Ref	f. Material	Same Batch			
You are login as ORG Trial One	Application F	Reference No.:	CORP-H	K41190-20185	7486		Application State	us:		Application Appr	oved		
TESTING LIMITED Login date and time	Application E	Batch No.:		K41190-20185	7486		Application Type			Certificate holde	r initiated - New COR	application	l i
21.08.2018 18:35	HK No.: Product Nan	20.	HK41190) CT NAME XXX	~~ ~~~		Previous App. R DO Request Ref						
Online Notification		Received Date:	21.08.20		~~ ~~~~		Client Date:	lefence No.		21.08.2018			
	Proposed Ef	fective Date:					Application Forn	n Image:		No File Chosen			
My Product Search		Received Date:					Justification (Urg	gent Applica	ation):				
+ New Registration		Acknowledgement:		ion Acknowled	gement								
- Change of Registered	Applicant Us	ername:	joelun										
Particulars	Cate	gory 1 - Specification	Appro	ved —									
Initiate CORP Application	Particular	s Proposed to Change			Recall	Cert. Re	print Required E	valuation C	Comment	and Result			
					Required								
Application Status - Action Required - Not Submitted - Application Submitted													
- Application Submitted	1. Specific	ation											^
Withdraw application	1.1-Chang	e in specifications of the produ	ict	t Yes V Not Required V									
+ Renewal of	Brief Desc	ription of Change and Reason:	change la	bel									\sim
Registration	Effective E	Date: 31.08.2018						Satisfacto	U vro	nsatisfactory	Acknowledged	Withdra	wn
+ Submission of Other Post-registration	Supportin	a Decumenter								,	5		
Supplement	Supporting Documents:												
+ Request to Cancel	1.1 Chang	e in specifications of the pro	auci										
Product Registration	i. Propose	ed specifications with the cha	ange(s) un	derlined or hi	ghlighted	*							
+ Payment	Documer	nts File Name	Remark			Screeni	ng Comment		Evaluatio	on Comment			
Application History													
+ User Profile													
+ System		<u>D702.pdf</u> The same file dy been uploaded in another											
+ oystem		n this submission											
Logout	Change C	ategories Allowed for Amend	iment:										
	Shange G										_		
											Change Eff	ective Date	Close

For the approved or partial approved application, user may click the "Change Effective Date" button to change the effective date of those approved categories as following:

	Change of Registered Particulars (CORP) Application		
	Step 1: Selection of Products and Change Categories		Back Next
You are login as ORG Trial One TESTING LIMITED	Urgent Application (subject to decision by Drug Office) Justification for urgent application	*Application Received Date: 21.08.2018 *Client Date: 21.08.2018	
Login date and time 21.08.2018 18:35	Certificate Holder Name:	Justification for changing the batch :	
Online Notification	TESTING LIMITED		~
My Product Search			\checkmark
+ New Registration	Previous Approval Letter : UPLOAD No File Chosen		
 Change of Registered Particulars 	HK No. Product Name		
Initiate CORP Application	INK NO. Product Name INK NO. PRODUCT NAME XXXXX XXXX		
Application Status - Action Required - Not Submitted	Please tick the appropriate change category and state the nature of the	change.	
- Application Submitted	Particulars Proposed to Change	Change Justification	New effective date
Withdraw application	+ 1 Specification		31.08.2018
+ Renewal of Registration			
+ Submission of Other Post-registration	+ 2 Label		
Supplement	+ 3 Package Insert		
+ Request to Cancel Product Registration	+ 4 Manufacturer		
+ Payment	+ 5 Registration Certificate Holder		
Application History	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)		
+ User Profile	+ 7 Excipients		
	+ 8 Indication / Dosage / Route of Administration		
+ System	+ 9 Other		
Logout			Back Next

Other than effective date, all information of product particulars is not allowed to change in the application of change in effective date.

For application of change in effective date, selected product can be "deselected"; no new product can be added. If any product is "deselected" from the batch, justification should be provided in the field "Justification for changing the batch". Other than effective date, supporting document(s) and information of product particulars are not allowed to change. The justification for change in effective date should be provided.

2.6.2 Withdraw application

Step 1: Click the menu item "Application Status" in the menu on the left.

The applications eligible to withdrawal will be shown.

								Withdraw Applicati	ion
ou are login as ORG Trial	Received \$	Ref. No.	\$ HK N	o. ¢	Product Name	¢	Change Categories 🗢	Status	¢
ne ESTING LIMITED	21.08.2018	CORP-HK41190-201857485	HK41190		PRODUCT NAME XXXXX XXXX		4	Application Evaluated	
ogin date and time 1.08.2018 18:35	21.08.2018	CORP-HK37565-201857482	HK37565		PRODUCT NAME XXXXX		5	Application Under Screening	
Online Notification	21.08.2018	CORP-HK41190-201857483	HK41190		PRODUCT NAME XXXXX XXXX		5	Application Under Screening	
My Product Search								Withdraw Applicati	ion
New Registration									
Change of Registered Particulars									
Initiate CORP Application									
Application Status - Action Required - Not Submitted									
- Application Submitted									
Application Submitted Withdraw application									
- Application Submitted Withdraw application									
- Application Submitted									
- Application Submitted Withdraw application Registration Submission of Other Post-registration									
-Application Submitted Withdraw application Registration Submission of Other Post-registration Supplement Request to Cancel									
- Application Submitted Withdraw application Registration Submission of Other Post-registration Supplement Request to Cancel Product Registration									
Application Submitted Withdraw application Registration Submission of Other Post-registration Supplement Request to Cancel Product Registration Payment									

User may select one or more applications and send the request of withdrawal to Drug Office:

÷	Withdrawal	of CORP Appli	cation							
								C	onfirm to Withdraw	Close
You are login as ORG Trial	Received \$	Ref. No.	\$	HK No.	\$ Product Name	\$	Change Categories	÷	Status	¢
One TESTING LIMITED	21.08.2018	CORP-HK41190- 201857485	HK41190		PRODUCT NAME	4			Application Evaluated	
Login date and time 21.08.2018 18:35	Reason(s) of Wit		aw reason	state here		_				
Online Notification										
My Product Search							*	-		
+ New Registration								C	onfirm to Withdraw	Close
- Change of Registered Particulars										
Initiate CORP Application										
Application Status - Action Required - Not Submitted - Application Submitted										
Withdraw application										
+ Renewal of Registration										
+ Submission of Other Post-registration Supplement										
+ Request to Cancel Product Registration										
+ Payment										
Application History										
+ User Profile										
+ System										
Logout										

User needs to provide the reason of withdrawal and then click "Confirm to Withdraw" to submit the request to Drug Office. The request of withdrawal will be handled by Drug Office.
2.6.3 DO Request Application

	-	request App	neau	1011 00	٥P	••••	• •	0 100 9000					
	DO	Request Chang	je of R	egistere	ed P	articula	ars (CORP) Applic	ation			CORP_DO_APPLI	CATIO
	Actio	on Required											
ou are login as FONG /innie	4	Request No. 🗢	HK No.	\$	Produc	t Name		\$	Status	¢ Req	uest l	Reason	\$
EFG COMPANY LIMITED	1	DO-REQ-201900011	HK63575		TEST 2	017031404			Request Sent	PRO	C Deci	ision 20/06/2019	
0.02.2020 14:55	2	DO-REQ-201900005	HK63546		TEST 2	019011902			Request Sent	TES	T Nev	w Request	
0 F 11 F F	3	DO-REQ-201900005	HK63549		TEST 2	017020605			Request Sent	TES	T Nev	w Request	
Online Notification	4	DO-REQ-201800029	HK45179		BOGE	MEDICATED	D POWD	ER	Request Sent	Test	Payn	nent	
My Product Search	Not s	Submitted											
New Registration	\$	Ref. No.	\$	Request No.	\$	HK No.	\$	Product Name	\$	Status	\$	Request Reason	\$
	1	CORP-DO-HK63666-20195846	9	DO-REQ-201	900062	HK63666		HENRY TEST		COPR Subr	nitted	try	
 Change of Registered Particulars 	2	CORP-DO-HK50508-20195871	0	DO-REQ-201	900070	HK50508		CHOLVATIN TAB 20MG		COPR Subr	nitted	Remark	
Initiate CORP Application													
Application Status - Action Required - Not Submitted - Application Submitted													
Withdraw application													
DO Request Application													
Change Effective Date													
Renewal of Registration													

Click the DO Request Application to open the DO Request Pool

Click the Request No from the Action Required to initiate a CORP to reply this request or Continue the application

IF the CORP DO REQUEST did not receive a Submitted CORP Application, the related product renewal will be suspended.

2.7 RENEWAL OF REGISTRATION

2.7.1 Online Notification

Step 1: Click the menu item "Online Notification" in the menu on the left.

	Onli	ne Notification						C	NLIN	IE_NOTIFICA	TION_VIEW_
T	New F	Product Registration									
		Notification Da	ite 🗢	Subject		¢	Pro	posed Name of Product	\$	PL No. 🖨	Payment Statu
You are login as	Open	24.07.2018 15:51:11		Screening Application		TES	ST EC	ERT CASE1		PL0010/2018	N/A
	<u>Open</u>	14.11.2017 11:06:22		Application Payment Request		TES	ST US	ER LOGIN 2		PL0081/2017	Unpaid
.ogin date and time 17.08.2018 13:44	<u>Open</u>	03.04.2017 10:47:03		Application Payment Request		TES	ST 20	17022401		PL0030/2017	Paid
	CORP	•									
Online Notification		Notification Date \$		Subject	\$	HK No.		N	ame o	of Product	4
My Product Search	<u>Open</u>	07.08.2018 17:35:15	Application Scre	ening Notification	HK63	517		WALKTRHOUGH			
ing r roddor o odron	<u>Open</u>	07.08.2018 09:52:51	Application Sub	mitted Notification	HK63	517		WALKTRHOUGH			
 New Registration 	Renev	val of Registration									
Initiate New Product Registration		Notification Date \$		Subject	\$		Na	ne of Product		\$ No.	of Renewals \$
Application	Open	22.01.2017 11:14:08	Renewal Remin	ler	TEST	016112301 , 016112303 ,				2	
Application Status - Action Required - Not Submitted - Application Submitted	Open	22.01.2017 10:33:00	Renewal Notifica	tion	TEST2	016112305, 016112305, 016112305				2	
Withdraw application	Cance	llation Request									
Channel of Desistant		Notification Date \$		Subject	\$	HK No.	\$	Na	me of	Product	\$
+ Change of Registered Particulars	<u>Open</u>	07.08.2018 17:40:25	Cancellation Reg	stration Request Submitted Notification	HK6353	33		TEST 20161208			
+ Renewal of	<u>Open</u>	07.08.2018 15:01:05	Cancellation Reg	stration Request Submitted Notification	HK6352	23		TEST2016112303			
Registration	Interv	iew									
+ Interview				Notification Date	\$			Subject	1		\$
+ Request to Cancel	<u>Open</u>		7 10:08:09			Testing 2017	0313				
Product Registration	Open	15.01.201	7 15:04:00			test2					
+ Payment	Non P	harmaceutical Produ	ict Alert								
Application History		Notification Date	>	Subject	\$	HK No. ¢	>	Nam	ne of I	Product	¢
	Open	21.03.2016 16:43:10	Renewal Pen	ling Notification		HK47678	Те	sting 20170313			
+ User Profile	Open	21.03.2016 16:43:10	Renewal Pen	ling Reminder		HK47678	te	st2			

There are four types of notification for renewals:

1. Renewal Notification

The online notification will be sent around 4 months before product expiry date to remind the certificate holder to renew the product(s).

- 2. Renewal Reminder The online notification will be sent 3 months before product expiry date to remind the certificate holder to renew the product(s).
- Renewal Notice of Expiry The online notification will be sent 1 month before product expiry date to remind the certificate holder to renew the product(s).
- 4. Expired Product Notice The online notification will be sent on the product expiry date to notice the certificate holder the product(s) have been expired.

Step 2: Click the "Open" link to read the notification.

Ť	Renewal	of Registra	ation			RENEWAL_NOTIFIC	CATION
You are login as ORG Trial One TESTING LIMITED Login date and time 21.08.2018 18:44	Renewal No					Print Manual Renewal Form	Back
Online Notification		26.04.2016 04:0					
My Product Search	HK No. ¢	PR No. \$	PRODUCT NAME XXXXX XXXX	Name of Product	¢	Required information	\$
+ New Registration	View Renewal Ap	_					
+ Change of Registered Particulars						Print Manual Renewal Form	Back
+ Renewal of Registration							
+ Submission of Other Post-registration Supplement							
+ Request to Cancel Product Registration							
+ Payment							
Application History							
+ User Profile							
+ System							
Logout							

Products that the login user has access rights to will be shown in the list.

Step 3: Click the "View Renewal Application Status" button to review the application status. The system will redirect to the listing of renewal applications under different status (Section **Error! Reference source not found.**).

2.7.2 Application Status: (i) Reply and Pay for Renewal of Registration; (ii) Payment Completed; (iii) Product Confirmed Not to Renew; and (iv) Requires Further Action Before Product Renewal

Listing of Renewal Applications under Different Status

Step 1: Click the menu item "Renewal of Registration" in the menu on the left.

+	Rene	wal of F	Registr	ation								RE	ENEWAL_STATUS
You are login as WONG David ABC COMPANY LIMITED Login date and time 24.08.2018 16:50	Please con In case cer	nplete the rer tificate holde	newal proce r(s) cannot	val of Registration dure 10 working days before th renew certificate(s) in due cours Saturday / Sunday / holiday(s).	e expiry date of the proc se, please contact our IT	luct certificate and c colleagues of PRS	omplete 2.0 help	e the relevant o desk at 2319	payment 8414 du	transacti iring offic	on before 5 e hours.	working	ı days.
Online Notification												Rene	w Not to Renew
My Product Search	+	HK36996	No. \$	PRODUCT NAME XXXX XXXX	Name of Product		\$	Notify E 28.06.2018	ate 🗢	25.08.2	opiry Date	♦ Bat	Batch No. \$
+ New Registration													
+ Change of Registered Particulars		t Comple	eted										
- Renewal of	H	IK No. 🜩		Name of Product	\$	Payment Date 🗢	Last E	Expiry Date	Expiry	Date \$	Cert Coll Dat	ection _{\$}	Batch No. 🜩
Registration	HK369	95	PRODUCT	NAME XXXX		22.08.2018	25.08.2	2018	25.08.202	3			Batch Four
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to Renew - Requires Further Action	Product	Confirm	ed Not t	o Renew									Reinstate
Before Product Renewal	\$	нк	No. 💠		Name of Product		\$	Reply D	ate 💠	E	piry Date	\$	Batch No. 🗢
+ Interview + Request to Cancel Product Registration + Payment	Please con In case cer	nplete the rer tificate holde	newal proce r(s) cannot	Before Product Renew dure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s).	e expiry date of the proc	luct certificate and c	omplete 2.0 help	e the relevant desk at 2319	payment 8414 du	transacti iring offic	on before 5 e hours.	working	I days.
Application History	¢	НК	No. \$		Name of Product		\$	Reaso	n ¢	Ð	piry Date	\$	Batch No. 💠
Application History		HK44475		PRODUCT NAME XXXX XXXX				BABE list		10.03.2	019	Bat	ich Two
+ User Profile		HK43560		PRODUCT NAME XXXX				PICS requirem	ent	04.09.2	018	Bat	ch Five
+ System													
Logout													
New list add		new	vers	ion:									

When released, the download link of the e-Certificate is enabled for one-time use. Please keep a copy of the e-Certificate for your record after downloading. HK No.
There are four types of status for renewal applications:

- 1. Reply and Pay for Renewal of Registration
- 2. Payment Completed
- 3. Product Confirmed Not to Renew
- 4. Requires Further Action Before Product Renewal

There are different actions that may be required before the renewal applications can be continued:

- Submission of BABE report: labeled as "BABE List" under the "Reason" column.
- Submission of Real-time stability report: labeled as "RSTR List" under the "Reason" column.
- Non-pharmaceutical product: labeled as "Non-Pharmaceutical Product" under the "Reason" column.
- Other required information

2.7.2.1 Renewal of Registration by Online Payment or in Person

Applicants can select to process the renewal by (i) online payment (Section Error! Reference source not found.); or (ii) in person (Section Error! Reference source not found.).

2.7.2.1.1 Renewal by Online Payment

Step 1:

Under the section "Reply and Pay for Renewal of Registration", select the checkbox(es) for the renewal application(s) decided for renewal. Only the renewal applications from the same renewal batch (shown under "Batch No.") can be processed and paid together at the same time. Click the "Renew" button to proceed.

.	Renew	val of Re	egistr	ation								R	ENEWAL_STA	ATUS
You are login as WONG David ABC COMPANY LIMITED Login date and time 24.08.2018 16:50	Please com In case cert	plete the renew	val proce) cannot	val of Registration dure 10 working days before the expiry d renew certificate(s) in due course, please Saturday / Sunday / holiday(s).	ate of the proc	duct certificate and c Coolleagues of PRS	complete 2.0 help	the relevant desk at 2319	payment 8414 du	transacti rring offic	on before s e hours.	5 workin	g days.	
Online Notification					f Product			N-476-5		-		Ren	w Not to Re Batch No.	new
My Product Search	₹	HK No HK36996	• \$	PRODUCT NAME XXXX XXXX	rProduct		\$	Notify E 28.06.2018	ate 🜩	25.08.2	kpiry Date	€ Ba	atch Four	Ť
+ New Registration														
+ Change of Registered	Paymen	t Complete	d											
Particulars	н	K No. 💠		Name of Product	¢	Payment Date 🔶	Last E	xpiry Date	Expiry	Date 💠	Cert Col Dat	lection _e	Batch No	÷
 Renewal of Registration 	HK3699	95 PR	RODUCT	NAME XXXX		22.08.2018	25.08.20	018	25.08.202	3			Batch Four	
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to Renew - Requires Further Action	Product	Confirmed	l Not t	o Renew									Reins	state
- Requires Further Action Before Product Renewal	¢	HK No.		Name of	Product		\$	Reply D	ate 💠	E	opiry Date	\$	Batch No.	¢
+ Interview														
+ Request to Cancel Product Registration	•			Before Product Renewal dure 10 working days before the expiry d				4h					- 4	
+ Payment	In case cert	ificate holder(s)) cannot	renew certificate(s) in due course, please Saturday / Sunday / holiday(s).	contact our IT	Colleagues of PRS	2.0 help	desk at 2319	8414 du	iring offic	e hours.	WURKIN	g uays.	
Application Listen:	\$	HK No	. ¢	Name o	f Product		\$	Reaso	n ¢	E	cpiry Date	\$	Batch No.	\$
Application History		HK44475		PRODUCT NAME XXXX XXXX				BABE list		10.03.2	D19	Ba	atch Two	
+ User Profile		HK43560		PRODUCT NAME XXXX				PICS requirem	ent	04.09.2	D18	Ba	atch Five	
+ System														
Logout														
New list add	ed for	new v	ersi	ion:										

Issued e-Certificate

Step 2:

- Select the one Recipient.
- Check the two checkbox "Before proceeding to the online payment for renewal of pharmaceutical product(s) / substance(s), I have read the Notification for Renewal of Registration Certificate / Reminder of Notification for Renewal of Registration Certificate."
- Click the "Renew Product" button to proceed.

Ť	If the error message PAY-E-00	ayment service page, please e 001 does appear and Kaspersi				-	rvice FAQ Question 1.	STATUS
You are login as WONG David	Renewal of Reg	istration						
ABC COMPANY LIMITED Login date and time 27.07.2023 12:09	Pay for Renewal Cert	tificate						
Online Notification						Renew Product	Print Notification of Payment	Back
My Product Search								
+ New Registration	Certificate Holder	\$	HK No. 🜩	PR No. \$	Name of Product		\$	
+ Change of Registered Particulars	ABC COMPANY LIMITED		HK37027	PR0335/1993	CEDAX CAP 400MG			
	No. of Product(s):	1						
- Renewal of Registration	Fee type:	Application Fee of Pharma	ceutical Produc	t Renewal				
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to	Payment Amount:	HK\$ 575.0						
 Payment Completed Product Confirmed Not to Renew 	Certificate Collect:	 e-Certificate 			7			
- Requires Further Action Before Product Renewal					-			
+ Submission of Other Post-registration	Recipient*:	susan_cheung_1 david_wong						
Supplement								
+ Interview		*Select only one recipient.	The e-Certificat	e will be available	for download on the day aft	er the last expiry date of r	registration.	
+ Request to Cancel Product Registration		Before proceeding to the p Renewal of Registration Ce	ayment for rene ertificate / Remi	ewal of pharmace nder of Notificatio	utical product(s) / substance n for Renewal of Registratio	s), I have read the Notific n Certificate.	cation for	
+ Payment	Z	name and address of certif	icate holder na	me and address (nacy & Poisons Board of Hou of the manufacturer, registrat product pack size provided	ion number name of activ	ve ingrédients	
Application History		website of the Board. For e (Phone No: 3974 4175).	nquiries, pleas	e contact the Drug	g Evaluation and Import/Exp	ort Control Division of the	Drug Office	
+ User Profile						Renew Product	Print Notification of Payment	Back
+ Printing Service								
+ System								
Logout								

Step 3: Proceed to payment at the external EGIS payment system.

Gov HK 香	港政府一站通		
or 🔁	nline Payment Service		
Help	Please select the payme	ent method :	
Customer Service Hotline 2319 8461	Type of Service Transaction Date Transaction Reference	DH Drug Office 29-03-2023 DHPRS-202303291025-94191	
Email pharmweb@ dh.gov.hk	Number Total Amount Payment Method*	HKD\$ 1,370.00	
			Cancel Payment Pay
	 After pressing the 'Pay' be successful. PPS Shop&Buy (PPS) of pay by PPS, please cha Merchant Name is appli Under exceptional cond Credit Card account tha Some users may receiv experience such a prob caused. Different credit card issu 	transaction reference number or PRINT this page for making enquiry on the pays button, please DO NOT leave this e-service until you receive the acknowledgem does not support payment via browsers of mobile devices (including mobile phon inge to use desktop computer. cable to credit card payment method only. itions, a refund may need to be arranged. If the payment is made by Credit Card t is used for the payment. e an error page or have to wait for several minutes before they get a response fr lem, please wait a moment and retry, or change to use other available payment r users may have implemented different mechanisms to authenticate the cardholder if you want to learn more about the J/Secure, Mastercard SecureCode and Veri	ent page, otherwise your transaction may not es and tablets) at the moment. If you wish to , the refund can normally be made to the om the credit card payment gateway. If you nethods. We apologise for any inconvenience 's identity during online payment. Please

Step 4: Confirmation on receiving the payment will be shown after payment. You may print the screen by clicking the "Print" button, or to print the receipt by clicking the "Print Receipt" button.

fou are login as WONG Javid Age COMPANY LIMITED Jogin date and time 24 08/2018 16:50 Online Notification	Renewal Payment Reference No.: EGIS Reference No.: Type of Payment: Transaction Time: Delivery Method:	: DHPRS-201808241655-91732 C201808242001297 Renewal 24.08.2018 16:56:30 Collect in Person in Drug Office			Print Receipt	
My Product Search	HK No.		Product Name		Expiry Date	
+ New Registration	HK36996	PRODUCT NAME XXXX XXXX			25.08.2018	
+ Change of Registered Particulars - Renewal of Registration	responsé as soon as po The certificate(s) will be			we product(s). We will process your	application and will provide	
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Comfirmed Not to Renew - Requires Further Action Before Product Renewal	9:00 a 2:00 p	ay to Friday m 1:00 pm im - 5:45 pm 6:00 pm on Monday)				
+ Interview	(Close	ed on Saturdays, Sundays & Public Holida	ays)			
+ Request to Cancel Product Registration		23198458 info@dh.gov.hk				
+ Payment					Print Receipt	t) Clos
Application History						
+ User Profile						
+ System						
Logout						

Click the "Print Receipt" button:

				ent Receipt of Renewal	
	Payment Receipt of Renewal		Name of Company BAUSCH & LOMB	(HK) LTD	
Name of Company		Payment Date	公司名稿 Payment Reference No: DHPRS-201906	131525-14151	
公司名稱		繳費日期	付款编號:		
BAUSCH & LOMB (HK) L1	D	13.06.2019	Name of Product 製品/物質名稱	HK Reg. No 香港註冊號碼	Expiry 屆滿 8
Payment Reference No:	DHPRS-201906131525-14151		1 "S.T." NATURAL TEARS EYE DROPS	HK58956	03.10.
付款编號: Receipt Reference No:					
收據編號: Cheque No:	123				
支票编號: Payment Method:	Cheque				
付款方法: Payment Amount:	HK\$575.00				
付款金額:					

第2頁(共2頁)

The payment of renewal of registration is completed.

													RENEWAL_S	FATUS
		val of R												
ou are login as WONG	Reply ar	nd Pay for	Renev	wal of Registration										
avid BC COMPANY LIMITED ogin date and time .08.2018 16:50	In case cert	ificate holder(s) cannot	edure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s).	rse, please contact our l'	luct certificate and co colleagues of PRS2	omplet 2.0 helj	e the relevant p desk at 2319 i	ayment 3414 du	transactio ring office	hours.	5 worł	king days.	
Online Notification												Re	enew Not to R	enew
Online Noulication	¢	HK N	lo. 💠		Name of Product		\$	Notify Da	te 🗢	Exp	piry Date	\$	Batch No.	\$
My Product Search		HK36996		PRODUCT NAME XXXX XXXX				28.06.2018		25.08.20	18		Batch Four	
New Registration														
Change of Registered Particulars	-	t Complet	ed										_	
Renewal of	н	KNo. ♦		Name of Product	¢	Payment Date 🗢	Last E	xpiry Date	Expiry	Date 💠	Cert Col Dat	lection te	n _≑ Batch N	^{lo.} \$
Registration	HK3699	95 P	RODUCT	NAME XXXX		22.08.2018	25.08.2	018 25	.08.2023				Batch Four	
Application Status														
Reply and Pay to Registration Payment Completed Product Confirmed Not to	Product	Confirme	d Not t	to Renew										
Renew				to Renew										
Renew - Requires Further Action Before Product Renewal	Product ¢	Confirme HK No		to Renew	Name of Product		¢	Reply Dat	te 🗢	Exp	piry Date	\$	Reir Batch No.	
Renew - Requires Further Action Before Product Renewal Interview	¢	HK No	o. \$	to Renew Before Product Renew			¢	Reply Dat	te \$	Exp	piry Date	\$		
Requires Further Action Before Product Renewal	¢ Require: Please com	нк м s Further A	o. ¢ Action	Before Product Renew	wal		omplete	e the relevant p	ayment	transactio	n before §		Batch No.	
Requires Further Action Refore Product Renewal Interview Request to Cancel Product Registration	Require: Please com In case cert	нк No s Further A plete the rene ificate holder(;	o. ¢ Action wal proce s) cannot	Before Product Renew	wal ne expiry date of the prov rse, please contact our l		omplete	e the relevant p	ayment	transactio	n before §		Batch No.	
Requires Further Action Requires Further Action Interview Request to Cancel Yroduct Registration	Require: Please com In case cert	нк No s Further A plete the rene ificate holder(;	o. ¢ Action wal proce s) cannot ot include	Before Product Renev edure 10 working days before th renew certificate(s) in due cours Saturday / Sunday / holiday(s).	wal ne expiry date of the prov rse, please contact our l		omplete	e the relevant p	ayment 3414 du	transactio ring office	n before §		Batch No.	\$
Requires Further Action Requires Further Action Interview Request to Cancel Yroduct Registration	Requires Please com In case cert Note: Worki	HK No s Further / iplete the rene ificate holder(ing days do no	o. ¢ Action wal proce s) cannot ot include	Before Product Renev edure 10 working days before th renew certificate(s) in due cours Saturday / Sunday / holiday(s).	wal he expiry date of the pro- rse, please contact our I		omplet 2.0 helj	e the relevant p i desk at 2319 (ayment 3414 du	transactio ring office	n before 5 hours.	5 worł	Batch No.	¢
Requires Further Action alone Product Renewal nterview Request to Cancel Product Registration Payment Application History	Requires Please com In case cert Note: Worki	HK No s Further A plete the rene ificate holder(ing days do no HK N	o. ¢ Action wal proce s) cannot ot include	Before Product Renev adure 10 working days before th renew certificatie(s) in due cour Saturday / Sunday / holiday(s).	wal he expiry date of the pro- rse, please contact our I		omplet 2.0 helj	e the relevant p o desk at 2319 f Reason	ayment 8414 du	transactio ring office Exp	n before 5 hours. piry Date	5 worł	Batch No. king days. Batch No.	\$
Advances Further Action actions Product Renewal Interview Request to Cancel Troduct Registration Payment Application History Jser Profile	Requires Please com In case cert Note: Worki	HK No s Further / iplete the rene ing days do no HK N HK44475	o. ¢ Action wal proce s) cannot ot include	Before Product Renev edure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s). PRODUCT NAME XXXX XXXX	wal he expiry date of the pro- rse, please contact our I		omplet 2.0 helj	e the relevant p desk at 2319 (Reason BABE list	ayment 8414 du	transactio ring office Ext 10.03.20	n before 5 hours. piry Date	5 worł	Batch No. king days. Batch No. Batch Two	\$
Anexe Further Action Request Forduct Renewal Interview Request to Cancel Product Registration Payment Application History User Profile System	Requires Please com In case cert Note: Worki	HK No s Further / iplete the rene ing days do no HK N HK44475	o. ¢ Action wal proce s) cannot ot include	Before Product Renev edure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s). PRODUCT NAME XXXX XXXX	wal he expiry date of the pro- rse, please contact our I		omplet 2.0 helj	e the relevant p desk at 2319 (Reason BABE list	ayment 8414 du	transactio ring office Ext 10.03.20	n before 5 hours. piry Date	5 worł	Batch No. king days. Batch No. Batch Two	¢
Nenew Rest Further Action Request Forduct Renewal Interview Request to Cancel Product Registration Payment Application History User Profile System Logout	Require: Please com In case cert Note: Work	HK No s Further J plete the rene first ab holder/ ing days do no HK N HK44475 HK443560	o. Action ewal proce s) cannot tinclude lo. \$	Before Product Renev adure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s). PRODUCT NAME X000X X00X PRODUCT NAME X000X	wal he expiry date of the pro- rse, please contact our I		omplet 2.0 helj	e the relevant p desk at 2319 (Reason BABE list	ayment 8414 du	transactio ring office Ext 10.03.20	n before 5 hours. piry Date	5 worł	Batch No. king days. Batch No. Batch Two	¢
Interview Further Action Request to Cancel Product Registration Payment Application History User Profile System Logout Logout Logw List add	Require: Please com In case cert Note: Work	HK No s Further J plete the rene first ab holder/ ing days do no HK N HK44475 HK443560	o. Action ewal proce s) cannot tinclude lo. \$	Before Product Renev adure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s). PRODUCT NAME X000X X00X PRODUCT NAME X000X	wal he expiry date of the pro- rse, please contact our I		omplet 2.0 helj	e the relevant p desk at 2319 (Reason BABE list	ayment 8414 du	transactio ring office Ext 10.03.20	n before 5 hours. piry Date	5 worł	Batch No. king days. Batch No. Batch Two	\$
-Regivand Pay for -Regivand Pay for Payment Completation -Payment Completation -Payment Completation Request to Cancel Product Registration Payment Application History User Profile System Logout Jew list add sued e-Certification Payment Payment Logout Jew list add State add State add State add State	Require: Please com In case cert Note: Work	нк кк s Further / plete the rene fifcate holder(r gadys do no нк N нК44475 нк44475 нк444560	o. ¢ Action wal proce s) cannot ot include to. ¢ Wers:	Before Product Renev adure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s). PRODUCT NAME X000X X00X PRODUCT NAME X000X	wal he expiry date of the prov se, please contact our f Name of Product	colleagues of PRS2	¢	the relevant p desk at 2319 i Reason BABE list PICS requireme	ayment 8414 du nt	transactio ring office Exp 10.03.20 04.09.20	n before 5 hours. piry Date	5 worł	Batch No. king days. Batch No. Batch Two	

2.7.2.1.2 Renewal in-person

Step 1:

Under the section "Reply and Pay for Renewal of Registration", select the checkbox(es) for the renewal application(s) decided for renewal. Only the renewal applications from the same renewal batch (shown under ("Batch No.") can be processed and paid together at the same time. Click the "Renew" button to proceed.

	Rene	wal of Re	gistra	ation								RENEWAL_ST	ATUS
You are login as WONG David ABC COMPANY LIMITED Login date and time 24.08.2018 16:50	Reply a	nd Pay for F	Renew	val of Registration dure 10 working days before the renew certificate(s) in due cours Saturday / Sunday / holiday(s).	expiry date of the proc e, please contact our IT	luct certificate and c colleagues of PRS	omplet 2.0 helj	e the relevan o desk at 231	t payment 9 8414 du	transaction befo iring office hours	ire 5 wor	king days.	
Online Notification											R	enew Not to Re	enew
Chilline Notification	Ŧ	HK No.	\$		Name of Product		\$	Notify	Date 🜲	Expiry Da	te 🗢	Batch No.	\$
My Product Search		HK36996		PRODUCT NAME XXXX XXXX				28.06.2018		25.08.2018		Batch Four	
+ New Registration													
+ Change of Registered Particulars	Paymen	t Complete	d										
r articulars	H.	IK No. 💠		Name of Product	\$	Payment Date 🗢	Last E	Expiry Date	Expiry	Date 🔶 Cert	Collectio Date	n _o Batch No	D. \$
 Renewal of Registration 	HK369	95 PR		IAME XXXX		22.08.2018	25.08.2	2018	25.08.202	3		Batch Four	
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to	Product	Confirmed	Not to	Renew									
Renew - Requires Further Action Before Product Renewal												Reins	state
Before Product Renewal	\$	HK No.	\$		Name of Product		\$	Reply	Date 🔶	Expiry Da	te 🗢	Batch No.	\$
+ Interview													
+ Request to Cancel Product Registration	Please con	nplete the renew;	al proced	Before Product Renew dure 10 working days before the renew certificate(s) in due course	expiry date of the proc	luct certificate and c	omplet	e the relevan	t payment	transaction befo	re 5 wor	king days.	
+ Payment	Note: Work	ting days do not i	include S	Saturday / Sunday / holiday(s).	e, please contact our n	colleagues of PRS	2.0 neij	J desk at 25	9 84 14 00	ining onice nours	•		
Application History	\$	HK No.	\$		Name of Product		\$	Reas	ion 🔶	Expiry Da	te 🗢	Batch No.	\$
		HK44475		PRODUCT NAME XXXX XXXX				BABE list		10.03.2019		Batch Two	
+ User Profile		HK43560		PRODUCT NAME XXXX				PICS require	ment	04.09.2018		Batch Five	
+ Svstem													
· System													

Step 2:

Click the "Print Manual Renewal Form" button. Please print the renewal form with the stamped company chop and proceed to the shroff of Drug Office for payment.

Ť	ATTENTION : If unable to open the online pay If the error message PAY-E-000				1 - C - C - C - C - C - C - C - C - C -	> advance setting. ease refer to <u>online payment se</u>		
You are login as WONG David	Renewal of Regi	stration					RENEWAL_PROCESS_S	TATUS
ABC COMPANY LIMITED Login date and time 27.07.2023 12:09	Pay for Renewal Certi	ficate						
Online Notification						Renew Product	Print Notification of Payment	Back
My Product Search								
+ New Registration	Certificate Holder	\$	HK No. 🜩	PR No. 💠	Name of Product		\$	
+ Change of Registered Particulars	ABC COMPANY LIMITED		HK37027	PR0335/1993	CEDAX CAP 400MG			
- Renewal of	No. of Product(s):	1						
Registration	Fee type:	Application Fee of Pharr	naceutical Produc	t Renewal				
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to	Payment Amount:	HK\$ 575.0						
Product Confirmed Not to Renew Requires Further Action	Certificate Collect:	 e-Certificate 						
Before Product Renewal	Recipient*:	susan_cheung_1						
+ Submission of Other Post-registration Supplement		O david_wong						
+ Interview		*Select only one recipier	it. The e-Certificat	e will be available	for download on the	lay after the last expiry date of r	egistration.	
+ Request to Cancel Product Registration		efore proceeding to the tenewal of Registration	payment for rene Certificate / Remi	wal of pharmace nder of Notificatio	itical product(s) / subs n for Renewal of Regi	tance(s), I have read the Notific stration Certificate.	ation for	
+ Payment		name and address of ce name of excipients, date	rtificate holder, na of registration, pa	me and address o ckage insert and	of the manufacturer, re product pack size pro	of Hong Kong to arrange the na gistration number, name of activ rided in this application to be dis	ve ingrédients, splaved on the	
Application History		(Phone No: 3974 4175).	r enquiries, please	e contact the Drug	Evaluation and Impo	rt/Export Control Division of the	Drug Office	
+ User Profile						Renew Product	Print Notification of Payment	Back
+ Printing Service								
+ System								
Logout								

2.7.2.1.3 Not to Renew Product Registration

Step 1:

Under the section "Reply and Pay for Renewal of Registration", select the checkbox(es) for the renewal application(s) decided not to renew the product registration. Click the "Not to Renew" button to proceed.



2.7.2.1.4 Reinstate Product Specified as Not Renew

Step 1:

Under the section "Product Confirmed Not to Renew", select the checkbox(es) for the renewal application(s) which was previously selected as not to renewal but decided to reinstate. Click the "Reinstate" button to proceed.

÷	Rene	wal of R	egistr	ation							RE	NEWAL_STA	TUS
	Product(s)) have been suc	cessfully	set to not renew									
(ou are login as WONG													
David ABC COMPANY LIMITED ogin date and time M.01.2018 17:20				val of Registration dure 10 working days before the expiry date of the proc renew certificate(s) in due course, please contact our l	luct certificate and c	omplete	e the releva	nt paymen	t transacti	on before 5	working	days.	
Online Notification	In case ce Note: Wor	rtificate holder(s king days do no) cannot t include	renew certificate(s) in due course, please contact our l Saturday / Sunday / holiday(s).	F colleagues of PRS	2.0 help	desk at 23	19 8414 d	uring offic	e hours.			
My Product Search											Renew	Not to Rei	new
+ New Registration	4	¢ HKN	o. ¢	Name of Product		\$	Notify	Date 🖨	E E	cpiry Date	\$	Batch No.	
•		HK56272		AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB					14.02.2	D18	Bato	h One	
+ Change of Registered Particulars		HK61778		AMLODIPINE TABLETS 10MG (HETERO)					26.02.2	D18	Bato	h One	
- Renewal of Registration	Payme	nt Complet	əd										
Application Status - Reply and Pay for Renewal of Registration - Payment Completed		HK No. 💠		Name of Product \$	Payment Date 🔶	Last E	xpiry Date	Expir	y Date 🌲	Cert Coll Date	ection _e	Batch No.	
 Payment Completed Product Confirmed Not to Renew 	HK56	375 A	CET 120M	G SUPP	30.01.2018	14.03.2	018	14.03.202	23			Batch Two	
- Requires Further Action Before Product Renewal	HK56	376 A	CET 160M	G SUPP	30.01.2018	14.03.2	018	14.03.202	23			Batch Two	
+ Submission of Other Post-registration Supplement	Produc	t Confirme	d Not t	o Renew								_	
+ Interview												Reins	tate
		⇒ HK N	o. ¢	Name of Product		\$	Reply	Date 🛊	E:	cpiry Date	\$	Batch No.	
+ Request to Cancel Product Registration		HK61779		AMLODIPINE TABLETS 5MG (HETERO)			31.01.2018		26.02.2	D18	Bato	h One	
+ Payment	Require	es Further /	Action	Before Product Renewal									
Application History	Please co	mplete the rene ertificate holder(s	wal proce	dure 10 working days before the expiry date of the proc renew certificate(s) in due course, please contact our l	duct certificate and c	omplete 2.0 heln	the relevant the the relevant the the the the the the the the the th	nt paymen 19 8414 d	t transacti uring offic	on before 5 e hours.	working	days.	
+ User Profile	Note: Wor	king days do no	t include	Saturday / Sunday / holiday(s).									
+ System	¢	HKN	¢.	Name of Product		\$	Rea	son 🖨	E	piry Date	\$	Batch No.	\$
Logout													

New list added for new version Issued e-Certificate

	Renewal										
are login as WONG	 Product(s) have be 	en successfully	/ set to not renew								
ic COMPANY LIMITED in date and time 1.2018 17:20	Reply and Pa	y for Rene	wal of Registration								
line Notification	In case certificate	nolder(s) canno	edure 10 working days before t t renew certificate(s) in due cou saturday / Sunday / holiday(s)	rse, please contact our l	duct certificate and on T colleagues of PRS	complete the relev S2.0 help desk at 2	ant payment tra 319 8414 durin	nsaction before 5 g office hours.	working da	ys.	
Product Search	,		,,,, (-)						Renew	Not to Ren	lew
		HK No #		Name of Product		≜ Not	fv Date 🔺	Exniry Date		Batch No	±
w Registration	HK56	272	AMERICAN HEALTH ABC PLU	S WITH LUTEIN TAB			1	4.02.2018	Batch (One	
ange of Registered rticulars	HK61	778	AMLODIPINE TABLETS 10MG	(HETERO)			2	6.02.2018	Batch (One	-
newal of gistration	Payment Cor	npleted									
plication Status ply and Pay for sewal of Registration syment Completed	HK No.	¢	Name of Product	\$	Payment Date 🌲	Last Expiry Date	Expiry Da	te 🔶 Cert Colle Date	ection	Batch No.	\$
nyment Completed oduct Confirmed Not to new	HK56375	ACET 120	MG SUPP		30.01.2018	14.03.2018	14.03.2023		Ba	tch Two	
equires Further Action fore Product Renewal	HK56376	ACET 160	MG SUPP		30.01.2018	14.03.2018	14.03.2023		Ba	tch Two	
bmission of Other st-registration pplement	Product Cont	firmed Not	to Renew								
erview										Reinst	ate
quest to Cancel	\$	HK No. 4		Name of Product			ly Date 💠	Expiry Date		Batch No.	\$
duct Registration	HK61	779	AMLODIPINE TABLETS 5MG (I	HETERO)		31.01.201	8 2	6.02.2018	Batch (One	
yment	Requires Fur	ther Action	Before Product Rene	wal							
olication History			edure 10 working days before t		dust sortificate and (complete the relay	ant novement tra	negation before E	working do		
er Profile	In case certificate	nolder(s) canno	t renew certificate(s) in due cou Saturday / Sunday / holiday(s)	rse, please contact our l	T colleagues of PRS	S2.0 help desk at 2	319 8414 durin	g office hours.	working da	ys.	
stem	\$	HK No. 💠		Name of Product		¢ Re	ason \$	Expiry Date	¢	Batch No.	
out											
	ded for no	w vei	sion								
ew list add			01011								

2.7.2.1.5 Requires Further Action Before Product Renewal

The product(s) under the section "Requires Further Action Before Product Renewal" cannot be renewed until the pending action is completed. But user can choose the products and click 'Not to Renew' to not to renew the products.

- For product(s) has "BABE List" under the "Reason" column. Certificate holder has to submit the Bioavailability and Bioequivalence (BABE) report to the Drug Office through the function "Submission of BABE" under "Submission of Other Post-registration Supplement" (Section Error! Reference source not found.)
- For product(s) has "RSTR List" under the "Reason" column. Certificate holder has to submit the Real-time Stability Test Report (RSTR) to the Drug Office through the function "Submission of RSTR" under "Submission of Other Post-registration Supplement" (Section **Error! Reference source not found.**)
- For product(s) has "Non-Pharmaceutical Product" under the "Reason" column. Certificate holder has to provide supporting documents to support the product(s) is pharmaceutical product.
- For product(s) has other required information under the "Reason" column.

Certificate holder has to following the instruction(s) stated under the "Reason" column.

•	Ren	ewa	al of Re	aistr	ation						RE	NEWAL_ST	ATUS
					set to not renew								
(ou are login as WONG David ABC COMPANY LIMITED Login date and time \$1.01.2018 17:20	Please	comple	te the renewa	al proce	val of Registration dure 10 working days before the expiry date of the pro-	duct certificate and c	omplete	the relevant payn	nent trans	action before	5 working	days.	
Online Notification	Note: W	/orking	days do not i	nclude	renew certificatē(s) în due course, pleáse contact our l' Saturday / Sunday / holiday(s).	Colleagues of PRO	2.0 neip	desk at 2319 641	4 during c	nice nours.			
My Product Search											Rene	W Not to Re	enew
+ New Registration		\$	HK No.	\$	Name of Product AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB		\$	Notify Date	\$	Expiry Date 2.2018	•	Batch No.	\$
+ Change of Registered		1	K56272										
Particulars] H	K61778		AMLODIPINE TABLETS 10MG (HETERO)				26.0	2.2018	Bat	ch One	
- Renewal of Registration	Paym	ent C	omplete	d									
Application Status - Reply and Pay for Renewal of Registration - Payment Completed		HK N	^{0.} \$		Name of Product \$	Payment Date 🔶	Last E	xpiry Date E	cpiry Date	Cert Col Da	lection _{\$}	Batch No). ¢
- Próduct Confirmed Not to Renew - Requires Further Action		56375			G SUPP	30.01.2018	14.03.2					Batch Two	
Before Product Renewal	HK	56376	ACE	= T 160M	G SUPP	30.01.2018	14.03.2	018 14.03	.2023			Batch Two	
+ Submission of Other Post-registration Supplement	Produ	uct Co	onfirmed	Not t	o Renew								
+ Interview												Reins	state
+ Request to Cancel		\$	HK No.	\$	Name of Product		\$	Reply Date	•	Expiry Date	•	Batch No.	\$
Product Registration] H	K61779		AMLODIPINE TABLETS 5MG (HETERO)			31.01.2018	26.0	2.2018	Ва	ch One	
+ Payment	Requi	ires F	urther A	ction	Before Product Renewal								
Application History	Please	comple	te the renewa	al proce	dure 10 working days before the expiry date of the pro	duct certificate and c	omplete	the relevant payr	nent trans	action before	5 working	days.	
+ User Profile	In case Note: W	certífica /orking	ate holder(s) days do not i	cannot nclude	renew certificatĕ(s) în due course, pleáse contact our l' Saturday / Sunday / holiday(s).	F colleagues of PRS	2.0 help	desk at 2319 841	4 during c	ffice hours.			
+ System		\$	HK No.	\$	Name of Product		\$	Reason	\$	Expiry Date	\$	Batch No.	\$
Logout													

New list added for new version Issued e-Certificate

2.7.2.2 Payment History (Renewal)

Step 1: Click the menu item "Payment History" in the menu on the left. Click the "Payment Ref No." for the product under the section "Renewal of Registration".

								繁
•	Payment H	listory						
	New Product	Registration	I					Total Number of Payment Records: 0
ou are login as Charles	PR No.	\$	Name of Product	\$	Payment Date	Amount(HK\$)		Payment Ref No.
e m CERT HOLDER 6 gin date is	Change of Re	gistered Par	ticulars Application					Total Number of Payment Records: 0
11.2014 12:50	HK No.	\$	Name of Product	\$	Payment Date	Amount(HK\$)		Payment Ref No.
Online Notification	Renewal of Re	egistration						Total Number of Payment Records: 3
My Product Search	HK No.	¢	Name of Product	\$	Payment Date	Amount(HK\$)		Payment Ref No.
New Registration	HK00863	INDAPAI TABLET	MIDE-TRIAL PROLONGED RELE S 1.5MG (MP2-2)(CH6)	ASE	27.11.2014		575.0	DHPRS-201411271258-90514
Change of Registered Particulars	HK00861	ULTIBRO	BREEZEHALER (MP1-2)(CH6)		27.11.2014		575.0	DHPRS-201411271258-90514
Particulars	HK00869	GRACIA	L TABLET (MP5-2)(CH6)		27.11.2014		575.0	DHPRS-201411271252-90513
Renewal Registration Other Post-registration Supplement								
Interview Request to Cancel Product Registration								
Payment								
Payment Pool Payment History Application History								
User Profile								
System								
Logout								

Step 2: The receipt can be reprinted by clicking the "Print Receipt" button.

			緊 简
	Renewal		Print Receipt Print Close
	Payment Reference No.	: DHPRS-201411271258-90514	
	Type of Payment:	Renewal	
You are login as Charles Lee	Transaction Time:	27.11.2014 12:59:15	
from CERT HOLDER 6 Login date is 27.11.2014 12:50			
Online Notification	HK No.	Product Name	Expiry Date
My Product Search	HK00863	INDAPAMIDE-TRIAL PROLONGED RELEASE TABLETS 1.5MG (MP2-2)(CH6)	01.02.2015
ing r roudor obdroir	HK00861	ULTIBRO BREEZEHALER (MP1-2)(CH6)	01.02.2015
+ New Registration	The Development of the second		
+ Change of Registered Particulars	soon as possible.	vledges your payment of HK\$1,150.00 for certificate fee regarding the above proposed product(s). We will process your ready for collection on / after 01.01.2015	request and will provide response as
+ Renewal Registration	Please kindly quote the	above Payment Reference Number for enquiries.	
+ Other Post-registration Supplement	General Enguiries:		
+ Interview	Office Hours: Monda	ay to Friday m - 1:00 pm	
+ Request to Cancel Product Registration	(up to	m - 5:45 pm 6:00 pm on Monday) d on Saturdays, Sundays & Public Holidays)	
- Payment	Tel: (852)	23198458 general@dh.gov.hk	
Payment Pool			
Payment History			Print Receipt Print Close
Application History			
+ User Profile			
+ System			
Logout			

2.7.2.3 Application History (Renewal)

- Click the menu item "Application History" in the menu on the left.
- Certificate holder can view the list of historic renewal applications, including paid application, certificate collected application.

tare login as Charles n CERT HOLDER 6 in date is 1.2014 12:50 nuline Notification Ay Product Search dew Registration Arrenge of Registered Particulars Total Number of Application Bate Renewal of Registration Corrent Application Bate Renewal of Registration Corrent Application Certain Cert														9
Are login as Charles Application Date PL No. • PR No. • HK No. • Name of Product • Payment Status Status • Last Action Application Date PL No. • PR No. • HK No. • Name of Product • Payment Status Status • Last Action Application Date Ref No. • HK No. • Name of Product • Charge of Registration Total Number of Application 27.11201- Number of Registration Harge of Registration Total Number of Application Date HK No. • Name of Product • Application Status • Last Action Number of Registration Harge of Registration Total Number of Application Total Number of Application 27.11201- Interview HK No. • Name of Product Paid 27.11201- Status • Last Action Total Number of Application 27.11201- Interview Paid 27.11201- 27.11201- 27.11201- Status • Last Action Paid 27.11201- 27.11201- Status • Last Action Paid 27.11201- 27.11201- Status • Last Action <th></th> <th>Applicatio</th> <th>n History</th> <th></th>		Applicatio	n History											
are login as Charles CERT HOLDER 6 Total Number of Application Rec CERT HOLDER 6 Application Date Ret No. ◆ HK No. ◆ Name of Product ◆ Charge of Registred Payment Status Last Action Nor Product Search Nor Product Search Name of Product ◆ Charge of Registration Application Date HK No. ◆ Name of Product ◆ Application Status ◆ Last Action Name of Registration Name of Product ◆ Application Status ◆ Last Action 27.11.201- Name of Registration Name of Product ◆ Application Status ◆ Last Action Nerview HK No. ◆ Name of Product ◆ Application Status ◆ Last Action Projeinent Total Number of Application Rec 27.11.201- 27.11.201- Norther Postpresize HK No. ◆ Name of Product ◆ Application Status ◆ Last Action Norther Postpresize HK No. ◆ Name of Product ◆ Name of Product ◆ Application Rec Norther Postpresize HK No. ◆ HK No. ◆ Name of Product ◆ Status ◆ Last Action Papication Date Ref No. ◆ HK No. ◆ Name of Product ◆ Status ◆ Last Action </th <th></th> <th>New Product</th> <th>Registratio</th> <th>n</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th>Tota</th> <th>I Number of A</th> <th>Appli</th> <th>cation Records:</th>		New Product	Registratio	n							Tota	I Number of A	Appli	cation Records:
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ange of Registered in our constraints of the second seco	v Registration	Renewal of R	Registration	J							Tota	I Number of A	Appli	cation Records:
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newal Registration 01 02 2015 HK000689 GRACIAL TABLET (MPS-2)(CH6) Pad 27.11.2014 ner Post-registration of application of application of Product Application Total Number of Application Record and applicatid application Record and a	ticulars	01.02.2015	HK00863	INDAPAMID	E-TRIAL PRO	LONGED R	ELEASE TABLET	S 1.5MG (MP2-2)(C	H6)		Paid			27.11.2014
1 10 22015 HK00889 GRACIAL TABLET (MP5-2)(CH6) Paid 27.11201- terp Post-registration performent Termination of application of Product Application Total Number of Application Rec status • Istatus • Last Action Application Date Ref No. • HK No. • Name of Product Status • Last Action Application Date Request Typet Ref No. • HK No. • Name of Product • Status • Last Action Application Date Request Typet Ref No. • HK No. • Name of Product • Status • Last Action Application Date Request Typet Ref No. • HK No. • Name of Product • Status • Last Action Application Date Request Typet Ref No. • HK No. • Name of Product • Status • Last Action application Date Request Typet Ref No. • HK No. • Name of Product • Status • Last Action application Date Request Typet Ref No. • HK No. • Name of Product • Status • Last Action application Date Sabel-HK00866-2014100070 HK00866 CEPPRA TABLET 1000MG (MP4-1)(CH6) Report Accepted 26.11.201- ar Profile Application Date </td <td>awal Registration</td> <td>01.02.2015</td> <td>HK00861</td> <td>ULTIBRO BR</td> <td>REEZEHALER</td> <td>(MP1-2)(CH</td> <td>16)</td> <td></td> <td></td> <td></td> <td>Paid</td> <td></td> <td></td> <td>27.11.2014</td>	awal Registration	01.02.2015	HK00861	ULTIBRO BR	REEZEHALER	(MP1-2)(CH	16)				Paid			27.11.2014
opplement Total Number of Application Total Number of Application Rec arview Application Date Ref No. ◆ HK No. ◆ Name of Product Status ◆ Last Action quest to Cancel duct Registration Ongoing Request Application Ref No. ◆ HK No. ◆ Name of Product Status ◆ Last Action Application Date Request Type Ref No. ◆ HK No. ◆ Name of Product Status ◆ Last Action Application Date Request Type Ref No. ◆ HK No. ◆ Name of Product Status ◆ Last Action 26.11.2014 BABE BABE-HK00866-2014100070 HK00866 CEPPRA TABLET 1000MG (MP4-1)(CH6) Report Accepted 26.11.2014 Interview Total Number of Application Rec Total Number of Application Rec Total Number of Application Rec	iewai registration	01.02.2015	HK00869	GRACIAL TA	ABLET (MP5-2)(CH6)					Paid			27.11.2014
Application Date Request Application Total Number of Application Recovery and the state of t	er Post-registration	Termination	of applicatio	n of Prod	luct Appl	ication					Tota	I Number of A	Appli	cation Records:
Application Date Request Type Ref No. HK No. Name of Product Status Last Action yment 26 11 2014 BABE BABE-HK00866-2014100070 HK00866 CEPPRA TABLET 1000MG (MP4-1)(CH6) Report Accepted 26 11 2014 plication History Interview Total Number of Application Rec er Profile Application Date Subject Application Status Status	rview	Application Date	>	Ref No.	\$	HK N	D. \$	Na	me of F	Product	\$	Status	\$	Last Action Date
yment 26 11 2014 BABE BABE-HK00066-2014100070 HK00066 CEPPRA TABLET 1000/MG (MP4-1)(CH6) Report Accepted 26.11.2014 plication History Interview Total Number of Application Record Accepted profile Application Date Subject Application Status		Ongoing Req	uest Applic	ation							Tota	I Number of A	Appli	cation Records:
er Profile Application Date Ap		Application Date	Request Type		Ref No.	¢	HK No.	•	Na	ame of Product	¢	Status	φ.	Last Action Date
Total Number of Application Rec er Profile Application Date	ment	26.11.2014	BABE	BABE-HK008	866-20141000	70	HK00866	CEPPRA TABL	ET 100	10MG (MP4-1)(C	H6)	Report Accep	oted	26.11.2014
Application bate	lication History	Interview									Tota	I Number of A	Appli	cation Records:
stem	r Profile	Applicat	ion Date 🖨		S	ubject		\$		Application	\$		Sta	atus 🗢
	tem													
aaut														

2.8 REQUEST TO CANCEL PRODUCT REGISTRATION

The End Of Life (EOL) function allows user to request for cancellation of a registered product.

2.8.1 Initiate EOL Application

Step 1:

• Click the menu item "Initiate EOL Application" under "Request to Cancel Product Registration" in the menu on the left.

	Request to C	ancel Product	Registration	s				
-								Close Next
	Step 1: Enter	Product for Ca	ncellation of I	Product Regis	tration, Re	ason(s) of Produ	ct Cancellation and Co	ntact Information.
You are login as WONG	Select Product							
David ABC COMPANY LIMITED Login date and time 15.10.2018 11:07	*HK No.	P	roduct Name			Expiry Date	Other Issue	
Online Notification	* Effective Date :							
My Product Search	* Reason(s) of Pro	duct Cancellation :						
+ New Registration								<u>^</u>
+ Change of Registered Particulars	* Doguost latter for	r Cancellation of Prod	ust Degistration -	UPLOAD				~
+ Renewal of Registration	(Please manual su	bmit original letter an	d registration cert)	No file chosen				
+ Submission of Other	* Contact Informatio	n for Product Cancell	ation :	* Phone No. :		* E	mail :	
Post-registration Supplement	* Address : Unit :							
+ Interview	Floor :							
 Request to Cancel Product Registration 	Block :							
Initiate EOL	Building :							
Application	Street No. : Street Name :							
Application Status	Sub-district :	Please Select			~			
- Application Submitted	Area :	Please Select			\checkmark			
Withdraw application								Close Next

Step 2:

• Click the button "Select Product", a dialog box is shown.

						Close
		Product for Cancellation of	of Product Registration	, Reason(s) of Product	Cancellation and Con	tact Information.
You are login as WONG David	Select Product					
ABC COMPANY LIMITED	*HK No.	Product Name		Expiry Date	Other Issue	
Login date and time 15.10.2018 11:07						
Online Notification	* Effective Date :					
My Product Search	* Reason(s) of Proc	duct Cancellation :				
+ New Registration						<u>^</u>
+ Change of Registered						~
Particulars	* Request letter for	Cancellation of Product Registration	UPLOAD			
+ Renewal of	(Please manual sul	bmit original letter and registration ce	rt) No file chosen			
Registration	Contact Information	n for Product Cancellation :				
+ Submission of Other Post-registration	* Contact Person :		* Phone No. :	* Ema	ill :	
Supplement	* Address :					
+ Intensiow	Unit :					
· Interview	Floor :					
 Request to Cancel Product Registration 	Block :					
-	Building :					
Initiate EOL Application	Street No. :					
	Street Name :					
- Not Submitted		Please Select	~			
	Area :	Please Select	~			
Withdraw application						Close Next

Step 3:

• Select a product and then click the button "Confirm".

						Close
	Step 1: Enter Pro) for Cancellation of	Product Registration, Reason(s) of Product Cano	cellation and Contact I	nformation.
u are login as WONG	Select Product					
VID	*HK No.	Produ	ct List		× sue	
gin date and time 10.2016 11.24			HK No.	Product Name	^	
		0	HK40870	2-4-2 OINTMENT(TEST)		
Online Notification	* Effective Date :	0	HK40981	CALCIUMFOLINAT EBEWE INJ 200MG (TEST)		
My Product Search		0	HK40985	CPC VITAMIN B1 TAB 100MG (TEST)		
	* Reason(s) of Product	0	HK41004	MEYSALIOL SPRAY (TEST)		
New Registration		0	HK41016	VITAMIN E CAP 400IU (TEST)		
Observe of Deviationed		0	HK41018	PIROCAM INJ 20MG/ML (TEST)		
Change of Registered Particulars		0	HK41025	TRANSBRONCHO TAB 30MG (TEST)	and the second second	
	Contact Information for	0	HK41026	PAINSTOP INJ 25MG/ML (TEST)		
Renewal of Registration	* Contact Person :	0	HK41441	ALLERSAN TAB		
	* Address :	Õ	HK42074	3TC ORAL SOLUTION 10MG/ML (TEST)		
Submission of Other Post-registration	Unit:	0	HK49574	ALBOL SUPER-CAL 600MG + VIT D3 TAB	and the second	
Supplement	Floor :	0	HK55147	0.3% POTASSIUM CHLORIDE AND 0.9% SODIUM CHLORIDE IV INF (THAI OTSUKA)		
Interview	Block : Building :	0	HK55411	0.15% POTASSIUM CHLORIDE AND 0.9% SODIUM CHLORIDE IV INF (THAI OTSUKA)		
Request to Cancel Product Registration	Street No. :	0	HK58139	PROMERIS DUO SPOT-ON FOR EXTRA LARGE DOGS (40.1 - 50KG) (VET)		
	Street Name :	۲	HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG)		
	Sub-district : Plea	0	HK59168	JURAMUNE ADULT C4 VACCINE (VET)		
Application Status	Area : Plea	0	HK60366	ACARBOSE TAB 50MG (HANGZHOU ZHONG	in an an an	
Not Submitted Application Submitted		0	HK60817	MEI) ALENDRONATE SANDOZ TAB 70MG		Close
Vithdraw application		0	HK61163	XGEVA SOLUTION FOR INJECTION 120MG		
Payment		0	HK63482	OMEPRAZOLE NORMON POWDER FOR SOLUTION FOR INFUSION 40MG	~	
		\cap	HK63505	TFST 1127		
Application History					 Res 1.400 (1.400 (1.400) 	

Step 4:

- The product information is filled in automatically.
- The "Other Issue" shows the recent communication about the product between certificate holder and Drug Officer.
- Fill the Contact Information.

Ť				Close
		for Cancellation of Product Registration	on, Reason(s) of Product	t Cancellation and Contact Information.
ou are login as WONG	Select Product			
BC COMPANY LIMITED	*HK No.	Product Name	Expiry Date	Other Issue
10.2016 11:24	HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	27.07.2019	Recent Notification(s) on Change of Registered Product
Online Notification	* Effective Date :			
My Product Search	* Reason(s) of Product Cancellatio	n:		
New Registration				^
Change of Registered Particulars				\checkmark
Renewal of Registration	Contact Information for Product Ca Contact Person : seaman.cai	* Phone No. : 11223344	* Email : sea	aman@abc.com
Submission of Other	Address : Unit : 382			
Post-registration Supplement	Floor : 3			
	Block : A			
Interview	Building : CHA LEUNG E	BUILDING		
Request to Cancel Product Registration	Street No. :			
Initiate EOL	Street Name :			
Application	Sub-district : CHA KWO LIN			
Application Status	rea : Please Select	~		

Step 5:

- Input the effective date and the reason(s) of product cancellation.
- Update the contact information for this product cancellation.
- Upload the Request letter for Cancellation of Product Registration
- Click the button "Next" to proceed.

•	Request to	Cancel Prod	uct Registrations	6			
T	Step 1: Ente	r Product for	Cancellation of F	roduct Registration, F	Reason(s) of Produ	ct Cancellation and Cont	Close (Next
You are login as WONG	Select Product)					
David ABC COMPANY LIMITED Login date and time 15.10.2018 11:07	*HK No.		Product Name		Expiry Date	Other Issue	
Online Notification	* Effective Date :	:					
My Product Search	* Reason(s) of P	roduct Cancellation	:				
+ New Registration							0
+ Change of Registered Particulars							·
+ Renewal of Registration	(Please manual s	tion for Product Can	Product Registration : r and registration cert) cellation :	UPLOAD No file chosen			
+ Submission of Other Post-registration Supplement	* Contact Person * Address : Unit :	ı:		* Phone No. :	*E	imail :	
+ Interview	Floor :						
 Request to Cancel Product Registration 	Block : Building :						
Initiate EOL Application	Street No. :						
Application Status	Street Name : Sub-district :	Please Select		~			
- Not Submitted - Application Submitted	Area :	Please Select		→ →			
Withdraw application							Close Next
Ť			uct Registration		n. Reason(s) of Pro	oduct Cancellation and C	Close Next
You are login as WONG	Select Product						
David ABC COMPANY LIMITED	*HK No.		Product Name		Expiry Date	Other Issue	
Login date and time 14.10.2016 11:24	HK58142		PROMERIS SPOT ON 320MG/1.6ML (VET)	FOR LARGE CATS (>4KG)	27.07.2019	Recent Notification(s) or	Change of Registered Product
Online Notification	* Effective Date	: 14.10.2016					
My Product Search	* Reason(s) of P	Product Cancellation	1:				
+ New Registration	This produc	ct is no longe	er produce				\sim
+ Change of Registered Particulars							·
+ Renewal of Registration		tion for Product Car n : seaman.cai		Phone No. : 11223344	* Email	seaman@abc.com	
+ Submission of Other Post-registration	Unit :	382					
Supplement	Floor :	3					
+ Interview	Block : Building :	A CHA LEUNG BI					
- Request to Cancel Product Registration	Street No. :						
Initiate EOL Application	Street Name : Sub-district :	CHA KWO LING	3	~			
Application Status	Area :	Please Select		~			Close Next
- Application Submitted							Close Next

Step 6:

• Click "Next" to save the information.

	Request to Cancel Pro	oduct Registrations				
Ť						Close Next
	Step 1: Enter Product(s) for Cancellation of	Product Registration, R	eason(s) of Product Ca	Incellation and Contact Inform	ation.
You are login as WONG	Select Product		- í			
David ABC COMPANY LIMITED	*HK No.	Product Name		Expiry Date	Other Issue	
Login date and time 14.10.2016 11:24	HK58142	PROMERIS SPOT ON FO 320MG/1.6ML (VET)	R LARGE CATS (>4KG)	27.07.2019	Recent Notification(s) on Change of Register	ed Product
Online Notification	* Effective Date : 14.10.2016					
My Product Search	* Reason(s) of Product Cancellat	tion :				
+ New Registration	This product is no los	nger produce			<u>^</u>	
+ Change of Registered Particulars					~	
 Description 	Contact Information for Product (* Contact Person : seaman.ca		hone No. : 11223344	* Email : seama	n@abc.com]
	* Address :			x		
Post-registration	Unit : 382		網頁訊息			
Supplement	Floor : 3					
+ Interview	Block : A		Are you sure to say	a ²		
	Building : CHA LEUNG	BUILDING				
 Request to Cancel Product Registration 	Street No. :					
Initiate EOL	Street Name :			取消		
Application	Sub-district : CHA KWO L	ING		AX/A		
Application Status	Area : Please Selec	:t	<u> </u>			
- Not Submitted - Application Submitted						Close Next

Step 7:

- Verify the information inputted in page1.
- Indicate return product registration certificate to Drug Office.



Scenario 1: Return registration certificate to Drug Office.

• Check the checkbox.

	Request to Car	ncel Product Registra	ations		
-					Back Save Confirm & Submit
You are login as WONG	Step 2: Indicate Registration.	the Return of Registr	ation Certificate, and Confirm S	ubmission of Your Req	uest of Cancellation of Product
David	HK No.		Product Name		Return Registration Certification to Drug Office
ABC COMPANY LIMITED Login date and time 14.10.2016 11:24	HK58142	PROMERIS SPOT ON FOR LA	RGE CATS (>4KG) 320MG/1.6ML (VET)		
	If "Return Registratio	on Certificate to Drug Office"	is checked, Drug Office will start to proce	ss your request when the regist	ration certificate is received.
Online Notification	Effective Date: 14.10	2016			
My Product Search	Reason(s) of Produc	t Cancellation: This product is	no longer produce		
+ New Registration	Contact Information	for Product Cancellation:			
+ Change of Registered Particulars	Contact Person : se	aman.cai	Phone No.: 11223344	Email : seaman	@abc.com
+ Renewal of Registration	Address : Unit :	382			
+ Submission of Other Post-registration Supplement	Floor: Block: Building: Street No.:	3 A CHA LEUNG BUILDING	à		
+ Interview	Street Name : Sub-district : Area :	CHA KWO LING			
 Request to Cancel Product Registration 	Aled :				
Initiate EOL Application	Warning:The cancell cancellation by Drug		s subject to approval by Drug Office.The ca	ancellation of product registrati	on cannot be revoked after the approval of
Application Status					Back Save Confirm & Submit

Scenario 2: Not return registration certificate to Drug Office.

• Un-check the checkbox and input the reason(s) not to return registration certificate to Drug Office.

-	Request to Can	cel Product Registrati	ons		
+		g			Back Save Confirm & Submit
		the Return of Registrati	ion Certificate, and Confirm S	ubmission of Your Requ	est of Cancellation of Product
You are login as WONG	Registration.		Product Name		
David ABC COMPANY LIMITED	HK NO.		Product Name		Return Registration Certification to Drug Office
Login date and time 14.10.2016 11:24	HK58142	PROMERIS SPOT ON FOR LARG	E CATS (>4KG) 320MG/1.6ML (VET)		
Online Notification	If "Return Registration	n Certificate to Drug Office" is (checked, Drug Office will start to proce	ss your request when the registra	ation certificate is received.
	If "Return Registratio	on Certificate to Drug Office" is	unchecked, please provide reason(s).		
My Product Search	The certificate				Ô
+ New Registration	Enective Date: 14.10.	2010			· .
+ Change of Registered Particulars	Reason(s) of Product	Cancellation: This product is no	longer produce		
+ Renewal of Registration	Contact Information f	or Product Cancellation:			
+ Submission of Other Post-registration Supplement	Contact Person : sea	iman.cai	Phone No.: 11223344	Email : seaman@	abc.com
ouppionent	Address :				
+ Interview	Unit : Floor : Block :	382 3 A			
- Request to Cancel Product Registration	Building : Street No. : Street Name :	CHA LEUNG BUILDING			
Initiate EOL Application	Sub-district : Area :	CHA KWO LING			
Application Status - Not Submitted - Application Submitted	Warning:The cancella cancellation by Drug	tion of registered product is su Office.	bject to approval by Drug Office.The ca	ncellation of product registration	n cannot be revoked after the approval of
Withdraw application					Back Save Confirm & Submit

Step 8:

• Click "Save" to save the application as draft or click "Confirm & Submit" to submit the application to Drug Office for evaluation.

	Request to Can	cel Product Registrati	ions		
					Back Save Confirm & Submit
	Step 2: Indicate t Registration.	he Return of Registrat	tion Certificate, and Confirm Su	ubmission of Your Requ	est of Cancellation of Product
You are login as WONG David	HK No.		Product Name		Return Registration Certification to Drug Office
ABC COMPANY LIMITED Login date and time 14.10.2016 11:24	HK58142	PROMERIS SPOT ON FOR LARG	GE CATS (>4KG) 320MG/1.6ML (VET)		
Online Notification	If "Return Registration	Certificate to Drug Office" is	checked, Drug Office will start to proces	s your request when the registra	tion certificate is received.
			s unchecked, please provide reason(s).		
My Product Search	The certificate	is missing.			\bigcirc
+ New Registration	Effective Date: 14.10.2	016			
+ Change of Registered Particulars	Reason(s) of Product (Cancellation: This product is no	o longer produce		
+ Renewal of Registration	Contact Information fo	or Product Cancellation:			
+ Submission of Other Post-registration Supplement	Contact Person : sear	nan.cai	Phone No. : 11223344	Email : seaman@	abc.com
+ Interview	Unit : Floor :	382 3			
- Request to Cancel Product Registration	Block : Building : Street No. : Street Name :	A CHA LEUNG BUILDING			
Initiate EOL Application	Sub-district : Area :	CHA KWO LING			
Application Status - Not Submitted - Application Submitted	Warning:The cancellat cancellation by Drug C		ubject to approval by Drug Office.The ca	ncellation of product registration	n cannot be revoked after the approval of
Withdraw application					Back Save Confirm & Submit

Step 9:

• The system then redirects to an acknowledgement page. User can click "Print" to print the submission acknowledgement.

	Request to Cancel F	Product Registrations	
Ť	Step 3: Acknowledge	ment	Print Close
You are login as WONG David ABC COMPANY LIMITED Login date and time 14.10.2016 11:24	You reference number is	r service. Your request for cancellation of product registration is subject to approval of Drug Office.	
Online Notification	Please quote this reference	e number for enquiries or for return of registration certificate to Drug Office.	
My Product Search	General enquiries:		
+ New Registration	Office Hours:	Monday to Friday	
+ Change of Registered		9:00 am - 1:00 pm	
Particulars		2:00 pm - 5:45 pm	
+ Renewal of Registration		(up to 6:00 pm on Monday)	
-		(Closed on Saturdays, Sundays & Public Holidays)	
+ Submission of Other Post-registration	Tel:	(852) 2319 8458	
Supplement	Email:	prs2_info@dh.gov.hk	
+ Interview			
- Request to Cancel Product Registration			
-	HK No. 💠		\$
Initiate EOL Application	HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	
Application Status			Print Close

Step 10:

• The system will send an online notification to the certificate holder with the following content.

	Online Notificat	ion			END_OF_PRODUCT_LIFE_NOTIFICAT
					Ba
are login as WONG d	Notification Date: 14.10.20	16 12:04:50			
COMPANY LIMITED in date and time 0.2016 11:24	Cancellation Reques	st Submiss	ion Notification	1	
nline Notification	Dear Sirs/Madams,				
mine Noulication	Cancellation of Drug/Produ	ict Registratio	n:		
ly Product Search					
lew Registration	HK No. HK58142	¢ PR02	PR No. 35/2008	\$	Name of Product PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320/MG/1.6ML (VET)
hange of Registered articulars	Thank you for your online ap providing professional and ex	plication dated	14.10.2016 for cancel rt to the Pharmacy and	lation of o	Irug/product registration. Please return the original certificate to the Drug Office. The Department of Health is Board and its Committee.
Renewal of Registration	We acknowledge the receipt	of your applica	tion and it is now bein	g process	ed.
Submission of Other Post-registration Supplement					Ba
Supplement					

2.8.1.1 Application Enquiry

The Application Enquiry function allows user to view all outstanding cancellation request including submitted application and application in draft.

Step 1:

- Click the menu item "Application Status Not Submitted Application submitted" under "Request to Cancel Product Registration" in the menu on the left.
- The "Initiate new EOL Application" button redirects the use to "Initiate EOL Application" function (Refer to 4.2.9.1).
- The not submitted pool contains all drafted request to cancel product registration application. User can click the hyperlink on the product name to edit the application.
- The application submitted pool contains all processing applications. User can view the processing status of the application. User can click the hyperlink on the product name to view the application detail.



2.8.1.2 Withdraw application

The Withdraw application function allows user to withdraw submitted application for cancellation of a registered product.

Step 1:

• Click the menu item "Withdraw application" under "Request to Cancel Product Registration" in the menu on the left.

•	EOL	Application Wi	thdrawal					
							Withdraw Applica	ation
You are login as WONG	\$	Date Received *	Ref No. 4	HK No.	\$	Product Name	\$ Status	\$
David ABC COMPANY LIMITED		24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX		Cancellation Request Submitted	
Login date and time 24.08.2018 17:51		07.08.2018	DE-REG-HK63533-20180807	HK63533	TEST 20161208		Cancellation Request Submitted	
Online Notification							Withdraw Applica	ation
+ New Registration + Change of Registered Particulars + Renewal of Registration + Interview								
Request to Cancel Product Registration Initiate EOL Application Application Status Not Submitted								
Application Submitted Withdraw application * Pownent.								

Step 2:

• Select the application(s) for withdrawal and click the button "Withdraw Application".

								Withdraw App	olication
	\$ Date Received *	R	lef No.	\$ HK No.	\$		Product Name	\$ Status	4
ou are login as WONG avid BC COMPANY LIMITED	24.08.2018	DE-REG-HK3699	95-20180824	HK36995	1	PRODUCT NAME XXXX		Cancellation Request Submitted	
ogin date and time 4.08.2018 17:51	07.08.2018	DE-REG-HK6353	33-20180807	HK63533	1	TEST 20161208		Cancellation Request Submitted	
Online Notification								Withdraw App	licatior
My Product Search									
New Registration									
New Registration									
- Change of Registered Particulars									
Particulars									
Particulars + Renewal of Registration									
Particulars • Renewal of Registration • Interview									
Renewal of Registration Interview Request to Cancel									
Particulars Renewal of Registration Interview Request to Cancel Product Registration Initiate EOL									

Step 3:

• Input the reason(s) of withdrawal and click the button "Confirm to Withdraw".

Ť	EOL Application	Withdrawal			Confirm to Withdraw Close
	Date Received \$	Ref No.	\$ HK No.	\$ Product Name	\$ Status
You are login as WONG David	24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX	Cancellation Request Submitted
ABC COMPANY LIMITED Login date and time 24.08.2018 17:51	Reason(s) of Withdrav	wal :		 ~	
Online Notification					
My Product Search				×	
+ New Registration					Confirm to Withdraw Clos

Step 4:

• Click the button "OK" to confirm withdrawal.

•	EOL Application	Withdrawal					
						Confirm to Withdraw	Close
	Date Received \$	Ref No.	\$ HK No.	>	Product Name	\$ Status	\$
You are login as WONG David	24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX		Cancellation Request Submi	tted
ABC COMPANY LIMITED Login date and time	* Reason(s) of Withdrav	val :					
24.08.2018 17:51	Reason				~		
Online Notification							
My Product Search			網頁訊息		×		
+ New Registration			納貝訊息			Confirm to Withdraw	Close
rion riogica allon						Committee withdraw	Close
+ Change of Registered Particulars				Are you sure to save?			
+ Renewal of							
Registration				確定 取消			
+ Interview				¥E/E — — — — — — — — — — — — — — — — — —			
- Request to Cancel							

2.9 PAYMENT

2.9.1 Payment Pool

Step 1: Click the menu item "Payment Pool" under the section "Payment" in the menu on the left.

You are login as VMG TEST USERI SEAMAN COMPANY LTD Login date and time 27 07 2023 1223	ATTENTION : If unable to open the on If the error message PA							-	ment service	<u>FAQ Q</u> uesti	on 1.	
Online Notification												
My Product Search	New Applicat	ion Pay	/ment								_	
+ New Registration				_					_		Print	Ready to Pay
+ Change of Registered Particulars	Application Re	ceived Date	PL No.	\$ I	PR No.	\$	Proposed Name of	Product	Payme	ent Status		÷
+ Renewal of Registration												
+ Submission of Other Post-registration Supplement												
+ Interview	New Applicat	ion Cei	tificate Payr	nent							_	
+ Request to Cancel Product Registration	Application Re	ceived Date	PL No.	¢	PR No.	¢	Proposed Name of	Product	\$ Paym	ent Status	(Ready to Pay
- Payment	Certificate Collection	n: 🔿 e-Cer	ificate									
Payment Pool Payment History	Recipient :	⊖ vmg_u	ser3									
Application History		⊖ vmg_u	ser1									
+ User Profile	CORP Updat		ly one recipient.	ont						_		
+ Printing Service		eu Cel	incate Fayn	ent							Ready t	o Pay Close
+ System	Application Received Date	Reference	e No.	¢ HK N	o. 💠	Name of Product		¢ C	hange ategories	Payment	Status	\$
Logout	Cert ficate Collection	_	ificate									
	Recipient :	⊖ vmg_u	ser3									
		⊖ vmg_u	ser1									
		*Select on	ly one recipient.									

List of applications that require payments will be shown for new product registration and change of registered particulars application. To pay for applications, multi select the applications by selecting the checkbox and click the "Ready to Pay" button to enter the payment flow.

You can select the collection method either by 'Received by post' or 'Collect in person in Drug Office'

After certificate holder selects the application(s) to pay and clicks "Ready for Pay" button, a confirmation message box will be prompt and will direct the page to payment gateway for online payment as following:



Select the payment method (Visa, Master, JBC, UnionPay, FPS or PPS) and press 'Pay' to proceed. Press 'Cancel payment' if you want to cancel the payment and back to payment pool.



After completion the online payment, system will redirect back to Drug Office PRS2.0 website with payment summary and allow user to print the payment receipt as following:

	Now Drodu	at Domiatra	tion			
•	New Produ	ct Registra				Print Receipt Close
	Payment Reference	ce No.: DHPRS-20	01808270916-91733			
	EGIS Reference N	lo.: C2018082	272000707			
ou are login as WONG lavid	Payment Method:	JCB				
BC COMPANY LIMITED ogin date and time	Type of Payment:	Certificate	Fee			
7.08.2018 09:08	Transaction Time:	27.08.201	8 09:16:40			
Online Notification	Delivery Method:	Received	By Post			
My Product Search	Application Rec	reived Date	Reference No	PR No	Product Name	
My Product Search ⊦ New Registration	Application Rec 27.02.2017		Reference No. ANP20179000024	PR No. PR0038/2017	Product Name TEST 2016022701	
New Registration	27.02.2017	' 10:22 acknowledges the r	ANP20179000024	PR0038/2017		ur application and will provide
New Registration Change of Registered Particulars	27.02.2017 The Drug Office a response as soor	' 10:22 acknowledges the r n as possible.	ANP20179000024	PR0038/2017 370.00 for application fee regardin	TEST 2016022701	ur application and will provide
New Registration Change of Registered Particulars Renewal of Registration	27.02.2017 The Drug Office a response as soor Please kindly quo General Enquiries	7 10:22 acknowledges the r n as possible. ote the above Paym	ANP20179000024 receipt of your payment of HK\$1,3	PR0038/2017 370.00 for application fee regardin	TEST 2016022701	ur application and will provide
New Registration Change of Registered Particulars Renewal of Registration	27.02.2017 The Drug Office a response as soor Please kindly quo General Enquiries Office Hours:	' 10:22 acknowledges the r n as possible. ote the above Paym	ANP20179000024 receipt of your payment of HK\$1,3	PR0038/2017 370.00 for application fee regardin	TEST 2016022701	ur application and will provide
New Registration Change of Registered Particulars Renewal of Registration Interview Request to Cancel Product Registration	27.02.2017 The Drug Office a response as soor Please kindly quo General Enquiries Office Hours:	10.22 acknowledges the r n as possible. ote the above Paym s: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on N	ANP20179000024 eccipt of your payment of HK\$1, nent Reference Number for enqui	PR0038/2017 370.00 for application fee regardin	TEST 2016022701	ur application and will provide
New Registration Change of Registered Particulars Renewal of Registration Interview Request to Cancel	27.02.2017 The Drug Office a response as soor Please kindly que General Enquiries Office Hours:	10.22 acknowledges the r n as possible. ote the above Paym s: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on N	ANP20179000024 ecceipt of your payment of HK\$1, nent Reference Number for enqui Monday) ays, Sundays & Public Holidays)	PR0038/2017 370.00 for application fee regardin	TEST 2016022701	ur application and will provide

The print out payment receipt is follow:

	Payment Receipt of Change of Registered Par	ticulars
Name of Company		Payment Date
公司名稱		総費日期
3 MED MEDICAL SUPPLIE	IS CO	26.08.2022
Payment Reference No:	DHPRS-202208261522-93716	
付款編號: EGIS Reference No:	C202208265000807	
EGIS編號:		
Payment Method: 付款方法:	JCB	
Payment Amount:	HK\$155.00	
	HK\$155.00	

2.9.2 Payment History

Step 1: Click the menu item "Payment History" under the section "Payment" in the menu on the left.

You are login as WONG David ABC COMPANY LIMITED Login date and time 27 08 2018 09:08			i y											
David ABC COMPANY LIMITED		Reais	New Product Periotration											
David ABC COMPANY LIMITED			tration					Total Number of Payment I	Records: 2					
David ABC COMPANY LIMITED	PR No.	\$	Name of Product	\$	Payment Date	\$	Amount(HK\$)	Payment Ref No.	4					
ABC COMPANY LIMITED Login date and time	PR0077/2015		HP TEST ONLINE 0401		01.04.2015		1100	0 DHPRS-201504011803-90002						
	PR0065/2015		TEST 2016022701		26.01.2015		1100	0 Not available from PRLS						
27.08.2018 09:08	Change of Re	gister	ed Particulars Applicati	on										
Online Notification	HK No.	•	Name of Product	•	Payment Date		Amount(HK\$)	Total Number of Payment Payment Ref No.	Records:					
My Product Search	HK NO. HK63552	Ŧ	TEST ATTACH	Ŧ	16.11.2017	Ŧ		0 DHPRS-201711161525-13744						
My Floduct Search	Renewal of R	enistra			10.11.2017		100	0 011110102010144						
New Registration	Renewaron R	egisti						Total Number of Payment	Records:					
Change of Registered	HK No.	\$	Name of Product	¢	Payment Date	\$	Amount(HK\$)	Payment Ref No.	¢					
⊢ Change of Registered Particulars	HK36996		PRODUCT NAME XXXX XXXX		24.08.2018		575.	0 DHPRS-201808241655-91732						
+ Request to Cancel Product Registration - Payment Payment Pool Payment History Application History														
⊦ User Profile														
System														

List of historical payments will be shown for new product registration, change of registered particulars and renewal application. To show the detailed information regarding each payment, click the payment reference number.

New Product Registration:

lew Prod	luct Registra	tion			Print Receipt	Close					
Payment Refere	ence No.: DHPRS	-201412091902-90540									
EGIS Reference	e No.: A20141	2090000618									
Payment Metho	d: PPS										
Type of Paymer	nt: Certifica	Certificate Fee									
Transaction Tim	ne: 29.01.20	29.01.2015.22:10.57 Collectin Person in Drug Office									
Delivery Method	d: Collect i										
Certificate Colle	ection Date: 09.12.20	014									
Application R 09.12.20	Received Date	Reference No. ANP20149000189	PR No. PR0103/2014	Product Name HP TEST 1209 NCE							
09.12.20 The Drug Offic	14 17:55	ANP20149000189	PR0103/2014		our application and will provi	de					
09.12.20 The Drug Offic response as so	014 17:55 ce acknowledges the re oon as possible.	ANP20149000189	PR0103/2014	HP TEST 1209 NCE	our application and will provi	de					
09.12.20 The Drug Offic response as so Please kindly o	014 17:55 ce acknowledges the re oon as possible. quote the above Paym	ANP20149000189 acceipt of your payment of HK\$1,3	PR0103/2014	HP TEST 1209 NCE	our application and will provi	de					
09.12.20 The Drug Offic response as so Please kindly o	014 17:55 ce acknowledges the re oon as possible. quote the above Paym	ANP20149000189 acceipt of your payment of HK\$1,3	PR0103/2014	HP TEST 1209 NCE	our application and will provi	de					
09.12.20 The Drug Offic response as so Please kindly o General Enquirio	014 17:55 ce acknowledges the re oon as possible. quote the above Paym ies:	ANP20149000189 acceipt of your payment of HK\$1,3	PR0103/2014	HP TEST 1209 NCE	ur application and will provi	de					
09.12.20 The Drug Offic response as so Please kindly o General Enquirio	114 17:55 ce acknowledges the re oon as possible. quote the above Paym ies: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm	ANP20149000189 sceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR0103/2014	HP TEST 1209 NCE	our application and will provi	de					
09.12.20 The Drug Offic response as so Please kindly o General Enquirio	114 17:55 ce acknowledges the re oon as possible. quote the above Paym les: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on M	ANP20149000189 cceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR0103/2014	HP TEST 1209 NCE	ur application and will provi	de					
09.12.20 The Drug Offic response as sr Please kindly o General Enquirk Office Hours:	h14 17:55 ce acknowledges the re oon as possible. quote the above Paym les: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on M (Closed on Saturda;	ANP20149000189 sceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR0103/2014	HP TEST 1209 NCE	sur application and will provi	de					
09.12.20 The Drug Offic response as so Please kindly o General Enquirio	114 17:55 ce acknowledges the re oon as possible. quote the above Paym les: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on M	ANP20149000189 sceipt of your payment of HKS1,3 ent Reference Number for enqui onday) /s, Sundays & Public Holidays)	PR0103/2014	HP TEST 1209 NCE	sur application and will provi	de					

Change of Registered Particular:

-	egistered Particu				Print Receipt CI	
	No.: DHPRS-201803201138	-13842				
S Reference No.						
ment Method:	Cash					
nsaction Time:	27.08.2018 09:53:09					
ivery Method:	Received By Post					
Application Received Date	Reference No.	HK No.	Product Name	Change Categories	Payment Status	
20.03.2018 00:00	CORP-HK63567-201851387	HK63567	TEST 20161226 01	5	Certificate Fee Paid	
	knowledges the receipt of your is possible. i the above Payment Reference			oove product(s). We will process your ap	plication and will provide	
neral Enquiries:	The above Payment Relevence	e Number for enquir	185.			
9:1 2:1 (u) (C	onday to Friday 00 am - 1:00 pm 00 pm - 5:45 pm p to 6:00 pm on Monday) losed on Saturdays, Sundays 52) 23198458	& Public Holidays)				
	s2_info@dh.gov.hk					
Email: pr	sz_inte@dit.gov.tik					
emaii: pr	nogen.gor.m				(Print Receipt) (Cl	USE
enewal:					Print Keceipt (C	RENEWAL_PAY
enewal: enewal			2		Print Keceipt (Ci	
enewal: enewal ayment Refer	ence No.: DHPRS-2018		12		Print Keceipt (Ci	RENEWAL_PAY
enewal: enewal ayment Refer GIS Reference	ence No.: DHPRS-2018 e No.: C201808242		12		Print Keceipt (Ci	RENEWAL_PAY
enewal: enewal ayment Refer GIS Reference ype of Payme	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal	001297	12		Print Keceipt (C)	RENEWAL_PAY
enewal: enewal ayment Refer GIS Reference ype of Payme ransaction Tir	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal me: 24.08.2018 1	001297 6:56:30			Print Keceipt (Ci	RENEWAL_PAY
enewal: enewal ayment Refer GIS Reference ype of Payme	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal me: 24.08.2018 1	001297			Print Keceipt (Ci	RENEWAL_PAY
enewal: enewal ayment Refer GIS Reference ype of Payme ransaction Tin elivery Metho	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal me: 24.08.2018 1 d: Collect in Per	001297 6:56:30	ce	Name	Print Keceipt (Ci	Print Receipt
enewal: enewal ayment Refer GIS Reference gype of Payme ransaction Tir velivery Metho	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal me: 24.08.2018 1 d: Collect in Per No.	001297 6:56:30 rson in Drug Offic	Ce Product	Name	Print Keceipt (Ci	RENEWAL_PAY Print Receipt
enewal: enewal ayment Refer GIS Reference ype of Payme ransaction Tir velivery Metho HK36996 The Drug Offit	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal ne: 24.08.2018 1 d: Collect in Per No. PRODUCT N	001297 6:56:30 rson in Drug Offic	ce Product	Name		RENEWAL_PAY Print Receipt (C
enewal: enewal ayment Refer GIS Reference ype of Payme ransaction Tin telivery Metho HK36996 The Drug Offit response as s	ence No.: DHPRS-2018 e No.: C201808242 nt: Renewal me: 24.08.2018 1 d: Collect in Per No. PRODUCT N ce acknowledges the reco	001297 6:56:30 rson in Drug Offic IAME XXXX XXXX eipt of your paym	Ce Product			RENEWAL_PAY Print Receipt (C

 fice Hours:
 Monday to Friday

 9:00 am - 1:00 pm

 2:00 pm - 5:45 pm

 (up to 6:00 pm on Monday)

 (Closed on Saturdays, Sundays & Public Holidays)

 Tel:
 (852) 23198458

 Email:
 prs2_into@dh.gov.hk

•
Print Receipt Close

2.10 APPLICATION HISTORY

Step 1: Click the menu item "Application History" in the menu on the left.

	Onlin	e Notification					ONLINE_NOTIFICATION_V	EW_
T	New Pr	oduct Registration					Archived Notific	atior
u are login as ORG Trial	No rela	ted notifications						
e STING LIMITED gin date and time	CORP						Archived Notific	atio
01.2021 15:42		Notification Date \$	Subject	\$	HK No.	\$	Name of Product	
nline Notification	Open	12.01.2021 17:44:04	Application Screening Notification		HK41190		PRODUCT NAME XXXXX XXXX	
	Open	05.06.2020 11:00:01	Application Submitted Notification		HK41190		PRODUCT NAME XXXXX XXXX	
ly Product Search	Open	03.10.2019 11:55:37	Application Submitted Notification		HK37565		PRODUCT NAME XXXXX	
In Desistanting	Open	04.03.2019 11:33:13	Application Approval Notification		HK31199		EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	
lew Registration	Open	27.02.2019 11:52:23	Certificate Fee Notification		HK65135		CELECOXIB FARMOZ	
Change of Registered	Open	26.02.2019 15:12:46	Application Approval Notification		HK42175 APT-INDOMETHACIN 25 CAP 25MG			
Particulars	Open	21.08.2018 18:25:53	Application Clarification Notification		HK41190		PRODUCT NAME XXXXX XXXX	
Renewal of	Open	21.08.2018 18:20:50	Application Screening Notification		HK41190		PRODUCT NAME XXXXX XXXX	
Registration	Open	21.08.2018 18:19:47	Application Submitted Notification		HK41190		PRODUCT NAME XXXXX XXXX	
lequest to Cancel	Open	21.08.2018 18:07:37	Application Submitted Notification		HK37565		PRODUCT NAME XXXXX	
roduct Registration	Renewa	al of Registration					Archived Notific	atio
Payment		-						auto
opplication History	No rela	ted notifications						
Jser Profile	Cancell	ation Request						
		Notification Date \$	Subject	¢	HK No.	φ	Name of Product	
System	Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification		HK31199		EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	
ogout	Non Dh	armaceutical Produ	at Alast					
			ict Alert					
	No rela	ted notifications						

List of historical applications will be shown for new product registration, change of registered particulars, renewal, termination of product, ongoing request and interview application. For the new product registration, change of registered particulars, termination of product and interview application, please click on the underlined navigation link to view additional detailed information regarding the application.

**** END ****