

APPLICATION USER MANUAL

FOR THE

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

(PRS 2.0)

OF THE

DEPARTMENT OF HEALTH

Version: 1.1.18

Jul 2023

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

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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
	Comorio (Diological)	Module 1	50MB	300MB
	Generic (Biological)	Module 2-5	Submit by	y CD/DVD
New Application	Conoria (Others)	Module 1	50MB	100MB
New Application	Generic (Others)	Module 2-5	Submit by	y CD/DVD
	NCE	Module 1	50MB	300MB
	NCE	Module 2-5	Submit by	y 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

With effect from 1 July 2023, the Phar electronic form for applications for ini For details, please visit https://www.drugoffice.gov.hk/eps/do/	macy and Poisons Board will only issue certi tial registration, renewal of registration and c en/popup launch of electronic certificate of	ficates of drug/ product registration in hange 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	\$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 	tware: kies and enable JavaScript	
	2. The private key and the PIN of your e	-Cert will not be transmitted during the trans	saction.
	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
	 You should disable options on your be computer. 	rowser to avoid storing or retaining your e-C	ert password on the personal
	5. For organizational e-Cert file location	, 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						
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)	* III					
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.	.					
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						
Step 2: Provide User / Organization Information						
Please provide the following information to create your account. Field with* are mandatory						
Login Information						
* Username usernam	me (i	Isername only allows alphabets (a-z, A-Z), num J-9), underscores (_) and Hyphens(-) and must -20 characters long.	ibers i be			
Note: Password would be automatically general	ted by the system and sent to the authorized	user through email.				
e-Cert (Organizational)						
* Organizational e. Cert File Location	C:\cort n12					
- Organizational e-Cert File Education	C.(cert.piz 测量					
* e-Cert PIN	Please select the e-Cert file, e.g. C:\cert.p12					
(Click W Check e-Cert Information in Hongkong Post)		1				
* Email address	eCert@emailAddress.com	(Case Sensitive)				
* Name of Organization	Name of Organization of e-Cert					
* Name of Organization * Business Registration Certificate Number	Name of Organization of e-Cert 12345878-000	(e.g. 12345678-123)				
* Name of Organization * Business Registration Certificate Number * Name of Authorized User	Name of Organization of e-Cert 12345678-000 Name of Authorized User of e-Cert	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User Contact Phone Number (852)	Name of Organization of e-Cert 12345878-000 Name of Authorized User of e-Cert 2319-8414	(e.g. 12345678-123)				
* Name of Organization * Business Registration Certificate Number * Name of Authorized User *Contact Phone Number (852) Position	Name of Organization of e-Cert 12346878-000 Name of Authorized User of e-Cert 2319-8414 Position	(e.g. 12345678-123)				
* Name of Organization * Business Registration Certificate Number * Name of Authorized User *Contact Phone Number (852) Position *Company Address	Name of Organization of e-Cert 12346878-000 Name of Authorized User of e-Cert 2319-8414 Position	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User 'Contact Phone Number (852) Position 'Company Address Unit:	Name of Organization of e-Cert 12346878-000 Name of Authorized User of e-Cert 2319-8414 Position Room 111	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User 'Contact Phone Number (852) Position 'Company Address Unit: Floor:	Name of Organization of e-Cert 12346878-000 Name of Authorized User of e-Cert 2319-8414 Position Room 111 11/F	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User 'Contact Phone Number (852) Position 'Company Address Unit: Floor: Block:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert 2319-9414 Position Room 111 11/F	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User 'Contact Phone Number (852) Position 'Company Address Unit: Floor: Block: Building:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert 2310-9414 Position Recent 111 11/F Building	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User 'Contact Phone Number (852) Position 'Company Address Unit: Floor: Blook: Building: Street No.:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert 2310-8414 Position Room 111 11/F Building 11	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User Contact Phone Number (852) Position Company Address Unit: Filoor: Blook: Building: Street No.: Street Name:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert [2310-8414 Position Room 111 11/F Building 11 Street	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User Contact Phone Number (852) Position Company Address Unit: Floor: Block: Building: Street No.: Street Name: Sub-district:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert 2310-8414 Position Room 111 11/F Building 11 Street	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User Contact Phone Number (852) Position Company Address Unit: Filoor: Block: Building: Street No.: Street Name: Sub-district: Area:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert [2310-8414 Position Room 111 11/F Building 11 Street	(e.g. 12345678-123)				
Name of Organization Business Registration Certificate Number Name of Authorized User Contact Phone Number (852) Position Company Address Unit: Filoor: Blook: Building: Street No.: Street Name: Sub-district: Area: E-cert Register:	Name of Organization of e-Cert 12346678-000 Name of Authorized User of e-Cert 2310-8414 Position Room 111 11/F Building 11 Street	(e.g. 12345678-123)				

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			
		Download Certif	ïcate - e-Cert (Organisational)	
	Please input either on English Name in Certifi	e of the following information:- cate :	Given Name	
	Email Address in Certif Subscriber Reference I	icate :	ingenièr	
Hongkong Post 香港野政 Linking people Delivering business 母心歌 就在9月	Warning: Any informa signatures and encry	tion and certificates downloaded from th tion.	nis web site shall only be used for lawful purpos	ses relevant to the use of digital
W3C WAI-AA	I acknowledge that	I have read the above warning message a	nd will abide by the purposes and limitations on use	a stated therein.
	2007 © Important Notices Privacy	Policy		
そ Hongkong Post e-Cert 香港郵政電子核證	The solution for e-Security			
	_	Download Certif	ïcate - e-Cert (Organisational)	
-		English Name in Certificate :		
	-	Email Address in Certificate :		1
		Email Address in Certificate : Organisation Name in English : Organisation Name in Chinese : Branch Name in English : Branch Name in Chinese :		
CERTIZEN Datasta C Hanne har c Hanne Frank C Hanne C Hanne Klangkong Post Staffic		imail Address in Certricate : Organisation Name in English : Organisation Name in Chinese : Branch Name in English : Branch Name in Chinese : BR Number : CR/CI : Others :		
Hanglong Post 64982 William Post 64982 William Post 64982		Imail Address in Certificate : Organisation Name in English : Organisation Name in Chinese : Branch Name in Chinese : Branch Name in Chinese : BR Number : CRICI : Others : Subscriber Reference Number : Type of Certificate : Issued by : Certificate Serial Number :	e-Cert (Organisational) Hongkong Poste-Cert CA 1 - 10 32 d4 32	
Hangtong Post 6888 With a set of the set of the set for a set of the set of the set of the set of the set of the set of the set of the set of t		Imail Address in Certificate : Organisation Name in English : Organisation Name in Chinese : Branch Name in Chinese : BR Number : CRCI : Others : Subscriber Reference Number : Type of Certificate : Susued by : Certificate Serial Number : Certificate Signature Algorithm :	e-Cert (Organisational) Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha1RSA Active	
Contraction of the second seco		Imail Address in Certificate : Organisation Name in English : Organisation Name in Chinese : Branch Name in Chinese : Branch Name in Chinese : BR Number : CRICI : Others : Subscriber Reference Number : Type of Certificate : Issued by : Certificate Serial Number : Certificate Serial Number : Certificate Serial Number : Certificate Status : Validity Period (dd/mm/yyyy) :	e-Cert (Organisational) Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha1RSA Active	
CARACTERISTIC	Note- The Certificate status displayed above locating its serial number in the latest the Certificate has been suspended on http://cr1.hongkongpost.gov.hi/cert/ce aware that the full CRL is larger in size aware that the full CRL is larger in size	Imail Address in Certificate : Organisation Name in English : Organisation Name in Chinese : Branch Name in Chinese : Branch Name in Chinese : BR Number : CRICI : Others : Subscriber Reference Number : Type of Certificate : Ssued by : Certificate Serial Number : Certificate Signature Algorithm : Certificate Subschweiter : Validity Period (dd/mm/yyyy) : Dov	e-Cert (Organisational) Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha1RSA Active vnload the Certificate the Certificate displayed above, you should verify if by Hongkong Post Certification Authority. If the series our and download the latest pritioned CRL of the i download the latest full CRL at http://crt1.hongkong	the Certificate has been suspended or revoked by al number of the Certificate is found in a CRL, then Certificate at spost gov hk/cr//eCertCA1-10CRL1.crl. Please be
Conception Post State	Note The Certificate status displayed abov locating its serial number in the latest the Certificate has been suspended o http://crti.thongkongpost.gov.hk/crt/eC aware that the full CRL is larger in siz	Imail Address in Certificate : Organisation Name in English : Organisation Name in English : Branch Name in English : Branch Name in English : BR Number : CRICI : Others : Subscriber Reference Number : Type of Certificate : Subscriber Reference Number : Certificate Signature Algorithm : Certificate Signature Algorithm : Certificate Status : Validity Period (ddimm/yyyy) : Dov Dev e is for information only. Before you rely on Certification Revocation List (CRL) issued revoked and should not be relied yopn. Y e. It may take a longer time to download.	e-Cert (Organisational) Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha1RSA Active vnload the Certificate the Certificate displayed above, you should verify if by Hongkong Post Certification Authority. If the set ou may download the latest partitioned CRL of the download the latest full CRL at http://crl1.hongkong	I the Certificate has been suspended or revoked by al number of the Certificate is found in a CRL, then Certificate at gpost.gov.hk/crifeCertCA1-10CRL1.crl. Please be
Contraction of the second of t	Note:- The Cortificate status displayed above locating its serial number in the latest http://criticate has been suspended o http://criticate.has	Imail Address in Certificate : Organisation Name in English : Organisation Name in Chinese : Branch Name in English : Branch Name in English : Branch Name in English : Branch Name in English : Crificate : Subscriber Reference Number : Cype of Certificate : Issued by : Certificate Serial Number : Certificate Serial Number : Certificate Signature Algorithm : Certificate Certificate Certificate Signature Algorithm : Certificate Certificate Certificate Signature Algorithm : Certificate Certificate Certificate Certificate Certificate Signature Algorithm : Certificate Certificate Certi	e-Cert (Organisational) Hongkong Post e-Cert CA 1 - 10 32 d4 32 sha1RSA Active vnload the Certificate the Certificate displayed above, you should verify if by Hongkong Post Certification Authority. If the seri unay download the latest partitioned CRL of the t download the latest full CRL at http://crfl.hongkong Back	the Certificate has been suspended or revoked by al number of the Certificate is found in a CRL, then Certificate at gpost gov.hk/cri/eCertCA1-10CRL1.crl. Please be

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:	Street	
	Sub-district:		
	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.

New User Registration						
Thank you for your registration						
Your registration request has been submitted to Drug Office successfully.						
Your Reference Number is: DO201808-001						
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
1	Change Passw The password has expired (8-20 characters containing	rord due to security reason and you alphabet(s) in upper case, alpi	u need to change password befo habet(s) in lower case and non-a	re continue. alphabet(s))		(Save)
You are login as FONG Winnie DEF COMPANY Login date and time 13.01.2015 20:46	Current Password : New Password : Confirm New Password :	••••••• •••••••				
- System	After you have saved the	password, you will be logged	out automatically and need to log	gin again.		
Change Password						Save
Logout						
	201	5 copyright important notices	s Last Revision Date: 09 JAN 2	2015 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/	y and Poisons Board will only issue co registration, renewal of registration an popup launch of electronic certificat	ertificates of drug/ product registration in Id change of registered particulars.	
	Welcome to Pharr	naceuticals Registration Syster	n (PRS2.0)
Use	ername: *	username	
Org	anizational e-Cert File Location:*	Choose File prs20-prod-test-2022.p12	
e-C Sys	ert PIN:* stem Password:*	Please select the e-Cert file, e.g. C:\cert.p12	
	ogin Reset		Request for New Account
С	ert Validation		Reset Password
FG	or support service, please contact P :00-13:00 and 14:00-17:45) or via 6	'RS2.0 help desk at (852) 3974 4195 during offic e-mail to ' <u>prs2_info@dh.gov.hk</u> '.	ce hours (Monday-Friday:
Pc 1.	ints to note: 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	software: r 11.0 or Chrome sookies and enable JavaScript .51.2 are enabled	
2.	The private key and the PIN of you	ar e-Cert will not be transmitted during the transa	ction.
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.	You should disable options on your computer.	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.

	Onli	ne Notification							ONL	INE_NOTIFIC	ATION_VIEW_01	
T	New F	ew Product Registration								Archiv	Archived Notifications	
		Notification Date	\$	Subject		4	Propose	ed Name of Product	\$	PL No. 🜩	Payment Status	
You are login as ORG	Open	21.01.2021 17:25:14		Application Payment Request			FACE CI	REAM		PL0001/2021	Paid	
TESTING LIMITED (TEST)	Open	21.01.2021 17:14:03		Screening Application			FACE CI	REAM		PL0001/2021	N/A	
09.02.2021 14:33	Open	06.11.2019 11:52:34		Application Payment Request			TEST O	PEN FILE CASE 3		PL0024/2019	Paid	
	Open	05.09.2019 16:10:27		Screening Application			TEST O	PEN 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									Archiv	red Notifications	
+ New Registration		Notification Data	Subject		•	HK No.		Name of Broduct				
+ Change of Registered	Open	28.01.2021.04:00:12	Application Effect	tive Deminder	•	HK63536	*	DEMO ON 2017 01 10			÷	
Particulars	Open	22.01.2021.09:47:20	nitted Notification	In Ossoo DEmo			TEST 20145	ENG ON 2017-01-13				
	Open	20.01.2021 03.47.20	Application Subr	witted Notification		HK63536		DEMO ON 2017 01 10				
+ Renewal of Registration	Open	20.01.2021 11.00.00	Application Sub	Intel Politication		1100000		DEMO ON 2017-01-18	,			
Request to change name and/or address	Renev	val of Registration								Archiv	ed Notifications	
of the certificate holder		Notification Date \$	Subject		¢	Name of Pro	duct			\$ No. o	f Renewals 🛛 💠	
+ Request to Cancel	Open	28.09.2019 02:06:59	Expired Product	Notice		DEMO ON 2	017-			1		
Product Registration	Open	20.07.2019 02:05:10	Expired Product	Notice		TEST OPEN	FILE CASE			1		
+ Pavment	Open	08.07.2019 04:00:11	Renewal Final R	eminder		DEMO ON 2	2017-			1		
Application History	Cancel	llation Request										
		Notification Date \$	Subject		\$	HK No.	\$	Name of Product			\$	
+ User Profile	Open	21.01.2021 15:49:10	Cancellation Regi	stration Request Submitted Notification		HK63517		WALKTRHOUGH				
+ Printing Service												
+ System	Non Ph	narmaceutical Produ	ict Alert									
	No rela	ted notifications										
LOGOUT												

2.1.2.1 Request Reset Password

Step 1: Click Reset Password to request reset password

Vint effect from for application of details, please visit itps://www.drugoffice.gov.h	the Pharmacy and Poisons Board will only issue certificates of drug/ product registration in ns for initial registration, network of registration and change of registrered particulars. <u>kleps/do/en/popup_launch_of_electronic_certificate_of_drug_product_registration_en.html</u>
	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 Reset Password * 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 TLS1.2 are enabled
	2. The private key and the PIN of your e-Cert will not be transmitted during the transaction.
	3. 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.
	You should disable options on your browser to avoid storing or retaining your e-Cert password on the personal computer.
	5. 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.	Please provide the following information to reset the password. Field with * are mandatory					
	User Information						
	* Username * Email address (User) * Organizational e-Cert File Location	username useraccount@email.com C:\cert.p12					
	* e-Cert PIN	el Submit					

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

set Password
INT-USER_REQ_RESET_PW_02 USR
An email has been sent to you for password reset, please reset your password with the link provided in the email within 15 minutes.
For support service, please call our office at (852) 3074 4195 or email to prs2 info@idb.gov.bk.during.office.bours -
Monday to Enday
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)
Casting
Commit

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 Passwerd						
	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.	
Lugin Now	

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

With effect from 1 July 2023, the Phar electronic form for applications for ini For details, please visit https://www.drugoffice.gov.hk/eps/do/	macy and Poisons Board will only issue certif itial registration, renewal of registration and c /en/popup launch of electronic certificate o	ficates of drug/ product registration in hange of registered particulars. If drug_product_registration_en.html	
	Welcome to Pharma	Iceuticals Registration System	n (PRS2.0)
	Username: *		
	e-Cert PIN:* System Password:*	Please select the e-Cert file, e.g. C:\cert.p12	
C	Login Reset Cert Validation * mandatory field		Request for New Account 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 offic nall to ' <u>prs2_info@dh.gov.hk'</u> .	e hours (Monday-Friday:
	Points to note: 1. Install and configure the required soft a. Web browser: Google Chrome b. Web browser settings: Accept cool c. Ensure TLS1.2 are enabled	ware: cies and enable JavaScript	
	 The private key and the PIN of your e You should be alert to your surroundir see your personal particulars and e-Ce 	-Cert will not be transmitted during the transa ngs before entering any personal information. I rt password.	ction. Make sure that no one can
	 You should disable options on your br computer. For organizational e-Cert file location 	owser to avoid storing or retaining your e-Cer , it is case-insensitive in Windows platform.	t password on the personal
	2015 convrict Limportant	notices Last Revision Date: 5 July2023 Version	10 1310

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-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.hk.
2015 serviceb Limendent selless Last Davidies Deter 5. http2020 - Version: 4.0.424s
If the F-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
(Varific) (Class.) Cannal
verny Clean Cancer
Result
This electronic certificate is valid. (at HKT 12:37, on 27/07/2023)
Free surrout any design planes exclusion DDDD () hale disk at /8500 2074 1405 disking affine haven
For support service, prease contact PKSz U nelp desk at (oz2) 30/4 4195 during omce nours (Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.tk.
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 unloaded 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@rth nov 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.

	N	laintain Com	oanv User Ac	C	ounts										
		Login User Name 🜲	User Name	\$	Position	Phone Number	Supervisor Name	New App.	CORP	Renewal	All Product	User Admin.	Supervisor	Status	
	1	irenechu	Irene Chu		Company Administrator	26482518		Y	Υ	Υ	Y	Υ	N	Activ	Edit
You are login as Irene Chu DEF COMPANY	2	issaclee	Issac Lee		Supervisor	26482522		N	N	Y	N	N	Y	Active	Edit
Login date and time 17.03.2015 11:31	3	winniefong	FONG Winnie		Company Staff	24925648		N	Υ	Ν	Ν	Ν	Ν	Active	Edit
Online Notification	4	edwintsang	Edwin Tsang		Senior Staff	26482520	Issac Lee	Y	Y	N	Ν	Ν	Ν	Active	Edit
My Product Search															
+ New Registration															
+ Change of Registered Particulars															
+ Renewal of Registration															
+ 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															
+ System															

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	ATE_01
T	View Details information on e-Cert					
You are login as Irene Chu	* Email Address of Authorized User	prs.winnie.fong@gmail.com	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 Bu 1 DEF Street 10067 KOWLOON	uilding 🔺			
+ Renewal of Registration			~			
+ Submission of Other Post-registration Supplement	Active Status	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 Deny	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-US	ER_PROFILE_UPDATE_01
T	View Details				
You are login as Irene Chu	* Email Address of Authorized User	prs.winnie.fong@gmail.com			
Login date and time	* Organization Name	DEF COMPANY			
1.00.2010 11.01	* 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	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 Dista					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:

O User A	ccount: Issac Leep	rs.issac.lee@gmail.cor	n 💽 Add					
	Application ID	PL No.	PR No.	HK No.	Name of Product		User Account 4	
		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	

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.con	n

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 4	¢
	PL0321/1987	PR0426/1987	HK29705	WARTEX	issaclee	prs.issac.lee@gmail.com	0
	PL0330/1987	PR0428/1987	HK29707	VERRUGON	issaclee	prs.issac.lee@gmail.com	1
	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	i.
	PL0121/2000	PR0301/2000	HK46915	OYSTER CALCIUM W/ VIT D	issaclee	prs.issac.lee@gmail.com	i

	User Account Detail			INT-USE	R_PROFILE_UP	DATE_01
T	View Details					
You are login as Irene Chu	* Email Address of Authorized User	prs.winnie.fong@gmail.com				
Login date and time	* Organization Name	DEF COMPANY				
1.03.2013 11.31	* Business Registration Certificate Number	r 00781432-000				
Online Notification	* Authorized User Name	FONG Winnie	î			
My Product Search	Position	Company Staff				
+ New Registration	Contact Phone Number	24925648				
+ Change of Registered Particulars	Company Address	04 11/F BLK A DEF Bui 1 DEF Street 10067 KOWLOON	lding			
Registration			-			
+ Submission of Other Post-registration Supplement	Active Status	Active Inactive				
ouppromotiv	Privileges Control					
+ Interview	Supervisor	Issac Lee 💌 (Only applicable	e for non-supervisor)			
+ Request to Cancel Product Registration	Product Information Application Submission					
+ Payment	New Product Registration	llow Deny				
Application History	Change of Registered Particulars Application	llow O Deny	Senior Privileges User Administrator	⊖Yes No		
- User Profile	Renewal of Registration	llow Deny	Access All products	OYes ●No		
Maintain Company's User Accounts	Cancel Product Registration	llow Deny	Supervisor	⊖Yes ●No		
Add Assess Dish					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	DFILE_UPDATE_01
T	View Details					
You are login as Irene Chu	* Email Address of Authorized User	prs.winnie.fong@gma	il.com			
Login date and time 17.03.2015 11:31	* Organization Name	DEF COMPANY				
Online Notification	* Business Registration Certificate Numb	per 00781432-000				
Chante reculication	* 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	Active Inactive				
+ Interview	Supervisor	Issac Lee 💌 (Only a	pplicable 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 Privile	eges strator	○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	
Add Access Disks						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.

							Add Access Right	Clear
T	Add Acces	ss Right						
	All Products	Add						
You are login as Irene Chu DEF COMPANY Login date and time 17.03.2015 12:27	Application I	D/PL No./PR No	o./HK No.	A	dd			
Online Notification	O User Accourt	nt:		- Ad	1)			
My Product Search	Add Access Rig	dication ID	PL No.	PR No.	HK No.	Name of Product	User Account	\$
+ New Registration	All Accessible	Staff						
+ Change of Registered Particulars	User Account:			- Add				
+ 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	Clear
Ť	Add Ac	cess Right						
	All Prod	lucts Add						
ou are login as WONG avid BC COMPANY LIMITED ogin date and time 7.08.2018 14:15	⊖ Applica	tion ID/PL No./PR No.	/HK No.	Add				
Online Notification		Application ID	PL No.	PR No.	HK No.	Name of Product	User Account	4
My Product Search	Add Acces	s Right to						
New Registration	All Access	sible Staff						
Change of Registered Particulars	User Acco	unt:		► 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								

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	Clear
	Add Access	Right						
You are login as WONG Javid ABC COMPANY LIMITED Jogin date and time 17.08.2018 14:15	O Application ID/	PL No./PR No.	/HK No.	Add				
Online Notification	Арр	lication ID	PL No.	PR No.	HK No.	Name of Product	User Account	¢
My Product Search	Add Access Right	: to						
+ New Registration	All Accessible St	aff						
+ Change of Registered	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.

	p-	•••••(5) ••					(Add Assess Black) (Cla
Ť	Add	Access Right					Add Access Right Clear
	All	Products Add					
You are login as WONG David ABC COMPANY LIMITED Login date and time 17 09 2019 14/24							
17.00.2010 14.34	⊖Use	r 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		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	kenny_liu prs.kenny.liu@gmail.com
+ Change of Registered Particulars							david_wong prs.david.wong@gmail.com
+ Renewal of Registration		ANP20179000064	PL0087/2017	PR0055/2017	HK63565	MY 20170512 1612	david wong prs.david wong@gmail.com
+ Interview		B : 144					
+ Request to Cancel Product Registration	Add Ad All Ac	ccess Right to					
+ Payment	User A	ccount: Susan CHEU	NGprs.susan.che	ung@gmail.com 🗸	Ad		
Application History							Add Access Right Clear
- User Profile							
Maintain Company's User 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	Add A	Access Right					Add Access Right Clear				
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 14:34	Application ID/PL No./PR No./HK No. HK63516 X Add										
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 🗸 (Ad	d		Add Assess Distal Class				
+ 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.

		Access Right					Add Access Right) (Clear				
David ABC COMPANY LIMITED	Application ID/PL No./PR No./HK No. HK83516 Add										
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 User Acc	ount: WONG David count: LIU Kennyprs.	prs.david.wong@gm kenny.liu@gmail.con	ail.com V Ad	d nove						
+ 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.

You are login as WONG David ABC COMPANY LIMITED Login date and time 17 Da 2018 14 34	Add A O All Pro O Applic	oducts Add	./HK No.	Add			Add Access Right) Clear
Online Notification	• User /	Application ID	DI No		HK No.	Name of Broduct	llear Account
My Product Search		ANP20169000040	PL 0035/2016	PR0029/2016	HK63518	TEST 2016112101	
,							kenny_liu prs.kenny.liu@gmail.com
+ New Registration		ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	kenny_liu prs.kenny.liu@gmail.com
+ Change of Registered Particulars		ANP20159000238	PL0183/2015	PR0001/2016		HP Test Generic 1005	kenny_liu prs.kenny.liu@gmail.com
+ Renewal of Registration		ANP20159000242	PL0019/2016	PR0017/2016		TEST 20160803	kenny_liu prs.kenny.liu@gmail.com
+ Interview		ANP20159000245	PL0190/2015	PR0003/2016		HP test 20151222	kenny_liu prs.kenny.liu@gmail.com
+ Request to Cancel Product Registration		ANP20159000246	PL0001/2016	PR0004/2016		ABC TABLES	kenny_liu prs.kenny.liu@gmail.com
+ Payment		ANP20159000217	PL0141/2015	PR0083/2015	HK63489	HP TEST MANUAL 0417	kenny_liu prs.kenny.liu@gmail.com
Application History		ANP20169000052				TEST ABC	kenny_liu prs.kenny.liu@gmail.com
- User Profile		ANP20169000053				TEST 20161216	kenny_liu prs.kenny.liu@gmail.com
Maintain Company's User Accounts	Add Acc	ess Right to					
Add Access Right	All Acce	essible Staff					
Remove/Transfer Access Right	L ser Acc	count: Susan CHEUNG-	prs.susan.cheung@	gmail.com 🗸 🗚			
+ System							Add Access Right Clear
Logout							

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/Transfer					
	Add Access Right											
	Transfe	r/Revoke From: Susan	CHEUNGprs.sus	an.cheung@gmail.co	m 🗸							
You are login as WONG David ABC COMPANY LIMITED	To: < <re< th=""><th>evoke from User>></th><th></th><th>~</th><th></th><th></th><th></th></re<>	evoke from User>>		~								
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@gmail.com					
My Product Search							Remove/Transfer					
+ 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												
Remove/Transfer Access Right												
+ System												
Logout												

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

-	Add	Assess Dight					Remove/Transfer
	Transfe	r/Revoke From: Susar	CHEUNGprs.sus	san.cheung@gmail.c	om(Supervisor) V		
You are login as WONG David ABC COMPANY LIMITED	1 0: < <r< th=""><th>evoke from User>></th><th></th><th>✓</th><th></th><th></th><th></th></r<>	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 Pegistration		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com
Thew Registration		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com
+ Change of Registered Particulars							Remove/Transfer
+ Renewal of Registration							

Step 3:

• 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.

1	Add Transfe	Access Right	CHEUNGprs.su	san.cheung@gmail.c	com(Supervisor) 🗸	1	(Remove/Transfer)
You are login as WONG David ABC COMPANY LIMITED Login date and time 17.08.2018 14:34	IO: << LIU Sus	Kevoke from User>> Kennyprs.kenny.liu@ an CHEUNGprs.susa	gmail.com n.cheung@gmail.co	m(Supervisor)	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							
+ 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					
T	Add /	Add Access Right										
	Transfe	r/Revoke From: Susan	CHEUNGprs.sus	san.cheung@gmail.c	om Supervisor) 🗸							
You are login as WONG David ABC COMPANY LIMITED	To:	Rennyprs kenny liu@	omail.com									
17.08.2018 14:34	Sus	an CHEUNGprs.susar	n.cheung@gmail.co	m(Supervisor)	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					
+ Change of Registered		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com					
Particulars	COMPANY LIMITED 8 2018 14:34 ILU Kennyors kenny liu/@amail.com ILU Kennyors kenny liu/@amail.com Susan CHEUNGprs susan cheung@gmail.com(Supervisor) Inine Notification ANP20169000032 PL0029/2016 PR0024/2016 V Product Search ANP20169000040 PL0038/2016 PR0030/2016 ew Registration ANP20169000040 PL0035/2016 PR0029/2016 enswal of egistration ANP20179000040 ILU Kennyors kenny liu/@amail.com				Remove/Transfer							
+ Renewal of Registration												
+ Interview												
+ Request to Cancel												

Step 3:

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

+	Add 4	Access Right					(Remove/Transfer					
	Transfer	Transfer/Revoke From: Susan CHEUNGprs susan cheung@amail.com(Supervisor)										
You are login as WONG David ABC COMPANY LIMITED	To: LIU K	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					
A New Devicestion		ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com					
+ New Registration		ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com					
+ Change of Registered Particulars							(Remove/Transfe)					
網頁訊息	×											
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.

	Onlir	ne Notificatior						ON	LINE_NOTIFIC	ATION_VIEV	N_01
Ť	New P	roduct Registrati	on						Archiv	ed Notificat	ions
		Notification Date		Subject			Propos	ed Name of Product	PL No. 🜩	Payment St	tatu \$
Ou are login as ORG	Open	21.01.2021 17:25:14		Application Payment Request			FACE (REAM	PL0001/2021	Paid	
ESTING LIMITED (TEST)	Open	21.01.2021 17:14:03		Screening Application			FACE (REAM	PL0001/2021	N/A	
9.02.2021 14:33	Open	06.11.2019 11:52:34		Application Payment Request			TEST (PEN FILE CASE 3	PL0024/2019	Paid	
	Open	05.09.2019 16:10:27		Screening Application			TEST (PEN FILE CASE 3	PL0024/2019	N/A	
Online Notification	<u>Open</u>	04.09.2019 11:17:16		Evaluation Application			TEST 2	017022401	PL0030/2017	N/A	
My Product Search	CORP								Archiv	ed Notificati	ions
New Registration		Notification Date	¢	Subject	4	HK No.		Name of Product			¢
Change of Registered	Open	28.01.2021 04:00:12		Application Effective Reminder		HK6353	5	DEMO ON 2017-01-19			
Particulars	Open	22.01.2021 09:47:20		Application Submitted Notification		HK6366	3	TEST 20145			
Renewal of	Open	20.01.2021 11:50:56		Application Submitted Notification		HK6353	6	DEMO ON 2017-01-19			
Request to change	Renew	al of Registration	ı]					Archiv	ed Notificati	ions
of the certificate holder		Notification Date	\$	Subject	4	Name o	f Product		No. of	Renewals	\$
Request to Cancel	Open	28.09.2019 02:06:59		Expired Product Notice		DEMO	ON 2017-		1		
Product Registration	Open	20.07.2019 02:05:10		Expired Product Notice		TEST O	PEN FILE CAS	E	1		
Payment	<u>Open</u>	08.07.2019 04:00:11		Renewal Final Reminder		DEMO	DN 2017-		1		
Application History	Cancel	ation Request									
Liser Profile		Notification Date	\$	Subject	\$	HK No.	\$	Name of Product			\$
Delation Operation	Open	21.01.2021 15:49:10		Cancellation Registration Request Submitted Notification		HK63517		WALKTRHOUGH			
Printing Service	N										
System	Non Ph	armaceutical Pro	du	ct Alert							
Logout	NO rela	eu nouncauons									

After click the Archived Notifications Button.	The archived application will be shown.
--	---

Online	Notification				ONLINE_NOTIFICATION_VIEW_01
Filter by I	Notification Date O Filt	er by HK No.			Back
From 23.0	8.2018 🛄 to 01.1	0.2018 Search			
CORP					
	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	Notification					ONLINE_NOTIFICATION_VIEW_(J1			
Filter by Notification Date Filter by HK No.										
From 29.	07.2020 🛄 to 29.01	I.2021 Search								
CORP										
	Notification Date 🜲	Subject	\$	HK No.	ŧ	Name of Product	¢			
Open	12.01.2021 17:37:19	Application Clarification Notification		HK42660		CALCIUM UNISON TAB SUUNG				
Open	12.01.2021 17:34:49	Application Screening Notification		HK42660		CALOUM UNISON TAB SOOMO				
Open	27.11.2020 04:00:10	Application Effective Reminder		HK42660		GALCIUM UNICON TAB 300MG				
Open	26.11.2020 14:45:02	Application Acknowledgement Notification		HK42660		CALCIUM UNICON TAB 300MO				
Open	26.11.2020 14:34:57	Application Screening Notification		HK42660		CALCIUM UNICON TAB 300MO				

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

Online	Notification			ONLINE_NOTIFICATION_V	IEW_01
⊖ Filter by N	Notification Date 💿 Filte	r by HK No.			Back
нк 41190 CORP	Search				
	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.

	Onlin	e Notification					0	NLINE_NOTIFI	CATION_VIEW_01
T	New P	roduct Registration						Arch	ived Notifications
		Notification Date	• +	Subject	4	e Pr	oposed Name of Product	♦ PL No.	Payment Status
You are login as	Open	12.01.2021 10:34:23		Certificate Payment Request		VOOIN	500 TABLETS 500MO	PL0975/20	16 Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8	START	PL0004/202	20 Paid
Login date and time 28.01.2021 15:06	Open	20.11.2020 16:45:42		Screening Application		BOURE	ON POWDER	PL0002/20	20 N/A
Online Notification	CORP							Arc	hived Notifications
My Product Search		Notification Date \$		Subject	\$ HK	No.	\$ N	ame of Product	÷
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification	HK42660		CALCION UNISON TA	5 300MG	
+ New Registration	Open	12.01.2021 17:38:55	Application Su	bmitted Notification	HK42660		OALOUM UNISON TA	B 900MO	
+ Change of Registered	<u>Open</u>	12.01.2021 17:38:55	Application Sci	reening Notification	HK42660		CALCIUM UNISON TA		
+ Renewal of	Renev	val of Registration						Arc	hived Notification
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	ication	DRUG NAM	IE XXXX T	AB 50MG	1	
+ Payment	Cance	ellation Request							
Application History		Notification Date \$		Subject	\$ H	No.	¢ !	lame of Product	t \$
Application matory	Open	26.01.2021 15:07:50	Cancellation R	tegistration Request Submitted Notification	HK31199		EFILIM FREEZE-DRIE	DEDREFORIN	-DM00P CM
+ User Profile									
+ System	Non F	harmaceutical Produ	uct Alert						
		Notification Date	\$	Subject	\$	HK No. 🗢	Na	me of Product	4
Logout	Open	11.02.2016 04:00:00	Renewal P	ending Reminder	HK	60464	OCTECTIN 500 CAP 500M	10-	
	Open	12.01.2016 04:00:02	Renewal P	ending Notification	HK	60464	OSTECTIN 500 CAD 5008	1 <u>C</u>	

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	outstanding 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 (& 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 Payment												
									Print	Ready to Pa			
		Application Received Date	PL No.	¢	PR No.	¢	Proposed Name of Product	\$	Payment Status	¢			
You are login as WONG David		31.05.2017 16:16	PL0070/2017				MY 20170531 1559		Ready for Application Paymer	t			
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 Paymer	t			
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.

	Onli	ne Notification						O	ILINE_NOTIFIC	ATION_VIEW_01
T	New F	Product Registration							Archiv	ed Notifications
		Notification Date	÷ +	S	ubject	\$	Pro	oposed Name of Product		Payment Status
You 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
Login date and time 28.01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application			BOURB	ON POWDER	PL0002/2020	N/A
Online Notification	COR	P							Archi	ved Notifications
My Product Search		Notification Date 🔶		Subject	*		No.	÷	ame of Product	•
	Open	12.01.2021 17:40:32	Applicaton With	drawal Rejected Notification		HK42660		CALCION UNISON TAE	300MG	
+ New Registration	Open	12.01.2021 17:38:55	Application Sub	mitted Notification		HK42660		OALOUM UNISON THE		
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Scr	eening Notification		HK42660		CALCIUM UNIDON TAE		
+ Renewal of	Rene	wal of Registration							Arehi	ved Notification
rtegisuauon		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 Notifi	cation		DRUG NAM	E XXXX T.	AB 50MG	1	
+ Payment	Cano	ellation Request								
Application History		Notification Date \$		Subject	\$	HK	No.	\$ N	ame of Product	\$
, opproduction in the conj	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notif	ication	HK31199		EPILIM FREEZE-DRIED	PDR FOR IV INJ	400MG
+ User Profile										
+ System	Non	Pharmaceutical Produ	uct Alert							
		Notification Date	\$	Subject		\$ F	K No. 🗢	Na	me of Product	¢
Logout	Open	11.02.2016 04:00:00	Renewal Pe	ending Reminder		HK6	0464	OCTECTIN 500-CAP 500M		
	Open	12.01.2016 04:00:02	Renewal Pe	ending Notification		HK6	0464	OSTECTIN 500 CAD 500M	<u> </u>	

Step 2:

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

Ť	Online Notificati	on							CORP_NOTIFICATION
You are login as EONG									View Detail Back
Winnie DEFG COMPANY Login date and time 17.08.2018 15:38	Application Clarifica	tion	Notificat	ion					
Online Notification	Notification Date: 24.08.20 Notification Letter: Clarifica	17 18 tionLe	:06:20 atter.pdf						
My Product Search	Dear Certificate Holder,								
+ New Registration	We want to inform you followi	ng ap	plication(s) h	ave been evaluation failed. Please fo	llow up at	ttached clarification lette	r required information to reply	appli	cation as soon as possible.
+ Change of Registered	Application Ref. No.	\$	HK No. \$	Name of Product	\$	Change Categories\$	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			
	Commenter of Desident File (n. DE) Channes	DO Data	1 - H	- 1-H CODD Ch		Re	eply Clarification	Letter Withdraw A	pplication
re login as FONG	Application Reference No :	CORP-HK63554-2017	50673	Application :	Status:	ter. material	Application Evalue	ated	
COMPANY	Application Batch No.:	CORP-HK63554-2017	50673	Application	Туре:		Certificate holder	initiated - New CORF	application
2018 15:38	HK No.: Draduat Name:	HK63554		Previous Ap	p. Reference	No.:			
ine Notification	Application Received Date:	18.08.2017		Client Date:	Reference in	U	18.08.2017		
Product Search	Proposed Effective Date:			Application I	Form Image:		No File Chosen		
	Hard Copy Received Date: Submission Acknowledgement:	Submission Acknowle	daement	Justification	(Urgent Appli	ation):			
v Registration	Applicant Username:	winnie_fong							
ticulars	Category 2 - Label Under	Evaluation —							
iewal of istration	Particulars Proposed to Change		Recall (Required	Cert. Reprint Require	ed Evaluation	Comment	and Result		
rview									
uest to Cancel duct Registration	2.Label								
ment	2.1-Change in label		Yes 🗸	Not Required	<u>_</u>				
lication History	Briet Description of Change and Reason:	tewst			Satisfac	tory U	nsatisfactory	Acknowledged	Withdrawn
r Profile	Supporting Documents:								
tem	2.1 Change in label								
out	i. Proposed label with the change(s) u	nderlined or highlighte	d *						
	Documents File Name	Remark	:	Screening Comment		Evaluatio	on Comment		
	test2 adf The same file has								
	already been uploaded in another								
	already been uploaded in another location in this submission								
	already been uploaded in another location in this submission Change Categories Allowed for Amend	lment:							
	afready been uploaded in another location in this submission Change Categories Allowed for Amend	Iment:	etter Sen	nt					
	Category 3 - Package Inse Particulars Proposed to Change	Iment: rt Clarification I	Letter Sen	nt	ed Evaluation	Comment	and Result		
	Category 3 - Package Inse Particulars Proposed to Change	Iment: rt Clarification I	etter Sen Recall Required	nt	ed Evaluation	Comment	and Result		_
	Category 3 - Package Inse Particulars Proposed to Change	Iment: rt Clarification I	etter Sen Recall Required	ntCert. Reprint Require	ed Evaluation	Comment 34	and Result		_
	Category 3 - Package Insert 3-Package Insert Categories Allowed for Amenic Category 3 - Package Inser 3-Package Insert	ment: rt Clarification I	Letter Sen Recall Required	tCert. Reprint Require	ed Evaluation	Comment 34	and Result		
	Category 3 - Package Inset 3-Package Inset Category 3 - Package Inset 3-Package Inset 3-Package Inset 3-Package Inset	iment: rt Clarification I	etter Sen Recall Required	t Cert. Reprint Require	ed Evaluation	Comment 34	and Result		_
	Category 3 - Package Inset 3-Package Inset Category 3 - Package Inset 3-Package Inset 3-Package Inset 3-Change Category Change 3-Package Inset 3-Change Inset 3-Change In package Inset Belf Description of Change and Reason	iment: rt Clarification I	Letter Sen Recall (Required	It Cert. Reprint Require	test 12	Comment 34	and Result		
	Category 3 - Package Inset Category 3 - Package Inset Particulars Proposed to Change 3.Package Inset 3.1-Change in package inset Brief Description of Change and Reason	Iment: rt Clarification I tost	Letter Sen Recall Required	ntCert. Reprint Require	test 12	Comment 34 :tory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inse aready been justicated in another location in this submission Change Categories Allowed for Amenic Category 3 - Package Inse Particulars Proposed to Change 3.Package Insert 3.Package Insert 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents:	Iment: rt Clarification I test	Letter Sen Recall (Required	ItCert. Reprint Require	ed Evaluation	Comment 34 tory U	and Result	Acknowledged	Withdrawn
	Aready been used as an another location in this submission Change Categories Allowed for Amenic Category 3 - Package Insee Particulars Proposed to Change 3.Package Insert 3.1-Change in package Insert Biref Description of Change and Reason Supporting Documents: 3.1 Change in package Insert	iment: rt Clarification I test	Letter Sen Recall (Required	t Cort. Reprint Require Not Required	ed Evaluation	34 ttory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package inset Supporting Documents: Supporting Documents: Leroposed package insert	ment: rt Clarification I test	Letter Sen Recall (Required Yes ()	Cert. Reprint Require	ed Evaluation	Comment 34 :tory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inser Category 3 - Package Inser Category 3 - Package Inser Supporting Documents: 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert 1. Proposed package insert with the ch Documents File Name	ment: rt Clarification I test test ange(s) underlined an Remark	etter Sen Recall (Required Yes)	Not Required	test 12	Comment 34 tory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inset Category 3 - Package Inset Category 3 - Package Inset 3.Package Inset 3.Package Inset 3.1-Change in package inset Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert E. Proposed package insert with the ct Documents File Name	Iment: t Clarification I tost ange(s) underlined an Remark	etter Sen Recall (Required Yes V)	t Cert. Reprint Require Not Required s - Screening Comment	ed Evaluation	Comment 34 tory U	and Result	Acknowledged	Withdrawn
	Aready been uploaded in another location in this submission Change Categories Allowed for Amenic Category 3 - Package Inset Articulars Proposed to Change 3.Package Insert 3.Package Insert 3.Package Insert S.J. Change in package Insert Bird Description of Change and Reason Supporting Documents: 3.1 Change in package Insert I. Proposed package Insert with the ch Documents File Name	Iment: rt Clarification I tost ange(s) underlined an Remark	Letter Sen Recall Yes V	t Cort. Reprint Require Not Required S screening Comment	test 12	Comment 34 tory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package inset Category 3 - Package inset Category 3 - Package inset 3.Package inset 3.Package inset 3.Change in package inset Dief Description of Change and Reason Supporting Documents: 3.1 Change in package inset L Proposed package inset L Proposed package inset L Proposed package inset L Proposed machage L Proposed Machage L Proposed Machage L Proposed L Propos	Iment: rt Clarification I test ange(s) underlined an Remark	Letter Sen Recall (Required Yes V)	tt	ed Evaluation	Comment 34 ttory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inset Category 3 - Package Inset Category 3 - Package Inset 3.Package Inset 3.Package Inset 3.1-Change in package inset Birl Description of Change and Reason Supporting Documents: 3.1 Change inset I. Proposed package inset I. Proposed package inset L Proposed package L Proposed L Proposed package L Proposed	Iment: rt Clarification I test ange(s) underlined an Remark	etter Sen Recall (Yes V)	Not Required	test 12	Comment 34 tory U	and Result	Acknowledged	Withdrawn
	Aready been uploaded in another location in this submission Change Categories Allowed for Amenic Category 3 - Package Inset Articulars Proposed to Change 3.Package Inset 3.Package Inset 3.1-Change in package insert Brief Description of Change and Reason Supporting Documents: 3.1 Change in package insert L Proposed package insert L Proposed package insert L Proposed package insert Leving and package insert	Iment: rt Clarification I test ange(s) underlined an Remark	Letter Sen Recall (Required Yes)	t Cert. Reprint Required	ed Evaluation	Comment	and Result	Acknowledged	Withdrawn
	Aready been uploaded in another location in this submission Change Category 3 - Package Inset Category 3 - Package Inset Articulars Proposed to Change J.Package Insert J.Package J.Package Insert J.Package	Iment: It Clarification I tost ange(s) underlined an Remark cosed change(s) with th	etter Sen Recall (Required Yes)	t Cert. Reprint Require Not Required	test 12	Comment 34 tory U	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inset Category 3 - Package	Iment: rt Clarification I tost ange(s) underlined an Remark osed change(s) with th Remark	Letter Sen Required Yes V	t Cert. Reprint Required	test 12	Comment 34 Evaluati	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inset Category 3 - Package Inset Category 3 - Package Inset Ange Categories Allowed for Amend Category 3 - Package Inset Ange Categories Allowed for Amend Ange Category 3 - Package Inset Ca	Iment: It Clarification I test Itest	e relevant s	tt Cert. Reprint Require Not Required 4 Screening Comment Screening Comment	test 12	Comment 34 tory U Evaluation	and Result	Acknowledged	Withdrawn
	Category 3 - Package inset Category 3 - Package inset Category 3 - Package inset 3.Package Inset 3.Package Inset 3.Package Inset 3.Package Inset 3.Change in package inset Brief Description of Change and Reason Supporting Documents: 3.1 Change in package inset I. Proposed package inset I. Proposed package inset I. Proposed package inset I. Documents File Name Institution in the submission II. Documents File Name	Iment: rt Clarification I test test ange(s) underlined an Remark osed change(s) with th Remark	Letter Sen Required Yes Y	t Cert. Reprint Require Not Required t Screening Comment screening Comment	ed Evaluation	Comment 34 tory U Evaluation	insatisfactory on Comment on Comment	Acknowledged	Withdrawn
	Change Categories Allowed for Annexe Category 3 - Package Inset Category 3	Iment: Tt Clarification I tost ange(s) underlined an Remark osed change(s) with th Remark	etter Sen Required Ves V	t Cert. Reprint Require Not Required I Streening Comment Screening Comment	Satisfac	Comment 34 tory U Evaluation	and Result	Acknowledged	Withdrawn
	Category 3 - Package Inset Category 3 - Package	Iment: It Clarification I It cla	e relevant s	t Cert. Reprint Require Not Required A Screening Comment Screening Comment	test 12	Comment 34 Evaluati	and Result	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.

	Onlii	ne Notification							ONL	INE_N	OTIFIC	ATION_VIEW_01
T	New F	Product Registration								(Archiv	ed Notifications
		Notification Dat	e 🜲	Subject		:	\$ F	ropos	sed Name of Product 👙	PI	. No. 🗢	Payment Status
You are login as	Open	12.01.2021 10:34:23		Certificate Payment Request			VOOH	1 500 -	TABLETS SOOMO	PL09	75/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request			JAVA	8 STA	RT	PL00	04/2020	Paid
Login date and time 28.01.2021 15:06	Open	20.11.2020 16:45:42		Screening Application			BOUR	BON	POWDER	PL00	02/2020	N/A
Online Notification	CORF	5									Archiv	ved Notifications
My Product Search		Notification Date \$		Subject	\$	н	K No.	\$	Nan	ne of Pr	oduct	\$
	<u>Open</u>	12.01.2021 17:40:32	Applicaton Wit	thdrawal Rejected Notification		HK42660		-	CALCIUM UNISON TAB 3	oomg	-	
+ New Registration	Open	12.01.2021 17:38:55	Application Su	Ibmitted Notification		HK42660			OALOUM UNISON TAB S	oomo	-	
+ Change of Registered	<u>Open</u>	12.01.2021 17:38:55	Application Sc	creening Notification		HK42660			CALCIUM UNISON TAD C	09MG	_	
Particulars												
+ Renewal of Registration	Rene	wal of Registration									Archi	ved Notifications
+ Renewal of Registration	Rene	wal of Registration		Subject	\$			Nam	e of Product	4	Archi	ved Notifications
 Renewal of Registration Request to Cancel Product Registration 	Rene Open	Notification Date \$ 27.01.2021 04:00:14 \$	Renewal Notif	Subject fication	¢	DRUG NA	ME XXXX	Nam TAB 5	e of Product i0MG	đ	Archine N	ved Notifications
+ Renewal of Registration + Request to Cancel Product Registration + Payment	Rene Open Canc	wal of Registration Notification Date 27.01.2021 04:00:14 ellation Request	Renewal Notif	Subject fication	¢	DRUG NAI	ME XXXX	Nam TAB 5	e of Product OM/G	4	Archine N	ved Notifications Io. of Renewals 💠
+ Renewal of Registration + Request to Cancel Product Registration + Payment Annication History	Rene Open Canc	wal of Registration Notification Date ¢ 27.01.2021 04:00:14 ellation Request Notification Date ¢	Renewal Notif	Subject lication Subject	¢ \$	DRUG NAI	ME XXXX K No.	Nam TAB 5	e of Product 00MG Nar	4 ne of Pr	Archine N 1	ved Notifications Io. of Renewals \$
Registration Registration Request to Cancel Product Registration Payment Application History	Canc Open	wal of Registration Notification Date 27.01.2021 04:00:14 ellation Request Notification Date 26.01.2021 15:07:50	Renewal Notif	Subject fication Subject Registration Request Submitted Notification	\$ \$	DRUG NAI HI HK31199	ME XXXX K No.	Nam TAB 5	e of Product IOMG Nar EPILIM FREEZE-DRIED 1	t ne of Pr PDR FO	Archine N 1	ved Notifications to. of Renewals \$ \$ \$
Renewal of Registration Reguest to Cancel Product Registration Payment Application History User Profile	Rene Open Canc	Notification Date ¢ 27.01.2021 04:00:14 ¢ ellation Request Notification Date ¢ 26.01.2021 15:07:50 ¢	Renewal Notif	Subject fication Subject Registration Request Submitted Notification	\$ \$	DRUG NAI HK31199	ME XXXX K No.	Nam TAB 5	e of Product IOMG Render the Contract of C	t ne of Pr DR FO	Archine N 1	ved Notifications Io. of Renewals \$ * *
Renewal of Registration Registration Request to Cancel Product Registration Payment Application History User Profile System	Rene Open Canc Open Non	wal of Registration Notification Date 27.01.2021 04:00:14 eliation Request 26.01.2021 15:07:50 Pharmaceutical Prod	Renewal Notif Cancellation F uct Alert	Subject fication Subject Registration Request Submitted Notification	\$ \$	DRUG NAI HI HK31199	ME XXXX K No.	Nam TAB 5	e of Product IOMG Reficience Product P	t ne of Pr PR TO	Archine N 1	ved Notifications Io. of Renewals \$ * *
Request to Cancel Product Registration Payment Application History User Profile System	Rene Open Canc Open Non	wal of Registration Notification Date 27.01.2021 04:00:14 ellation Request Notification Date 26.01.2021 15:07:50 Pharmaceutical Prod Notification Date	Renewal Notif	Subject fication Subject Registration Request Submitted Notification Subject	\$	DRUG NAI HK31199	ME XXXX K No.	Nam TAB 5	e of Product IOMG National Press Product of National Nati	e of Pro	Archina N 1	ved Notifications Io. of Renewals ¢ ******** ******** *
Request of Cancel Product Registration Payment Application History User Profile System Logout	Rene Open Canc Open Non	Notification Date 27 01 2021 04:00:14 26 01 2021 15:07:50 Pharmaceutical Prod Notification Date 11.02 2016 04:00:00 	Renewal Notif Cancellation F uct Alert Renewal P	Subject fication Subject Registration Request Submitted Notification Subject Pending Reminder	\$	DRUG NAI HK31199 + KK31199	ME XXXX K No. HK No. 4 160464	Nam TAB 5	e of Product IOMG Received Annual Products (Received Annual Products) Nam	e of Pro	Archine N 1	ved Notifications Io. of Renewals Hoomo- *

Step 2:

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

Ť	Renew	al of	Regis	trati	on			RENEWAL_NOTIFI	CATION
You are login as WONG David ABC COMPANY LIMITED Login date and time 17 08 2018 1544	Renewal I	Final R	Reminde	er				Print Product List	Back
Online Notification My Product Search	Notification [Notification]	Date: 20. Letter: <u>R</u>	.03.2018 1 enewal Fi	0:52:49 nal Rer) minder.pdf				
+ New Registration	HK No. HK61844	PR	PR No.	¢ Pi	Nan RODUCT NAME XXXX	ne of Product \$		Required information	•
+ Change of Registered	HK61840	PR	0659/2012	PI	RODUCT NAME XXXX				
Particulars	HK36789	PR	0830/1992	P	RODUCT NAME XXXX		BABE Requirement		
+ Renewal of Registration	View Renewa	I Applicat	tion Status	2					_
+ Interview								Print Product List	Back

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

+	Renev	val of F	Registr	ation								RENEWAL_S	TATUS
You are login as WONG David ABC COMPANY LIMITED Login date and time 27.07.2023 10:04	Reply an Please com transaction a In case cert Note: Worki	nd Pay for plete the re at least 5 w ificate holde ng days do	or Renew newal proce orking days er(s) cannot not include	ral of Registration dure at least 10 working days before the expiry date of the renew certificate(s) in due co Saturday / Sunday / holiday(s	s before the expiry date of certificate. wrse, please contact our I1 s).	the certificate. I colleagues of I	f you make PRS2.0 hel	online paym p desk at 39	ent via PRS 74 4195 dui	2.0, please of 2.0, please of 100 controls and 100 controls	omplete tr rs.	ne relevant payn	ient
Online Notification											R	enew Not to R	tenew
My Product Search	\$	HK No.	¢	Name of Product			¢	Notify Date	¢	Expiry Date	\$	Batch No.	¢
+ New Registration		HK37027		CEDAX CAP 400MG				15.09.2022		12.09.2023		Batch Five	
+ Change of Registered Particulars	Payment	t Comple	eted										
- Renewal of Registration	HK No.	\$	Name of Pro	duct	\$	Payment Date	♦ Last E	xpiry Date ⇔	Expiry Date	e ¢ Cert Date	Collection	Batch No.	\$
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to Renew - Requires Further Action Before Product Renewal	Issued e When releas HK No.	-Certific sed, the dov \$	ate wnload link o Name of Pro	f the e-Certificate is enabled soluct	for one-time use. Please I \$	eep a copy of t Payment Date	he e-Certifi \$ Last E	cate for your xpiry Date \$	record afte Expiry Date	r downloading e \$ e-Ce	rtificate	Batch No.	\$
+ Submission of Other Post-registration Supplement	FIGUUCE	comm		Kellew								Rei	istate
+ Interview	\$	HK No.	\$	Name of Product			\$	Reply Date	\$	Expiry Date	\$	Batch No.	\$
+ Request to Cancel Product Registration	Requires	s Furthe	r Action	Before Product Rene	ewal								
+ Payment	Please com transaction In case cert	plete the re at least 5 w ificate holde	newal proce orking days er(s) cannot	dure at least 10 working days before the expiry date of the renew certificate(s) in due co	s before the expiry date of certificate.	the certificate. I colleagues of I	f you make PRS2.0 hei	online paym p desk at 39	ient via PRS 74 4195 dui	2.0, please of 2.0, p	omplete th	ne relevant payn	nent
Application History	Note: Worki	ng days do	not include :	Saturday / Sundaý / holiday(s	s).							Not to R	tenew
+ User Profile	¢	HK No.	¢	Name of Product			¢	Reason	¢	Expiry Date	¢	Batch No.	\$
+ Printing Service		HK63572		TEST 2017011901				BABE list		23.08.2023		Batch Four	
+ System		HK36996		NULCER TAB 400MG				CORP Requ	irement	25.08.2023		Batch Four	
Logout		HK44460		FENSTAN TAB 500MG				CORP Requ	irement	10.03.2024		Batch Two	

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.

	Onlii	ne Notification					O	LINE_NOTIFIC	ATION_VIEW_01
	New P	Product Registration						Archiv	ed Notifications
		Notification Dat	e 💠	Subject	\$	Pro	posed Name of Product	¢ PL No. ¢	Payment Status
You are login as	Open	12.01.2021 10:34:23		Certificate Payment Request		VOOIN 5	00 TABLETS SOOMO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8 S	TART	PL0004/2020	Paid
Login date and time 28.01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application		BOURBO	IN POWDER	PL0002/2020	N/A
Online Notification	CORF	5						Archi	ved Notifications
My Product Search		Notification Date \$		Subject	\$ НК	No. 🕯	⊧ Na	ame of Product	\$
	Open	12.01.2021 17:40:32	Applicaton With	hdrawal Rejected Notification	HK42660		CALCION UNISON TAB	300MG	
+ New Registration	Open	12.01.2021 17:38:55	Application Sul	bmitted Notification	HK42660		OALOUM UNISON TAB		
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sci	eening Notification	HK42660		CALCIUM UNISON TAB		
+ Renewal of Registration	Rene	wal of Registration						Archi	ved Notifications
-		Notification Date \$		Subject	\$	N	ame of Product	¢ 1	lo. of Renewals 💠
+ Request to Cancel Product Registration	<u>Open</u>	27.01.2021 04:00:14	Renewal Notifi	cation	DRUG NAME	E XXXXX TA	B 50MG	1	
+ Payment	Canc	ellation Request							
Application History		Notification Date \$		Subject	\$ HK	No. 🗧	¢ N	ame of Product	¢
replication motory	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification	HK31199		EFILIM FREEZE-DRIEL	PDR FOR IV INJ	400MG
+ User Profile									
+ System	Non	Pharmaceutical Prod	uct Alert						
		Notification Date	\$	Subject	\$ H	K No. 🗢	Na	ne of Product	\$
Logout	Open	11.02.2016 04:00:00	Renewal Pe	ending Reminder	HK60)464	OCTEOTIN 500 CAP 500M		
	Open	12.01.2016 04:00:02	Renewal Pe	ending Notification	HK60	0464	OSTECTIN 500 CAD 500M	<u> </u>	

Step 2:

• View the notification detail.

+	Online Notifica	tion				END_OF_PRODUCT_LIFE_NOTIFICA	TION
							аск
You are login as WONG David	Notification Date : 07.08.2	018 17:40:25					
ABC COMPANY LIMITED Login date and time 17.08.2018 15:51	Cancellation Reque	st Submis	sion Notificatio	n			
Online Natification	Dear Sirs/Madams,						
Online Noulication	Cancellation of Drug/Proc	uct Registrat	ion:				
My Product Search	1000		00.11-			Name of Baseline	_
+ New Registration	нк No. НК63533	• PR	рк No. 0034/2016	٥	TEST 20161208	Name of Product	•
+ Change of Registered Particulars	Thank you for your online a providing professional and o	pplication date executive supp	d 07.08.2018 for canc ort to the Pharmacy a	ellation of d nd Poisons	rug/product registration. F Board and its Committee.	lease return the original certificate to the Drug Office. The Department of Health is	\$
+ Renewal of Registration	We acknowledge the receip	t of your applie	cation and it is now be	ing process	ed.		
+ Interview							
+ Request to Cancel							Jack

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.

	Onli	ne Notification					ON	INE_NOTIFIC	ATION_VIEW_01
	New F	Product Registration						Archiv	ed Notifications
		Notification Date	÷ +	Subject	\$	Prop	oosed Name of Product	PL No. 🗢	Payment Statuts
You are login as	Open	12.01.2021 10:34:23		Certificate Payment Request		VOOIN 5	TABLETS SOOMO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request		JAVA 8 S	TART	PL0004/2020	Paid
Login date and time 28.01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application		BOURBO	N POWDER	PL0002/2020	N/A
Online Notification	COR	5						Archiv	ved Notifications
My Product Search		Notification Date \$		Subject	\$ HK	No. 🖨	Na	me of Product	\$
	<u>Open</u>	12.01.2021 17:40:32	Applicaton With	ndrawal Rejected Notification	HK42660		CALCIUM UNISON TAB	SOOMG	
+ New Registration	Open	12.01.2021 17:38:55	Application Sub	omitted Notification	HK42660		OALOUM UNISON TAD	OMOO	
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Scr	eening Notification	HK42660		CALCIUM-UNISON TAB	209MO	
+ Renewal of Registration	Rene	wal of Registration						Archi	ved Notifications
rtegiouduon		Notification Date \$		Subject	\$	N	ame of Product	\$ N	lo. of Renewals 💠
+ Request to Cancel Product Registration	<u>Open</u>	27.01.2021 04:00:14	Renewal Notifi	cation	DRUG NAM	E XXXXX TA	B 50MG	1	
+ Payment	Canc	ellation Request							
Application History		Notification Date \$		Subject	\$ HK	No. 🗧	: Na	me of Product	\$
, opproducti i notorij	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification	HK31199		CFILIM FREEZE-DRIED	PDR FOR IV INJ	400MG
+ User Profile									
+ System	Non	Pharmaceutical Prod	uct Alert						
•		Notification Date	\$	Subject	ф Н	K No. 🗢	Nam	e of Product	-
Logout	Open	11.02.2016 04:00:00	Renewal Pe	ending Reminder	HK6	0464	BETEOTIN 600 OAP 600MC	-	
	Open	12.01.2016 04:00:02	Renewal Pe	ending Notification	HK6	0464	OSTECTIN 500 CAD 500MC	. <u> </u>	

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 Pharmace	/ and
My Product Search	Poisons Ordinance and Poisons Board and its	d its regula Committee	tions. Registration s.	of the	e 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	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	regulations.					
Falticulars	HK No.	\$	PR No.	\$	Name of Product	\$
+ Renewal of Registration	HK47678	PR1	402/2000		PRODUCT NAME XXXX	
+ Interview						
+ 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 P	roduct	Search											
					ши								Searc	clear
		•			IK									
OU are login as ORG Trial ne Esting Limited	PR No			PR	/	- PR	/							
ogin date and time 8.01.2021 09:10	PL No			PL	1	- PL	1							
Online Notification	Produ	ct Name												
My Product Search	Active	Ingredien	t(s)	● C0	ntains All () Con	tains Either On		Natch						
► New Registration					-									
 Change of Registered Particulars 													Searc	h Clear
- Renewal of								Product Information						
Registration	Seq.	HK No.		Pre	oduct Name	No. In	of Active predient	Active	Ingredient(s)			Status	PI	R No.
 Request to Cancel Product Registration 														
+ Payment	(H) (H)		1 to 1 of	l rows	() (H) [1	0 V	nlication for	Dedistration of Pharmaceutical Pr	oduct					
Application History	Seq.	Application Ref.	PL No.	PR No.	Product	Name	No. of Active	Active Ingred	ient(s)		Status	Submission Date	Last Updated	Last Update
+ User Profile		Trainip of					ingrouioni				_		2,	Duto
+ System)	1 to 1 of	1 rows	() () ()	0 🗸								
Leanut						Change of Re	istered Part	cular(s) of Registered Pharmaceu	tical Product					
Logout	Seq.	HK No. A	pplication Ref. Number	i	Product Name	No. of Active Ingredient		Active Ingredient(s)	Application Type	Category	Status	Submission Date	Last Updated By	Last Update Date
			41-4-6			0.14								
		·	1 to 1 of	I rows		0 🗸		Broduct Bonowal						
	Seq.	HK No.		Produc	t Name	No. of Activ	•	Active Ingredient(s)		Status	Expir	y Last Up	dated	Last
						Ingredient					Date	B	y	Update Date
	R ()	1 to 1 of	1 rows) (H) (H)	0 🗸								
				2015 0			Devision D							

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	Produ	uct Name	n#(a)	© 000	taina All 🗢 Cante	aiaa Fithar Oa	a 🗢 Event Mi	ntah						
My Product Search	Active	e ingreaie	nu(s)	0.00		ains Either On	e O Exact Ma	aton						
+ New Registration														
+ Change of Registered Particulars													Sear	ch Clear
+ Renewal of							Mast	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	nt	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	ve It	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.

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T	HK N	io.		нк	- нк		7						Sear	rch Clea
ou are login as ORG Tria	I PR N	io.		PR 0060	/ 1995	- PR	8888 /2	2019						
ne ESTING LIMITED		_		DI DI										
ogin date and time 3.01.2021 09:10	PL N	0.			′	PL	/							
Online Notification	Prod	uct Name	ent/s)	Contains 4		ains Fithe	r One O Exact	Match						
My Product Search		- Ingreate												
New Registration	iÞ													
Change of Registered Particulars													Sear	rch Clea
Pagawal of								Product Information						
Registration	Seq.	HK No.		Product Na	ame		No. of Active		Active Ingredier	it(s)		Status	F	PR No.
Request to Cancel Product Registration	1	HK41190	PRODU	ICT NAME XXXXX >	DOXX	1	3	C1.1 biodiastase 25mg/1tab C1.2 dried aluminium hydrox C1.3 methiosulfonium chlorio	et ide gel 192mg/1t le 25mg/1tablet	ablet		Active	PR055	2/1996
Payment	2	HK42175	APT-IN	DOMETHACIN 25 C	AP 25MG	1	1	C1.1 indomethacin 25mg/1c	apsule			Active	PR082	2/1996
Application History	3	HK60366	DRUG I	AME XXXX TAB 50	MG		1	C1.1 acarbose 50mg/1tablet				Active	PR121	1/2009
User Profile					000	Ne	w Application fo	r Registration of Pharmaceut	ical Product					
System	Seq.	Applicatio Ref. Number	n PL No.	PR No.	Product	lame	No. of Active Ingredient	Active	ingredient(s)		Status	Submission Date	Last Updated By	Last Updat Date
Logout														
	•	<u>)</u>	1 to 1 of	1 rows	D 🖲 1) 🗸								
						Change o	of Registered Par	ticular(s) of Registered Pharr	naceutical Produ	uct				
	seq.	HK NO.	Application Ref. Number	Product Na	me	NO. OF Active Ingredient	t A	tive ingredient(s)	Аррисаtion Туре	Category	statue	Date	Updated By	Update Date
		HK41100	CODD	DDODUOT NUME	XXXXXX	3	C1.1 biodiastas	e 25mg/1tablet	Certificate	5	Application	21/08/2018	Drug Office	21/08/201
	1	anver i rad	HK41190- 201857483	XXXX			C1.2 dried alum 192mg/1tablet C1.3 methiosulf	inium hydroxide gel onium chloride 25mg/1tablet	initiated - New CORP application		Under Screening			
	1	HK41190	CORP- HK41190- 201857483 CORP- HK41190- 201857485	PRODUCT NAME XXXX	XXXXXX	3	C1.2 dried alum 192mg/1tablet C1.3 methiosulf C1.2 dried alum 192mg/1tablet C1.3 methiosulf	inium fiydroxide gel onium chloride 25mg/1tablet e 25mg/1tablet inium fydroxide gel onium chloride 25mg/1tablet	noider initiated - New CORP application Certificate holder initiated - New CORP application	4	Application Evaluated	21/08/2018	Drug Office	21/08/201
	2	HK41190	CORP- HK41190- 201857483 CORP- HK41190- 201857485 CORP- HK41190- 202050013	PRODUCT NAME XXXX PRODUCT NAME XXXX	XXXXXXX XXXXXXX	3	C1.1 biodiastas G1.2 dried alum 192mg/1tablet C1.3 methiosulf C1.2 dried alum 192mg/1tablet C1.3 methiosulf C1.1 biodiastas C1.2 dried alum 192mg/1tablet C1.3 methiosulf	Inium Frydroxide gel onium chloride 25mg/1tablet = 25mg/1tablet onium chloride 25mg/1tablet onium chloride 25mg/1tablet inium frydroxide gel onium chloride 25mg/1tablet	holider initiated - New CORP application Certificate holder initiated - New CORP application Certificate holder initiated - New CORP application	4 3,4,7	Application Evaluated Application Evaluated	21/08/2018	Drug Office Drug Office	21/08/20
	1 2 3 4	HK41190 HK41190 HK42175	CORP- HK41190- 201857483 CORP- HK41190- 201857485 CORP- HK41190- 202050013 CORP- HK42175- 201753899- 02	PRODUCT NAME SXXXX PRODUCT NAME XXXX APT-INDOMETHA CAP 25MG	X0000X X0000X CIN 25	3	C1.2 oned alum 192ng/1ablet C1.3 methiosuff C1.2 dried alum 192ng/1ablet C1.2 dried alum 192ng/1ablet C1.3 methiosuff C1.1 biodiastass C1.2 dried alum 192ng/1ablet C1.3 methiosuff C1.1 indometha	Inium Trydroxide gel onium chloride 25mg/11ablet anium chloride 25mg/11ablet inium Trydroxide gel onium chloride 25mg/11ablet a 25mg/11ablet onium chloride 25mg/11ablet cin 25mg/1capsule	holider initiated - New CORP application Certificate holder initiated - New CORP application Certificate holder initiated - New CORP application Certificate holder initiated - Response to clarificate	4 3,4,7 1,2,3,4,5,6,7,8	Application Evaluated Application Evaluated Application Application Application	21/08/2018 05/08/2020 18/04/2017	Drug Office Drug Office ORG Trial One	21/08/201 12/01/202 27/02/201
	1 2 3 4	HK41190 HK41190 HK42175	CORP- HK41190- 201857483 CORP- HK41190- 201857485 CORP- HK41190- 202050013 CORP- HK41175- 201753699- 02	PRODUCT NAME PRODUCT NAME PRODUCT NAME PRODUCT NAME APT-INDOMETHA CAP 25MG	XXXXXX XXXXXXX CIN 25	3	C1.2 methiosuff C1.3 methiosuff C1.3 methiosuff C1.2 methiosuff C1.2 dried alum ft0ray ftablet C1.3 methiosuff C1.2 dried alum ft0ray ftablet C1.3 methiosuff C1.3 methiosuff C1.1 indometha	Inium Trydroxide gel anium chloride 25mg/11ablet a 25mg/11ablet inium chloride 25mg/11ablet anium chloride 25mg/11ablet a 25mg/11ablet anium chloride gel anium chloride 25mg/11ablet cin 25mg/1capsule	holider initiated - New CORP application Certificate holder initiated - New CORP application Certificate holder initiated - New CORP application Certificate holder initiated - Response to clarification letter	4 3,4,7 1,2,3,4,5,6,7,8	Under Screening Application Evaluated Application Evaluated Application Approved	21/08/2018 05/06/2020 18/04/2017	Drug Office Drug Office ORG Trial One	21/08/201 12/01/202 27/02/201
	1 2 3 4	HK41190 HK41190 HK42175	CORP- HK41190- 201857483 CORP- HK41190- 201857485 CORP- HK41190- 20205785 CORP- HK41190- 20205013 CORP- HK42175- 201753899- 02	PRODUCT NAME SOOX PRODUCT NAME SOOX PRODUCT NAME SOOX APT-INDOMETHA CAP 25MG 4 rows	XXXXX XXXXXX CIN 25	3 3 1	C1_2 one abaut C1_3 methiouil C1_3 methiouil C1_1 biodiastae C1_2 dried abum C1_3 methiouil C1_3 methiouil C1_3 dried abum C1_2 dried abum C1_3 dried abum C1_3 dried abum C1_3 dried abum C1_4 dried abum C1_4 dried abum C1_5 dried abum C1_6 dried abum C1_6 dried abum C1_6 dried abum C1_7 dried abum C1_6 dried abum C1_6 dried abum C1_6 dried abum C1_6 dried abum C1_6 dried abum C1_7 dried abum C1_	Inium Sydroxide gel onium chloride 25mg/11ablet e 25mg/11ablet inium chloride 25mg/11ablet onium chloride 25mg/11ablet e 25mg/11ablet onium chloride gel onium chloride 25mg/11ablet oni 25mg/1capsule	holider initiae CORP holider bolider Certificate holider application Certificate holider initiated holider initiated holider initiated holider	4 3,4,7 1,2,3,4,5,8,7,8	Onder Screening Application Evaluated Application Evaluated Application Approved	21/08/2018 05/08/2020 18/04/2017	Drug Office Drug Office ORG Trial One	21/08/201 12/01/202 27/02/201
	1 2 3 4 (*) (*)	HK41190 HK41190 HK42175	CORP- HK41190- HK4190- 201857483 CORP- HK4190- 201857485 CORP- HK4190- 20250013 CORP- HK4190- 20250013 CORP- HK42175- 201753699- 02	PRODUCT NAME SOOX PRODUCT NAME XXXX PRODUCT NAME XXXX APT-INDOMETHA GAP 25MG 4 rows Product Name	XXXXXX XXXXXXX CIN 25	3 1 No. of Ingre	C112 corporation C13 methiosuil C11 methiosuil C11 bioGiastas C12 dried alum C11 bioGiastas C13 methiosuil C11 fiodisstate C13 methiosuil C11 indometha	Inium Frydroxide gel onium chloride 25mg/1tablet = 25mg/1tablet inium hydroxide gel onium chloride 25mg/1tablet = 25mg/1tablet inium hydroxide gel onium chloride 25mg/1tablet cin 25mg/1capsule Product Renewal Active Ingredien	Noder Henrich	4 3,4,7 1,2,3,4,5,8,7,8 Statu	Application Evaluated Application Evaluated Application Application Approved	21108/2018 05/08/2020 18/04/2017	Drug Office Office ORG Trial One	21/08/201 12/01/202 27/02/201 Last Update Date
	1 2 3 4 (*) (*) (*) (*) 1	HK41190 HK41190 HK42175 HK No. HK60366	CORP- HK41100- HK41100- 201857483 CORP- HK41190- 201857485 CORP- HK41190- 202050013 CORP- HK42175- 201753899- 02	PRODUCT NAME PRODUCT NAME PRODUCT NAME PRODUCT NAME PRODUCT NAME APT-INDOMETHA CAP 25MG 4 rows Product Name NAME XXXX TAB 50	XXXXXX XXXXXXX CIN 25 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	3 3 1 No. of Ingre	C1.1 indometha C1.3 methiosulf C1.3 methiosulf C1.1 biodiastas C1.2 dried alum 192mg/1tablet C1.3 methiosulf C1.1 biodiastas C1.1 indometha C1.1 indometha C1.1 indometha C1.1 indometha	Inium Trydroxide gel onium chloride 25mg/11ablet e 25mg/11ablet inium Chloride 25mg/11ablet anium chloride 25mg/11ablet e 25mg/11ablet ein 25mg/11ablet ein 25mg/11ablet ein 25mg/11ablet ein 25mg/11ablet active Ingredien active Ingredien	Noder - New CORP application Dealer - Initiated - New CORP application - New CORP application - New CORP - application - New CORP - application - New CORP - application - New CORP - application - Certificate - New CORP - application - New CORP - - New CORP - - New CORP - New CORP - - New CORP - New CORP -	4 3,4,7 1,2,3,4,5,8,7,8 Statu Pending Reply	Application Evaluated Application Evaluated Application Application Application for 15/03/2	21108/2018 05/08/2020 18/04/2017 ry Lest U 9 2021 Drug Off	Drug Office Drug Office ORG Trial One Drug Orden	21/08/20 12/01/20 27/02/20 27/02/20 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	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					

• 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		
re login as WONG	Application F	Reference No.:	CORP-H	K63532-201750110		Application Status:		Certificate Fee F	aid	
COMPANY LIMITED date and time 2018 16:16	Application E HK No.:	Satch No.:	HK63532	K42074-201750071		Application Type: Previous App. Referen	nce No.:	Certificate holde	r initiated - New CORF	application
ine Notification	Application F	re. Received Date:	13.03.20	17010501 (lesio) 17		Client Date:	.e INU	13.03.2017		
Product Search	Hard Copy F	Received Date:				Justification (Urgent A	pe. pplication):	No File Chosen		
v Registration	Submission	Acknowledgement:	Submiss	ion Acknowledgemer	t					
inge of Registered ticulars	Cate	gory 5 - Registration	Certifica	te Holder App	olied —					
newal of jistration	Particular	s Proposed to Change		Recal Requi	Cert. Re red	print Required Evalua	tion Comment	t and Result		
rview	5.Registra	ation Certificate Holder								
uest to Cancel duct Registration	5.1-Chang	e in name and / or address of	the current	registration	Require					
ment	Brief Desc	rintion of Change and Reason	sadsa	100	- Roquire					
lication History	Effective D	Date: 14.03.2017	. outou			Satis	sfactory L	Insatisfactory	Acknowledged	Withdrawn
er Profile	Supportin	g Documents:								
tem	5.1 Chang	e in name and / or address	of the curre	ent registration certi	ficate holder					

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	e Notification						ONLINE_	NOT	FICATION_VIEW_01
T	New Pro	oduct Registration							Ar	chived Notifications
	No relat	ed notifications								
You are login as ORG Trial One TESTING LIMITED Login date and time	CORP								Ar	chived Notifications
27.01.2021 09:43		Notification Date \$		Subject	¢	HK No.	\$	Name of F	rodu	ct ¢
Online Notification	Open	12.01.2021 17:44:04	Application Screening Notifica	ation		HK41190		PRODUCT NAME XXXXX XXXX		
	Open	05.06.2020 11:00:01	Application Submitted Notifica	ation		HK41190		PRODUCT NAME XXXXX XXXX		
My Product Search	Open	03.10.2019 11:55:37	Application Submitted Notifica	ation		HK37565		PRODUCT NAME XXXXX		
	Open	04.03.2019 11:33:13	Application Approval Notificat	ion		HK31199		EPILIM FREEZE-DRIED PDR FO	R 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 Notificat	ion		HK42175		APT-INDOMETHACIN 25 CAP 2	5MG	
Registration Application	Open	21.08.2018 18:25:53	Application Clarification Notifi	cation		HK41190		PRODUCT NAME XXXXX XXXX		
	Open	21.08.2018 18:20:50	Application Screening Notifica	ation		HK41190		PRODUCT NAME XXXXX XXXX		
- Action Required	Open	21.08.2018 18:19:47	Application Submitted Notifica	ation		HK41190		PRODUCT NAME XXXXX XXXX		
 Not Submitted Application Submitted 	Open	21.08.2018 18:07:37	Application Submitted Notifica	ation		HK37565		PRODUCT NAME XXXXX		
Withdraw application	Renewa	l of Registration							Ar	chived Notifications
+ Change of Registered Particulars		Notification Date \$		Subject	\$		Na	me of Product	¢	No. of Renewals 🖨
	Open	27.01.2021 04:00:14	Renewal Notification			DRUG NAME XXXX	TAB	50MG	1	
+ Renewal of Registration	Cancella	ation Request								
+ Request to Cancel Product Registration		Notification Date \$		Subject	\$	HK No.	\$	Name of F	rodu	ct 🗢
+ Payment	Open	26.01.2021 15:07:50	Cancellation Registration Rec	uest Submitted Notification		HK31199		EPILIM FREEZE-DRIED PDR FO	DR IV	INJ 400MG
Application History	Non Pha	armaceutical Produ	uct Alert							
+ User Profile	No relati	ed notifications								
+ System										
Logout										
		2015 copy	right Important notices	Last Revision Date: 02 Sep 202	20 Versi	on: 1.0.99 (PP)				

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.

	Guidance										Save Save and Exit	ext
Ť	New Pro	duct Reg	jistrati	on						NEW_PR	ODUCT_REGISTRATION_VIEW_	01
	The maximum File upload is	upload size of not allowed for	single file	is 50MB, v 2 - 5. pleas	vhile the ma	ximum total files to Dru	upload size pe o Office via CD	r applicatio	n is 100 MB. essarv.			
You are login as ORG Trial One	Proposed Nan	me of Product (English):					PL I	No.:	PR No.:	HK No.:	
TESTING LIMITED Login date and time	Madulad	Hadda 2	Ander		a dula d	Madula E						
20.01.2021 11.20	module 1	module z	Modu	le 5 N	lodule 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												П
- New Registration	For priori	Application ity application	s, the foll	owing supp	porting docu	uments are i	equired:					
Initiate New Product Registration Application	a. for o appro b. for o	change of nam oval of registra change of prod	e, dosage ation of th luct certifi	form or ac e applied icate holde	tive ingredi product and er, a statem	ient, letter i I the origina ient from m	rom applicant l registration (anufacturer fo	: of surrend certificate r the chang	ler original rej of the existing ge.	gistration upon g product; or		
Application Status	1.0 Applicati	on Form*	Generic (New Che	mical Entity	(NCE)						
 Not Submitted Application Submitted 	1.0.1 Name o	of Drug / Pharm	aceutical F	Product / S	ubstance							
Withdraw application	1.0.1.1 Prop	osed Name of P	roduct / Su	ubstance				_				
+ Change of Registered Particulars	a. P b. P	roposed Name	of Produc	:t (English) :t (Chinese): * 2), if any:	PRODUCT		9				
+ Renewal of	c. N	lames / Propos	ed Names	Used in O	ther Places							
Registration	N	ame: PRODUC	T NAME			Place:	GERMANY		~			
Product Registration	N	ame: PRODUC	T NAME			Place:	UNITED KING	DOM	~			
+ Payment	N	ame:				Place:	Please Select	t Addate				
Application History	1.0.1.2 Name	e of Active Subs	stance(s) /	Ingredient	(s) (Please li	st below)		And mo				
+ User Profile	No.	. of Componer	nt(s)* 1 💊	<								
+ System					Activ	e Ingredien	:		Active Ing	redient		
Logout									Lab	el		
-												
	Cor	mponent 11. *	bisbentia	amine				~	bisbentiamin	e label		
		2.	None of	the above				ĭ	New Ingredie	nt Name		
		3.	Please Se	elect	ille							
		4.	Please Se	elect				~				
								Add More	e			
	1.0.1.3 Appli	ication Type: (p	lease sele	ct one) *								
	01	Human biologi	cal pharma	aceutical p	product							
	•	Human chemic	al pharma	ceutical p	roduct							
		Human vaccine Pharmaceutica	e I substanc	e								
	o'	Veterinary biol	ogical pha	armaceutio	al product							
	Õ	Veterinary che	mical pha	rmaceutic	al product							
	01	Veterinary vac	cine									
	0,	ATP - gene the	rapy prod	uct								
	0,	ATP - tissue en	gineered	product								
												5
	Guidance			2015 co	ovright Impo	ortant notices	Last Revision	Date: 02 Se	ep 2020 Vers	ion: 1.0.99 (PP)	Save Save and Exit	đ
				2010 00			22011029/2001		-p 2020 Veis			

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.

Application History	Guidance								Back Save Save and Exi
lew Product	Registra	ation						NEW_PF	RODUCT_REGISTRATION_VIEW_O
he maximum upload sile upload is not allow	size of single	file is 1MB, les 2 - 5, plea	while the m ase submit	aximum total u	pload size per a o Office via CD/	application is	10MB.		
Proposed Name of Pro	duct (Englisl	h): PRODUCT	NAME			PL No		PR No.:	HK No.:
Module 1 Mod	ule 2 M	odule 3	Module 4	Module 5					
module 1 mod			module 1	inodate o					
Page 1 Page 2	Page 3	Page 4	Page	5 Page 6	Page 7	Page 8	Page 9	Application Form	
1.0.2 Dose Form (App Component D 1 [1.0.3 Indication, Rout Indication:* Indication of th 1 Component R 1 [1.0.4 Container, Closs No. of Product P 1. Product Pare	licable to Dru lose Form of Cream e(s) of Admir e Drug toute of adm Wiscellaneou ure and Admi ack Size(s): ² ::: Size* [2 × (e.g ury Container	ag/Pharmace product:* y inistration and inistration* is nistrative De 12's blister// : 2 x 14's bt r (container with tho or	Add d Dosage Do Do Do Do Do Do Do Do Do Do	sage:* sage of the Dr Add luding descripti 1000's bottle/t ' ' Coposed Shelf'	Apply for Data	Exclusivity/ irom which it pox) age condition	/Description is constructe	d Stability Report*	In-Use Stability Report
Component Packa (e.g. Alur 1 Alur	ging Materia glass, lu, HDPE)*	I Type of cc (e.g. vial, bottle)*	ontainer blister,	24	Do not store o	dity (RH)) over 25°C 🗸	Duratio (Month) 24 Uploa No of F	n Start date 10.05.2015 ile(s): 1	Upload No of File(s): 0
					-				
2. Product Pac	k Size* 2 x	48's blister/	box	9					
Component Packa (e.g. Alu/A 1	(e.g ary Containe rect contact ging Materia glass, lu, HDPE)*	: 2 x 14's bl r (container with the pro- l Type of cc (e.g. vial, bottle)*	ister/box, that is in F oduct) I ntainer blister,	1000's bottle/t Proposed shelf ife (months)* 24	box, 15g tube/t Proposed stora (Temperature Relative Humi Do not store o	box) age condition (°C) and dity (RH)) over 25°C V	Duratio (Month) 24 Uploa No of F	Stability Report* n Start date 10.05.2015	In-Use Stability Report Upload No of File(s): 0
Application History	Guidance							(E	Back Save Save and Exit Ne

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.

Juidance										Back Save	Save and Exit	
w Proc	duct Re	gistrati	on						NEW_P	RODUCT_REG	ISTRATION_VI	w
maximum	upload size	of single file	is 50MB, wh	ile the ma	ximum total up	bload size per	application	is 100MB.				
posed Nam 3)	e of Product	t (English): I	ndapamide-Tr	ial Prolong	ed Release Tab	plets 1.5mg (A	P6) PLN	o.:	PR No.:	нк	No.:	
odule 1	Module 2	2 Modu	le 3 Mo	dule 4	Module 5							
vage 1	Page 2	Page 3	Page 4	Page 5	Page 6	Page 7	Page 8	Page 9	Application Form			
.5 Legal St	atus											
).6 Applicar	nt Informatio	n										
a. Us b. Er	sername : mail Address	s: prs.wir	_tong inie.fong@gr	nail.com								
.6.1 Propo	sed Registrat	tion Certifica	ate Holder									
a. Na b. Ac U Bi Si Si A	ame: ddress: Init: 382 uilding: P treet No.: ub-district: urea: KC	DEFG COMP 2 Floor: PHLC Street Nam SHEK KIP MI DWLOON	Block:									
c. BF	RC Number:	0078143	2-000 Phor	ie Numbe	r: (852) Fa	ax Number: (852)					_
d.Co *: En	ontact Perso John Ho nail*: john.l	n for this Ar	plication Phone No.* pany. Fax No	: 2319231	19	Position*:	Administra	tor				
e. Bu	usiness Type	•*: () () () () () () () () () () () () () (Manufac Manufac Importe Local br Licensec anufacturer	turer r anch, sub I wholesal is require	sidiary, repres le dealer who d to manufact	sentative, ag has entered sure the phar	ent or distr into a conti maceutical	ibutor of a n act with the product or s	nanufacturer outside Ho licensed manufacturer substance	ong Kong r under which	the licensed	
.6.2 Staff r	responsible f	for Pharmaco	vigilance									
. 6.2 Staff r a. Na	ame of Staff	for Pharmaco	vigilance Peter	Lam]					
0.6.2 Staff r a. Na b. Co (24	ame of Staff ontact Perso hours)	for Pharmacc f: on HK Telep	Peter hone No.: (8	Lam 52) 23192	2319	Position:	Supervisor	·	Email: john.ho@defco	mpany.		

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.

maximum	upload size of	single file is	1MB, w	nile the	max	cimum to	tal uplo	oad size per	applic	ation	is 10MB.			
posed Nam	e of Product (E	English): PRC	DUCT I	NAME		e mea to	Drug c			PL N	lo.:	PR No.:		HK No.:
Module 1	Module 2	Module	3 M	odule	4	Modu	le 5							
Page 1	Page 2	Page 3 P	age 4	Pag	e 5	Pag	ge 6	Page 7	Pa	ge 8	Page 9	Application F	orm	
.0.7 Manufac	turers													
.0.7.1.a Man	ufacturer appe	eared on prod	uct labe	el of fini	she	d produc	t*							
lace/Regio	n* :	C	GERMAN	Y					~	Manu	ufacturing ac	tivities/role*		
lame of Mar	nufacturer* :	N		AME XXX	xxx						Batch Roloas	Manufacturor		
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.0.7.1.b All (Other Manufact	turer(s) involv	ved in tl	ne prepa	arati	ion of th	e produ	ict/substanc	e					
• Y	es 🔿 No													
Man	ufacturing act	ivities/role*	P	lace/Re	gio	n*		Name of	f Manu	factui	er*		_ 8	
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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.

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roposed Nan	me of Product (English): (ONLINE 2	20170712			PL N	o.:	PR No.:	HK No.:
Module 1	Module 2	Modu	le 3	Module 4	Module 5					
Page 1	Page 2	Page 3	Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form	
When Next Plea	ase list the act Component1— ame of Active	tive ingre	dient(s)	ed to use the "l e content of ex and the excip Quantity	Dient(s) as st	on to export ou can use th ated in the ength Unit)*	the inputted ne "Import" fu Master Form Dose \	excipient lis nction to ret iula: /alue* Dose	t and save in your comp rieve the saved excipie Unit* i	uter in .csv file format. nt list. Reference / Monograph Standard
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				Additional Info test	ormation					Add
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E 1.0.8.2 Are t prod 1.0.8.3 Does • @	This compone xcipient* adipic acid there any anima tuct? No () Yes the product co) No () Yes, pl	ent does r v al and/or h ntain hum lease fill i	Quantity Quantity (Strengt 0. uman or nan plasm n the fo	Additional Info test any excipien (Value)* 5 AHU igin materials (ma-derived ingre llowing.	t. : (Strength Ur J excluding hur edients?	nit)* D V	ose Value* 1	Dose Uni TEST ials) containe	Import CS it* Function	Add / Export as CSV Clean all Data n Reference / Add Standard Please Selt Remove acturing process of the medicinal

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.

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e maximum up	uct Regis	stratior	า				N	EW_PRODUCT	_REGISTRATION_VIEW
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oposed Name	of Product (En	glish): PRO	DUCT NAME			PL No.:	PR No.:		HK No.:
Module 1	Module 2	Module	3 Module 4	Module 5					
Page 1 F	Page 2 Pa	ge 3 F	Page 4 Page	5 Page 6	Page 7 Page	8 Page 9	Application Fo	orm	
.0.9 Other Mar	rketing Authori	zation App	lications						
.0.9.1 Is there	another count	ry/region v	vhere an authoriza	tion is granted fo	r the same product?				
* () N	lo (i) Yes								
0921f109	1 is vos aro ti	here any di	fferences which h	we therapoutic in	dications dosage (ontraindication	s or side effects bet	ween this appli	cation and authorization
for the	same product i	in other co	untries/regions (as	specified in 1.0.9	9.4)	onerandication	s of side effects bet	ween this uppli	
* 💿 N	lo 🔿 Yes								
0.9.3 Is there	another count	ries/region	s where an author	ization was refus	ed / suspended / rev	oked by the co	mpetent authorities	for the same pr	roduct?
*	lo 🔿 Yes								
.0.9.4 Please I	list marketing a	uthorizatio	on application(s) fo	r the same produ	ct in other country/	region here :			
Count	ry/Region	1	Status	Date of Autho	prization Product N	ame	Free Sale Certificate(FSC) attached	Authorization Number	Expire Date of FSC
GERM	ANY	~	Approved 🗸	01.08.2018	PRODUCT	NAME	Upload		
UNITE	ED KINGDOM	~	Approved V	01.08.2018	PRODUCT	NAME	Upload No of File(s): 1		
					Remov	e Add Mor	•		

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.

ew P	rodu	ict Reg	istrati	on							NEW_P	RODUCT_REGISTRATION_
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e upload	l is not	allowed for	modules	2 - 5, pl	ease submit th	e files to Drug	Office via CE	D/DVD if nece	essary.			
posed	Name o	of Product (E	inglish): F	PRODUC	CT NAME			PLN	lo.:	PF	No.:	HK No.:
Module	1	Module 2	Modu	ile 3	Module 4	Module 5						
Page 1	Pa	age 2 F	age 3	Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Applica	tion Form	
1.0 Anr	exed D	ocuments/ir	formatio	n/sample	9							
.* Pr	ototype	e sales pack	/outer a	nd innei	r container lat	els (Reference	e for 1.0.4 o	f Page 2)			Prototyp	e Sale Pack(s) List
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. Int	formati	ion on the c	iverseas l	legal sta	tus of the pro	duct.					Upload No of File(] (<u>s): 0</u>
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. Aı re	ithoriza lated to	ation letter o this applie	from the cation) (i	applica f applica	nt authorizing able)	a person/con	npany to dea	al with the c	ommunicati	on matters	Upload No of File(] (<u>s): 0</u>
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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.

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oposed Nar	ne of Produc	t (English):	PRODUC	T NAME			PL N	o.:	PF	No.:	HK No.:
Module 1	Module	2 Mod	ule 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 Annexe	ed Documents	s/informatio	on/sample	÷					_		
Detaile personr	d informatio nel. (Referen	n regarding ice for 1.0.	g the mar 7 of Page	nufacturer in 1 e 4)	respect of its	manufacturi	ng and quali	ty control fa	cilities and	Lipload	
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complia		e US, Austr				spect to min		the risk of	rence for		
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(For NC Official	E) evidence of	registratio	n approv	al of the prod	luct (e.g. orig	inal or certi	fied true cop	ies of free s	ale	List show	ing free sale certificate in othe
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Latvia, Switzer	Lithuania, L land, UK and	uxembourg J USA (Refe	, Málta, erence fo	Poland, Portu r 1.0.9.4 of Pa	gal, Románia, age 6)	Slovak Rep	ublic, Sloven	ia, Spaín, Sv	veden,		
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referen	ice no.)									Upload	c): 0
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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.

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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 applicati File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if ne	on is 100MB. cessary.	
Proposed Name of Product (English): Indapamide-Trial Prolonged Release Tablets 1.5mg (AP6) PL (CH3)	No.: PR No.:	HK No.:
Module 1 Module 2 Module 3 Module 4 Module 5		
2.1 Overall CTD Table of Contents of Modules 2-5		
Remarks:		
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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)		
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2.3.P Drug Product (name, dosage form)		
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2.3.A Appendices		
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2.3.R Regional Information		
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2.5 Clinical Overview		
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2.6.1 Introduction		
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2.6.2 Pharmacology Written Summary		
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2.6.6 Toxicology Written Summary		
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2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Method		
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2.7.2 Summary of Clinical Pharmacology Studies		
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2.7.3 Summary of Clinical Efficacy (indication)		
Remarks		
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2.7.4 Summary of Clinical Safety		
Remarks:		
2.7.5 References		
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2.7.6 Synopses of individual studies		
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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.

Guidance	Back Save Save and Exit Next
New Product Registration	NEW_PRODUCT_REGISTRATION_VIEW_MODULE_03
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 necer	is 100MB. ssary.
Proposed Name of Product (English): Indapamide-Trial Prolonged Release Tablets 1.5mg (AP6) PL No. (CH3)	D.: PR No.: HK No.:
Module 1 Module 2 Module 3 Module 4 Module 5	
3.1 Module 3 Table of Contents	
Remarks:	
3.2.S.1 General Information	
Remarks:	
3.2.S.1.1 Nomenclature	
Remarks:	
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3 2 S 1 2 Structure	
Remarks:	
Remarks:	
3.2.3.2.1 Manufacturer(s)	
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3.2.S.2.2 Description of Manufacturing Process and Process Controls	
V	
3.2.S.2.3 Control of Materials	
Kemarks:	
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3.2.S.2.4 Controls of Critical Steps and Intermediates	
Remarks:	
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3.2.S.2.5 Process Validation and/or Evaluation	
Remarks:	
3.2.5.2.6 Manufacturing Process Development	
Remarks:	
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3.2.S.3.1 Elucidation of Structure and other Characteristics	
Remarks:	
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3.2.5.3.2 Impurities	
Remarks:	
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3.2.5.4.1 Specification	
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3.2.5.4.3 Validation of Analytical Procedures	
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3.2.5.4.4 Batch Analyses Remarks:	
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3.2.5.6 Container Closure Systems	
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3.2.S.7.2 Post Approval Stability Protocal and Stability Commitment	
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3.2.5.7.3 Stability Data	
2.2.0.1 Description and Composition of the Deve Description	
Remarks:	
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3.2.P.2 Pharmaceutical Development	
Remarks:	
3.2.P.3 Manufacture	
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2 3 D 2 1 Manufacturor(c)	
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3.2.P.3.2 Batch Formula	
Remarks:	
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3.2.P.3.3 Description of Manufacturing Process and Process Controls	
3.2.D.3.4 Controls of Critical States and Intermediates	
Remarks:	
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3.2.P.3.5 Process Validation and/or Evalution	
Remarks:	
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3.2.P.4 Control of Excipitents [name]	
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3.2.P.4.1 Specification(s)	
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3.2.P.4.2 Analytical Procedures	
Remarks:	
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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	
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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	
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3.2.P.5.2 Analytical Procedures	
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3.2.P.5.3 Validation of Analytical Procedures	
Remarks:	
3.2.P.5.4 Batch Analyses	
Nellidiks:	
3.2.P.5.5 Characterization of Impurities	
Remarks:	
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3.2.P.5.6 Justification of Specification(s)	
Remarks:	
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3.2.P.6 Reference Standards or Materialstermediates	
Remarks:	
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3.2.P.7 Container Closure System	
Remarks:	
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3.2.P.8 Stability	
Remarks:	
3.2.B.8.1 Stability Summary and Conclusion	
Remarks:	
3.2.P.8.2 Post-approval Stability Protocal and Stability Commitment	
Remarks:	
<u>^</u>	
<u>v</u>	
3.2.P.8.3 Stability Data	
Remarks:	
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3.2.A.1 Facilities and Equipment (name.manufacturer)	
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3.2.A.2 Adventitious Agents Safety Evaluation [name,dosage,form,manufacturer]	
Remarks:	
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nemarks:	
3.2.R Regional Information	
Remarks:	
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V	
3.3 Literature references	
Remarks:	
Guidance	Back Save Save and Exit Ne

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			В	ack Save Save and Exit Ne
New Product Registration			NEW_PRODUCT_REG	GISTRATION_VIEW_MODULE_0
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(CH3)	lide-That Prolonged Release Tablets 1.5mg (AP6)	PL NO.:	PR NO.:	HK NO.:
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A 1 Hedule 4 Table of Cententr	module 4 module 5			
A. I Module 4 Table of Contents				
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4.2.1.1 Primary Pharmacodynamics				
Remarks:				
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4.2.1.2 Secondary Dharmanedynamics				
Pomarke				
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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 Repo	rts (if separate reports are available)			
Remarks:				
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4.2.2.2 Absorption				
Remarks:				
0				
4.2.2.3 Distribution				
<u> </u>				
4.2.2.4 Metabolism				
Remarks:				
0				
4.2.2.5 Excretion				
Remarks:				
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4.2.2.6 Pharmacokinetic drug interactions (non	nclinical)			
Remarks:				
0				
4.2.2.7 Other pharmacokinetics studies				
Remarks:				
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4.2.3.1 Single-Dose Toxicity (in order by specie	es, by route)			
kemarks:				
\sim				
4.2.3.2 Repeat-Dose Toxicity (in order by speci	ies, by route, by duration; including supportive to	xicokinetics evaluations)		
Remarks:				
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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 madium term studies (including range, finding studies that cannot appropriately be included under repeat-dose toyicity 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 following the bandless characterized and the study designs are used, the following the bandless characterized and the study designs are used.
Sub-inequings should be induined accordingly.)
4.2.3.5.1 Pertility and early embryonic development
Remarks:
4.2.3.5.2 Embryo-fetal development
Remarks:
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:	
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.

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New Product Registration	NEW_PRODUCT_RE	GISTRATION_VIEW_MODULE_0
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		
5.1 Module 5 Table of Contents		
Remarks:		
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5.2 Tabular Listing of All Clinical Studies		
Remarks:		
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5.3.1.1 Bioavailiability (BA) Study Reports		
Remarks:		
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5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports		
Remarks:		
5.3.1.3 In Vitro - In Vivo Correlation Study Reports		
Remarks:		
E 2.1.4 Percente of Disconstruined and Association Heather de familiaries		
5.3.1.4 Reports of bioanalytical and Analytical Methods for Human Studies		
V		
5.3.2.1 Plasma Protein Binding Study Reports and Related Information		
Remarks:		
<u> </u>		
5.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies		
Remarks:		
<u> </u>		
5.3.2.3 Reports of Studies Using Other Human Biomaterials		
Remarks:		
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5.3.3 Reports of Human Pharmacokinetics (PK) Studies		
Remarks:		
5.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports and Related Information		
Remarks:		
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5.3.3.2 Patient PK and Initial Tolerability Study Reports and Related Information		
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5.3.3.3 Intrinsic Factor PK Study Reports and Related Information		
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Remarks:		
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:		
5.3.5.3 Reports of Analyses of Data from <i>M</i> ore 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		
Kemarks:		
Application History Guidance		

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 Exit Next
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Withdraw application	1.0.1.1 Prop	osed Name of P	roduct / Substa	nce							
+ Change of Registered	a. P	roposed Name	of Product (En	glish):*	PRODUCT	AME	0				
Particulars	b. P	roposed Name	of Product (Ch	inese), if any:							
+ Renewal of Registration	c. N N	ames / Propos ame: PRODUC	ed Names Used	I in Other Places	Place:	GERMANY		~			
+ Request to Cancel	N	ame: PRODUC	T NAME		Place:	UNITED KING	DOM	~			
Product Registration	N	ame:			Place:	Please Selec	t	~			
+ Payment							Add Mc	are			
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	Guidance									Save	Save and Exit Next
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Step 16: Click the "Proceed to Submit" button.

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	APPLICATION		SISTRATION OF A DRUC	, PHARMACEUTICAL	
		PROI	DUCT / SUBSTANCE		
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diantiana					
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	12345678 (Submitted By	:WONG David)			
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	23198414 (Contact Pers	on:David Wong)			
nail Address:	prs.david.wong@gmail.c	om (Contact Person: om (Submitted By:W	(David Wong)		
me of Manufacturer:					
Name of manufacturer ap	peared on product label of finishe	d product: MANU	NAME XXXXXX		
Address of manufacturer:	appeared on product label of finis	hed product: MAN	U ADDR XXXXXX XXXXXX XXXX	xxx	
I Company(ies) involved	in the preparation of the produ	ct/substance			
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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
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Unline Notification	Page 1 Pa	age 2 I	Page 3 Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form			
My Product Search									Letter and the second se	-		
- New Registration	Priority Appl For priority a a. for chan	lication application: use of name	s, the following : e. dosage form o	supporting docu r active ingredi	ments are n ent. letter f	equired: rom applicant	t of surrend	ler original re	egistration upon			
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			2015	5 copyright Impo	rtant notices	Last Revision	n Date: 02 S	ep 2020 Ver	rsion: 1.0.99 (PP)			

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.

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	Guidance					Ba	CK Submit Application

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:	2018.08.17		
	Proposed Nar	me of Product (English)	PL No.
	PRODUCT NA	ME	PL0023/2018
The Drug Office ackn will provide response	nowledges your on as soon as possit	-line submission for application ble.	of new product registration. We will process your request and
or enquiries, please c	all us quoting this	reference number.	
General enquiries:			
Seneral enquiries:	Office Hours::	Monday to Friday	
ieneral enquiries:	Office Hours::	Monday to Friday 9:00 am - 1:00 pm	
ieneral enquiries:	Office Hours::	Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm	
ieneral enquiries:	Office Hours::	Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on Monday)	
ieneral enquiries:	Office 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, Sund	ays & Public Holidays)
seneral enquiries:	Office Hours:: Tel:	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 (852) 2319 8458	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"

					0		N	EW_PRODUCT	REGISTRA	TION_STA
Ť	New	Product Reg	jistration							-
	New Su	Ibmission								
ou are login as	InitiateNe	ew Product Registrat	tion							
ogin date and time	Action	Required							_	
Online Natification		♦ Application Date	Application ID	PL No. 💠	PR No. 🔶	Proposed Name of Product (English)	No. of submission ♥	Application Status	Status Date ♥	Payment Status
My Product Search	1	17.07.2018	ANP20189000108	PL0010/2018		TEST ECERT CASE1	1	Request for Outstanding	24.07.2018	No
- New Registration	2	31.07.2017	ANP20179000079	PL0082/2017		TEST LOGIN2	1	Request for Outstanding Information	22.06.2018	No
Initiate New Product Registration Application	3	31.07.2017	ANP20179000078	PL0081/2017		TEST USER LOGIN 2	1	Request for Outstanding Information	14.11.2017	No
Application Status	Not Sul	bmitted								
 Action Required Not Submitted Application Submitted 		Latest Dra	ft Date 🗢	Application ID	\$	Proposed Name of Product (E	nglish)	\$	Application	Status ¢
Withdraw application	1	10.08.2018	ANP2	0189000153	TEST NC	<u>E2</u>		Penc	ling	
windraw application	2	18.07.2018	ANP2	0189000132	TEST OP	EN FILE CASE 3		Pend	ling	
 Change of Registered Particulars 	Applica	tion Submitted	Application ID	DI No	00 No	Desmand Name of Deschool (Capitab)	No. of	Application	Ctatus	Deverant
. Descurred of		♦ Application Date	Application ID _©	PL NO. ¢	PR NO. ¢	Proposed Name of Product (English)	submission *	Status	Date +	Status
+ Renewal of Registration	1	10.08.2018	ANP20189000151	PL0022/2018		TEST NCE CASE	1	Application Submitted	15.08.2018	No
+ Request to Cancel Product Registration	2	06.08.2018	ANP20189000133	PL0019/2018		TEST 2015	1	Screening	10.08.2018	No
+ Payment										
Application History										
+ User Profile										
+ Syciem										
oystem										

 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.

	New P	Product R	Registratio	n						N	IEW_PROD	UCT_REG	ISTRAT	TION_STATU
	Now Col	mission	3											
	New Suc	omission												
You are login as ORG Trial One	InitiateNev	w Product Regi	stration											
TESTING LIMITED Login date and time 27.01.2021 10:22	Action R	Required												
	\$ App	plication Date	Application IB	PL No‡	PR No‡	Propo	sed Name of	Product (English)	No. of submission	Application S	itatus‡ St	atus Dat ¢	Payme	ent Status
Online Notification	Not Sub	mitted												
My Product Search		Lates	t Draft Date 🛛 🖨		Application	ID :	\$	Propo	sed Name of Product (E	English)	\$	Appli	cation S	itatus 🗢
	1	27.01.2021		ANP202	219000005		FACE OF	REAM				Pending		
- New Registration	2	26.01.2021		ANP202	219000001		PRODUC	T NAME				Pending		
Initiate New Product	3	01.03.2019		ANP201	199000002		TEST DF	UG 20190301				Pending		
Registration Application	Applicat	ion Submit	ted											
Application Status		Application Date	Application	on ID _{\$}	PL No.	\$	PR No.	Proposed Nam	e of Product (English)	No. of submission ^{\$}	Applicati Status	ion Sta Da	ate \$	Payment Status
- Action Required - Not Submitted - Application Submitted	1	26.01.2021	ANP202190	00004	PL0001/2021			PRODUCT NAME	E	1	Application Submitted	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	ght Impo	ortant notice	s Las	t Revision D	ate: 02 Sep 2020	Version: 1.0.99 (PP))				

New list added for new version:

Issued E-Certificate

Application Date	Application	on ID	\$ PL No. \$	PR No. \$	HK No. 🗢	Proposed N	lame of Proc	duct (Englis	h) \$	Status Date	Download
he download link of the	e-Certificate is ena	abled for (one-time use.	Please keep a	copy of the	e-Certificat	e for your re	ecord after o	lownloading.		
	Guidance									Save	Save and Exit
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	File upload is not al	lowed for i	modules 2 - 5, pl	ease submit the	files to Drug	Office via CE	DVD if nece	ssary.			
ou are login as ORG Trial ne STING LIMITED	Proposed Name of F	Product (E	inglish):				PL N	o.:	PR No.:	нк	No.:
gin date and time .01.2021 11:20	Module 1 M	odule 2	Module 3	Module 4	Module 5						
Online Notification	Page 1 Pag	e 2 P	age 3 Page	4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form		
My Product Search											
New Registration	Priority Applic For priority ap for chapped	cation plications,	, the following s	supporting docu	iments are r	equired:	of surrounds	e original re	virtration upon		
Initiate New Product Registration Application	approval o b. for change	e of name, e of produ	tion of the appli tion certificate h	ed product and older, a statem	the original ent from ma	registration nufacturer fo	certificate o r the change	f the existin e.	g product; or		
Application Status - Action Required - Not Submitted - Application Submitted	1.0 Application For 1.0.1 Name of Drug	rm* 🔿 G g / Pharma	Seneric New (Chemical Entity	(NCE)						
Withdraw application	1.0.1.1 Proposed N	lame of Pro	oduct / Substanc	e			_				
Change of Registered Particulars	a. Propos	ed Name o ed Name o	of Product (Engl of Product (Chir	ish):" iese), if any:	PRODUCT I	IAME	0				
Renewal of Registration	c. Names	/ Propose	ed Names Used i	n Other Places	Place:	GERMANY		~			
Request to Cancel Product Registration	Name:	PRODUCT	T NAME		Place:	UNITED KING	DOM	~			
Payment	Name:				Place:	Please Selec	t	~			
Application History	1.0.1.2 Name of Ad	ctive Subst	tance(s) / Ingredi	ent(s) (Please lis	st below)		Add Mor	e			
User Profile	No. of C	omponent	t(s)* 1 🗸								
System				Active	e Ingredient			Active In Appeared	gredient on Product		
Logout								Ldi	Jei		
	Compone	ent 11. * [bisbentiamine				~	bisbentiamir	ne label		
		2.	None of the ab	ove Name			Y	New Ingredi	ent Name		
		3.	Please Select				~				
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							Add More)			
	1.0.1.3 Application	n Type: (pl	ease select one)	*							
	Human	n biologica	al pharmaceutic	al product							
) Humai	n vaccine	it pharmaceucica	at product							
	O Pharm	naceutical	substance								
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	Guidance									Save	Save and Fxit
	()		2015	copyright Impo	rtant notices	Last Revisio	n Date: 02 Se	p 2020 Ver	sion: 1.0.99 (PP)		

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
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You are login as ORG Trial	Initia	teNew F	roduct Re	gistration												
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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
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You are login as ORG Trial	File upload is not allowed fo	or modules 2 - 5, plea	ase submit the	e files to Drug	g Office via CL	D/DVD if nec	essary.	DD N	112	N	
One TESTING LIMITED	Proposed Name of Product	(English).				FLI	NO	FR NO	пк	NO	
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 approval of registr	me, dosage form or a ration of the applies	active ingred	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.	· · · · · · · · · · · · · · · · · · ·			
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	c. Names / Propo	osed Names Used in	Other Places	Diama							
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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 🗸									
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Lopout							Appeared	on Product bel			
208001											
	Component 11.	* bisbentiamine				~	bisbentiami	ne label			
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	 Pharmaceutic Veteripary bio 	al substance: plogical pharmaceut	tical product								
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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'

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ew Product Reg	jistration				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	imum total up files to Drug	load size per applicat Office via CD/DVD if	on is 10MB. ecessary.		
oposed Name of Product (English): PRODUCT NAME	Ĩ	1	L No.: PL0023	8/2018 PR No.:	HK No.:
Module 1 Module 2	Module 3 Module 4	Module 5				
Page 1 Page 2	Page 3 Page 4 Page 5	Page 6	Page 7 Page	8 Page 9	Application Form	
 Priority Application For priority application a. for change of name approval of registra b. for change of prod O Application Form* 	s, 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	iments are re ent, letter fi I the original ent from ma (NCE)	equired: om applicant of surr registration certifica nufacturer for the ch	ender original te of the exis ange.	registration upon ting product; or	
0.1 Name of Drug / Pharm	aceutical Product / Substance					
0.1.1 Proposed Name of P	roduct / Substance					
a Proposed Name	of Product (English):*					
a. Proposed name		PRODUCTIN				
b. Proposed Name	of Product (Chinese), if any:					
c. Names / Propos	ed Names Used in Other Places					
Name: PRODUC	T NAME	Place: (GERMANY	\sim		
Name: PRODUC	T NAME	Place: L	INITED KINGDOM	\checkmark		
Name:		Place: P	lease Select	\sim		
0.1.2 Name of Active Subs	stance(s) / Ingredient(s) (Please li	st below)				
No. of Componer	nt(s)* 1 🗸					
	Activ	e Ingredient		Active	ingredient i on Product	
				L	abel	
Component 11. *	bisbentiamine			✓ bisbentiar	nine Label	
2.	None of the above			✓ New Ingre	dient Name	
2	New Ingredient Name					
3.	Please Select			×		
4.	Please Select			~		
0.1.3 Application Type: (p	lease select one) *					
Human biologic	cal pharmaceutical product					
Human chemic	al pharmaceutical product					
Human vaccine Dearmacoutica	Lsubstanco					
 Veterinary biol 	ogical pharmaceutical product					
 Veterinary che 	mical pharmaceutical product					
	rine					
 Veterinary vacu 	cine					

Application Version 1	$\overline{}$	
CTD in PDF format Application Submitted: Application History.p	df	
C Document List		
Page 2		
ComponentDuration (Month) Start date 1 24 08.01.20	eport : 115	In-Use Stability Report
Stability Report.pdf		
2. Product Pack Size: 3x10's blister/pack		
Stability R	eport	In-Use Stability Report
1 24 08.01.20	115	
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 1 and		
Flodatt Laber	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>	
Givip Ceruncate of Other Ivianutacturer 1	GMP.pdf	
ML of Other Manufacturer 1	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:		
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 odf	
Authorization letter from the	<u></u>	
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		
GMP Certificate of Manufacturer Appeared on Product Label	Product Information.pdf	
GMP Certificate of Other Manufacturer 1	GMP.pdf	
Page 8 Other Country/Region 1	<u>onviP.pdi</u>	
Page 9	Free Sales Certificate.pdf	
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)		
Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)	Product Specification.pdf	
Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)	Method of Analysis.pdf	
Reputable documentary evidence to substantiate the content of package insert. Cross-referencing to documents should be wade her enforcing to	Certificate of Analysis.pdf	
page number of the reference and the relevant parts 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	Fuidence Down of a 10	
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label	<u>Evidence Document.pdf</u>	
ML of Other Manufacturer 1	March 10	
version. : 1.1.10	<u>ML.pdf</u>	

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.:] Submission Date: 07.02.2016
Submission Date: 07.03.2010
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 V
CTD in PDF format Application Submitted: Application History pdf
Page 2 1 Product Pack Size: 6y10's blictar/nack
Stability Report In-Use Stability Report
ComponentDuration (Month) Start date 1 24 08.01.2015
Stability Report.pdf
2. Product Pack Size: 3x10's blister/pack
ComponentDuration (Month) Start date In-Use Stability Report
Stability Keport.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
GMP Certificate of Other Manufacturer 1
ML of Other Manufacturer 1
ML.pdf
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
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
Copy of business registration certificate.
(Reference for 1.0.0.1 of Page 5) 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,
at any stage of registration, any information and/or documents relating to the product/substance upon
request within the prescribed timeframe Product Information.pdf
GMP Certificate of Manufacturer Appeared on Product Label
GMP Certificate of Other Manufacturer 1
GMP.pdf
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
per finished product specifications) (Reference for 1.0.8 of Page 5)
Certificate of Analysis.pdf
the content of package inset. 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.pdf
ML. of Ouer Manufacturer 1 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.

	Onlir	ne Notification				ONL	INE_NOTIFIC	ATION_VIEW_01
T	New P	roduct Registration					Archiv	ed Notifications
		Notification Date	e \$	Subject	\$ F	roposed Name of Product 👙	PL No. \$	Payment Statuts
You are login as	Open	12.01.2021 10:34:23		Certificate Payment Request	VOON	S00 TADLETS S00MO	PL0975/2016	Paid
	Open	20.11.2020 17:13:29		Certificate Payment Request	JAVA	8 START	PL0004/2020	Paid
Login date and time 28.01.2021 15:06	<u>Open</u>	20.11.2020 16:45:42		Screening Application	BOUR	BON POWDER	PL0002/2020	N/A
Online Notification	CORF	5					Archiv	ved Notifications
My Product Search		Notification Date 🗢		Subject	\$ HK No.	¢ Nan	e of Product	¢
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 3	UUMG	
+ New Registration	<u>Open</u>	12.01.2021 17:38:55	Application Su	bmitted Notification	HK42660	GALOUM UNISON TAB S	OMO	
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sc	eening Notification	HK42660	CALCIUM UNISON TAD S	09MO	
+ Renewal of Registration	Rene	wal of Registration					Archiv	ved Notifications
		Notification Date 🗢		Subject	\$	Name of Product	\$ N	lo. of Renewals 🜲
+ Request to Cancel Product Registration	Open	27.01.2021 04:00:14	Renewal Notif	cation	DRUG NAME XXXX	TAB 50MG	1	
+ Payment	Canc	ellation Request						
Application History		Notification Date \$		Subject	\$ HK No.	\$ Nar	ne of Product	\$
	Open	26.01.2021 15:07:50	Cancellation F	egistration Request Submitted Notification	HK31199	EFILIM FREEZE-DRIED	DR FOR IV INJ	400MG
+ User Profile								
+ System	Non	Pharmaceutical Prod	uct Alert					
Logout		Notification Date	¢	Subject		Nam	e of Product	\$
Logout	Open	11.02.2016 04:00:00	Renewal P	enaing Reminaer	HK60464	OCTED TIN 500 CAP 500MO	-	
	Open	12.01.2016 04:00:02	Renewal P	ending ivotrication	HK60464	CETECHINE DU CALLEUMAC		

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

	New F	Product Registration							Archiv	ed Notifications
		Notification Dat	e \$	Subject		\$	Pr	oposed Name of Product		Payment Statu
You are login as	Open	12.01.2021 10:34:23		Certificate Payment Request			VOOIN	500 TABLETS SIGNO	PL0975/2016	Paid
	<u>Open</u>	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	\$	HK	lo.	\$ N	ame of Product	4
	Open	12.01.2021 17:40:32	Applicaton Wit	ndrawal Rejected Notification		HK42660		CALCION UNISON TAE	300MG	
+ New Registration	Open	12.01.2021 17:38:55	Application Su	omitted Notification		HK42660		CALOUM UNISON TAB SOME		
 Change of Registered Particulars 	Open	12.01.2021 17:38:55	Application Sc	plication Screening Notification HK42660 CALCION UNISON TA					-369MG	
 Renewal of Registration 	Rene	wal of Registration							Archi	ved Notification
registration		Notification Date \$		Subject	\$			Name of Product	÷ 1	lo. of Renewals
 Request to Cancel Product Registration 	<u>Open</u>	27.01.2021 04:00:14	Renewal Notif	cation		DRUG NAME	XXXXX T	AB 50MG	1	
+ Payment	Canc	ellation Request								
Application History		Notification Date \$		Subject	\$	НК	No.	\$ N	ame of Product	4
Application History	Open	26.01.2021 15:07:50	Cancellation R	egistration Request Submitted Notification		HK31199		CPILIM FREEZE-DRIED	POR FOR IV INJ	400MG
► User Profile										
+ System	Non	Pharmaceutical Prod	uct Alert							
		Notification Date	\$	Subject		\$ H	K No. 🗢	Na	me of Product	
Logout	Open	11.02.2016 04:00:00	Renewal P	ending Reminder		HK60	464	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 (來函請錄明比檔案號碼) (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		ONLINE_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.

d size of single file is 1 owed for modules 2 - 5 roduct (English): PRO adule 2 Module 3 2 Page 3 Pa ation Nications, the followin of name, dosage forr registration of the ag of product certificate m* Generic • Ne / Pharmaceutical Prod ame of Product / Subst. ed Name of Product (C / Proposed Names Use PRODUCT NAME PRODUCT NAME	1MB, while the max 5, please submit the DDUCT NAME 3 Module 4 Page 4 Page 5 ring supporting document ring supporting document (Intersection of the support ring supporting document (Intersection of the support ring support in the support in the support ring support in the suppor	Module 5 Page 6	Page 7 Pa	lication is 10MB. D if necessary. PL No.: PL002 'age 8 Page surrender origina ificate of the exi e change.	23/2018 PR No.: 9 Application Form al registration upon isting product; or	HK No.: Comments for page Page 1 Section 1.0 Section 1.0.1.1 Please update the proposed names used in ohter places
ation Micro Market Control of the second of	5, please submit the DDUCT NAME 3 Module 4 Page 4 Page 5 ring supporting document range of the support of the supplied product and te holder, a statem New Chemical Entity duct / Substance stance (English):* (Chinese), if any: sed in Other Places and and the support of the support support of the support of the support mediant (s) (Dlease literature)	Module 5 Page 6 Page 6 Page 6 Page 6 Page 6 Page 6 Page 7	Office via CD/DVD Page 7 Pa quired: om applicant of s registration certi iufacturer for the AME ? ERMANY NITED KINGDOM ease Select	D if necessary. PL No.: PL002 Page 8 Page surrender origina ificate of the exi e change.	23/2018 PR No.: 9 Application Form al registration upon sisting product; or	HK No.: Comments for page Page 1 Section 1.0 Section 1.0.1.1 Please update the proposed names used in ohter places
roduct (English): PRO odule 2 Module 3 e 2 Page 3 Pa ation blications, the followin of name, dosage forr registration of the ag of product certificator m ^a Generic • Ne / Pharmaceutical Prod ame of Product / Subst ed Name of Product (C / Proposed Names Use PRODUCT NAME PRODUCT NAME	Module 4 A Module 4 Page 4 Page 4 Page 5 Page 4 Page 5 Page 5 Pa	Module 5 Page 6 Page 6 ments are ree ent, letter fro I the original r ent from man (NCE) PRODUCT NZ Place: GI Place: UI Place: P	Page 7 Pa quired: om applicant of s registration certi- nufacturer for the AME 2 ERMANY NITED KINGDOM ease Select	PL No.: PL002 Page 8 Page Surrender origina ificate of the exi e change.	9 Application Form al registration upon sting product; or	HK No.: Comments for page Page 1 Section 1.0 Section 1.0 Section 1.0.1.1 Please update the proposed names used in ohter places Section 1.0.1.2
Adule 2 Module 3 2 Page 3 Pa ation Mications, the followin of name, dosage form registration of the ap of product certificator m ^a Generic • Ne / Pharmaceutical Product Ame of Product / Subst ad Name of Product (E ad Name of Product (C / Proposed Names Use PRODUCT NAME PRODUCT NAME tive Substance(s) / Ingr	3 Module 4 Page 4 Page 5 Ing supporting document and a citive ingraduent applied product and te holder, a statem Hew Chemical Entity duct / Substance itance (English):* (Chinese), if any: sed in Other Places	Module 5 Page 6 Page 6 Page 6 Page 6 Page 7	Page 7 Pa	Page 8 Page surrender origina ificate of the exi e change.	9 Application Form al registration upon sting product; or	Comments for page Page 1 Section 1.0 Section 1.0 Section 1.0.1.1 Please update the proposed names used in ohter places Section 1.0.1.2
2 Page 3 Page 5	Page 4 Page 5 ing supporting doc: rm or active ingred applied product and te holder, a statem we Chemical Entity duct / Substance itance (English):* (Chinese), if any: sed in Other Places prodient(s) (Places Ii	Page 6 Uments are received, letter fro I the original r UMCE) PRODUCT NA Place: Gr Place: U Place: P	Page 7 Pa	Page 8 Page surrender origina ificate of the exi e change.	9 Application Form al registration upon isting product; or	Comments for page Page 1 Section 1.0 Section 1.0 Section 1.0.1.1 Please update the proposed names used in ohter places Section 1.0.1.2
ation blications, the followin of name, dosage forr registration of the a of name, dosage forr registration of the a of name, dosage for () Pharmaceutical Product anne of Product / Subst. ed Name of Product (C de Name of Product (C / Proposed Names Use PRODUCT NAME PRODUCT NAME Entry Substance(s) / Ingr	ring supporting document mor active ingredi applied product and te holder, a statem tew Chemical Entity duct / Substance stance (English):* (Chinese), if any: sed in Other Places	Iments are red ient, letter fro the original r ent from man (NCE) PRODUCT NA PRODUCT NA Place: Gi Place: UI Place: Pl	quired: om applicant of s registration certii unfacturer for the AME RMANY RITED KINGDOM ease Select	surrender origina ificate of the exi e change.	al registration upon isting product; or	Comments for page Page 1 Section 1.0 Section 1.0 Section 1.0.1.1 Please update the proposed names used in ohter places Section 1.0.1.2
PRODUCT NAME	rredient/s) (Dlease li	Place: Ul Place: Pl	NITED KINGDOM ease Select	~		Section 1.0.1.2
tive Substance(s) / Ingr	redient(s) (Dlease li	Place: Pl	ease Select	×		Section 1.0.1.2
tive Substance(s) / Ingr	redient(s) (Dlease li	Place. Pl		•		
omponent(s)* 1 🗸	Active	st below) e Ingredient	(e	Active Appeare	Ingredient d on Product Label	© S C Section 1.0.1.3
at 11 * bichoptiamic	100			M bishoptia	mina Label	<u>^</u>
2. None of the	abovo			V New Ingr	odient Name	
New Ingredie	ient Name			+ new nigh		
3. Please Selec	ct					۵۵ (
4. Please Selec	ct			~		
			Ad	ld More		
Type: (please select or biological pharmaceu chemical pharmaceu vaccine aceutical substance ary biological pharma	one) * eutical product utical product naceutical product					
T E C V ac	 11. * bisbentiam None of the New Ingred Please Sele Please Sele Please Select of piological pharmace themical pharmace raccine reutical substance ry biological pharmace 	11. * bisbentiamine 2. None of the above New Ingredient Name 3. Please Select 4. Please Select ype: (please select one) * biological pharmaceutical product themical pharmaceutical product themical substance ry biological pharmaceutical product	11. bisbentiamine None of the above New Ingredient Name Please Select Please Select please Select pre: (please select one) * piological pharmaceutical product hemical pharmaceutical product raccine eutical substance ry biological pharmaceutical product			Appeared on Product Label 11. bisbentiamine bisbentiamine Label Appeared on Product Label 1. bisbentiamine Label 2. None of the above New Ingredient Name New Ingredient Name New Ingredient Name 3. Please Select V Red More ype: (please select one) Add More ype: (please select one) biological pharmaceutical product themical pharmaceutical

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

T		
You are login as	19	

New Submission

27.01.2021 11:02		♦ Application ♦ Date	Application ID	PL No.	\$	PR No. 💠	Proposed Name of Product (English)	No. of	Application +	Status ¢	Payment
Online Notification	1	06.04.2020	ANP20209000002	PL0023/2018			PRODUCT NAME	1	Request for Outstanding	20.11.2020	No
My Product Search	2	29.11.2019	ANP20199000004	PL0005/2019			CALMING RELIFE	2	Pending for	04.12.2019	No
- New Registration	Not Sub	mitted							Аррисацон гее		
Initiate New Product		Latest Dra	ft Date 💠	Application	ID	\$	Proposed Name of Product (E	inglish)	\$	Application	Status 🕈
Registration Application	1	20.11.2020	ANP	20209000006		TESTAAA			Pend	ling	
Application Status	2	09.10.2020	ANP	20209000005		OCTOBE	R UAT		Pend	ling	
- Action Required - Not Submitted	Applicat	ion Submitted									
- Application Submitted		♦ Application Date	Application ID _{\$}	PL No.	¢	PR No. 💠	Proposed Name of Product (English)	No. of submission \$	Application Status	Status Date ≑	Payment
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
+ Request to Cancel	4	03.11.2016	ANP20169000317	PL0886/2016		PR0717/2016	CETIZAL TABLETS 5MG	4	Withdraw Application	20.11.2020	Yes
Product Registration	5	23.06.2017	ANP20179000747	PL0270/2017		PR0260/2017	CILOSOL 100 TABLETS 100MG	2	Withdraw Application	20.11.2020	Yes
+ Payment			1100017000700						Request		
Application History	6	09.01.2019	ANP20179000769	PL0001/2019			SULSA 500 TABLETS 500MG	3	Screening	09.10.2020	No
+ Liser Profile	1	12.05.2020	ANP20209000003	PL0003/2020		PR0003/2020	<u>TEST2020</u>	1	Certificate	05.06.2020	Yes
	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	31.01.2020	Yes
Logout	10	17 12 2018	ANP20179000740	PI 0005/2018		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	Yes

Application ristory	Juida	ince								Jave Jave and EXIL
oplications F	Requ	ire Ac	tion						NEW_	PRODUCT_REGISTRATION_VIEW_
e maximum upload : e upload is not allow	size of ved for	single file modules	is 1MB, wh 2 - 5, please	ile the max submit the	imum total up files to Drug	oad size per Office via CD	application i /DVD if nece	s 10MB. ssarv.		
posed Name of Pro	duct (E	nglish): P	RODUCT	AME	, in the second s		PL N	o.: PL0023/2	018 PR No.:	HK No.:
		J								
Module 1 Mod	ule 2	Modul	le 3 M	odule 4	Module 5					
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 appli a. for change o approval of r b. for change o Application Form	ion cations f name egistra f produ	, the follo , dosage f tion of the uct certifi Generic (owing supp form or ac e applied p cate holde New Cher	orting docu tive ingred product and r, a statem nical Entity	uments are re ient, letter fri I the original ient from mar (NCE)	quired: om applicant registration c ufacturer fo	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 /	Pharma	aceutical P	roduct / Su	bstance	(102)					• S ()
0.1.1 Proposed Nam	ne of Pr	oduct / Su	Ibstance							Section 1.0.1.1
a. Proposed	Name	of Produc	t (English)	*	PRODUCT N	AME 🔮				Please undate the
b. Proposed	Name	of Produc	t (Chinese), if any:						proposed names used
c. Names / F	Propose	ed Names	Used in Ot	her Places						in onter places
Name: PR	ODUCT	T NAME			Place: G	ERMANY		~		
Name: PF	ODUCT	ΓΝΑΜΕ			Place: U	NITED KINGD	OM	~		<u> </u>
Name:					Place: Pl	ease Select		~		Section 1.0.1.2
							Add Mor	e		
.1.2 Name of Activ	e Subst	tance(s) /	Ingredient(s) (Please li	st below)					
No. of Com	ponen	t(s)* 1 🗸	•							×
			_	Active	e Ingredient			Active Ing Appeared o Lab	redient n Product el	© 5
Component	11. * [bisbentia	mine				~ 1	oisbentiamir	e Label	^
	2.	None of t	he above				~ 1	New Ingredie	ent Name	✓
		New Ingre	edient Nan	ie						
	3. [Please Se	lect				~			• S 🔾
	4. [Please Se	lect				~			
							Add More			
.1.3 Application Ty	pe: (pl	ease selec	t one) *							
 Human bi Human cl Human va Pharmace Veterinar Veterinar 	iologica hemica accine eutical y biolo y chen	al pharma Il pharmac substance ogical pha nical phar	ceutical p ceutical pr e rmaceutica maceutica	roduct oduct al product l product						
⊖ Veterinar	y vacc	ine								
nlication History	Suidan	a								Save Save and Exit

Step2: Update the information according to the comments (if any) given by pharmacist officer or any changes.

upplication history Guid					NIENA/ F	Save Save and EXIT
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posed Name of Product (English): PRODUCT NAME		PI	No.: PL0023/20)18 PR No.:	HK No.:
Module 1 Module 2	Module 3 Module	4 Module 5				
Page 1 Page 2	Page 3 Page 4 Pag	e 5 Page 6	Page 7 Page 8	Page 9	Application Form	
Priority Application						Comments for page Page 1
For priority application	s, the following supporting	documents are re	quired:			Section 1.0
a. for change of nam	e, dosage form or active in	gredient, letter fro	om applicant of surre	nder original re	gistration upon	
b. for change of prod	luct certificate holder, a st	atement from man	ufacturer for the cha	nge.	g product, or	^
Application Form*	Generic New Chemical E	ntity (NCE)				
		, (,				× ×
.1 Name of Drug / Pharm	aceutical Product / Substanc	e				• S
.1.1 Proposed Name of P	roduct / Substance					Section 1.0.1.1
a. Proposed Name	of Product (English):*	PRODUCT N	AME 😮			
b. Droposed Name	of Droduct (Chinaca) if ar					Please update the proposed names used
b. Proposed Name	of Product (chinese), if an	y.				in ohter places
c. Names / Propos	ed Names Used in Other Pla	aces				×
Name: PRODUC	T NAME	Place: G	ERMANY	~		05
Name: PRODUC	TNAME	Place: U	NITED KINGDOM	\checkmark		03
Name:		Place: Pl	ease Select	~		Section 1.0.1.2
			Add A	lore		
.1.2 Hame of Active Sub	stance(s) / Incredient(s) (Pler	se list below)				
No. of Componen	nt/c)* 1 X	,				~
No. of component	ic(s) 1 •					
	A	ctive ingredient		Active ing Appeared of	n Product	• 2
				Lab	el	Section 1.0.1.3
Component 11. *	bisbentiamine			 bisbentiamin 	e Label	
2.	None of the above		`	New Ingredie	ent Name	×
	New Ingredient Name					
3.	Please Select		`			• 3
4.	Please Select			<u> </u>		
			Add Mo	re		
.1.3 Application Type: (p	lease select one) *					
	al pharmaceutical product					
O Human biologic	al pharmaceutical product					
 ⊖ Human biologic ● Human chemic 	at pharmacedereat produce					
 ⊖ Human biologio ● Human chemic ○ Human vaccine 	in pharmaceucieur produce					
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 Human biologi Human chemic Human vaccine Pharmaceutica Veterinary biol Veterinary vaccine 	l substance ogical pharmaceutical prod mical pharmaceutical prod	uct				

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.

market 11									NEW	PRODUCT PEG	ISTRATION VIEW O
opiciati	ons Red	quire Ad	ction						NLW.	_FRODUCT_REG	ISTRATION_VIEW_C
le maximum le upload is	not allowed f	of single file or modules 2	1s 50MB, whi 2 - 5, please s	le the max ubmit the	files to Drug	Office via Cl	D/DVD if ne	ion is 100MB. ecessary.			
roposed Nar CH6)	me of Product	t (English): Ir	ndapamide-Tr	al Prolong	ed Release T	ablets 1.5mg ((AP8) P	L No.: PL1052/	2015 PR No.:	нк	No.:
Module 1	Module	2 Modul	le 3 Mod	fule 4	Module 5						
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 Informatic	'n								Section 1	.0.5
		CUIC AS									
a. u b. f	Email Addres	cH6_AL charles	lee@ch6.co	m.hk							
.0.6.1 Prop	osed Registra	tion Certifica	ate Holder								~
											@S 🔾 U
a.r b./	vame : Address :	CERT HOLDI	EK 6							Section 1	.0.6.1
1	Unit: 04	4 Floor:	11 Bloc	k: A							
10 10	Building: /	ABC Building	5 								^
	Street No.:	1 Street Na	me: ABC SI	reet							~
	Sub-district: Area: KC	Shek Kip Me Wloon									
c I	hone Numbe	er (852) E	ax Number:	(852)						Section 1	.0.6.2
d.C	ontact Perso	n		()							
fo	or this applic	ation*: Johr	n Ho	Ph	none No*:	23192319		Position*: A	dministrator		^
E	mail*: testin	g@hk.com	Fax N	o.*: 35234	4534						~
e.E	Business Type	•*: (Manufac	turer							
		(Importer Local brain 	anch, subs	sidiary, repr	esentative, a	agent or d	istributor of a	manufacturer outside	Hong	• S () U
		Ko	ng	استا ما					he Berned area from		Ab - 12
		ma	anufacturer	is require	d to manufa	cture the ph	armaceuti	cal product of	r substance	er under which	the licensed
										- Contraction of	
.0.6.2 Perso	on responsible	e for Pharma	covigilance								
a. N	name of Pers	on : P	eter Lam	52 22102	219	Position	Super-	isor	Email •		
D. (ting@hk.com	in his retepi	none no. : o	23192	517	Posición	Superv	1501	Lindit .		
tes	C112(w)18, (1111										
tes (2	4 hours)										

Step 4: After finish updating the application, click the "Application Form" tab.

e maximum		uire Acti	on					NE	W_PRODUCT_RE	GISTRATION_VIEW
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oposed Nan H6)	me of Product (English): Inda	pamide-Trial P	rolonged Rel	ease Tablets 1.	5mg (AP8)	PL No.: PL10	52/2015 PR No.:	Н	K No.:
Module 1	Module 2	Module	3 Module	4 Mod	ule 5					
Page 1	Page 2	Page 3 P	age 4 Pa	ige 5 Pa	age 6 Pag	e 7 Page	8 Page	9 Application For	rm	
.0.5 Legal S	itatus								Commer	nts for page Page 3
0.6 Applica	ant Information								Section	1.0.5
a. l	Jsername :	CH6_ADMI	N							~
b. E	Email Address	charles.le	e@ch6.com.h	k						
0.6.1 Prop	osed Registrati	on Certificate	Holder							~
a. 1	Name: C	ERT HOLDER	6							@ S 🔘
b. A	Address :		ana an anns an						Section	1.0.6.1
l I	Unit: 044 Building: AB	Floor: 1 C Building	1 Block:	A						^
5	Street No.: 1	Street Name	e: ABC Stree	t						
10	Sub-district: SI	HEK KIP MEI								
	August Month									020
,	Area: KOV	VLOON								6-0
с. Р	Area: KOV Phone Number	: (852) Fax	Number: (852	2)					Section	1.0.6.2
c. F d.C	Area: KOV Phone Number: ontact Person	: (852) Fax	Number: (852	?)	lo *• 231923	19	Position*	Administrator	Section	1.0.6.2
c. F d.Cr fc Ei	Area: KOV Phone Number ontact Person or this applicat mail*: [testing	(852) Fax tion*: John H @hk.com	Number: (852 lo Fax No.*:	2) Phone N	lo*: 231923	19	Position*:	Administrator	Section	1.0.6.2
c. F d.Cr fc Ei e. B	Area: KOV Phone Number: ontact Person or this applicat mail*: testing Business Type*	: (852) Fax tion*: John H @hk.com	Number: (852 lo Fax No.*: Manufacture	2) Phone N 35234534	lo*: 231923	19	Position*:	Administrator	Section	1.0.6.2
c. F d.C fc EI e. B	Area: KOV Phone Number ontact Person or this applicat mail*: testing Business Type*	: (852) Fax tion*: John H @hk.com : O	Number: (852 lo Fax No.*: Manufacture Importer	2) Phone N 35234534 er	lo*: 231923 [;]	19	Position*:	Administrator	Section	1.0.6.2
c. F d.C fc e. E	Area: KOV Phone Number: ontact Person or this applicat mail*: testing Business Type*	: (852) Fax tion*: John H @hk.com : O	Number: (852 lo Fax No.*: Manufacture Importer Local branch	2) Phone N (35234534 er n, subsidiary	lo*: 231923	19 ive, agent or	Position*:	Administrator	Section	1.0.6.2
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F d.C F e. E 0.6.2 Persc a. N	Area: KOV Phone Number: ontact Person or this applical mail*: [testing Business Type* on responsible Name of Person Contact Person	s: (852) Fax tion*: John H @hk.com :	Number: (852 Fax No.*: Manufacture Importer Local branch Licensed wh ufacturer is re rigilance er Lam te No 852	Phone N 35234534 r n, subsidiary olesale deal equired to m	lo*: 231923 /, representat ler who has er hanufacture th	ive, agent or ntered into a ne pharmaceu	Position*: distributor o contract with ical product	Administrator f a manufacturer outsic n the licensed manufac : or substance	Section	1.0.6.2
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Step 5: Click the "Proceed to Submit" button.

Application History Gu	ildance						Back Prin	t Proceed To Sub
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								FORM6_VIEW
		PHARM	ACY AND PO	ISONS ORDI	NANCE (CHAPT	TER 138)		
	AF	PLICATION FO	RM FOR REG	SISTRATION	OF A DRUG / PI	HARMACEUTICA	L	
			PRO	DUCT / SUBS	TANCE			
ote: A specimen sales pack id supporting documents is	of the drug/	product or sample of the	ne substance and t country of origin sh	the relevant literatu	re must be submitted if required.	together with the applic	ation. Supplement	ary documentation
ume of the Drug / Product	t / Substanc	e*: * (*(*Delete as ap PRODUCT NAME	opropriate))					
ose Form / Package Size(s) :							
Dose Form								
Component 1		Cream						
Fackage Size(s).		Product Pack Size	2 x 12's blister/box					
tailed Qualitative and Qu	uantitative C	omposition :	2 x 48 s blister/box					
omponent 1	liant(a)	Quantity (Strangth	Lipit (Strongth Lip	ait) Daa	a Value Dese	Lloit Deference /	Managaraph Stand	and
Name of Active ingred	nent(s)	Value)	Unit (Strength Ur	nit) Dos	e value Dose	Unit Reference?	monograph Stand	aru
bisbentiamine New Ingredient Name		1.5 200	mg	1	tablet tablet	EP		
dications: 1. Indication of the Drug								
egistered and Marketed ir	n Which Cou	Intries/Places : GEI UN	RMANY ITED KINGDOM					
ame of Applicant:		Δ	BC COMPANY LI	MITED				
usiness Registration No.:		0	0671890-000					
What Capacity the Appli	cant Makes	This Application: In	mporter					
usiness Address of Appli	cant: 382,	3, A, CHA KWO LING	, KOWLOON					
el No.:	2319	98414 (Contact Persor	:David Wong)					
	1234	45678 (Submitted By:V	VONG David)					
acsimile No.:								
	2319	98414 (Contact Persor	n:David Wong)					
mail Address:	prs.o	david.wong@gmail.cor	m (Contact Person:	(David Wong)				
	prot							
ame of Manufacturer:								
Name of manufacturer ap	peared on pr	oduct label of finished	product: MANU	NAME xxxxxx				
Address of manufacturer:	appeared on	product label of finishe	ed product: MAN	U ADDR XXXXXX	XXXXXX XXXXXX			
Il Company(ies) involved	in the prepa	aration of the product	t/substance					
Name of Manufacture	er Address	of Manufacturer						
1. MANU NAME xxxxxx	MANU A	DDR XXXXXX XXXX						
			DECLA	RATION OF	APPLICANT			
I wish to apply for the information given in	registration c n this applica	of the said pharmaceut tion is correct.	ical products under	r the Pharmacy and	d Poisons Ordinance.	I hereby declare that, to	o the best of my kn	owledge and belief,
Name: WONG David	I					Position he	ld:	
			e-Cert Authentic	ation:				
			Please select the	e-Cert file, e.g. C:	cert.p12			
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Guidance							Back Prin	Proceed To Subr

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 P
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roposed Name of Product (English): PRODU	JCT NAME	inter to brug		PLI	No.: PL0023/2	018 PR No.:	HK No.:	
Module 1 Module 2	Module 3	Module 4	Module 5						
Page 1 Page 2	Page 3 Pag	e 4 Page 5	Page 6	Page 7	Page 8	Page 9	Application Form		
Profity Application For priority application a. for change of nam approval of registra b. for change of prod .0 Application Form* .0.1 Name of Drug / Pharm .0.1.1 Proposed Name of P a. Proposed Name b. Proposed Name c. Names / Propose Name: PRODUC Name: PRODUC	s, the following e, dosage form i tition of the app uct certificate I Generic (*) New aceutical Produc roduct / Substan of Product (Eng of Product (Chi ed Names Used T NAME T NAME	supporting doc. or active ingredi lied product and holder, a statem Chemical Entity at / Substance ce glish):* in Other Places	Internet Service Constraints are re- ent, letter fr the original ent from main (NCE) PRODUCT N Place: C Place: C	equired: com applicant of registration cer inufacturer for the IAME CAME	surrenc tificate ne chang	ler original re of the existin ge.	gistration upon g product; or		
Name:			Place: P	lease Select		~			
1.0.1.2 Name of Active Subs	stance(s) / Ingred	lient(s) (Please lis	t below)						
No. of Componer	nt(s)* 1 🗸								
		Active	Ingredient			Active Ins	redient		
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Component 11. *	bisbentiamine				~	bisbentiamir	ne Label		
2.	None of the ab	ove			~	New Ingredie	ent Name		
2	New Ingredient	t Name							
3.	Please Select								
4.	Please Select				~				
.0.1.3 Application Type: (p	lease select one)*							
Human biologia Human chemic Human vaccine Pharmaceutica Veterinary biol Veterinary che Veterinary vac	cal pharmaceuti al pharmaceutic l substance ogical pharmace mical pharmace cine	cal product cal product eutical product eutical product							
Juidance								Edit Application	Next Pri

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.

(a						(-	
Application History Guidance						Ba	eck Print Proceed To S
he maximum upload size of singl le upload is not allowed for mod	e file is 1MB, while the m ules 2 - 5, please submit t	aximum total upl the files to Drug	load size per a Office via CD/I	pplication is 10MB. WD if necessary.			
roposed Name of Product (Englis	sh): PRODUCT NAME			PL No.: PL002	23/2018	PR No.:	HK No.:
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nte: A snariman salas nark of the r	rug/product or sample of th	a substance and	the relevant lite	rature must be submi	itted togethe	with the application Su	unlementary documentatio
nd supporting documents issued by	the health authority in the o	country of origin sl	hould be submi	ted if required.	inter togethe		ippromotivally accounterinatio
ame of the Drug / Product / Subs	tance *: * (*(*Delete as ap PRODUCT NAME	opropriate))					
se Form / Package Size(s) :							
Dose Form							
Component 1	Cream						
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tailed Qualitative and Quantitati	ve Composition :						
mponent 1							
Name of Active Ingredient(s)	Quantity (Strength Value)	Unit (Strength U	Init)	Dose Value D	ose Unit	Reference / Monogra	aph Standard
1. bisbentiamine	1.5	mg		1 ta	ablet	EP	
2. New Ingredient Name	200	mcg		1 ta	ablet		
dications:							
1. Indication of the Drug							
egistered and Marketed in Which	Countries/Places : GEI UNI	RMANY ITED KINGDOM					
ame of Applicant:	A	BC COMPANY LI	IMITED				
usiness Registration No.:	0	0671890-000					
What Capacity the Applicant Ma	kes This Application: In	nporter					
usiness Address of Applicant:	382, 3, A, CHA KWO LING	, KOWLOON					
el No.:	23198414 (Contact Person	David Wong)					
	12345678 (Submitted By:W	VONG David)					
acsimile No.:							
	23198414 (Contact Person	David Wong)					
mail Address:	prs.david.wong@gmail.con	n (Contact Person	n:David Wong)				
	prs.david.wong@gmail.con	n (Submitted By:W	WONG David)				
ame of Manufacturer:							
Name of manufacturer appeared of	on product label of finished	product: MANU	NAME xxxxxx				
ddress of Manufacturer:							
Address of manufacturer appeared	d on product label of finishe	ed product: MAN	NU ADDR XXXX	XX XXXXXX XXXXX	x		
ll Company(ies) involved in the p	reparation of the product	/substance					
Name of Manufacturer Add	ress of Manufacturer						
1. MANU NAME xxxxx MAN	NU ADDR XXXXXX XXXXX	XXXXXXX					
		DECLA	RATION O	FAPPLICANT			
				10.1			
 I wish to apply for registration formation given in this apply 	on of the said pharmaceuti blication is correct.	cal products under	er the Pharmacy	and Poisons Ordinar	nce. I hereby	y declare that, to the bes	t of my knowledge and belie
Name: WONC Devid						Desition holds	
Name: WONG David						Position neid:	
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Guidance						Ba	Submit Application

Version. : 1.1.18

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

Submission Date: 2018.08.1	39000154 17			
Ргоро	osed Name of	Product (English)	PL No.	
PROE	DUCT NAME		PL0023/2018	
The Drug Office acknowledges will provide response as soon	s your on-line s as possible.	ubmission for applicatior	of new product registration. We will process your req	quest and
or enquiries, please call us quo General enquiries:	oting this referen	nce number.		
Office H	Hours:: Mor	iday to Friday		
	<mark>9:00</mark>) am - 1:00 pm		
	9:00 2:00) am - 1:00 pm) pm - 5:45 pm		
	9:00 2:00 (up) am - 1:00 pm) pm - 5:45 pm to 6:00 pm on Monday)		
	9:00 2:00 (up (Clo) am - 1:00 pm) pm - 5:45 pm to 6:00 pm on Monday) sed on Saturdays, Sund	ays & Public Holidays)	
Tel:	9:00 2:00 (up (Clo (852) am - 1:00 pm) pm - 5:45 pm to 6:00 pm on Monday) sed on Saturdays, Sund 2) 2319 8458	ays & 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	ine Notification					ONL	NE_NOTIFIC	ATION_VIEW_01
	New	Product Registration						Archiv	ed Notifications
		Notification Date	e 🜢	Subject		⇔ Pr	oposed Name of Product 🛔	PL No. ≜	Payment Statuts
You are login as	Open	12.01.2021 10:34:23		Application Payment Request		VOOIN	500 TABLETS SOOMO	PL0975/2016	Paid
	Open	20 11 2020 17:13:29		Certificate Payment Request		JAVA 8	START	PI 0004/2020	Paid
Login date and time 28.01.2021 15:06	Open	20.11.2020 16:45:42		Screening Application		PROD	JCT NAME	PL0023/2018	N/A
Online Notification	COR	Р						Archiv	ved Notifications
My Product Search		Notification Date \$		Subject	\$	HK No.	\$ Nam	e of Product	\$
	Open	12.01.2021 17:40:32	Applicaton With	drawal Rejected Notification		HK42660	CALCION UNISON TAB 3	JUMIG	
+ New Registration	Open	12.01.2021 17:38:55	Application Sub	mitted Notification		HK42660	GALOIUM UNISON TAD S		
+ Change of Registered	<u>Open</u>	12.01.2021 17:38:55	Application Scre	eening Notification		HK42660	CALCIUM UNISON TAD S	9MO	
+ Renewal of	Rene	ewal 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 Notific	ation		DRUG NAME XXXX T	AB 50MG	1	
+ Payment	Cano	cellation Request							
Application History		Notification Date \$		Subject	\$	HK No.	\$ Nan	e of Product	\$
, approximit in the corry	Open	26.01.2021 15:07:50	Cancellation Re	egistration Request Submitted Notification		HK31199	EPILIM FREEZE-DRIED P	DR FOR IV INJ	400MG
+ User Profile									
+ System	Non	Pharmaceutical Prod	uct Alert						
		Notification Date	\$	Subject		\$ HK No. \$	Name	of Product	4
Logout	Open	11.02.2016 04:00:00	Renewal Pe	nding Reminder		HK60464	OCTEOTIN 599 CAP 599MO	-	
	Open	12.01.2016 04:00:02	Renewal Pe	nding Notification		HK60464	OSTECTIN 500 CAD 500MC	_	

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	b							Ar	chived Notifications
My Product Search		Notification Date \$		Subject	¢	нки	No.	\$ N	ame of Produ	t \$
	Open	12.01.2021 17:40:32	Applicaton Wit	ndrawal Rejected Notification		HK42660		CALCIUM UNISON TAE	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	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 🗢
	<u>Open</u>	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	luct Alert							
Logout		Notification Date	\$	Subject		¢ H	K No. 🗢	Na	me of Produc	¢ (
Logoui	Open Open	11.02.2016 04:00:00	Renewal P	ending Reminder		HK60	1464	OUTLOTIN 600 CAP 500N	.	
	Open	12.01.2016 04:00:02	Renewal P	ending Notification		HK60	1464	OVIED HALFOO CAD SOON	<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
▲Application(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_NC	TIFICATION_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	ding information by post or in person to the drug office:	
Drug Registration and Import / Export (3/F, Public Health Laboratory Centre 382 Nam Cheong Street Shek Kip Mei Kowloon Hong Kong	Control Division	
For enquiries, please call our hotline at (a product under the process of new product	(852) 2319 8458 or email to prs_enquiry@dh.gov.hk quoting the reference number of this application or the PL number of PR ct registration.	l 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.

Nev	Application Pa	yment					
						Print Ready to Pa	ay)
	Application Received Date	PL No.	PR No.	\$	Proposed Name of Product \$	Payment Status \$	
	31.05.2017 16:16	PL0070/2017			MY 20170531 1559	Ready for Application Payment	
Nev	Application Pa	vment					
INCV		yment				Print Ready to Pa	ay
	Application Received Date	PL No.	PR No.	¢	Proposed Name of Product \$	Payment Status 🗢	
	31.05.2017 16:16	PL0070/2017			MY 20170531 1559	Ready for Application Payment	
中 列							
-							
	選ば手以表機 ● Microsoft XPS Docume Print to Evernote ■ RM335HP2055DN (HP マ 状態: 就緒 位置: 註解:	ent Writer 佛徳 LaserJet P2055 可列印到檔案()	至 OneNote 2010) 客好設定(R) 零技印表機の)				
	頁面範圍 ● 全部(L) ◎ 選擇範圍(T) ● 本頁(U) ◎ 頁數(3): 1 請輸入一個頁碼或單一分頁算 例如 5-12	(分數(C): □自動分頁(0) 0 </td <td></td> <td></td> <td></td> <td></td> <td></td>					
		(1)440 (4X/M 5+(A)				

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

Online Payment Service						
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 transaction reference number or PRINT this page for making enquiry on the payment status when necessary. After pressing the 'Pay' button, please DO NOT leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful. 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. Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use other available payment methods. We apologise for any inconvenience caused. Different credit card issuers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please contact your card issuer if you want to learn more about the J/Secure, Mastercard SecureCode and Verified by Visa service. 					

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	uct Regis	stration			Print Receipt Close			
Payment Refere	ayment Reference No.: DHPRS-201907261629-14197							
Payment Method	d: Cash							
Type of Paymen	t: Appli	Application Fee						
Transaction Tim	e: 16.01	16.01.2020 11:20:30						
Application R	eceived Date	Reference No.	PR No.	Product Name				
25.07.20	19 15:33	ANP20199000015	PR0014/2019	TESTBBC				
Please kindly q	uote the above	Payment Reference Number for enquir	ies.					
General Enquirie	es:							
Office Hours:	Monday to Fri	day						
	9:00 am - 1:0	0 pm						
	2:00 pm - 5:4	5 pm						
	(up to 6:00 pr	n on Monday)						
	(Closed on Saturdays, Sundays & Public Holidays)							
Tel:	(852) 3974 41	75						
Email:	prs2_info@dh	1.gov.hk						

Print Receipt Close
Name of Company		Payment Date
公司名稱		繳費日期
CERT HOLDER 6		30.1.2015
Barmont Defenses No.	DUBBS 201501200212 00574	
Payment Reference No: 付款编號:	DHPRS-201501300213-90574	
EGIS Reference No: EGIS編號:	A201501300000043	
Payment Method:	PPS	
付款方法:		
Payment Amount:	HK\$1,100.00	
付款金額:		

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. 參考編號
indapamide-Trial Prolonged Relea ng (AP8)(CH6)	se 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	ne Notification					0	NLIN	NE_NOTIFIC	TION_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		Applcation Payment Request		VOOINS	00 TABLETS SOUNG		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	•							Archiv	ed Notifications
My Product Search		Notification Date \$		Subject	\$ НК	No. a	÷ !	Name	of Product	¢
	Open	12.01.2021 17:40:32	Applicaton Wit	hdrawal Rejected Notification	HK42660		CALCION ONISON TA	D 301	UMG	
+ New Registration	Open	12.01.2021 17:38:55	Application Su	bmitted Notification	HK42660		OALOUM UNISON TA	B 900	omo	
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sc	reening Notification	HK42660		CALCIUM UNISON TA	.D 904	940	
+ Renewal of Registration	Rene	wal of Registration							Archiv	ved Notifications
-		Notification Date \$		Subject	\$	N	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	E XXXX TA	AB 50MG		1	
+ Payment	Canc	ellation Request								
Application History		Notification Date \$		Subject	\$ HK	No.	¢ I	Name	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	\$	Subject	ф Н	K No. 🜩	N	ame (of Product	¢
Logout	<u>Open</u>	11.02.2016 04:00:00	Renewal P	ending Reminder	HK60)464	OCTECTIN 500 CAP 500	40		
	Open	12.01.2016 04:00:02	Renewal P	ending Notification	HK60	0464	OSTECTIN 500 CAD 5001	AC	-	

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

	Online	Notification					ONL	INE_NOTIFIC	ATION_VIEW_01
T	New Pro	duct Registration						Archive	ed Notifications
		Notification Date	e \$	Subject		\$ F	roposed Name of Product \$	PL No. \$	Payment Statuts
You are login as	Open 1	2.01.2021 10:34:23		Application Payment Request		VOOR	1 500 TABLETS SOOMO	PL0975/2016	Paid
	Open 2	0.11.2020 17:13:29		Certificate Payment Request		JAVA	8 START	PL0004/2020	Paid
Login date and time 28.01.2021 15:06	Open 2	0.11.2020 16:45:42		Screening Application		PRO	DUCT NAME	PL0023/2018	N/A
Online Notification	CORP							Archiv	ed Notifications
My Product Search		Notification Date \$		Subject	¢	HK No.	¢ Nan	e of Product	¢
	Open	12.01.2021 17:40:32	Applicaton With	hdrawal Rejected Notification		HK42660	CALCION UNISON TAB 3	JUMG	
+ New Registration	Open	12.01.2021 17:38:55	Application Sul	bmitted Notification		HK42660	OALOUM UNISON TAD S	90MO -	
+ Change of Registered Particulars	<u>Open</u>	12.01.2021 17:38:55	Application Sci	reening Notification		HK42660	CALCIUM UNISON TAD 9	39MO	
+ Renewal of	Renewa	al of Registration						Archiv	ved Notifications
Registration		Notification Date \$		Subject	\$		Name of Product	\$ N	o. of Renewals 🜲
 Request to Cancel Product Registration 	Open	27.01.2021 04:00:14	Renewal Notifi	ication		DRUG NAME XXXX	TAB 50MG	1	
+ Payment	Cancell	ation Request							
Application History		Notification Date \$		Subject	\$	HK No.	\$ Nar	ne of Product	\$
, approxition (notor)	Open	26.01.2021 15:07:50	Cancellation R	Registration Request Submitted Notification		HK31199	EPILIM FREEZE-DRIED F	DR FOR IV INJ	400MG
+ User Profile									
+ System	Non Ph	armaceutical Prod	uct Alert						
		Notification Date	\$	Subject		\$ HK No. \$	Name	of Product	4
Logout	Open	11.02.2016 04:00:00	Renewal P	ending Reminder		HK60464	OCTECTIN 500 CAP 500MO	-	
	Open	12.01.2016 04:00:02	Renewal P	ending Notification		HK60464	OSTECTIN 500 CAD 500MC	_	

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	PL No. :	PL0031/2017	
ABC COMPANY LIMITED	PR No. :	PR0038/2017	
16.01.2020 11:13	HK No. :	HK63573	
Online Malifantian	Proposed Name of Product (English) :	TEST 2016022701	
Online Noulication	Notification Detail :	Cert Payment Notification.pdt	
My Product Search	Attachment(s) :	2	
+ 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,	ntrol Division	
Request to change name and/or address of the certificate holder	Kowloon, Hong Kong	52) 3974 4175 or email to ors2. Info@rdh onv.bk quoting the reference number of this application or	the PL number of PR number of your product
+ Request to Cancel Product Registration	under the process of new product registr		
+ Payment			
Application History			
+ User Profile			
+ Printing Service			
+ System			
Logout			

PHARMACY AND POISONS ((CHAPTER 138)	ORDINANCE	
香港法例第138章藥劑業及	毒藥條例	
		Date 日期: 30/01/2015
NOTIFICATION OF PAY 徽黄通知書	MENT	
A. Payment Particulars 甲:繳費詳情		
This is to notify you to pay for the following application(s)/ 用译如 關下鄉东下別由講住計冊之费田	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		UV\$1 270
藥劑製品註冊證明書 (HK\$1,370)	1	HK\$1,570
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
Ť	New Product Registration	
	Notification Date :	17.08.2018 15:01:28
You are login as WONG	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) :	
my rouder ocaren	1 Go To Cortificate Payment :	
+ New Registration	1. Go To Certificate Payment .	
+ Change of Registered Particulars	2. In alternative to (1) you may send the	outstanding information by past or in parson to the Drug Office:
L Denouval of	Drug Registration and Import / Export (Subtatining monitation by post of in person to the brug once.
Registration	3/F, Public Health Laboratory Centre	
+ 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 registr	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 Paymen	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
Certifica	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

on 🔁	nline Payment Service	9							
Help	Please select the paym	ent method :							
Customer Service Hotline 2319 8461 Email pharmweb@ dh.gov.hk	Type of Service Transaction Date Transaction Reference	DH Drug Office 29-03-2023 DHPRS-202303291025-94191							
	Number Total Amount Payment Method*								
		Cancel Payment Pay							
	 Please take note of the 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 the Some users may receiv experience such a prob caused. Different credit card issi 	 Please take note of the transaction reference number or PRINT this page for making enquiry on the payment status when necessary. After pressing the 'Pay' button, please DO NOT leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful. 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. Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use other available payment methods. We apologise for any inconvenience caused 							
	contact your card issue	if you want to learn more about the J/Secure, Mastercard SecureCode and Verified by Visa service.							

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 Prod	uct Registration			Print Receipt Clos
Payment Refer	ence No.: DHPRS-201501	300534-90575		
EGIS Reference	No.: A20150130000	0026		
Payment Metho	d: PPS			
Type of Paymer	nt: Certificate Fee			
Transaction Tim	ne: 30.01.2015 05:3	6:24		
Delivery Metho	d: Collect in Perso	n in Drug Office		
Certificate Colle	ection Date: 06.02.2015			
Applicatio 29.01 The Drug Offic response as s	n Received Date .2015 14:02 e acknowledges the receipt of oon as possible.	Reference No. ANP20159000003 your payment of HK\$1,370.00 for applica	PR No. PR0002/2015 tion fee regarding the above prod	Product Name Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6) duct(s). We will process your application and will provide
Applicatio 29.01 The Drug Offic response as s Please kindly	in Received Date 1.2015 14:02 e acknowledges the receipt of oon as possible. quote the above Payment Refe	Reference No. ANP20159000003 your payment of HK\$1,370.00 for applica erence Number for enquiries.	PR No. PR0002/2015 tion fee regarding the above prod	Product Name Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6) duct(s). We will process your application and will provide
Applicatio 29.01 The Drug Offic response as s Please kindly General Enquiri	in Received Date 1.2015 14:02 ie acknowledges the receipt of oon as possible. quote the above Payment Refe es:	Reference No. ANP20159000003 your payment of HK\$1,370.00 for applica erence Number for enquiries.	PR No. PR0002/2015 tion fee regarding the above prod	Product Name Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6) duct(s). We will process your application and will provide
Applicatio 29.01 The Drug Offic response as s Please kindly General Enquiri Office Hours:	n Received Date 1.2015 14:02 e acknowledges the receipt of 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	Reference No. ANP20159000003 your payment of HK\$1,370.00 for applica erence Number for enquiries.	PR No. PR0002/2015 tion fee regarding the above prod	Product Name Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6) duct(s). We will process your application and will provide
Applicatio 29.01 The Drug Offic response as s Please kindly General Enquiri Office Hours: Tel:	n Received Date 1.2015 14:02 e acknowledges the receipt of 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 (852) 23198458	Reference No. ANP20159000003 your payment of HK\$1,370.00 for applica erence Number for enquiries.	PR No. PR0002/2015 tion fee regarding the above prod	Product Name Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6) duct(s). We will process your application and will provide

Name of Company		Payment Date
公司名稱		繳費日期
CERT HOLDER 6		30.1.2015
Payment Reference No: 付款編號: EGIS Reference No: EGIS編號: Payment Method:	DHPRS-201501300534-90575 A201501300000026 PPS	
付款方法: 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	e Notification						ONLINE_I	OTIFICATION	VIEW_01
T	New Pro	oduct Registration							Archived No	tifications
	No relat	ed notifications								
You are login as ORG Trial One TESTING LIMITED Login date and time	CORP								Archived No	tifications
27.01.2021 09:43		Notification Date \$		Subject	¢	HK No.	¢	Name of Pr	oduct	¢
Opline Natification	Open	12.01.2021 17:44:04	Application Screening Notifical	ion		HK41190		PRODUCT NAME XXXXX XXXX		
	Open	05.06.2020 11:00:01	Application Submitted Notifical	ion		HK41190		PRODUCT NAME XXXXX XXXX		
My Product Search	Open	03.10.2019 11:55:37	Application Submitted Notificat	ion		HK37565		PRODUCT NAME XXXXX		
	Open	04.03.2019 11:33:13	Application Approval Notification	n		HK31199		EPILIM FREEZE-DRIED PDR FO	R 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	n		HK42175		APT-INDOMETHACIN 25 CAP 25	MG	
Registration Application	Open	21.08.2018 18:25:53	Application Clarification Notific	ation		HK41190		PRODUCT NAME XXXXX XXXX		
, approxim	Open	21.08.2018 18:20:50	Application Screening Notificat	ion		HK41190		PRODUCT NAME XXXXX XXXX		
Application Status - Action Required	Open	21.08.2018 18:19:47	Application Submitted Notifical	ion		HK41190		PRODUCT NAME XXXXX XXXX		
 Not Submitted Application Submitted 	Open	21.08.2018 18:07:37	Application Submitted Notifical	ion		HK37565		PRODUCT NAME XXXXX		
Withdraw application	Renewa	I of Registration							Archived No	tifications
 Change of Registered Particulars 		Notification Date \$		Subject	¢		Na	ne of Product	No. of Re	enewals 💠
	Open	27.01.2021 04:00:14	Renewal Notification			DRUG NAME XXX	CX TAB	50MG	1	
+ Renewal of Registration	Cancella	ation Request								
Product Registration		Notification Date \$		Subject	\$	HK No.	\$	Name of Pr	oduct	\$
+ Payment	Open	26.01.2021 15:07:50	Cancellation Registration Requ	uest Submitted Notification		HK31199		EPILIM FREEZE-DRIED PDR FO	R IV INJ 400MG	
Application History	Non Pha	armaceutical Produ	uct Alert							
+ User Profile	No relat	ed notifications								
+ System										
Logout										

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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		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.	۵	PR No.	۵	Proposed Name of Product (English)		Application 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) \$		Application Status	\$
2018.07.18	PL0019/2018				TEST 2015	Screening		
Date of Withdrawal Request :	20.08.2018							
Reason(s) of Withdrawal :	The withdraw reason	state h	ere					
						•	Save	Cancel

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".

	New	Product	Registration Withdr	awal					
									Withdraw application
You are login as ORG Trial			Application Date \$	PL No.	\$	PR No.	Proposed Name of Product (En	iglish) 💠	Application Status \$
One TESTING LIMITED		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									
			2015 copyright I	mportant notices	Last Rev	ision Date: 02 Sep 2020	Version: 1.0.99 (PP)		

Ť	New Pro	oduct Reg	istration					N	EW_PRODUCT	_REGISTRA	FION_STAT	
	New Subm	ission										
You are login as ORG Trial	InitiateNew P	roduct Registrat	ion									
TESTING LIMITED Login date and time 20.08.2018 14:24	Action Red	quired										
	¢	Application Date	Application ID	¢ ^{PL No.} ¢	PR	No. ¢	Proposed Name of Product (English)	No. of submission \$	Application Status	Status Date	Payment Status	
Online Notification	1	17.07.2018	ANP2018900010	08 PL0010/2018			TEST ECERT CASE1	1	Withdraw Application Request	20.08.2018	No	
- New Registration	2	31.07.2017	ANP2017900007	9 PL0082/2017			TEST LOGIN2	1	Request for Outstanding Information	22.06.2018	No	
Initiate New Product Registration Application	3	31.07.2017	ANP2017900007	78 PL0081/2017			TEST USER LOGIN 2	1	Request for Outstanding Information	14.11.2017	No	
Application Status	Not Submi	tted										
- Action Required - Not Submitted	φ.	Latest Draf	t Date 💠	Application ID	\$		Proposed Name of Product (E	nglish)	\$	Application 9	Status 🗢	
- Application Submitted	1	10.08.2018	AN	IP20189000153	1	EST NCE	2		Pend	ling		
Withdraw application	2	18.07.2018	AN	IP20189000132	1	EST OPE	N FILE CASE 3		Pend	ling		
+ Change of Registered	Application Submitted											
Particulars	٠	Application Date	Application ID	♦ PL No. ♦	PR	^{No.} ¢	Proposed Name of Product (English)	No. of submission \$	Application Status	Status Date €	Payment Status	
+ Renewal of Registration	1	06.08.2018	ANP2018900013	3 PL0019/2018			TEST 2015	1	Withdraw Application Request	20.08.2018	No	
+ Interview	2	10.08.2018	ANP2018900015	1 PL0022/2018			TEST NCE CASE	1	Application Submitted	15.08.2018	No	
+ Request to Cancel Product Registration	3	24.02.2017	ANP2017900002	PL0030/2017	PR0036	/2017	TEST 2017022401	1	Evaluation	31.07.2018	Yes	
+ Payment												
Application History												
+ User Profile												
+ System												
Logout												

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

	Applicatio	Application History											
T	New Product Registration										Total Number of Application Records:		
You are login as	Application Date	PL No.	PR No.	¢ Н	K No. ♦		Name of Proc	luct	\$	Payment Statuş	Status	Last U Da	pdated te
Login date and time 20.08.2018 15:46	06.08.2018	PL0019/2018				TEST 2015				No	Withdraw Application Approved	06.08.20	18
Online Notification	Change of R	egistered P	articulars							Total	Number of Ap	plication Re	cords:1
My Product Search	Application Date	F	lef No.	¢ Н	K No. ♦	Nan	ne of Product	¢ 0	Change ategories \$	Payment Statuş	Status	Last U Date	pdated _{\$}
+ New Registration	23.05.2018	CORP-HK56673	-201851497	HK566	73	VICK-CLONA	ZEPAM TAB 2MG	5		Certificate Fee Paid	Application Withdrawn	23.06.20	18
+ Change of Registered Particulars	Renewal of F	Registration	1							Total	Number of App	lication Re	cords:0
+ Renewal of Registration	Expiry Date 🜲	HK No. 👌	2			Name of Prod	uct		\$	Applicati	ion Status	Last Up Da	odated te
+ Interview	Termination	of Product	Registration							Total	Number of App	lication Re	cords:0
+ Request to Cancel	Application Date		Ref No.	\$	HK N	D. ¢	Ná	ame of Pro	duct	\$	Status 🗢	Last Updat	ed Datte
	Interview									Total	Number of App	lication Re	cords:0
+ Payment	Applicati	on Date	1	Su	bject		\$	A	oplication	\$	5	status	\$
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	ı											
		Notification E)ate 💠			Subject			\$	Prop	oosed Name of Prod	luct 💠	PL No.	Payment Statuts
You are login as	<u>Open</u>	20.08.2018 15:45:31		Confirmation f	for withdrawal					TEST 201	5		PL0019/20	118 N/A
	<u>Open</u>	14.11.2017 11:06:22		Application Pa	ayment Reque	est				TEST US	ER LOGIN 2		PL0081/20	117 Unpaid
Login date and time 17.08.2018 13:44	<u>Open</u>	03.04.2017 10:47:03		Application Pa	ayment Reque	est				TEST 201	7022401		PL0030/20	17 Paid
Online Notification	CORP													
My Product Search	Open	NOTIFICATION Date @	Application Scr	rooping Notificat	Subject			•	HK NG). ç	WALKTRUOUGU	Name	e of Product	÷
	Open	07.08.2018 09:52:51	Application Sub	omitted Notificat	tion				HK63517		WALKTRHOUGH			
+ New Registration														
+ Change of Registered Particulars	Renew	val of Registration			Subject			*		Nar	as of Product		A	No of Renewals 🛎
+ Renewal of	Open	29.06.2018 04:20:28	Renewal Notific	ation	Subject			•	APO-LEVETIRA	CETAM T	AB 500MG		• 1	No. of Renewals \$
Registration	Open	23.06.2018 02:13:33	Expired Product	t Notice					VICK-CLONAZE	EPAM TAE	2MG		1	
+ Interview	Cance	Ilation Request												
+ Request to Cancel Product Registration		Notifica	tion Date	\$		Subject	¢		HK No.	¢		Name o	of Product	\$
+ Payment	Intervi	iew												
Application History				Noti	ification Date					\$		S	ubject	¢
+ User Profile	Non P	harmaceutical Prod	luct Alert											
+ System		Notificat	tion Date	\$		Subject	\$		HK No.	\$		Name o	of Product	\$
	Onlir	ne Notification										ONLI	NE_NOTIFI	CATION_VIEW_01
T	New P	Product Registration	n											
	Notificat	tion Date :	20.08.20	18 15:45:31										
You are login as	PL No. :	:	PL0019/2	2018										
Login date and time	PR No.		-											
20.08.2018 15:46	HK No.		-	45										
Online Notification	Notificat	tion Dotail :	n): 165120	15										
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	I the outstanding	g information b	y post or in	person to the	Drug Offi	ice:						
+ Interview	Drug R 3/F, Pu	Registration and Import / Exp ublic Health Laboratory Cent	oort Control Divis tre	sion										
+ Request to Cancel Product Registration	Shek K Hong K	Kip Mei Kowloon Kong												
+ 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	o prs2_info@	@dh.gov.hk q	uoting the	refe	rence number o	f this app	lication or the PL n	umber o	of PR numbe	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:										
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	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										
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										
. Deversent	+ 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 Next									

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)			
You are login as ORG Trial Dne			*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 w	*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 	TESTING LIMITED			
Initiate CORP Application	HK No. Product Name			
Application Status	Add Product) (Remove Product) (Select from all product)		_	
- Not Submitted - Application Submitted	Please tick the appropriate change category and state the nature of the	cnange	Priof Description of Change and Descen	
Withdraw application	+ 1 Specification		bier Description of Change and Reason	
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)			
* Fayment	+ 7 Excipients			
Application History	+ 8 Indication / Dosage / Route of Administration			
+ User Profile	+ 9 Other			
+ System				\sim
Logout			L	Pack Novt
				Dack 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)			
You are login as ORG Trial One			*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	Justification for same category/sub-category application			
My Product Search	<u></u>			
+ 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	9.	
- 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)			
, a a a a	+ 7 Excipients			
Application History	+ 8 Indication / Dosage / Route of Administration			
+ User Profile	+ 9 Other			
+ System				\bigcirc
Logout			L	Back Novt
				DOCK NEXL

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
			Commin

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	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-caunder processing	ategory which is	
Online Notification	diructi processing.		
My Product Search	0		
+ New Registration	Certificate Holder Name:		
- Change of Registered Particulars			
Initiate CORP	HK No. Product Name		
Application	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	change.	
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			\sim
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		
			~
			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.
- 2) 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	hted, and Other Suppor	ting Documents Close Back	elete Save & Close						
	For uploading Clean	Copy of Supporting Documents, please i	efer to Step 3	-	Next						
You are login as VMG TEST USER1 TEAMAN COMPANY	Application Type: Application Received Dat	Certificate holder initiated - New CORP ap e: 07.12.2021	plication								
.ogin date and time 7.12.2021 10:47	Product Selected:										
	# HK No.	Product Name		Proposed Effective Date 1	7						
Online Notification	1 HK63722	PRODUCT_20211116		1 week after approval 1 weer after approval							
My Product Search											
+ New Registration	*Remarks 1. For CORP application sub	omitted on or after 1 December 2021, the available options i	or the effective date proposed by th	he applicant would only include 1 week or	1 year after approval.						
 Change of Registered Particulars 	2. Applicants can apply for c twice ¹ .	hange of implementation date (CIMP) subsequent to the ap	proval of CORP, and for each appre	oved CORP, the applicant can apply for C	IMP no more than						
Initiate CORP Application	3. CORP shall be implement	led within 2 years after approval ¹ .									
Application Status	¹ This requirement applies to CORP approved on or after 1 December 2021.										
Action Required Not Submitted	Change Category and Supp	porting Documents. (Only relevant supporting documen	ts will be processed)								
Withdraw application	The recommendation resol	Letter if no highlighed Copy ution of scanning for the supporting document is 360dp	i								
DO Request	i. Letter summarising th	ne proposed changes									
Application	Remark	li i la	Docun	nents File Name							
Change Effective Date											
+ Renewal of Registration			UPL No File	OAD e Chosen							
+ Submission of Other Post-registration	Add File Remove File										
Supplement	ii. Proposed label(s) wit	th the change(s) underlined or highlighted*									
+ Interview	Remark # Please	e specify the name of the Uploaded File in "Remark", (if apr	Docun licable)	nents File Name							
Request to change name and/or address of the certificate holder			UPL	OAD							
+ Request to Cancel			No File	e 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	gistered Pa	Parti	icula	ars	s ((СС	ЭR	(P)	Ар	plica	atio	n																
Ť	Step 2 For up	2: Upload ploading	ling Highligh Clean Copy	ighte <mark>py o</mark> l	ed C of Su	Cop upp	py por	of rtir	Sung	uppo Doc	orti <mark>cun</mark>	ing D nents	Doc <mark>s, p</mark>	um lea	ents <mark>se re</mark>	fer to	o Ste	p 3					(Close	Back	Delete		ave & Clos	e (Vext
You are login as CHAN	Applic Applic	cation Type: cation Recei	: ived Date:			Ce 20	ərtifi).07.	icate 1.201	te ho 18	older	· initia	ated - N	New	COR	RP appl	lication														
HONG KONG RED CROSS BLOOD TRANSFUSION	Product	Selected:																												
SERVICE Login date and time	#	HK No.		F	Produ	uct N	Nan	me													Prop	osed I	Effecti	ve Da	te					
01.08.2018 18:11	1	HK44456		N	MON	IOFI	IX-V	VF H	HUN	MAN	FAC	TOR I	IX FO	OR IN	VJ 5001	U				Г	•	Expec	ted D	ate:						
Online Notification																					01	Jaysa	aπer a	pprov	ai:	~				
My Product Search	2	HK46073		1	INTR	RAG/	AM	PN	NOR	RMAL	L IMN	MUNO	GLC	BUL	IN INJ	6%														
	3	HK58570		F	ALBU	JME	EX 5	5 IN	VF 12	2.5G	\$/250	ML																		
+ New Registration	4	HK58571		A	ALBU	JME	EX 2	20 II	INF 1	10G/	/50M	IL .																		
 Change of Registered Particulars 	Change	Category a	nd Supporting E	g Doc	cume	ents.	i. (O)nly	y rel	levan	nt su	ıpporti	ting o	docu	iments	will be	e proc	essed)												
Initiate CORP Application	Please u The reco	pload Deck	aration Letter if on resolution of	if no of sca	o high annir	nligh ng fi	hed for t	l Co the	opy sup	pport	ting (docun	ment	t is 3	60dpi															
Application Status	5 Regi	istration	Certificate H	e Hol	lder	r																								
 Action Required Not Submitted Application Submitted 	5.1 Ch i. Copy o	ange in i of the Certif	name and / o	/ or orpora	add	dre: n on) SS n the	e C	f th Chan	1e c i nge o	:urre of Na	ent n ame (fo	r egi or in	i stra icorp	ation orated	certi I comp	ficat any o	e hol nly)	der											
Withdraw application			Remark																	Doci	uments	File	Name							
DO Request Application										_									$\hat{}$	Up	load									
+ Renewal of Registration	Add Fil	e Remove	File																	NOT	ile Uli	USEII								
+ Submission of Other Post-registration Supplement																							(Close	Back	Delete)(\$	ave & Clos	e)(I	Vext

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

Expected Date:							
Days after approximation	0	3 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:		•	
	31 32 33 34 35 36 37 38 39 40 41 42 43 44 45	*	
cuments File Name	46	h	
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	Documents	s File Name	The same file
	# Please specify the name of the Uploaded File in "Remark". (if applicable)			been uploaded in another location in this submission #
		Upload test201707	7 <u>02.pdf</u>	
Add File R	emove File			
3 Package	Incort			
o i achage	insen			
3.1 Chang Proposed p	e in package insert ackage insert with the change(s) underlined and highlighted*			
3.1 Chang . Proposed p	e in package insert ackage insert with the change(s) underlined and highlighted* Remark	Document	s File Name	The same file
3.1 Chang Proposed p	e in package insert ackage insert with the change(s) underlined and highlighted* Remark # Please specify the name of the Uploaded File in "Remark". (if applicable)	Document	s File Name	The same file has already been uploaded in another location in this submission #
3.1 Chang Proposed p	e in package insert ackage insert with the change(s) underlined and highlighted* Remark # Please specify the name of the Uploaded File in "Remark". (if applicable)	Document	s File Name	The same file has already been uploaded in another location in this submission #

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	ticulars (CORP) Application			_				
T	Step 2 For up	2: Upload	ding Highligh Clean Copy	ted Copy of Supporting Documents of Supporting Documents, please refer to Step 3			Close	Back	Delete	Save & Close) Nex:
You are login as CHAN	Applic Applic	ation Type ation Rece	: ived Date:	Certificate holder initiated - New CORP application 20.07.2018							
HONG KONG RED CROSS BLOOD TRANSFUSION	Product	Selected:									
Login date and time	#	HK No.		Product Name		Proposed Effe	ctive Date	•			
Online Notification	1	HK44456		MONOFIX-VF HUMAN FACTOR IX FOR INJ 500IU		 Expected Days after 	Date:	: 🗸			
Max Desident Consult	2	HK46073		INTRAGAM P NORMAL IMMUNOGLOBULIN INJ 6%							
Wy Product Search	3	HK58570		ALBUMEX 5 INF 12.5G/250ML							
+ New Registration	4	HK58571		ALBUMEX 20 INF 10G/50ML							
 Change of Registered Particulars 	Change	Category a	nd Supporting D	ocuments. (Only relevant supporting documents will be processed)							
Initiate CORP Application	Please u The reco	pload Declommendation	aration Letter if r on resolution of s	o highlighed Copy canning for the supporting document is 360dpi							
Application Status	5 Regi	stration	Certificate H	older							
 Action Required Not Submitted Application Submitted 	5.1 Ch i. Copy o	ange in of the Certif	name and / o fication of Incorp	r address of the current registration certificate hold pration on the Change of Name (for incorporated company only)	ler						
Withdraw application			Remark		Docu	uments File Nan	ne				
DO Request Application						pload					
+ Renewal of Registration	Add File	e Remove	e File		NOT	lie Chosen	_				_
+ Submission of Other Post-registration Supplement							Close	Back	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 F	Particulars (CORP) Application			
Ť	Step 3: Change Product	Particulars		Close Back Delete	Save & Close Next
	Application Type:	Certificate holder initiated - New Cl	ORP application		
You are login as ORG Trial One	Application Received Date:	21.08.2018			
TESTING LIMITED Login date and time	Product Selected:				
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	on 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	ıtre]
+ 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:		
Application History	d.				
+ User Profile	Contact Person for Application*:	this Trial	Phone No*:	23198414	
+ System	Position*:	Trial	Email*:	trial@test.com	
Logout	e. Business Type*:	nufacturer			
	 Licensed who 	lesale dealer			
	 Local branch, Licensed who pharmaceutical procession 	subsidiary, representative, agent or distributor lesale dealer who has entered into a contract w duct or substance	of a manufacturer outside Hong Kong vith the licensed manufacturer under whi	ch the licensed manufacturer is required to	manufacture the
	1.0.6.2 Staff responsible for I	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	formation/sample			
	* 7 Copy of business registra	ation certificate. (Reference for 1.0.6.1 of Pa	ige 3) 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.

	Change of Registered	d Particulars (CORP) Application					
	Application Summary			Close	Back Delete	e) Save & Close	Confirm & Submit
	Application Type: Application Received Date:	Certificate holder initiated - New CORP appli 21.08.2018	ication				
You are login as OKG That One	·						
TESTING LIMITED Login date and time	Product Selected:	Berteitting		Proper	1 Effective Dat		
21.08.2018 17:56	# HK NO.	Product Name		Рюрозе	d Effective Date		
Online Notification	1 HK37565	PRODUCI NAME XXXXX					
Mr. Destinat Pageb	2 HK41190	PRODUCT NAME XXXXX XXXX					
My Product Search	Change Category:						
+ New Registration	Particulars Proposed to Chang	ge		Brief Der	scription of Chan	ige and Reason	
 Change of Registered Particulars 	5.1 Change in name and / or a	address of the current registration certificate holder		change c	company location	1	
Initiate CORP Application	Supporting Documents 5 Registration Certific	s: ate Holder					
Application Status - Action Required - Not Submitted	5.1 Change in name an i. Copy of the Certification of	nd / or address of the current registration Incorporation on the Change of Name (for incorporated	certificate holde	ər			
- Application Submittee	Remark			Documents File N	Name		
Withdraw application				No File Chosen			
+ Renewal of Registration							
+ Submission of Other Post-registration Supplement		DECL	ARATION				
+ Request to Cancel Product Registration	DECLARATION BY T changes have been i	THE APPLICANT: I hereby declare that to the best of my ke identified and are being applied for the approval to change	nowledge and belief the the registered particula	at the information ar(s).	given in this app	lication is correct a	and all the
+ Payment							
Application History							
+ User Profile	The product / subs	stance					
+ System	is supplied to the Depart of the supplied to the set of the set	artment of Health via tender or direct purchase agreements					
Logout	O Is not supplied to the D	Department of Health via tender or direct porchase agreeme	ants.				
				Close	Back Deletr	e Save & Close	Confirm & Submit

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	ered 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 s	hould be subjected to o	ur final approval	L.						
TESTING LIMITED Login date and time	For	enquiries, please ca	all us quoting this refere	nce number.							
21.08.2018 17:56	Gen	eral enquiries:									
Online Notification			Office Hours:	Monday to Frid	day						
My Product Search				9:00 am - 1:00	i pm						
+ New Registration				2:00 pm - 5:45	i pm						
Observe of Deviational				(up to 6:00 pm	i on Monday)						
Particulars		(Closed on Saturdays, Sundays & Public Holidays)									
Initiate CORP			Tel:	(852) 2319 84	58						
Application Status			Email:	prs2_info@dh.	.gov.hk						
- 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. Pro	posed 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				
+ Request to Cancel	Chan	ge Category:									
Product Registration	Particu	ilars Proposed to C	hange				Brief Description of Change and Reason				
+ Payment	5.1 C	hange in name and	I / or address of the curr	rent registration	certificate holder		change company location				
Application History	Supp	orting Docum	ents:								
+ User Profile	5 Reg	istration Cert	ificate Holder								
+ System	5.1 Cl i. Copy	hange in nam of the Certificatio	e and / or addres	is of the cu the Change of	rrent registration certificate ho Name (for incorporated company only)	lder					
Logout		Rema	ark			Docum	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

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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

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 1	Proposed to Chang	e	Change Re	eason

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

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

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

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

	Ch	ange of Re	egistered Particu	llars (CORP) Ap	plication			CORP_APPI	LICATION_STATUS
	Please	e be reminded that Submission	for approved application(s), y	ou are required to submit app	lication(s) for ch	ange of implementation date	5 working days be	fore the effective dat	e, if necessary.
You are login as ORG Tria	I Initia	te New CORP App	plication						
Dne TESTING LIMITED Login date and time 26.01.2021.11:20	Acti	on Required							
	\$	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	4	Application	Not Necessary
My Product Search						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Lyundulou	
+ 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	App	lication 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 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 Paid
+ 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									
			2015 copyright Impor	tant notices Last Revision	Date: 02 Sep 20	20 Version: 1.0.99 (PP)			
New List ad	dde	d							
Issued E-Certific	ate								
♠ Received 4	Bate	hNo.≜	Ref. No.		۵	Change Categories	≜ S	itatus 🚖 Dov	vnload 🔺

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

	Change of Registered Particulars (CORP) Application											
	Please New	be reminded that Submission	for approved application(s), y	ou are required to submit app	lication(s) for ch	ange of implementation date	5 working days be	fore the effective dat	e, if necessary.			
You are login as ORG Trial	Initiat	e New CORP App	olication									
TESTING LIMITED Login date and time 26.01.2021 11:20	Actio	on Required										
0 F 11 F F	\$	Received 🖕	Batch No. 🖕	Ref. No. 🖕	HK No. 🖕	Product Name 🖕	Change	Status 🖕	Payment Status			
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										
- 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 _¢			
- 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	CORP-HK42175-201753699- 02	HK42175	APT-INDOMETHACIN 25 CAP 25MG	1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Paid			
+ 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												
			2015 copyright Impor	tant notices Last Revision	Date: 02 Sep 20	20 Version: 1.0.99 (PP)						

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	Letter Withdraw A	Application Close
	Summary	e-Product File (e-PF) Change	DO Req.	Clarification Letter	Ack. Letter	CORP Change Hist	ory Ref. Mai	terial Same Batch		
You are login as ORG Trial One	Application F	Reference No.:	CORP-H	K41190-201857485		Application Status	:	Application Eval	uated	
TESTING LIMITED Login date and time 21.08.2018 18:26	Application E HK No.: Product Nan	Batch No.:	CORP-H HK41190 PRODUC	K41190-201857485) CT NAME XXXXX XX	xx	Application Type: Previous App. Ref DO Request Refe	erence No.: rence No.:	Certificate holde	r initiated - New COR	P application
Online Notification	Application F	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	mage: nt Application)	No File Chosen		
+ New Registration	Submission Applicant Us	Acknowledgement: sername:	<u>Submissi</u> joelun	ion Acknowledgemen	t					
- Change of Registered Particulars	Cate	gory 4 - Manufacturer	Clarifi	ication Letter S	ent —					
Initiate CORP Application	Particular	s Proposed to Change		Recall	Cert. Re	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				atisfactory	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	test20170	0702.pdf The same file								~
+ System	has alrea	dy been uploaded in another								
Logout	Change C	ategories Allowed for Amend	iment:							
								Reply Clarification	Letter Withdraw	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

	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		*Ap	plication Received Date: 21.08.2018	
TESTING LIMITED	✓	*Cli	ent Date: 21.08.2018	
21.08.2018 18:26	Certificate Holder Name:	Jus	tification for changing the batch :	
Online Notification	TESTING LIMITED			^
My Product Search				\sim
+ New Registration	HK No. Product Name			
- Change of Registered Particulars	Image: With the second secon			
Initiate CORP	Please tick the appropriate change category and state the nature of the	change		
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 Registration	+ 4 Manufacturer			
+ Submission of Other Post-registration Supplement	+ 4.1 Change in name and / or address of the current manufacturer		test	<
+ Request to Cancel Product Registration	+ 4.2 Change in new manufacturer			
+ Payment				Ç
Application History	+ 5 Registration Certificate Holder			
+ User Profile	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)			
+ System	+ 7 Excipients			
Logout	+ 8 Indication / Dosage / Route of Administration			
	+ 9 Other			_
				Ç
				Back

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

•	Cha	ange of F	Re	gistered Parti	cu	lars (CORP) Ap	plicatio	n				CORP_APP	LICATION_STATU
	Please New	e be reminded ti Submissio	nat n	for approved application(s), yo	ou are required to submit app	olication(s) fo	r ch	ange of implementation da	ate :	5 working days be	fore the effective da	e, if necessary.
You are login as ORG Trial	Initia	te New CORP	App	lication									
CESTING LIMITED Login date and time 26.01.2021 11:20	Actio	on Require	d										
Online Natification	\$	Received	¢	Batch No.	¢	Ref. No. 💠	HK No.	\$	Product Name	¢	Change Categories \$	Status 💠	Payment Status
My Product Search	1	21.08.2018		CORP-HK41190-20185748	35	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-HK37565-20215000)5	CORP-HK37565-202150005	HK37565		PRODUCT NAME XXXXX		1	Application Saved	Not Necessary
Initiate CORP Application	Application Submitted												
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-HK41190-20205001	13	CORP-HK41190-202050013	HK41190		PRODUCT NAME XXXXX XXXX		3,4,7	Application Evaluated	Not Necessary
Withdraw application	2	03.10.2019		CORP-HK37565-20185748	34	CORP-HK37565-201857484	HK37565		PRODUCT NAME XXXXX		3	Application Under Screening	Not Necessary
DO Request Application	3	04.03.2019		CORP-HK31199-20195001 01	13-	CORP-HK31199-201950013- 01	HK31199		EPILIM FREEZE-DRIED PE FOR IV INJ 400MG	DR	1,5,7	Application Approved	Certificate Fee Paid
+ Renewal of Registration	4	25.04.2017		CORP-HK42175-20175369 02	99-	CORP-HK42175-201753699- 02	HK42175		APT-INDOMETHACIN 25 CAP 25MG		1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Paid
+ Request to Cancel	5	21.08.2018		CORP-HK37565-20185748	32	CORP-HK41190-201857483	HK41190		PRODUCT NAME XXXXX XXXXX		5	Application Under Screening	Not Necessary
Product Registration	6	21.08.2018		CORP-HK37565-20185748	32	CORP-HK37565-201857482	HK37565		PRODUCT NAME XXXXX		5	Application Under Screening	Not Necessary
+ Payment	7	03.07.2017		CORP-HK31199-20175723	30	CORP-HK31199-201757230	HK31199		EPILIM FREEZE-DRIED PE FOR IV INJ 400MG	DR	3	Application Screening Accepted	Not Necessary
Application History													
+ User Profile													
+ System													
Logout													
				2015 copyright In	npor	tant notices Last Revision	Date: 02 Se	p 20	020 Version: 1.0.99 (PP)				

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:

	atus									
						Continue Ap	pplication	Delete Application	Close	
Summary e-Product File (e-	PF) Change DO Req.	Clarification Letter	Ack. Letter	CORP Change History	Ref. Material	Same Batch				
You are login as ORG Trial Application Reference No.:	CORP-H	K37565-201857484		Application Status:		Application Saved				
TESTING LIMITED Application Batch No.:	CORP-H	K37565-201857484		Application Type:		Certificate holder	initiated - Ne	ew CORP applicatio	n	
21.08.2018 18:26 HK No.:	HK3/565			Previous App. Refere	100 NO.:					
Online Notification Application Received Date:	21.08.20	18	Client Date: 2				21.08.2018			
Proposed Effective Date:				Application Form Ima	je:	No File Chosen				
My Product Search Hard Copy Received Date:				Justification (Urgent A	pplication):					
+ New Registration Category 3 - Pack	age Insert Initia	ated								
- Change of Registered Particulars Proposed to Cl	nange	Recall	Cert. Re	print Required Evalua	tion Commen	t and Result				
		Requir	ed							
Application										
Application Status 3.Package Insert									^	
Not Submitted Application Submitted 3.1-Change in package inse	rt	Yes	Yes 🗸 Not Required 🗸							
Withdraw application Brief Description of Change	and Reason: tets									
+ Renewal of				Sati	sfactory	Insatisfactory	Acknowle	edged Withdra	awn	
Registration Supporting Documents:										
+ Submission of Other Post-registration 3.1 Change in package ins	ert									
Change Categories Allower	d for Amendment:									
+ Request to Cancel										
						Continue A	pplication	Delete Application	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)				
You are login as ORG Trial		*Ap	plication Received Date: 21.08.2018		
TESTING LIMITED	✓	*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					
+ Submission of Other					
Supplement	+ 3.2 Addition of package insert				~
+ Request to Cancel Product Registration					\sim
+ Payment	+ 4 Manufacturer				
Application History	+ 5 Registration Certificate Holder				
+ User Profile	+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)				
L Custom	+ 7 Excipients				
+ System	+ 8 Indication / Dosage / Route of Administration				
Logout	+ 9 Other				
				Back	Next

3) Application Submitted

•	Change of Registered Particulars (CORP) Application											
	Please New	be reminded tha Submission	t for approved application(s), you are required to submit ap	plication(s) for ch	nange of implementation date	5 working days be	fore the effective dat	e, if necessary.			
You are login as ORG Trial One	Initiat	e New CORP Ap	plication									
TESTING LIMITED Login date and time 26.01.2021 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-HK41190-20185748	5 <u>CORP-HK41190-201857485</u>	HK41190	PRODUCT NAME XXXXX XXXXX	4	Application Evaluated	Not Necessary			
+ 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	5 <u>CORP-HK37565-202150005</u>	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary			
Initiate CORP Application	Application Submitted											
Application Status	φ.	Received 🔶	Batch No.	¢ Ref. No. ¢	HK No. 🔶	Product Name 🔶	Change Categories 🗢	Status 🔶	Payment Status			
- Not Submitted - Application Submitted	1	05.06.2020	CORP-HK41190-202050013	3 <u>CORP-HK41190-202050013</u>	HK41190	PRODUCT NAME XXXXX XXXXX	3,4,7	Application Evaluated	Not Necessary			
Withdraw application	2	03.10.2019	CORP-HK37565-201857484	4 <u>CORP-HK37565-201857484</u>	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary			
DO Request Application	3	04.03.2019	CORP-HK31199-201950013 01	3- <u>CORP-HK31199-201950013-</u> 01	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	1,5,7	Application Approved	Certificate Fee Paid			
+ Renewal of Registration	4	25.04.2017	CORP-HK42175-201753699 02	9- <u>CORP-HK42175-201753699-</u> 02	HK42175	APT-INDOMETHACIN 25 CAP 25MG	1,2,3,4,5,6,7,8	Application Approved	Certificate Fee Paid			
	5	21.08.2018	CORP-HK37565-201857482	2 <u>CORP-HK41190-201857483</u>	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary			
Product Registration	6	21.08.2018	CORP-HK37565-201857482	2 <u>CORP-HK37565-201857482</u>	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary			
+ Payment	7	03.07.2017	CORP-HK31199-201757230	0 <u>CORP-HK31199-201757230</u>	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	3	Application Screening Accepted	Not Necessary			
Application History												
+ User Profile												
+ System												
Logout												
			2015 copyright Im	portant notices Last Revisior	n Date: 02 Sep 20	020 Version: 1.0.99 (PP)						

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	Letter	Ack. Letter	CORP Change His	istory Ref	f. Material	Same Batch					
You are login as ORG Trial	Application F	Reference No.:	CORP-H	K41190-2018	57486		Application Statu	US:		Application Appr	oved				
TESTING LIMITED Login date and time	Application E	Batch No.:	CORP-HI HK41190	K41190-2018	57486		Application Type Previous App. Re	e: leference No	0.:	Certificate holde	r initiated - New COR	P applicatior	ı		
21.08.2018 18.35	Product Nan	ne:	PRODUC	T NAME XXX	xx xxx	C	DO Request Ref	ference No.:	:						
Online Notification	Application F	Received Date:	21.08.20	18			Client Date:								
My Product Search	Proposed Effective Date: Hard Copy Received Date:					Application Form Image: No File Chosen Justification (Urgent Application):									
+ New Registration	Submission . Applicant Us	Acknowledgement: ername:	<u>Submissi</u> joelun	on Acknowled	<u>igement</u>										
- Change of Registered 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					
Application Status					Required	1									
- Áction Required - Not Submitted - Application Submitted	I Required ubmitted I.Specification												~		
Withdraw application	1.1-Chang	e in specifications of the produ	ct	Yes V Not Required											
+ Renewal of Registration	Brief Desc	ription of Change and Reason:	change la	bel											
	Effective E	Date: 31.08.2018	Satisfactory					ory U	nsatisfactory	Withdra	wn				
+ Submission of Other Post-registration Supplement	Supportin	g Documents:													
+ Request to Cancel	1.1 Chang	e in specifications of the pro	duct												
Product Registration	i. Proposed specifications with the change(s) underlined or highlighted *														
+ Payment	Documer	nts File Name	Remark			Screen	ng Comment		Evaluatio	on Comment					
Application History															
+ User Profile	test2017(0702.pdf The same file											\sim		
+ System	has alrea	dy been uploaded in another													
Logout	Change C	ategories Allowed for Amend	ment:												
											_				
											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									
	Urgent Application (subject to decision by Drug Office)											
You are login as ORG Trial		*Application Received Date: 21.08.2018										
TESTING LIMITED	~ · · · · · · · · · · · · · · · · · · ·	*Client Date: 21.08.2018										
21.08.2018 18:35	Certificate Holder Name:	Justification for changing the batch :										
Online Notification	TESTING LIMITED		^									
My Product Search			\sim									
+ New Registration	Previous Approval Letter : UPLOAD No File Chosen											
 Change of Registered Particulars 												
Initiate CORP Application	HK No. Product Name Image: With the state of t											
Application Status	Please tick the appropriate change category and state the nature of the change.											
 Not Submitted Application Submitted 	Particulars Proposed to Change	Change Justification	New effective date									
Withdraw application	+ 1 Specification		21.09.2019									
+ Renewal of Registration			51.06.2016									
+ 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)											
	+ 7 Excipients											
+ User Profile	+ 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.

	With	drawal of CO	ORP Application						
								Withdraw Applica	tion
You are login as ORG Trial		Received 🜩	Ref. No.	\$ HK No.	\$	Product Name	\$ Change Categories 💠	Status	\$
TESTING LIMITED		21.08.2018	CORP-HK41190-201857485	HK41190		PRODUCT NAME XXXXX XXXX	4	Application Evaluated	
21.08.2018 18:35		21.08.2018	CORP-HK37565-201857482	HK37565	1	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 Applica	tion
+ New Registration									
- Change of Registered Particulars									
Initiate CORP Application									
Application Status - Action Required - Not Submitted - Application Submitted									
Withdraw application									
Registration									
+ Submission of Other Post-registration Supplement									
+ Request to Cancel Product Registration									
+ Payment									
Application History									
+ User Profile									
+ System									
Logout									

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	¢
	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	thdrawal: withdr	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

	-		P		٩v	• • • • • •		0 100 900					0000 00	
•	DO	Request Char	nge of R	egistere	ed P	articula	ırs (CORP) Appli	ica	ation			CORP_DO_/	APPLICATION
	Acti	on Required												
You are login as FONG		Request No.	🔶 HK No.	\$	Produc	ct Name		\$	\$	Status	\$	Request F	Reason	\$
DEFG COMPANY LIMITED	1	DO-REQ-201900011	HK63575		TEST 2	2017031404				Request Sent		PRC Decis	sion 20/06/2019	
10.02.2020 14:55	2	DO-REQ-201900005	HK63546		TEST 2	2019011902				Request Sent		TEST New	v Request	
	3	DO-REQ-201900005	HK63549		TEST 2	2017020605				Request Sent		TEST New	v Request	
Online Notification	4	DO-REQ-201800029	HK45179		BOGE	N MEDICATED	POWD	ER		Request Sent		Test Paym	ient	
My Product Search	Not	Submitted												
+ New Registration	\$	Ref. No.	\$	Request No.	\$	HK No.	\$	Product Name		\$	Status	÷ +	Request Reason	\$
	1	CORP-DO-HK63666-201958	3469	DO-REQ-201	900062	HK63666		HENRY TEST			COPR	Submitted	try	
 Change of Registered Particulars 	2	CORP-DO-HK50508-201958	<u>3710</u>	DO-REQ-201	900070	HK50508		CHOLVATIN TAB 20MG			COPR	Submitted	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							ONLI	NE_NOTIF	ICATION_VIEW_01
	New	Product Registration									
		Notification Da	te \$	Subject		¢	P	roposed Name of Produ	ict 💠	PL No.	Payment Statuts
You are login as	Open	24.07.2018 15:51:11		Screening Application			TEST E	ECERT CASE1		PL0010/20	018 N/A
	Open	14.11.2017 11:06:22		Application Payment Request			TEST U	JSER 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 Payment Request			TEST 2	017022401		PL0030/20	017 Paid
	CORF	>									
Online Notification		Notification Date \$		Subject	\$	HKI	lo.	¢	Name	of Product	
My Product Search	<u>Open</u>	07.08.2018 17:35:15	Application Scre	ening Notification		HK63517		WALKTRHOUGH			
my r rodder ocaren	Open	07.08.2018 09:52:51	Application Sub	mitted Notification		HK63517		WALKTRHOUGH			
- New Registration	Renev	wal of Registration									
Initiate New Product Registration		Notification Date 🗢		Subject	¢		N	ame of Product		¢	No. of Renewals 💠
Application Status	<u>Open</u>	22.01.2017 11:14:08	Renewal Remin	der		TEST2016112 TEST2016112	301 , 303 ,			2	
- Action Required - Not Submitted - Application Submitted	<u>Open</u>	22.01.2017 10:33:00	Renewal Notifica	ition		TEST2016112 TEST2016112	305 , 305			2	
Withdraw application	Cance	llation Request									
+ Change of Registered		Notification Date 👙		Subject	φ.	HK N). ¢		Name o	of Product	\$
Particulars	<u>Open</u>	07.08.2018 17:40:25	Cancellation Reg	istration Request Submitted Notification		HK63533		TEST 20161208			
+ Renewal of	<u>Open</u>	07.08.2018 15:01:05	Cancellation Reg	istration Request Submitted Notification		HK63523		TEST2016112303			
Registration	Interv	iew									
+ Interview				Notification Date		φ		Sub	ect		¢
+ Request to Canaal	<u>Open</u>	13.03.2017	10:08:09			Testing	2017031	3			
Product Registration	<u>Open</u>	15.01.2017	15:04:00			test2					
+ Payment	Non P	harmaceutical Produ	ct Alert								
Application History		Notification Date	1	Subject		\$ HK	No. \$	1	lame of	Product	\$
	<u>Open</u>	21.03.2016 16:43:10	Renewal Pen	ling Notification		HK476	78	Testing 20170313			
+ User Profile	<u>Open</u>	21.03.2016 16:43:10	Renewal Pen	Jing Reminder		HK476	78	test2			

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 Registr	ation			RENEWAL_NOTIFIC	CATION
You are login as ORG Trial One TESTING LIMITED Login date and time 21.08.2018 18:44	Renewal No	tification				Print Manual Renewal Form	Back
Online Notification	Notification Date	26.04.2016 04:0	0:02	Name of Bandoot		Descional information	
My Product Search	нк No. Ф	PR No.	PRODUCT NAME XXXXX XXXX	Name of Product	ę	Required information	Φ
+ New Registration	View Renewal Ap	oplication Status					
+ 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	Regist	ration								RE	NEWAL_STATUS
You are login as WONG David ABC COMPANY LIMITED Login date and time 24.08.2018 16:50	Reply a Please cor In case ce Note: Worl	nd Pay 1 mplete the r rtificate hold king days d	for Rene enewal prod ler(s) canno p not includ	wal of Registration edure 10 working days before the trenew certificate(s) in due cou e Saturday / Sunday / holiday(s)	he expiry date of the pro- rse, please contact our l'	luct certificate and c Colleagues of PRS	complete 2.0 help	e the relevant desk at 2319	payment 8414 di	transacti iring offic	on before (e hours.	5 working	days.
Online Notification												Rene	Not to Renew
My Broduct Soarch	÷	Н	K No. 🤤	>	Name of Product		\$	Notify D	ate 🗢	E	cpiry Date	\$	Batch No. 🗢
My Product Search		HK36996		PRODUCT NAME XXXX XXXX				28.06.2018		25.08.2	D18	Bat	sh Four
+ New Registration	_												
+ Change of Registered	Paymer	nt Comp	leted										
Farticulars	1	HK No. 💠		Name of Product	\$	Payment Date 🜲	Last E	xpiry Date	Expiry	Date 🔶	Cert Col Dat	lection _{\$}	Batch No. 💠
 Renewal of Registration 	HK369	995	PRODUC	F NAME XXXX		22.08.2018	25.08.2	018 :	25.08.202	3			Batch Four
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to Renew	Produc	t Confirr	med Not	to Renew									Reinstate
- Requires Further Action Before Product Renewal	¢	н	K No. 🗧	2	Name of Product		¢	Reply D	ate 💠	E	opiry Date	\$	Batch No. \$
+ Interview													
+ Request to Cancel Product Registration	Require Please cor	es Furthe	er Action	Before Product Rene	wal	fuct certificate and c	complete	the relevant	payment	transact	on before §	5 working	days.
+ Payment	Note: Wor	king days d	o not includ	e Saturday / Sunday / holiday(s)		Colleagues of Fixe	2.0 1161	deak at 2016	0414 00	ining offic	e nours.		
Application History	¢	H	K No.	>	Name of Product		\$	Reaso	n \$	E	cpiry Date	\$	Batch No. 🗢
		HK44475		PRODUCT NAME XXXX XXXX				BABE list		10.03.2	D19	Bat	ch Two
+ User Profile		HK43560		PRODUCT NAME XXXX				PICS requirem	ient	04.09.2	D18	Bat	ch Five
+ System													
Logout													
New list add	led for	new	vers	sion:									

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. 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.

.	Renev	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	Reply ar Please com In case cert Note: Work	nd Pay for I plete the renew ificate holder(s) ing days do not	Renev val proce) cannot include	val of Registration dure 10 working days before the expiry dr renew certificate(s) in due course, please Saturday / Sunday / holiday(s).	ate of the proc contact our IT	duct certificate and c colleagues of PRS	complete 2.0 help	the relevant desk at 2319	payment 8414 du	transacti ring offici	on before ! e hours.	5 workin	g days.	
Online Notification				Name of	Deaduct		•	N-46. D			mins Data	Ren	Not to Re	new
My Product Search		HK36996	• •	PRODUCT NAME XXXX XXXX	Product		Ŧ	28.06.2018	ale 🜩	25.08.20	D18	В	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	25.08.2	018 2	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
Before Product Renewal	\$	HK No.	\$	Name of	Product		\$	Reply D	ate 🗢 🗢	Ð	piry Date	\$	Batch No.	\$
+ Interview														
+ Request to Cancel Product Registration	Require: Please com	s Further A	Action val proce	Before Product Renewal dure 10 working days before the expiry da	ate of the proc	luct certificate and c	omplete	the relevant	payment	transacti	on before !	5 workin	g days.	
+ Payment	In case cert Note: Work	ificate holder(s) ing days do not) cannot include	renew certificate(s) in due course, please Saturday / Sunday / holiday(s).	contact our H	colleagues of PRS	2.0 help	desk at 2319	8414 du	ring offici	e hours.			
Application History	\$	HK No	• •	Name of	Product		\$	Reaso	n ¢	Ð	piry Date	\$	Batch No.	\$
		HK44475		PRODUCT NAME XXXX XXXX				BABE list		10.03.20	019	Ba	atch Two	
+ User Profile		HK43560		PRODUCT NAME XXXX				PICS requirem	ent	04.09.20	018	B	atch Five	
+ System														
Logout														
New list add	ed for	new v	ers	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	ATTENTION : If unable to open the online pa If the error message PAY-E-00	iyment service page, please e)01 does appear and Kaspers	enable the TLS1 ky Internet Seci	.1 and TLS1.2 fro urity software insta	m the Internet Option > adva alled on you device, please re	nce setting. efer to <u>online payment se</u>	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			
0 1 1	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 Amount:	HK\$ 575.0						
- Payment Completed - Product Confirmed Not to Renew	Certificate Collect:	e-Certificate						
- Requires Further Action Before Product Renewal	Desirient				-			
+ Submission of Other Post-registration Supplement	Recipient":	<pre>susan_cheung_1 david_wong</pre>						
+ Interview		*Select only one recipient.	The e-Certificat	e will be available	e for download on the day afte	er the last expiry date of r	egistration.	
+ Request to Cancel Product Registration		Before proceeding to the p Renewal of Registration Co	ayment for rene ertificate / Remi	ewal of pharmace nder of Notificatio	utical product(s) / substance(n for Renewal of Registration	s), I have read the Notific h Certificate.	ation for	
+ Payment		By submitting this applicati name and address of certifiname of excipients, date of	ion, consent is g ficate holder, na f registration, pa	iven to the Pharn me and address o ackage insert and	nacy & Poisons Board of Hon of the manufacturer, registrati product pack size provided in	g Kong to arrange the na on number, name of active n this application to be dis	nme of product, /e ingredients, splayed on the	
Application History		Website of the Board. For e (Phone No: 3974 4175).	enquiries, pleas	e contact the Drug	g Evaluation and Import/Expo	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
	 Please take note of the 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 issue contact your card issued 	transaction reference number or PRINT this page for making enquiry on the p button, please DO NOT leave this e-service until you receive the acknowledge loes not support payment via browsers of mobile devices (including mobile ph nge to use desktop computer. cable to credit card payment method only. titions, a refund may need to be arranged. If the payment is made by Credit Ca is used for the payment. e an error page or have to wait for several minutes before they get a response em, please wait a moment and retry, or change to use other available payment wers may have implemented different mechanisms to authenticate the cardhol if you want to learn more about the J/Secure, Mastercard SecureCode and V	ayment status when necessary. ement page, otherwise your transaction may not iones and tablets) at the moment. If you wish to ard, the refund can normally be made to the e from the credit card payment gateway. If you it methods. We apologise for any inconvenience der's identity during online payment. Please ferified by Visa service.

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 Rec Company LIMITED Joint 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			RENEWAL P. 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	The Drug Office acknow response as soon as po The certificate(s) will be Please kindly quote the	wledges the receipt of your payment of i ossible. a ready for collection on / after 07.09.20 a above Payment Reference Number for	HK\$575.00 for application fee regarding the al 18 r enquiries.	bove product(s). We will process your	application and will provide	
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to Renew - Requires Further Action Before Product Renewal	General Enquiries: Office Hours: Monda 9:00 a 2:00 p	ay to Friday m - 1:00 pm m - 5:45 pm				
+ Interview	(up to (Close	6:00 pm on Monday) ed on Saturdays, Sundays & Public Holi	idays)			
+ Request to Cancel Product Registration	Email: (852) / Email: prs2_i	23198458 info@dh.gov.hk				
+ Payment					Print Receipt	Clos
Application History						
+ User Profile						
+ System						
Logout						

Click the "Print Receipt" button:

			Paym	ent Receipt of Renewal	
	Payment Receipt of Renewal		Name of Company BAUSCH & LOMB	(HK) LTD	
Name of Company		Payment Date	公司石稿 Payment Reference No: DHPRS-201906	131525-14151	
公司名稱		繳費日期	付款编號:		
BAUSCH & LOMB (HK) L	TD	13.06.2019	Name of Product 製品/物質名稱	HK Reg. No 香港註冊號碼	Expiry Date 屆滿日期
Payment Reference No: 付款编號: Receipt Reference No:	DHPRS-201906131525-14151		1 "S.T." NATURAL TEARS EYE DROPS	HK58956	03.10.2019
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.

	D			- 4 ¹							REM	IEWAL_STATUS
Ť	Renew	val of Re	gisti	ation								
You are login as WONG	Reply an	d Pay for	Renev	val of Registration								
David ABC COMPANY LIMITED Login date and time 24.08.2018 16:50	Please com In case certi Note: Worki	plete the renev ficate holder(s ng days do not	val proce) cannot include	edure 10 working days before th renew certificate(s) in due cour Saturday / Sunday / holiday(s).	e expiry date of the prod se, please contact our IT	uct certificate and c colleagues of PRS	omplete 2.0 help	e the relevant payn o desk at 2319 841	nent tr 4 duri	ansaction before 5 ng office hours.	working c	lays.
Online Notification											Renew	Not to Renew
Chille Notification	\$	HK No	• ÷		Name of Product		\$	Notify Date	\$	Expiry Date	\$	Batch No. \$
My Product Search		HK36996		PRODUCT NAME XXXX XXXX				28.06.2018		25.08.2018	Batch	Four
+ New Registration												
+ Change of Registered Particulars	Payment	t Complete	d	Name of Product		Payment Date	L set F	vnin/ Data Ev	nin D	ata Cart Coll	action	Batch No.
- Renewal of Registration	НК3699	5 PF	RODUCT	NAME XXXX	\$	22.08.2018	25.08.2	2018 25.08.	2023	ate ♦ Cerr com Date	E	Batch Four
Application Status - Reply and Pay for Renewal of Registration - Product Confirmed Not to	Product	Confirmed	l Not t	o Renew								
Renew - Requires Further Action Before Product Renewal												Reinstate
Defore Product Renewal	\$	HK No.	. ¢		Name of Product		\$	Reply Date	\$	Expiry Date	\$	Batch No. 🗢
+ Interview	Requires	Eurther A	ction	Before Product Reney	wal							
+ Request to Cancel Product Registration	Please com	niete the renev	val proce	dure 10 working days before th	e expiry date of the prod	luct certificate and c	omplete	the relevant navn	ient tr	ansaction before 5	working c	lavs
+ Payment	In case certi Note: Worki	ficate holder(s ng days do not) cannot include	renew certificate(s) in due cour Saturday / Sunday / holiday(s).	se, please contact our IT	colleagues of PRS	2.0 help	desk at 2319 841	4 duri	ng office hours.		
Application History	\$	HK No	• •		Name of Product		\$	Reason	\$	Expiry Date	\$	Batch No. 🗢
+ User Profile		HK44475		PRODUCT NAME XXXX XXXX				BABE list		10.03.2019	Batch	Two
+ Sustam		HK43560		PRODUCT NAME XXXX				PICS requirement		04.09.2018	Batch	n Five
- Gystein												
Logout												
New list add Issued e-Certificat	ed for te	new v	ers	ion								
When released, the down	load link of th	e e-Certifica	te is en	abled for one-time use. Ple	ase keen a conv of t	he e-Certificate f		r record after do	wolo	ading		
HK No. \$ N	ame of Produc	e e continica		abled for one ame doe. The	Payment Date	Last Expiry	Date\$	Expiry Date	\$	e-Certificate	Bate	ch No. 🔶

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.

	Renev	val of Reg	istra	ation							REN	EWAL_STATUS
You are login as WONG David ABC COMPANY LIMITED Login date and time 24.08.2018 16:50	Reply an Please com In case cert Note: Work	nd Pay for Re plete the renewal p ifficate holder(s) ca ing days do not inc	new proced nnot r lude S	al of Registration dure 10 working days before the expiry date of the pro enew certificate(s) in due course, please contact our l durdar/ Sumary / holicay(s).	duct certificate and c t colleagues of PRS	omplete 2.0 help	the relevan desk at 23	it payment f 19 8414 dur	ransactio	on before 5 w e hours.	orking d	ays.
Online Natification										(Renew	Not to Renew
Online Nobilication	Ŧ	HK No.	\$	Name of Product		\$	Notify	Date \$	Ex	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	Paymen	t Completed										
, and a dial of	н	KNo. ≑		Name of Product \$	Payment Date 🜲	Last E	xpiry Date	Expiry	Date 🔶	Cert Collect Date	tion _‡	Batch No. 🔶
 Renewal of Registration 	HK369	95 PROD		IAME XXXX	22.08.2018	25.08.2	018	25.08.2023			B	atch Four
Application Status - Reply and Pay for Renewal of Registration - Payment Completed - Product Confirmed Not to Renew	Product	Confirmed N	ot to	Renew								Reinstate
- Requires Further Action Before Product Renewal	÷	HK No.	۵	Name of Product		÷	Reply	Date ≜	Fx	niny Date d		Batch No.
+ Interview	•	in the	•	Numb of Froduct		•	Reply	bute ¥	LA	phy Dute 4		Daten No. V
+ Request to Cancel Product Registration	Require Please com	s Further Act	ion I	Before Product Renewal	duct certificate and o	omplete	the relevant	it payment f	ransactio	on before 5 w	orking d	ays.
+ Payment	Note: Work	ing days do not inc	lude S	Saturday / Sunday / holiday(s).	r concagues or rito	2.0 11610	deak at 20	10 04 14 00	ing onice	nours.		
Application History	\$	HK No.	\$	Name of Product		\$	Rea	son ¢	Ex	piry Date 🛛 🖨		Batch No. 🛛 🗢
		HK44475		PRODUCT NAME XXXX XXXX			BABE list		10.03.20	19	Batch	Two
+ User Profile		HK43560		PRODUCT NAME XXXX			PICS require	ment	04.09.20	18	Batch	Five
+ System												
Logout												

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	yment service page, please 01 does appear and Kaspe	e enable the TLS1 rsky Internet Secu	.1 and TLS1.2 fro urity software inst	m the Internet Option alled on you device, pl	> advance setting. ease refer to <u>online payment se</u>	rvice FAQ Question 1.	
You are login as WONG	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	Payment Amount:	HK\$ 575.0						
Product Confirmed Not to Renew Portuge European 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 o	lay after the last expiry date of r	egistration.	
+ Request to Cancel Product Registration		efore proceeding to the tenewal of Registration	e payment for rene Certificate / Remi	wal of pharmace nder of Notificatio	utical product(s) / subs n for Renewal of Regis	tance(s), I have read the Notific stration Certificate.	ation for	
+ Payment		By submitting this applic name and address of ce name of excipients, date	ation, consent is g rtificate holder, na of registration, pa	iven to the Pharn me and address o ckage insert and	acy & Poisons Board 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	me of product, re ingredients, splayed on the	
Application History		(Phone No: 3974 4175).	r enquiries, please	e contact the Drug	g Evaluation and Impo	t/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.

	Dam	and of D									REI	NEWAL_STA	TUS
Ť	Product(s) have been su	ccessfully	ation set to not renew									
(ou are login as WONG David ABC COMPANY LIMITED Login date and time 31.01.2018 17:20	Reply Please c	and Pay fo	r Renev	val of Registration edure 10 working days before the expiry date of the pro-	Juct certificate and c	omplete	the relevar	ıt paymen	transacti	on before 5	working	lays.	
Online Notification	In case o Note: We	certificate holder orking days do n	(s) cannot ot include	renew certificate(s) in due course, please contact our l' Saturday / Sunday / holiday(s).	Colleagues of PRS	2.0 help	desk at 23	19 8414 di	uring office	e hours.			
My Product Search											Renew	Not to Rer	new
+ New Registration		\$ HK	No. 💠	Name of Product		\$	Notify	Date 💠	Đ	piry Date	\$	Batch No.	\$
. non nogodiation		HK56272		AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB					14.02.20)18	Batc	n One	
+ Change of Registered Particulars		HK61778		AMLODIPINE TABLETS 10MG (HETERO)					26.02.20)18	Batc	h One	
- Renewal of Registration	Paym	ent Comple	ted										
Application Status - Reply and Pay for Renewal of Registration		HK No. 🔶		Name of Product \$	Payment Date 🜲	Last E	xpiry Date	Expiry	Date 💠	Cert Coll Dat	ection _{\$}	Batch No.	φ.
 Payment Completed Product Confirmed Not to Renew 	HK5	6375	ACET 120N	IG SUPP	30.01.2018	14.03.2	018	14.03.202	3			Batch Two	
- Requires Further Action Before Product Renewal	HK5	6376	ACET 160N	IG SUPP	30.01.2018	14.03.2	018	14.03.202	3			Batch Two	
+ Submission of Other Post-registration Supplement	Produ	ict Confirme	d Not t	o Renew									_
+ Interview												Reins	tate
		¢ HK	No. 🗢	Name of Product		\$	Reply	Date 💠	Đ	piry Date	φ	Batch No.	φ.
Product Registration		HK61779		AMLODIPINE TABLETS 5MG (HETERO)			31.01.2018		26.02.20)18	Batc	h One	
+ Payment	Requi	res Further	Action	Before Product Renewal									
Application History	Please c	complete the ren	ewal proce	dure 10 working days before the expiry date of the pro	duct certificate and c	omplete	the relevan	it paymen 19 8414 d	transacti	on before 5	working	days.	
+ User Profile	Note: W	orking days do n	ot include	Saturday / Sunday / holiday(s).	Concugues of Fixe.	2.0 neip	ucon di 20	10 0414 0	anng onici	. 1100/0.			
+ System		¢ HK M	lo. \$	Name of Product		\$	Reas	son 🗢	Ex	piry Date	\$	Batch No.	\$
Logout													

New list added for new version Issued e-Certificate

t	Rene	wal of	Regist	ration							RE	NEWAL_STA	1105
	Product(s)) have been	successfully	set to not renew									
u are login as WONG													
C COMPANY LIMITED in date and time 01.2018 17:20	Reply a	and Pay f	for Rene	wal of Registration	of the prov	duct cortificate and c	complete the releva	at powerent	transactiv	an hoforo 5	working	dave	
Online Notification	In case ce Note: Wor	rtificate hold king days d	ler(s) cannol o not include	renew certificate(s) in due course, please co Saturday / Sunday / holiday(s).	ontact our l	T colleagues of PRS	2.0 help desk at 2	319 8414 du	ring office	e hours.	working	uays.	
ly Product Search											Renew	Not to Rei	new
ew Registration		ь	K No 📤	Name of P	roduct		≜ Notit	v Date 🔺	Ex	niny Date	•	Batch No	
aw registration		HK56272		AMERICAN HEALTH ABC PLUS WITH LUTER	N TAB				14.02.20)18	Bato	h One	
hange of Registered articulars		HK61778		AMLODIPINE TABLETS 10MG (HETERO)					26.02.20)18	Bato	h One	
tenewal of tegistration	Payme	nt Comp	leted										
pplication Status Reply and Pay for enewal of Registration Payment Completed		HK No. 🔶		Name of Product	\$	Payment Date 💠	Last Expiry Date	Expiry	Date 🜲	Cert Colle Date	ction	Batch No.	÷
Product Confirmed Not to	HK563	375	ACET 120	MG SUPP		30.01.2018	14.03.2018	14.03.2023				Batch Two	
Requires Further Action afore Product Renewal	HK563	376	ACET 160	VIG SUPP		30.01.2018	14.03.2018	14.03.2023	3			Batch Two	
ubmission of Other lost-registration upplement	Produc	t Confiri	ned Not	to Renew									
nterview												Reins	tate
Request to Cancel	•	HK61770	KNo. 🖨	Name of P	roduct		Repl 21.01.2019	y Date 💠	Ex	piry Date	¢ Rote	Batch No.	\$
roduct Registration		111011113		ANEODITINE PADEETO SING (TETERO)			51.01.2010		20.02.20	/10	Date	IT ONE	
ayment	Require	es Furth	er Action	Before Product Renewal									
pplication History	Please co	mplete the r	enewal proc	edure 10 working days before the expiry date	e of the pro	duct certificate and c	complete the releva	int payment	transactio	on before 5	working	days.	
lser Profile	In case ce Note: Wor	ertificate holo king days d	ler(s) cannol o not include	t renew certificatĕ(s) în due course, pleáse co Saturday / Sunday / holiday(s).	ontact our l'	T colleagues of PRS	2.0 help desk at 2	319 8414 du	ring office	e hours.	Ĭ	1	
ystem	\$	H	KNo. 💠	Name of Pr	roduct		¢ Re	ason 💠	Ex	piry Date	φ	Batch No.	φ
ogout													
ow list add	led fo	or nev	v ver	sion									
	~~~ IU												
sued e-Certifica	ate												

#### 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	iewa	al of Re	aistr	ation						RE	NEWAL_ST	ATUS
	Product	t(s) hav	e been succe	ssfully	set to not renew								
You are login as WONG David VBC COMPANY LIMITED Login date and time M.01.2018 17:20	Reply	/ and	Pay for F	Renew al proce	val of Registration dure 10 working days before the expiry date of the pro-	Juct certificate and c	omplete	the relevant payn	ient transad	tion before 5	working	days.	
Online Notification	Note: W	/orking	days do not i	nclude	Saturday / Sunday / holiday(s).	Colleagues of PRS	2.0 neip	desk at 2519 641	4 during on	ice nours.			
My Product Search											Renev	Not to Re	enew
+ New Registration		\$	HK No.	\$	Name of Product		\$	Notify Date	\$	Expiry Date	¢ 0	Batch No.	\$
+ Change of Registered			K00272		AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB				14.02	.2018	Bati	:n One	
Particulars		] H	K61778		AMLODIPINE TABLETS 10MG (HETERO)				26.02	2018	Bat	ch One	
- Renewal of Registration	Paym	nent 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 Ex	piry Date 🝦	Cert Colle Date	ection _‡	Batch No	^{),} ¢
- Product Confirmed Not to Renew Requires Further Action	нк	56375	ACE	ET 120M	G SUPP	30.01.2018	14.03.2	018 14.03.	2023			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
+ Paguast to Cancel		\$	HK No.	\$	Name of Product		\$	Reply Date	\$	Expiry Date	•	Batch No.	\$
Product Registration			Kb1779		AMEODIPINE TABLETS 5MG (HETERO)			31.01.2018	26.02	.2018	Ва	ch One	
+ Payment	Requ	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	luct certificate and c	omplete	the relevant payn	ent transad	tion before 5	working	days.	
+ User Profile	In case Note: W	certífica /orking	ate holder(s) days do not i	cannot nclude	renew certificatē(s) in due course, please contact our l' Saturday / Sunday / holiday(s).	F colleagues of PRS	2.0 help	desk at 2319 841	4 during off	ice 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".

						*
	Payment H	listory	/			
	New Product	Registr	ation			Total Number of Payment Records: 0
ou are login as Charles	PR No.	\$	Name of Product 🗢	Payment Date	Amount(HK\$)	Payment Ref No.
ee rom CERT HOLDER 6 ogin date is	Change of Re	gistere	d Particulars Application			Total Number of Payment Records: 0
7.11.2014 12:50	HK No.	\$	Name of Product 🔶	Payment Date	Amount(HK\$)	Payment Ref No.
Online Notification	Renewal of Re	egistrat	ion			Total Number of Payment Records: 3
My Product Search	HK No.	\$	Name of Product 🗢	Payment Date	Amount(HK\$)	Payment Ref No.
+ New Registration	HK00863	H T	NDAPAMIDE-TRIAL PROLONGED RELEASE ABLETS 1.5MG (MP2-2)(CH6)	27.11.2014	575.0	DHPRS-201411271258-90514
<ul> <li>Change of Registered</li> <li>Particulars</li> </ul>	HK00861	U	ILTIBRO BREEZEHALER (MP1-2)(CH6)	27.11.2014	575.0	DHPRS-201411271258-90514
T articulars	HK00869	G	RACIAL TABLET (MP5-2)(CH6)	27.11.2014	575.0	DHPRS-201411271252-90513
<ul> <li>Renewal Registration</li> </ul>						
<ul> <li>Other Post-registration</li> <li>Supplement</li> </ul>						
Interview						
<ul> <li>Request to Cancel Product Registration</li> </ul>						
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 from CERT HOLDER 6 Login date is 27.11.2014 12:50	Transaction Time:	27.11.2014 12:59:15	
Online Notification	HK No.	Product Name	Expiry Date
My Product Soarch	HK00863	INDAPAMIDE-TRIAL PROLONGED RELEASE TABLETS 1.5MG (MP2-2)(CH6)	01.02.2015
My Froduct Search	HK00861	ULTIBRO BREEZEHALER (MP1-2)(CH6)	01.02.2015
+ New Registration	The Drug Office acknowl	edges your payment of HK\$1,150.00 for certificate fee regarding the above proposed product(s). We will process your r	equest and will provide response as
+ Change of Registered Particulars	soon as possible. The certificate(s) will be	ready for collection on / after 01.01.2015	
+ Renewal Registration	Please kindly quote the a	above Payment Reference Number for enquiries.	
+ Other Post-registration Supplement	Conoral Enguirios		
+ Interview	Office Hours: Monday 9:00 an	y to Friday n - 1:00 pm	
+ Request to Cancel Product Registration	2:00 pn (up to 6 (Closer	n - 5:45 pm :00 pm on Monday) fon Saturdavs: Sundavs: & Public Holidavs)	
- Payment	Tel: (852) 2 Email: pharmg	3198458 eneral@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.

	Applicatio	n History										
T	New Product	Registration	n						т	otal Number of	Appl	ication Records:0
	Application Date	PL No. 💠	PR No. 💠	HK No.	\$		Name of Product	¢	Payment Sta	tu <b>\$</b> Status	\$	Last Action Date
ou are login as Charles ee om CERT HOLDER 6 ogin date is	Change of Re	egistered Pa	rticulars						т	otal Number of	Appi	ication Records:1
.11.2014 12:50	Application Date	Ref	ŕNo. ≑	HK No.	\$	Name of	Product 🔶	Change	Payment Sta	tu <u>ş</u> Status	÷	Last Action Date
Online Notification	17.09.2014	COPP HK00870 1	01450206	HK00870		3B CARSULES (M		1	Not Necessar	( Application		27 11 2014
My Product Search	17:03:2014	00101-1110007-0-2	01430230	11(00070		30 OAI 30EE3 (MI	0-1)(0110)		Normeeessar	Withdrawn		27.11.2014
New Registration	Renewal of R	Registration	J						т	otal Number of	Appl	ication Records:3
Change of Registered	Expiry Date \$	HK No. 🗢	1			Name of Product		\$	Appl	ication Status	\$	Last Action Date
Particulars	01.02.2015	HK00863	INDAPAMIDE-TR	JAL PROLONGE	ED RE	LEASE TABLETS 1	.5MG (MP2-2)(CH6)		Paid			27.11.2014
Renewal Registration	01.02.2015	HK00861	ULTIBRO BREEZ	EHALER (MP1-	2)(CH	6)			Paid			27.11.2014
renenarregionation	01.02.2015	HK00869	GRACIAL TABLE	.T (MP5-2)(CH6)					Paid			27.11.2014
Other Post-registration Supplement	Termination	of applicatio	n of Product	t Applicati	on				т	otal Number of	Appl	ication Records:0
Interview												
	Application Date	Þ	Ref No.	¢ I	HK No	). ¢	Name	of Product	\$	Status	\$	Last Action Date
Request to Cancel Product Registration	Application Data Ongoing Rec	⊧ quest Applica	Ref No. ation	\$	HK No	). \$	Name	of Product	¢ T	Status otal Number of	¢ Appl	Last Action Date
Request to Cancel Product Registration	Application Date Ongoing Rec Application Date	¢ quest Applica Request Type¢	Ref No. ation Re	≑ I	¢	o. ¢ HK No. ¢	Name	of Product Name of Product	\$ T	Status otal Number of \$ Status	¢ Appl	Last Action Date ication Records:1 Last Action Date
Request to Cancel Product Registration Payment	Application Date Ongoing Rec Application Date 26.11.2014	¢ quest Applica Request Type¢ BABE	Ref No. ation Re BABE-HK00866-2		¢	•. ♦ HK No. ♦ HK00866	Name CEPPRA TABLET	Name of Product 1000MG (MP4-1)(Cl	\$ T 16)	Status otal Number of  Status Report Acce	¢ Appl ¢ pted	Last Action Date
Request to Cancel Product Registration Payment Application History	Application Date Ongoing Rec Application Date 26.11.2014 Interview	¢ quest Applica Request Type¢ BABE	Ref No. ation Re BABE-HK00866-2	♦ 1 If No. 2014100070	¢	<b>HK No. ♦</b> HK00866	Name CEPPRA TABLET	of Product Name of Product 1000MG (MP4-1)(Ci	¢ T 16) T	Status otal Number of Status Report Acce otal Number of	¢ Appli pted Appli	Last Action Date ication Records:1 Last Action Date 26.11.2014 ication Records:0
Request to Cancel Product Registration Payment Application History User Profile	Application Date Ongoing Rec Application Date 26.11.2014 Interview Applicat	cuest Application     Request Type     BABE	Ref No. ation Re BABE-HK00866-2	ef No. 2014100070 Subject	¢	•. ↓ HK No. ↓ HK00866	Name CEPPRA TABLET	of Product Name of Product 1000MG (MP4-1)(Cl Application	\$ T 16) T	Status otal Number of Status Report Acce otal Number of	¢ Appli pted Appli Sta	Last Action Date ication Records:1 Last Action Date 26.11.2014 ication Records:0 atus \$
Request to Cancel Product Registration Payment Application History User Profile System	Application Date Ongoing Rec Application Date 26.11.2014 Interview Applicat	Caracteristics Carac	Ref No. ation Re BABE-HK00866-7	¢ I ef No. 2014100070 Subject	¢	•. ↓ HK No. ↓ HK00866 ¢	Name CEPPRA TABLET	of Product Name of Product 1000MG (MP4-1)(Cl Application	¢ T 16) T	Status otal Number of Status Report Acce otal Number of \$	<ul> <li>Appli</li> <li>pted</li> <li>Appli</li> <li>State</li> </ul>	Last Action Date ication Records:1 Last Action Date 26.11.2014 ication Records:0 atus ¢

### 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 Ca	ancei Product Reg	Istrations				
<b>-</b>							Close Next
	Step 1: Enter F	Product for Cancella	ation of Product Regi	stration, Re	ason(s) of Product Ca	ncellation and Conta	ct Information.
You are login as WONG	Select Product						
David ABC COMPANY LIMITED Login date and time 15.10.2018 11:07	*HK No.	Product N	ame		Expiry Date	Other Issue	
Online Notification	* Effective Date :						
My Product Search	* Reason(s) of Prod	uct Cancellation :					
+ New Registration							~
+ Change of Registered Particulars	* Deguest letter for /	Concellation of Draduct Dea					~
+ Renewal of Registration	(Please manual sub	mit original letter and regist	ration cert) No file chosen				
+ Submission of Other	* Contact Information	for Product Cancellation :	* Phone No. :		* Email :		
Post-registration Supplement	* Address :						
+ Interview	Floor :						
<ul> <li>Request to Cancel Product Registration</li> </ul>	Block :						
	Building :						
Application	Street No. : Street Name :						
Application Status	Sub-district : P	lease Select		~			
- Application Submitted	Area : P	lease Select		$\checkmark$			
Withdraw application							Close Next

### Step 2:

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

			<b>v</b>					
								Close Next
	Step 1: Enter	Product for	Cancellation of	Product Regis	tration, Re	ason(s) of Product	Cancellation and Co	ntact Information.
You are login as WONG	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 Pro	duct Cancellation	:					
+ New Registration								<u>^</u>
+ Change of Registered	L							$\checkmark$
Particulars	* Request letter fo	r Cancellation of F	roduct Registration :	UPLOAD				
+ Renewal of Registration	(Please manual su	ibmit original lettei	r and registration cert;	No file chosen				
	Contact Informatio	n for Product Can	cellation :					
+ Submission of Other Post-registration	* Contact Person :			* Phone No. :		^ Emai		
Supplement	Unit :							
+ Interview	Floor :							
- Request to Cancel	Block :							
Product Registration	Building :							
Initiate EOL	Street No. :							
Application	Street Name :							
Application Status - Not Submitted	Sub-district :	Please Select			~			
- Application Submitted	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 Can	cella	tion and Contact Information.
ou are login as WONG	Select Product				-	
avid BC COMPANY LIMITED	*HK No.	Produ	ct List		×	sue
ogin date and time	The second second		THE M-	Due doub Marrie	-	
	Re-	0	HK40870	2-4-2 QINTMENT(TEST)	^	
Online Notification	* Effective Date	0	HK40981	CALCIUMEOLINAT EBEWE IN 200MG (TEST)		
Mu Deeduct Cooreb		0	HK40985	CPC VITAMIN B1 TAB 100MG (TEST)		
wy Product Search	* Reason(s) of Product	0	HK41004	MEYSALIOL SPRAY (TEST)		
New Registration		0	HK41016	VITAMIN E CAP 400IU (TEST)		
		0	HK41018	PIROCAM IN J 20MG/ML (TEST)		
Change of Registered Particulars		0	HK41025	TRANSBRONCHO TAB 30MG (TEST)		
	Contact Information for	0	HK41026	PAINSTOP INJ 25MG/ML (TEST)		
Renewal of Registration	* Contact Person :	0	HK41441	ALLERSAN TAB		
regionation	* Address :	0	HK42074	3TC ORAL SOLUTION 10MG/ML (TEST)		
Submission of Other	Unit :	Õ	HK49574	ALBOL SUPER-CAL 600MG + VIT D3 TAB		
Supplement	Floor :	0	HK55147	0.3% POTASSIUM CHLORIDE AND 0.9% SODIUM		
Interview	Block :	0	HK55411	0.15% POTASSIUM CHLORIDE AND 0.9%		
Request to Cancel	Street No. :	0	HK58139	PROMERIS DUO SPOT-ON FOR EXTRA LARGE		
Trouder registration	Street Name :	۲	HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG)	1	
	Sub-district : Plea	-	11/20140	320MG/1.6ML (VET)		
	Area : Plea	0	HK59168	DURAMUNE ADULT C4 VACCINE (VET)		
Application Status - Not Submitted		0	HK60366	MEI)		Class Nov
- Application Submitted		0	HK60817	ALENDRONATE SANDOZ TAB 70MG		(Close) (nex
Withdraw application		0	HK61163	XGEVA SOLUTION FOR INJECTION 120MG		
Payment		0	HK63482	OMEPRAZOLE NORMON POWDER FOR SOLUTION FOR INFUSION 40MG	~	
		$\cap$	HK63505	TFST 1127	-	

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.

	Request to Ca	ncel Product F	Registrations							
<b>—</b>								(	Close	Next
	Step 1: Enter P	roduct(s) for C	ancellation of Produc	t Registration, F	leason(s) of Prod	luct Cano	ellation and Co	ontact Informa	tion.	
You are login as WONG	Select Product									
David ABC COMPANY LIMITED	*HK No.	Proc	luct Name		Expiry Date	O	ther Issue			
Login date and time 14.10.2016 11:24	HK58142	PRC 320	MERIS SPOT ON FOR LARGE C MG/1.6ML (VET)	ATS (>4KG)	27.07.2019	R	ecent Notification(s) on	Change of Registered	Product	
Online Notification	* Effective Date :									
My Product Search	* Reason(s) of Produc	ct Cancellation :								
+ New Registration										
+ Change of Registered Particulars								*		
+ Renewal of Registration	Contact Information for Contact Person :	or Product Cancellati seaman.cai	on : * Phone No. :	11223344	* Email :	seaman@	abc.com			
+ Submission of Other Post-registration Supplement	Unit: 382	2								
+ Interview	Block : A									
<ul> <li>Request to Cancel Product Registration</li> </ul>	Street No. :	IA LEUNG BUILDI	NG							
Initiate EOL Application	Street Name : Sub-district : CH	HA KWO LING		~						
Analisation Otatus	rea : Ple	ease Select		~						
- Not Submitted - Application Submitted								(	Close	Next

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	LCT Registrations				
T	Step 1: Ente	r Product for	Cancellation of P	roduct Registration, Re	ason(s) of Product (	Cancellation and Conta	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	Contact Informat	ion for Product Can submit original letter	roduct Registration : and registration cert) cellation :	No file chosen			
+ Submission of Other Post-registration Supplement	* Contact Person * Address : Unit :	ı:		* Phone No. :	* Emai	1:	
+ Interview	Floor :				]		
<ul> <li>Request to Cancel Product Registration</li> </ul>	Block : Building :				]		
Initiate EOL	Street No. :				]		
Application Status	Street Name :				]		
<ul> <li>Not Submitted</li> <li>Application Submitted</li> </ul>	Area :	Please Select Please Select		<u> </u>			
Withdraw application							Close Next
Ť	Request to Step 1: Ente	Cancel Prod	uct Registrations	f Product Registration	, Reason(s) of Produ	ict Cancellation and Co	Close Next
You are login as WONG	Select Product	i)		-			
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 F 320MG/1.6ML (VET)	OR LARGE CATS (≽4KG)	27.07.2019	Recent Notification(s) on	Change of Registered Product
Online Notification	* Effective Date	14.10.2016					
My Product Search	* Reason(s) of P	roduct Cancellation	:				
+ New Registration	This produc	ct is no longe	er produce				0
+ Change of Registered Particulars	L						*
+ Renewal of Registration	Contact Informat * Contact Persor	tion for Product Car n : seaman.cai	icellation : *	Phone No. : 11223344	* Email : s	seaman@abc.com	
+ Submission of Other Post-registration	Unit :	382					
Supplement	Floor :	3					
+ Interview	Block : Building :	A CHALEUNG B					
- Request to Cancel Product Registration	Street No. :						
Initiate EOL Application	Street Name : Sub-district :	CHA KWO LING	3	~			
Application Status	Area :	Please Select		~			
- Application Submitted							Close Next

Step 6:

• Click "Next" to save the information.

	Request to Cancel Pro	duct Registrations				
Ť						Close Next
	Step 1: Enter Product(s)	) for Cancellation of	Product Registration, R	eason(s) of Product Ca	ncellation and Contact Inform	nation.
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 FO 320MG/1.6ML (VET)	OR LARGE CATS (>4KG)	27.07.2019	Recent Notification(s) on Change of Registe	red Product
Online Notification	* Effective Date : 14.10.2016					
My Product Search	* Reason(s) of Product Cancellati	ion :				_
+ New Registration	This product is no lon	iger produce			<u>^</u>	
+ Change of Registered Particulars					~	]
+ Renewal of Registration	Contact Information for Product C * Contact Person : seaman.ca	cancellation : i * F	Phone No. : 11223344	* Email : seama	n@abc.com	
0.1.1.1.60	* Address :		(			
Post-registration	Unit : 382		網員訊息 =			
Supplement	Floor: 3					
+ Interview	Block : A			a2		
	Building : CHA LEUNG	BUILDING				
<ul> <li>Request to Cancel Product Registration</li> </ul>	Street No. :					
I-W-H FOI	Street Name :			He we have a second sec		
Application	Sub-district : CHA KWO LI	NG		AX/A		
Application Status	Area : Please Select	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	itions		
<b>·</b>					Back Save Confirm & Submit
	Step 2: Indicate Registration.	the Return of Registra	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 LAP	RGE CATS (>4KG) 320MG/1.6ML (VET)		
	If "Return Registration	on Certificate to Drug Office" i	is checked, Drug Office will start to proces	ss your request when the regis	tration 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 : sea	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			
+ Interview	Street Name : Sub-district :	CHA KWO LING			
- Request to Cancel Product Registration	Aled .				
Initiate EOL Application	Warning:The cancell cancellation by Drug	ation of registered product is Office.	subject to approval by Drug Office. The ca	incellation 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 Registration	ons		
+		g			Back Save Confirm & Submit
	Step 2: Indicate	the Return of Registrati	ion Certificate, and Confirm S	ubmission of Your Requ	est of Cancellation of Product
You are login as WONG	Registration.		2 1 1 1		
David	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	is missing.			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			
- Request to Cancel Product Registration	Building : Street No. :	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
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.
	*If "Return Registration	n Certificate to Drug Office" is	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. :	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	ion of registered product is s Office.	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	Thank you for using ou You reference number is DE-	r service. Your request for cancellation of product registration is subject to approval of Drug Office. REG-HK58142-20161014	
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. 🗢	Product Name	\$
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_NOTIFICATI
					Ba
are login as WONG	Notification Date : 14.10.20	016 12:04:50			
COMPANY LIMITED in date and time 0.2016 11:24	Cancellation Reque	st Submiss	sion Notification	1	
	Dear Sirs/Madams,				
mine Noulication	Cancellation of Drug/Prod	uct Registratio	on:		
ly Product Search					
lew Registration	HK No. HK58142	¢ ₽R02	PR No. 235/2008	\$	Name of Product PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)
hange of Registered articulars	Thank you for your online ap providing professional and e	plication dated xecutive suppo	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 receip	of your applica	ation and it is now bein	g proces:	ed.
Submission of Other Post-registration					
Supplement					Ва

#### 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 Applic	ation
	\$	Date Received -	Ref No.	\$ HK No.	\$	Product Name	\$ Status	\$
David ABC COMPANY LIMITED		24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX		Cancellation Request Submitted	
24.08.2018 17:51		07.08.2018	DE-REG-HK63533-20180807	HK63533	TEST 20161208		Cancellation Request Submitted	
Online Notification							Withdraw Applic	ation
My Product Search								
+ New Registration								
· 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								
+ Payment.								

#### Step 2:

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

	EOL	Application Wi	thdrawal						
								Withdraw Applica	ition
You are login as WONG	\$	Date Received -	Ref No.	\$ HK No. 💠		Product Name	\$	Status	\$
David ABC COMPANY LIMITED		24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX		Ģ	Cancellation Request	
Login date and time 24.08.2018 17:51		07.08.2018	DE-REG-HK63533-20180807	HK63533	TEST 20161208		09	Cancellation Request Submitted	
Online Notification								Withdraw Applica	tion
My Product Search									
+ 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									
+ Pavment.									

Step 3:

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

-	EOL Application	Withdrawal						Confirm to Withdraw	Cluse
	Date Received \$	Ref No.	¢	HK No.	\$	Product N	lame	\$ Status	÷
You are login as WONG	24.08.2018	DE-REG-HK36995-20180824		HK36995	PRODUCT NAME XXXX			Cancellation Request Submitte	ted
ABC COMPANY LIMITED	Reason(s) of Withdra	val :							
24.08.2018 17:51						~			
Online Notification									
My Product Search						$\sim$			
+ New Registration								Confirm to Withdraw	Close

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	24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX		Cancellation Request Submi	tted
ABC COMPANY LIMITED	* Reason(s) of Withdra	wal :					
24.08.2018 17:51	Reason				~		
Online Notification							
My Product Search					~		
my riodder ocdien			網頁訊息	L			
+ New Registration						Confirm to Withdraw	Close
+ Change of Registered Particulars			?	Are you sure to save?			
+ Renewal of Registration				確定 取満			
+ Interview							
- 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.

Ť	ATTENTION : If unable to open the on	line payment service p Y-E-0001 does appear	age, please enable t and Kaspersky Inter	he TLS1.1 and	d TLS1.2 from the oftware installed o	Internet Option > advance set	ting. online payment	service FAQ Que	estion 1.	
You are login as VMG TEST USER1 SEAMAN COMPANY LTD Login date and time 27.07.2023 12:23										
Online Notification										
My Product Search	New Applicat	tion Paymen	t							
+ New Registration									Print	Ready to Pay
+ Change of Registered Particulars	Application Re	eceived Date PL No.	\$	PR No.	\$	Proposed Name of Product	¢	Payment Status		÷
+ Renewal of Registration										
+ Submission of Other Post-registration Supplement										
+ Interview	New Applicat	tion Certifica	te Payment	t						
+ Request to Cancel	Application Re	ceived Date DI No		PP No	•	Proposed Name of Product		Payment Status		Ready to Pay
- Payment	Certificate Collectio	n e-Certificate		TRAD.	•	Toposca Name of Froduct	•	T uyment Status		·
Payment Pool	Recipient :	⊖ vmg_user3								
Payment History		⊖ vmg_user1								
Application History		*0-1								
+ User Profile	CORP Undat	A Cortificat	e Pavment						_	
+ Printing Service			e i ayment						Ready	to Pay Close
+ System	Application Received Date	♣ Reference No.	¢ Hk	(No. 💠	Name of Product		♦ Change Catego	e _{\$} Paym	ent Status	¢
Logout	Cert ficate Collectio	n : _{e-Certificate}	]							
	Recipient :	⊖ vmg_user3	]							
		⊖vmg_user1								
		*Select only one re	ipient.							

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:

	New Dredu	at Degistre	ation			
•	New Produ	ict Registra				Print Receipt Close
	Payment Reference	ce No.: DHPRS-2	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	ceived Date	Reference No.	PR No.	Product Name	
My Product Search	Application Rec 27.02.2017	ceived Date 7 10:22	Reference No. ANP20179000024	PR No. PR0038/2017	Product Name TEST 2016022701	
My Product Search New Registration Change of Registered Particulars	Application Rec 27.02.2017 The Drug Office a response as soon	ceived Date 7 10:22 acknowledges the r n as possible.	Reference No. ANP20179000024 receipt of your payment of HK\$1,3	PR No. PR0038/2017 370.00 for application fee regardin	Product Name TEST 2016022701 g the above product(s). We will process yo	ur application and will provide
My Product Search New Registration Change of Registered Particulars Renewal of Registration	Application Rec 27.02.2017 The Drug Office a response as soon Please kindly que	ceived Date 7 10:22 acknowledges the r n as possible. ote the above Payn	Reference No. ANP20179000024 receipt of your payment of HK\$1,3 nent Reference Number for enqui	PR No. PR0038/2017 370.00 for application fee regardin ries.	Product Name TEST 2016022701 g the above product(s). We will process yo	ur application and will provide
My Product Search New Registration Change of Registered Particulars Renewal of Registration Interview	Application Rec 27.02.2017 The Drug Office i response as soon Please kindly que General Enquiries Office Hours:	ceived Date r 10:22 acknowledges the r n as possible. ote the above Payn s: Monday to Eriday	Reference No. ANP20179000024 receipt of your payment of HK\$1, nent Reference Number for enqui	PR No. PR0038/2017 370.00 for application fee regardir ries.	Product Name TEST 2016022701 g the above product(s). We will process yo	ur application and will provide
My Product Search New Registration Change of Registered Particulars Regestration Interview Request to Cancel Product Registration	Application Rec 27.02.2017 The Drug Office : response as soor Please kindly que General Enquiries Office Hours:	ceived Date 7 10:22 acknowledges the r n as possible. ote the above Payn s: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm	Reference No. ANP20179000024 receipt of your payment of HK\$1,3 nent Reference Number for enqui	PR No. PR0038/2017 370.00 for application fee regardin ries.	Product Name TEST 2016022701 g the above product(s). We will process yo	ur application and will provide
My Product Search New Registration Change of Registered Particulars Renewal of Registration Interview Request to Cancel Product Registration Payment	Application Rec 27.02.2017 The Drug Office : response as soor Please kindly qu General Enquiries Office Hours:	ceived Date 7 10:22 acknowledges the r n as possible. ote the above Payn s: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on 1) (Closed on Saturd:	Reference No. ANP20179000024 receipt of your payment of HK\$1,3 nent Reference Number for enqui	PR No. PR0038/2017 370.00 for application fee regardir ries.	Product Name TEST 2016022701 g the above product(s). We will process yo	ur application and will provide
My Product Search New Registration Change of Registered Change of Registered Renewal of Renewal of Registration Interview Registration Payment Payment Payment Pool	Application Rec 27.02.2017 The Drug Office : response as soon Please kindly que General Enquiries Office Hours:	ceived Date 7 10-22 acknowledges the in a s possible. ote the above Payn s: Monday to Friday 9:00 am - 1:00 pm 2:00 pm - 5:45 pm (up to 6:00 pm on 1 (Closed on Saturdi (852) 2319845	Reference No. ANP20179000024 receipt of your payment of HK\$1, nent Reference Number for enqui	PR No. PR0038/2017 370.00 for application fee regardin ries.	Product Name TEST 2016022701 g the above product(s). We will process yo	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		繳費日期
3 MED MEDICAL SUPPLIE	IS CO	26.08.2022
Payment Reference No:	DHPRS-202208261522-93716	
付款编號: ECIS Beforence Nor	(2002002/2000002	
EGIS Kelerence No: EGIS編號:	C202208265000807	
rayment Method: 付款方法:	усв	
Payment Amount:	HK\$155.00	
付款方法: Payment Amount: 付款金額:	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	New Product	Regis	i y										
You are login as WONG David ABC COMPANY LIMITED Login date and time	New Product	Reais	New Broduct Boxistration										
You are login as WONG David ABC COMPANY LIMITED Login date and time			tration					Total Number of Payment I	Records: 2				
You are login as WONG David ABC COMPANY LIMITED Login date and time	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	UK No.	•	Name of Deadure	•	Devenue Dete		A	Iotal Number of Payment	Records:				
Mu Braduat Saarah	HK 83552	Ŧ		Ŧ	16 11 2017	Ŧ	Amount(HKS)	DHPRS-201711161525-13744					
My Floduct Search	Renewal of R	enistra	ation		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.	¢				
Particulars	HK36996		PRODUCT NAME XXXX XXXX		24.08.2018		575.	0 DHPRS-201808241655-91732					
Fequest 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 Registrat	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								
Delivery Methor	d: Collect i	Collect in Person in Drug Office								
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						
Application R 09.12.20 The Drug Offic response as so	Received Date 014 17:55 ce acknowledges the re oon as possible.	Reference No. ANP20149000189 acceipt of your payment of HK\$1,3	PR No. PR0103/2014 V70.00 for application fee regardi	Product Name HP TEST 1209 NCE ng the above product(s). We will process yo	our application and will provi	de				
Application R 09.12.20 The Drug Offic response as so Please kindly of	Received Date 114 17:55 ce acknowledges the re oon as possible. quote the above Paym	Reference No. ANP20149000189 ecceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014 070.00 for application fee regardi iries.	Product Name HP TEST 1209 NCE ng the above product(s). We will process yo	our application and will provi	de				
Application R 09:12:20 The Drug Offic response as of Please kindly of General Enquirie	Received Date 014 17:55 ce acknowledges the re oon as possible. quote the above Paym ies:	Reference No. ANP20149000189 ecceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014 170.00 for application fee regardi iries.	Product Name HP TEST 1209 NCE ng the above product(s). We will process yo	our application and will provi	de				
Application R 09.12.20 The Drug Offic response as so Please kindly o General Enquirie Office Hours:	Received Date 114 17:55 ce acknowledges the re oon as possible. quote the above Paym les: Monday to Friday	Reference No. ANP20149000189 acceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014 170.00 for application fee regardi irles.	Product Name HP TEST 1209 NCE Ing the above product(s). We will process yo	our application and will provi	de				
Application R 09.12.20 The Drug Offic response as so Please kindly o General Enquirie Office Hours:	Received Date 114 17:55 ce acknowledges the re oon as possible. quote the above Paym les: Monday to Friday 9:00 am - 1:00 pm	Reference No. ANP20149000189 scelpt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014 /70.00 for application fee regard	Product Name HP TEST 1209 NCE ng the above product(s). We will process yo	ur application and will provi	de				
Application R 09.12.20 The Drug Offic response as sr Please kindly o General Enquirk Office Hours:	Received Date 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	Reference No. ANP20149000189 acceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014	Product Name HP TEST 1209 NCE ng the above product(s). We will process yo	our application and will provi	de				
Application R 09.12.20 The Drug Offic response as si Please kindly o General Enquirk Office Hours:	Received Date 114 17:55 25 acknowledges the re oon as possible. quote the above Paym les: Monday to Friday 9:00 am - 1:00 pm (up to 6:00 pm on M	Reference No. ANP20149000189 acceipt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014 770.00 for application fee regardi	Product Name HP TEST 1209 NCE	ur application and will provi	de				
Application R 09.12.20 The Drug Offic response as so Please kindly o General Enquirik Office Hours:	Acceived Date 114 17:55 ee 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 (up to 6:00 pm on M (Closed on Saturda;	Reference No. ANP20149000189 scelpt of your payment of HK\$1,3 ent Reference Number for enqui	PR No. PR0103/2014	Product Name HP TEST 1209 NCE ng the above product(s). We will process yo	sur application and will provi	de				
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#### Change of Registered Particular:

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he Drug Office ack sponse as soon a	nowledges the receipt of you s possible.	r payment of HK\$15	5.00 for application fee regarding the a	above product(s). We will process your ap	plication and will provide		
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 Tice 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_info@dh.gov.hk

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Print Receipt Close

## 2.10 APPLICATION HISTORY

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

	Online	e Notification					ONLINE_NOTIFICATION_V	/IEW_01
T	New Pro	oduct Registration					Archived Notifi	cations
	No relat	ed notifications						
You are login as ORG Trial								
ESTING LIMITED	CORP						Archived Notifie	cations
6.01.2021 15:42		Notification Date \$	Subject	\$	HK No.	\$	Name of Product	\$
Online Notification	Open	12.01.2021 17:44:04	Application Screening Notification		HK41190		PRODUCT NAME XXXXX XXXX	
onino riounouson	Open	05.06.2020 11:00:01	Application Submitted Notification		HK41190		PRODUCT NAME XXXXX XXXX	
My Product Search	Open	03.10.2019 11:55:37	Application Submitted Notification		HK37565		PRODUCT NAME XXXXX	
	Open	04.03.2019 11:33:13	Application Approval Notification		HK31199		EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG	
New 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	
- Request to Cancel	Open	21.08.2018 18:07:37	Application Submitted Notification		HK37565		PRODUCT NAME XXXXX	
Product Registration	Renewa	l of Registration					Archived Notifi	cations
r rayment	No relat	ed notifications						
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+ User Profile	Cancell	ation Request						
		Notification Date \$	Subject	\$	HK No.	•	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	
Logout	Non Pha	armaceutical Produ	uct Alert					
	No relat	ed notifications						
		2015 copy	right   Important notices Last Revision Date: 02 Sep	2020 Versi	on: 1.0.99 (PP)			

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 ****