



APPLICATION USER MANUAL

FOR THE

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

(PRS 2.0)

OF THE

DEPARTMENT OF HEALTH

Version: 1.1.18

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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
New Application	Generic (Biological)	Module 1	50MB	300MB
		Module 2-5	Submit by CD/DVD	
	Generic (Others)	Module 1	50MB	100MB
		Module 2-5	Submit by CD/DVD	
	NCE	Module 1	50MB	300MB
		Module 2-5	Submit by CD/DVD	
CORP Application	All Case	All scope	5MB	100MB
Renewal Application	All Case	All scope	No File 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 Pharmacy and Poisons Board will only issue certificates of drug/ product registration in electronic form for applications for initial registration, renewal of registration and change of registered particulars. For details, please visit https://www.drugoffice.gov.hk/eps/do/en/popup_launch_of_electronic_certificate_of_drug_product_registration_en.html



Welcome to Pharmaceuticals Registration System (PRS2.0)

Username: *	<input type="text"/>
Organizational e-Cert File Location: *	<input type="button" value="Choose File"/> No file chosen Please select the e-Cert file, e.g. C:\cert.p12
e-Cert PIN: *	<input type="text"/>
System Password: *	<input type="password"/>
<input type="button" value="Login"/> <input type="button" value="Reset"/>	<input type="button" value="Request for New Account"/>
<input type="button" value="Cert Validation"/> * mandatory field	<input type="button" value="Reset Password"/>

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'.

Points to note:

1. Install and configure the required software:
 - a. Web browser: Google Chrome
 - b. Web browser settings: Accept cookies and enable JavaScript
 - c. 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.
4. 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:

- 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 INT-USER_REG_01 USR

Step 1: Agreement on the Terms and Conditions ("Terms") for the Use of the Pharmaceuticals Registration System 2.0 ("PRS2.0")
Terms for the Use of PRS2.0

**TERMS AND CONDITIONS FOR THE USE OF
PHARMACEUTICALS REGISTRATION SYSTEM 2.0 (PRS2.0)**

1. Introduction

The following are the terms and conditions ("Terms") for the use of the Pharmaceuticals Registration System 2.0 ("PRS2.0") operated by the Department of Health ("DH") of the Government ("Government") of the Hong Kong Special Administrative Region of the People's Republic of China ("Hong Kong"). The Government agrees to provide the Services (as defined in Clause 3 below) and you, as the user of PRS2.0 ("User"), agree to use the Services in accordance with the Terms.

2. Acceptance of Terms of Use

Your accessing and using PRS2.0 is taken as your agreement to be legally bound by these Terms as may be modified and/or supplemented from time to time by the Government without prior notice to any User. Please check the website at https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp regularly for any modification and/or supplement which may be made.

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 Cancel

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

INT-USER_REG_02 USR

Login Information

* Username Username only allows alphabets (a-z, A-Z), numbers (0-9), underscores (_) and Hyphens(-) and must be 5-20 characters long.

Note: Password would be automatically generated by the system and sent to the authorized user through email.

e-Cert (Organizational)

* Organizational e-Cert File Location [瀏覽...](#)

* e-Cert PIN

Information on e-Cert

(Click [Hong Kong Post](#) Check e-Cert Information in Hongkong)

* Email address (Case Sensitive)

* Name of Organization

* Business Registration Certificate Number (e.g. 12345678-123)

* Name of Authorized User

* Contact Phone Number (852)

Position

* Company Address

Unit:

Floor:

Block:

Building:

Street No.:

Street Name:

Sub-district:


Area:

E-cert Register: ☐

E-Cert Token:

[Back](#) [Continue](#) [Cancel](#)

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

 The solution for e-Security

Download Certificate - e-Cert (Organisational)

Please input **either one** of the following information:-

English Name in Certificate :

Suriname Given Name

Email Address in Certificate :

Subscriber Reference Number :

Warning: Any information and certificates downloaded from this web site shall only be used for lawful purposes relevant to the use of digital signatures and encryption.

☒ acknowledge that I have read the above warning message and will abide by the purposes and limitations on use stated therein.

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 The solution for e-Security

Download Certificate - e-Cert (Organisational)

English Name in Certificate :

Email Address in Certificate :

Organisation Name in English :

Organisation Name in Chinese :

Branch Name in English :

Branch Name in Chinese :

BR Number :

CR/CI :

Others :

Subscriber Reference Number :

Type of Certificate : e-Cert (Organisational)

Issued by : Hongkong Post e-Cert CA 1 - 10

Certificate Serial Number : 32 d4 32

Certificate Signature Algorithm : sha1RSA

Certificate Status : Active

Validity Period (dd/mm/yyyy) :

[Download the Certificate](#)

Note:-
The Certificate status displayed above is for information only. Before you rely on the Certificate displayed above, you should verify if the Certificate has been suspended or revoked by locating its serial number in the latest Certification Revocation List (CRL) issued by Hongkong Post Certification Authority. If the serial number of the Certificate is found in a CRL, then the Certificate has been suspended or revoked and should not be relied upon. You may download the latest partitioned CRL of the Certificate at <http://crl1.hongkongpost.gov.hk/crl/eCertCA1-10CRL2.crl>. Alternatively, you may download the latest full CRL at <http://crl1.hongkongpost.gov.hk/crl/eCertCA1-10CRL1.crl>. Please be aware that the full CRL is larger in size, it may take a longer time to download.

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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.

New User Registration INT-USER_REG_03 USR

Step 3: Review and confirm the account details
Please check your account details before submission.

* 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:	
Area:	

[Print](#) [Edit](#) [Submit](#) [Cancel](#)

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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 INT-USER_REG_04 USR

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](#)

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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

Registration Approved Inbox x

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

Your registration request has been approved by DO.

Username: winniefong
Password: mauzkiQx

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Welcome to Pharmaceuticals Registration System (PRS2.0)

Username: *

Organizational e-Cert File Location: *

e-Cert PIN: * ☐

System 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 'prs2_info@dh.gov.hk'.

Points to note:

1. Install and configure the required software:
 - a. Web browser: Internet Explorer 11.0 or Chrome
 - b. Web browser settings: Accept cookies and enable JavaScript
 - c. Ensure TLS1.0, TLS1.1 and 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.
4. 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:

- For first time login, user will be redirected to the change password page. Input the one-time 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.

Change Password

The password has expired due to security reason and you need to change password before continue.

(8-20 characters containing alphabet(s) in upper case, alphabet(s) in lower case and non-alphabet(s))

Current Password :

New Password :

Confirm New Password :

• After you have saved the password, you will be logged out automatically and need to login again.

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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 Pharmacy and Poisons Board will only issue certificates of drug/ product registration in electronic form for applications for initial registration, renewal of registration and change of registered particulars. For details, please visit https://www.drugoffice.gov.hk/eps/do/en/popup_launch_of_electronic_certificate_of_drug_product_registration_en.html



The image shows the login page for the Pharmaceuticals Registration System (PRS2.0). At the top center is a logo of a red stick figure with arms raised, enclosed in a square frame. Below the logo is the title "Welcome to Pharmaceuticals Registration System (PRS2.0)" in a red serif font. The login form is on the left, with labels for "Username: *", "Organizational e-Cert File Location: *", "e-Cert PIN: *", and "System Password: *". There are "Login" and "Reset" buttons below the password field. A "Cert Validation" button is below the "Login" button, with a note "* mandatory field". To the right of the form is a red rectangular box containing the input fields: a text box for "username", a "Choose File" button followed by the text "prs20-prod-test-2022.p12", a checkbox labeled "Please select the e-Cert file, e.g. C:\cert.p12", and two password input fields with asterisks. To the right of the red box are two buttons: "Request for New Account" and "Reset Password".


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'.

Points to note:

1. Install and configure the required software:
 - a. Web browser: Internet Explorer 11.0 or Chrome
 - b. Web browser settings: Accept cookies and enable JavaScript
 - c. Ensure TLS1.0, TLS1.1 and 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.
4. 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 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.



You are login as ORG
TRIAL ONE
TESTING LIMITED (TEST)
Login date and time
09.02.2021 14:33

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- Request to change name and/or address of the certificate holder
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + Printing Service
- + System
- Logout

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	21.01.2021 17:25:14	Application Payment Request	FACE CREAM	PL0001/2021	Paid
Open	21.01.2021 17:14:03	Screening Application	FACE CREAM	PL0001/2021	N/A
Open	06.11.2019 11:52:34	Application Payment Request	TEST OPEN FILE CASE 3	PL0024/2019	Paid
Open	05.09.2019 16:10:27	Screening Application	TEST OPEN FILE CASE 3	PL0024/2019	N/A
Open	04.09.2019 11:17:16	Evaluation Application	TEST 2017022401	PL0030/2017	N/A

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	28.01.2021 04:00:12	Application Effective Reminder	HK63536	DEMO ON 2017-01-19
Open	22.01.2021 09:47:20	Application Submitted Notification	HK63668	TEST 20145
Open	20.01.2021 11:50:56	Application Submitted Notification	HK63536	DEMO ON 2017-01-19

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals
Open	28.09.2019 02:06:59	Expired Product Notice	DEMO ON 2017-	1
Open	20.07.2019 02:05:10	Expired Product Notice	TEST OPEN FILE CASE	1
Open	08.07.2019 04:00:11	Renewal Final Reminder	DEMO ON 2017-	1

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	21.01.2021 15:49:10	Cancellation Registration Request Submitted Notification	HK63517	WALKTRHOUGH


Non Pharmaceutical Product Alert

No related notifications

2.1.2.1 Request Reset Password

Step 1: Click Reset Password to request reset password

With effect from 1 July 2023, the Pharmacy and Poisons Board will only issue certificates of drug/ product registration in electronic form for applications for initial registration, renewal of registration and change of registered particulars. For details, please visit https://www.drugoffice.gov.hk/eps/do/en/popup_launch_of_electronic_certificate_of_drug_product_registration_en.html



Welcome to Pharmaceuticals Registration System (PRS2.0)

Username: *

Organizational e-Cert File Location: * No file chosen
[Please select the e-Cert file, e.g. C:\cert.p12](#)

e-Cert PIN: *

System 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 'prs2_info@dh.gov.hk'.

Points to note:

1. Install and configure the required software:
 - a. Web browser: Google Chrome
 - b. Web browser settings: Accept cookies and enable JavaScript
 - c. 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.
4. 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.

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



Reset Password

INT-USER_REQ_RESET_PW_01 USR

Please provide the following information to reset the password. Field with * are mandatory

User Information

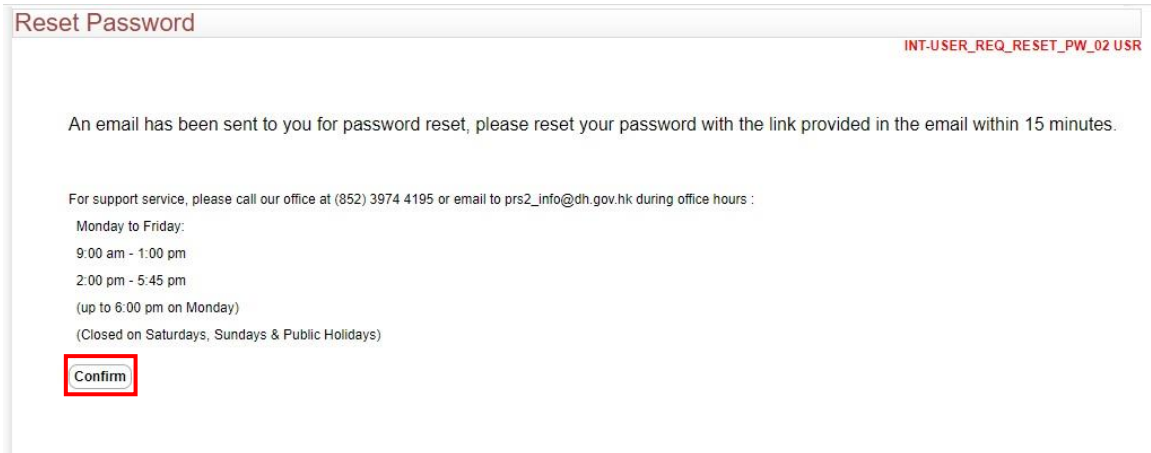
* Username

* Email address (User)

* Organizational e-Cert File Location
[Please select the e-Cert file, e.g. C:\cert.p12](#)

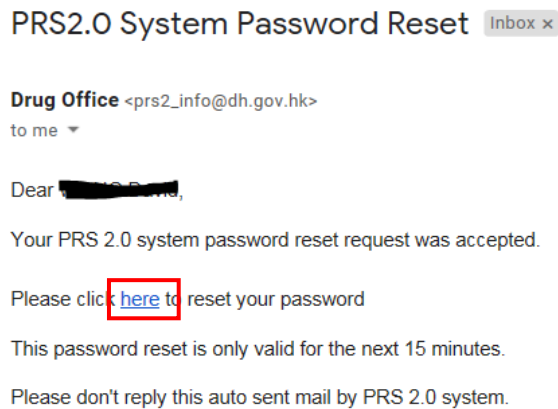
* e-Cert PIN

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

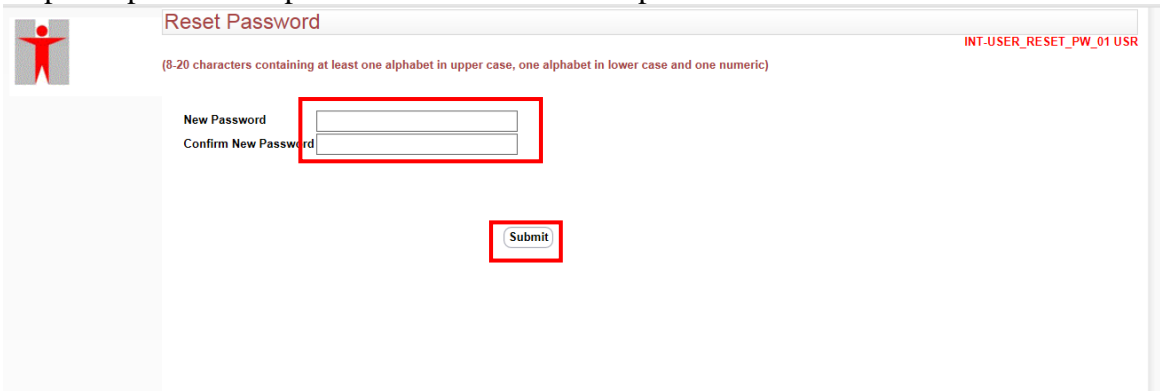


2.1.3 Reset Password

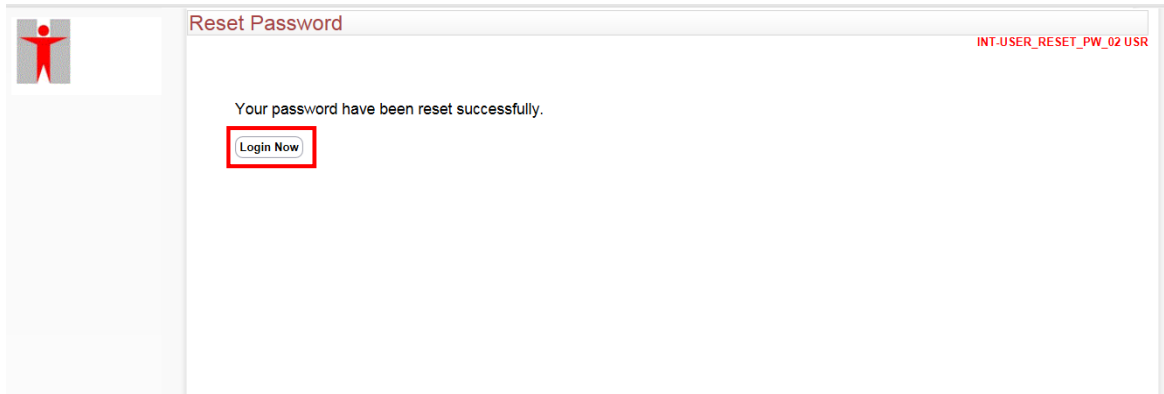
Step 1: Open the reset password email and click here



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



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

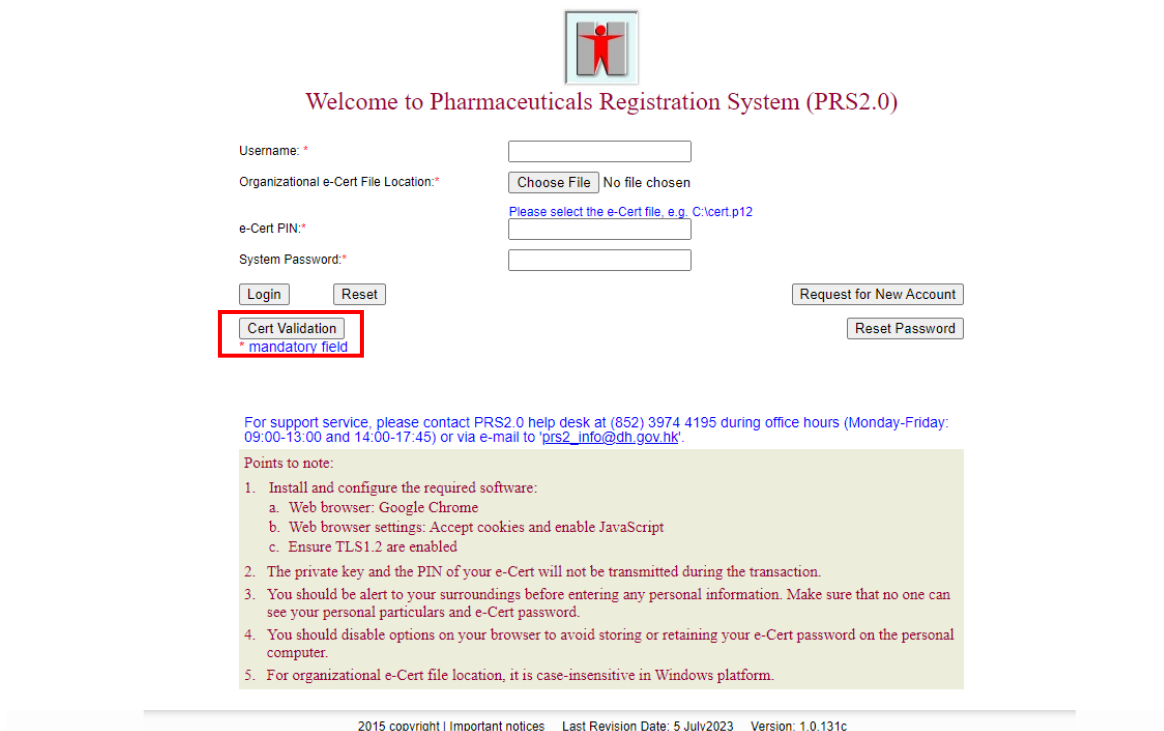


The screenshot shows the 'Reset Password' page of the Pharmaceuticals Registration System. On the left is a sidebar with a red stick figure icon. The main content area has a title bar 'Reset Password' and a red text identifier 'INT-USER_RESET_PW_02 USR'. Below the title bar, a message states 'Your password have been reset successfully.' and a red-bordered button labeled 'Login Now' is visible.

2.1.4 Product E-Cert Validation

Step1: Click the Cert Validation button.

With effect from 1 July 2023, the Pharmacy and Poisons Board will only issue certificates of drug/ product registration in electronic form for applications for initial registration, renewal of registration and change of registered particulars. For details, please visit https://www.drugoffice.gov.hk/eps/do/en/popup_launch_of_electronic_certificate_of_drug_product_registration_en.html



The screenshot shows the 'Welcome to Pharmaceuticals Registration System (PRS2.0)' login page. At the top center is a red stick figure icon. Below it is the title 'Welcome to Pharmaceuticals Registration System (PRS2.0)'. The login form includes fields for 'Username: *', 'Organizational e-Cert File Location: *' (with a 'Choose File' button and 'No file chosen' text), 'e-Cert PIN: *', and 'System Password: *'. There are 'Login' and 'Reset' buttons. A red-bordered box highlights the 'Cert Validation' button, with a red asterisk and the text '* mandatory field' below it. To the right are 'Request for New Account' and 'Reset Password' buttons. Below the login fields is a support contact message: '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'. A 'Points to note:' section follows, listing five items: 1. Install and configure the required software (a. Web browser: Google Chrome, b. Web browser settings: Accept cookies and enable JavaScript, c. 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, 4. 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. At the bottom is a footer with '2015 copyright | Important notices', 'Last Revision Date: 5 July2023', and 'Version: 1.0.131c'.

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 Please upload the PDF file of the electronic certificate.
No File Chosen

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.

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If the E-Cert is Valid

Verification System for Electronic Certificate of Drug/ Product Registration

Please enter the serial number printed on the upper right-hand corner of the electronic Certificate of Drug/ Product Registration ("electronic certificate").

* Serial no.

* Electronic certificate Please upload the PDF file of the electronic certificate.
No File Chosen

Result
This electronic certificate is valid. (at HKT 12:37, on 27/07/2023)

For support service, please contact PRS2.0 help desk at (852) 3974 4195 during office hours (Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.hk.

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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 Please upload the PDF file of the electronic certificate.
No File Chosen

Result
The uploaded PDF file is NOT the same as the valid electronic certificate on record. (at HKT 10:10, on 10/07/2023)

For support service, please contact PRS2.0 help desk at (852) 3974 4195 during office hours (Monday-Friday: 09:00-13:00 and 14:00-17:45) or via e-mail to prs2_info@dh.gov.hk.

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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.**)

The screenshot displays the PRS2.0 application interface. On the left is a vertical menu with various options. The main area shows a table titled 'Maintain Company User Accounts' with columns for user details and permissions. A red box highlights the 'Edit' link in the first row of the table. Another red box highlights the 'Maintain Company's User Accounts' menu item in the left sidebar.

Left Menu:

- 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
- Maintain Company's User Accounts**
- Add Access Right
- Remove/Transfer Access Right
- + System
- Logout

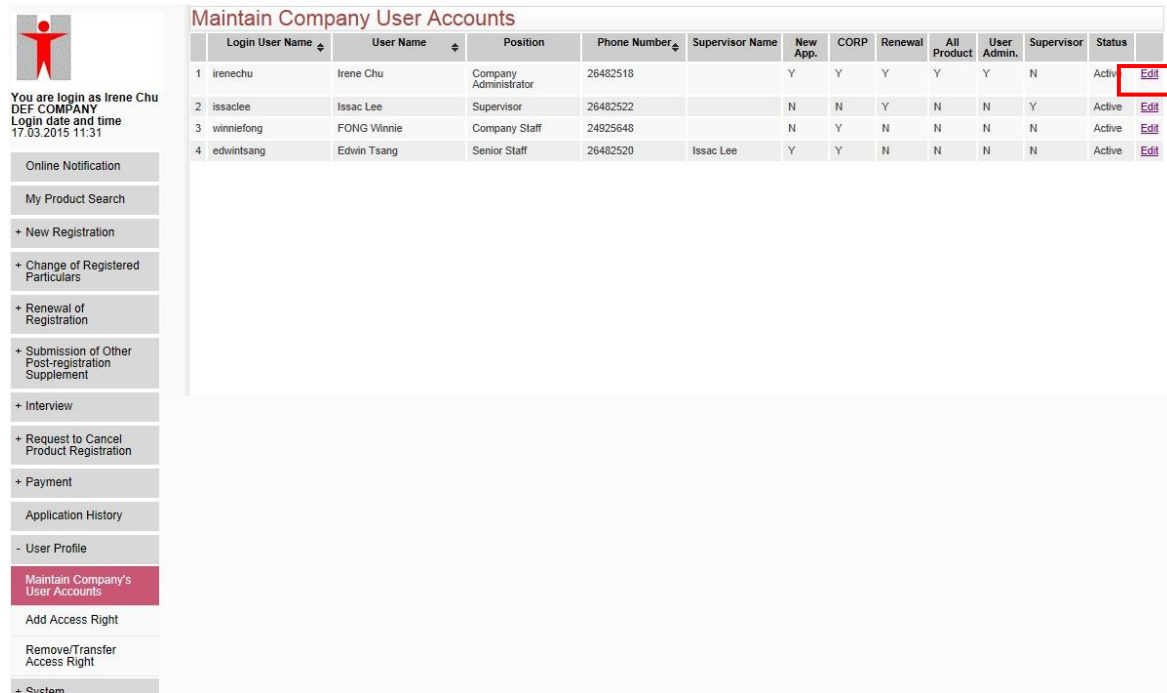
Table: Maintain Company User Accounts

	Login User Name	User Name	Position	Phone Number	Supervisor Name	New App.	CORP	Renewal	EOL	All Product	User Admin.	Supervisor	Status	
1	trial_one	ORG Trial One				Y	Y	Y	Y	N	Y	N	Active	Edit

2.2.1.1 Edit user account profile

Step 1:

- Click “Edit” to edit a company user account profile.

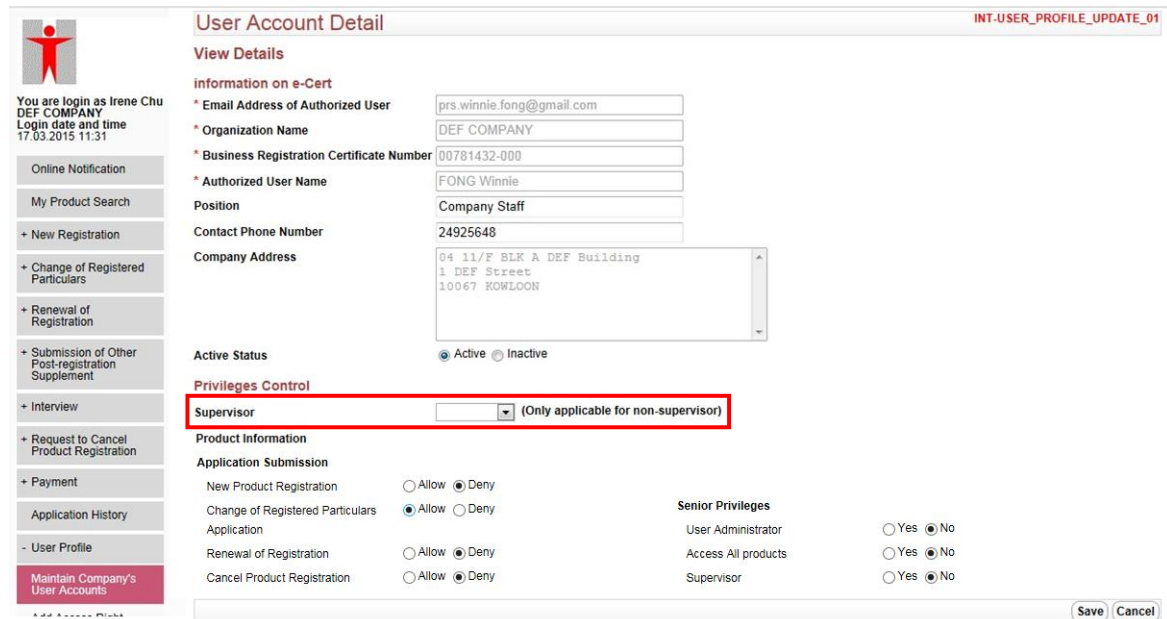


Maintain Company User Accounts

	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	Y	Y	Y	Y	N	Active	Edit
2	issaclee	Issac Lee	Supervisor	26482522		N	N	Y	N	N	Y	Active	Edit
3	winniefong	FONG Winnie	Company Staff	24925648		N	Y	N	N	N	N	Active	Edit
4	edwintsang	Edwin Tsang	Senior Staff	26482520	Issac Lee	Y	Y	N	N	N	N	Active	Edit

Step 2:

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



User Account Detail INT-USER_PROFILE_UPDATE_01

View Details

Information on e-Cert

* Email Address of Authorized User: prs.winnie.fong@gmail.com

* Organization Name: DEF COMPANY

* Business Registration Certificate Number: 00781432-000

* Authorized User Name: FONG Winnie

Position: Company Staff

Contact Phone Number: 24925648

Company Address: 04 11/F BLK A DEF Building
1 DEF Street
10067 KOWLOON

Active Status

☒ Active ☐ Inactive

Privileges Control

Supervisor (Only applicable for non-supervisor)

Product Information

Application Submission

New Product Registration: ☐ Allow ☒ Deny

Change of Registered Particulars: ☒ Allow ☐ Deny

Application: ☐ Allow ☒ Deny

Renewal of Registration: ☐ Allow ☒ Deny

Cancel Product Registration: ☐ Allow ☒ Deny

Senior Privileges

User Administrator: ☐ Yes ☒ No

Access All products: ☐ Yes ☒ No

Supervisor: ☐ Yes ☒ No

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-USER_PROFILE_UPDATE_01

View Details

Information on e-Cert

* Email Address of Authorized User: pr.s.winnie.fong@gmail.com

* Organization Name: DEF COMPANY

* Business Registration Certificate Number: 00781432-000

* Authorized User Name: FONG Winnie

Position: Company Staff

Contact Phone Number: 24925648

Company Address: 04 11/F BLK A DEF Building
1 DEF Street
10067 KOWLOON

Active Status: ☒ Active ☐ Inactive

Privileges Control

Supervisor: (Only applicable for non-supervisor)

Product Information

Application Submission

New Product Registration: ☐ Allow ☒ Deny

Change of Registered Particulars: ☒ Allow ☐ Deny

Application: ☒ Allow ☐ Deny

Renewal of Registration: ☐ Allow ☒ Deny

Cancel Product Registration: ☐ Allow ☒ Deny

Senior Privileges

User Administrator: ☐ Yes ☒ No

Access All products: ☐ Yes ☒ No

Supervisor: ☐ Yes ☒ No

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:

User Account: Issac Lee-----pr.s.issac.lee@gmail.com **Add**

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>		PL0321/1987	PR0426/1987	HK29705	WARTEX	issaclee pr.s.issac.lee@gmail.com
<input type="checkbox"/>		PL0330/1987	PR0428/1987	HK29707	VERRUGON	issaclee pr.s.issac.lee@gmail.com
<input type="checkbox"/>		PL0253/1994	PR0558/1994	HK40985	CPC VITAMIN B1	issaclee pr.s.issac.lee@gmail.com
<input type="checkbox"/>		PL0531/1994	PR0392/1994	HK41132	VITAMIN B6 (CPC)	issaclee pr.s.issac.lee@gmail.com

Winnie’s access rights of products before assignment:


User Account: FONG Winnie-----pr.s.winnie.fong@gmail.com **Add**

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>		PL0121/2000	PR0301/2000	HK46915	OYSTER CALCIUM W/ VIT D	winniefong pr.s.winnie.fong@gmail.com

Issac’s access rights of products after assignment:

User Account: Issac Lee-----pr.s.issac.lee@gmail.com **Add**

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



You are login as Irene Chu
DEF COMPANY
Login date and time
17.03.2015 11:31

- Online Notification
- 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

User Account Detail

INT-USER_PROFILE_UPDATE_01

View Details

Information on e-Cert

* Email Address of Authorized User

* Organization Name

* Business Registration Certificate Number

* Authorized User Name

Position

Contact Phone Number

Company Address

Active Status ☒ Active ☐ Inactive

Privileges Control

Supervisor (Only applicable for non-supervisor)

Product Information

Application Submission

New Product Registration	<input type="radio"/> Allow <input checked="" type="radio"/> Deny
Change of Registered Particulars Application	<input checked="" type="radio"/> Allow <input type="radio"/> Deny
Renewal of Registration	<input type="radio"/> Allow <input checked="" type="radio"/> Deny
Cancel Product Registration	<input type="radio"/> Allow <input checked="" type="radio"/> Deny

Senior Privileges

User Administrator	<input type="radio"/> Yes <input checked="" type="radio"/> No
Access All products	<input type="radio"/> Yes <input checked="" type="radio"/> No
Supervisor	<input type="radio"/> Yes <input checked="" type="radio"/> No

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_PROFILE_UPDATE_01

View Details

Information on e-Cert

* Email Address of Authorized User: prs.winnie.fong@gmail.com

* Organization Name: DEF COMPANY

* Business Registration Certificate Number: 00781432-000

* Authorized User Name: FONG Winnie

Position: Company Staff

Contact Phone Number: 24925648

Company Address: 04 11/F BLK A DEF Building
1 DEF Street
10067 KOWLOON

Active Status

☒ Active ☐ Inactive

Privileges Control

Supervisor: Issac Lee (Only applicable for non-supervisor)

Product Information

Application Submission

New Product Registration: ☐ Allow ☒ Deny

Change of Registered Particulars: ☒ Allow ☐ Deny

Renewal of Registration: ☐ Allow ☒ Deny

Cancel Product Registration: ☐ Allow ☒ Deny

Senior Privileges

User Administrator: ☐ Yes ☒ No

Access All products: ☐ Yes ☒ No

Supervisor: ☐ Yes ☒ No

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.

The screenshot shows the 'Add Access Right' web application interface. On the left is a sidebar menu with a red stick figure icon at the top. The menu items are: 'Online Notification', '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' (highlighted with a red box), 'Maintain Company's User Accounts', 'Add Access Right' (highlighted with a red box), and 'Remove/Transfer Access Right'. The main content area is titled 'Add Access Right' and contains the following elements: a header bar with 'Add Access Right' and 'Clear' buttons; a section with three radio buttons: 'All Products' (selected), 'Application ID/PL No./PR No./HK No.', and 'User Account', each with an 'Add' button; a table with columns: Application ID, PL No., PR No., HK No., Name of Product, and User Account; a section titled 'Add Access Right to...' with a dropdown menu set to 'All Accessible Staff' and an 'Add' button; and a footer bar with 'Add Access Right' and 'Clear' buttons.

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 Add Access Right Clear

☒ All Products Add

☐ Application ID/PL No./PR No./HK No. Add

☐ User Account: Add

<input type="checkbox"/>	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
--------------------------	----------------	--------	--------	--------	-----------------	--------------

Add Access Right to...

User Account: Add

Add Access Right Clear

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.

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2018 14:15

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
Maintain Company's User Accounts
Add Access Right
Remove/Transfer Access Right
+ System
Logout

Add Access Right Add Access Right Clear

☒ All Products Add

☐ Application ID/PL No./PR No./HK No. Add

☐ User Account: Add

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>						

Add Access Right to...

All Accessible Staff

User Account: Add

Add Access Right Clear

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

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2018 14:34

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
Maintain Company's User Accounts
Add Access Right
Remove/Transfer Access Right
+ System
Logout

Add Access Right Add Access Right Clear

☒ All Products Add

☐ Application ID/PL No./PR No./HK No. Add

☐ User Account: Add

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input checked="" type="checkbox"/>	ANP20169000012	PL0010/2016	PR0012/2016	HK63516	PAYMENT TEST	david_wong prs.david.wong@gmail.com
<input type="checkbox"/>	ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	kenny_liu prs.kenny.liu@gmail.com david_wong prs.david.wong@gmail.com susan_cheung_1 prs.susan.cheung@gmail.com
<input checked="" type="checkbox"/>	ANP20179000064	PL0087/2017	PR0055/2017	HK63565	MY 20170512 1612	david_wong prs.david.wong@gmail.com

Add Access Right to...

All Accessible Staff

User Account: Susan CHEUNG-prs.susan.cheung@gmail.com Add


Add Access Right Clear

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).



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.03.2018 14:34

- 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
- Maintain Company's User Accounts
- Add Access Right**
- Remove/Transfer Access Right
- + System
- Logout

Add Access Right Clear

All Products Add

Application ID/PL No./PR No./HK No. [HK63516] Add

User Account: Add

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>	ANP20169000012	PL0010/2016	PR0012/2016	HK63516	PAYMENT TEST	david_wong prs.david.wong@gmail.com

Add Access Right to...

All Accessible Staff

User Account: [LIU Kenny---prs.kenny.liu@gmail.com] Add

Add Access Right Clear

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.

Add Access Right

☐ All Products **Add**

☒ Application ID/PL No./PR No./HK No. **Add**

☐ User Account: **Add**

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>	ANP2016900012	PL0010/2016	PR0012/2016	HK63516	PAYMENT TEST	david_wong prs.david.wong@gmail.com

Add Access Right to...

All Accessible Staff

User Account: **Add**

User Account: **Remove**

User Account: **Remove**

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.

Add Access Right

☐ All Products **Add**

☐ Application ID/PL No./PR No./HK No. **Add**

☒ User Account: **Add**

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>	ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20159000238	PL0183/2015	PR0001/2016		HP Test Generic 1005	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20159000242	PL0019/2016	PR0017/2016		TEST 20160803	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20159000245	PL0190/2015	PR0003/2016		HP test 20151222	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20159000246	PL0001/2016	PR0004/2016		ABC TABLES	kenny_liu prs.kenny.liu@gmail.com
<input checked="" type="checkbox"/>	ANP20159000217	PL0141/2015	PR0083/2015	HK63489	HP TEST MANUAL 0417	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20169000052				TEST ABC	kenny_liu prs.kenny.liu@gmail.com
<input type="checkbox"/>	ANP20169000053				TEST 20161216	kenny_liu prs.kenny.liu@gmail.com

Add Access Right to...

All Accessible Staff

User Account: **Add**

Add Access Right **Clear**

Add Access Right **Clear**

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.

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
04.05.2016 10:53

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
Maintain Company's User Accounts
Add Access Right
Remove/Transfer Access Right
+ System
Logout

Add Access Right Remove/Transfer

Transfer/Revoke From: Susan CHEUNG---prs.susan.cheung@gmail.com

To: <<Revoke from User>>

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>	ANP20159000243	PL0185/2015	PR0116/2015	HK63505	TEST 1127	susan_cheung prs.susan.cheung@gmail.com

Remove/Transfer

Step 2:

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

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

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2016 14:34

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration

Add Access Right Remove/Transfer

Transfer/Revoke From: Susan CHEUNG---prs.susan.cheung@gmail.com(Supervisor)

To: <<Revoke from User>>

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>	ANP20169000032	PL0029/2016	PR0024/2016	HK63517	WALKTRHOUGH	susan_cheung_1 prs.susan.cheung@gmail.com
<input type="checkbox"/>	ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	susan_cheung_1 prs.susan.cheung@gmail.com
<input type="checkbox"/>	ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com
<input type="checkbox"/>	ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com

Remove/Transfer

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.

Add Access Right Remove/Transfer

Transfer/Revoke From: Susan CHEUNG---prs.susan.cheung@gmail.com(Supervisor) ▼

To: <<Revoke from User>>
LIU Kenny---prs.kenny.liu@gmail.com
Susan CHEUNG---prs.susan.cheung@gmail.com(Supervisor)

	HK No.	Name of Product	User Account
<input type="checkbox"/> ANP2016900032 PL0029/2016 PR0024/2016 HK63517 WALKTRHOUGH	susan_cheung_1	prs.susan.cheung@gmail.com	
<input type="checkbox"/> ANP2016900041 PL0038/2016 PR0030/2016 HK63522 TEST2016112301	susan_cheung_1	prs.susan.cheung@gmail.com	
<input type="checkbox"/> ANP2016900040 PL0035/2016 PR0029/2016 HK63518 TEST_2016112101	susan_cheung_1	prs.susan.cheung@gmail.com	
<input type="checkbox"/> ANP2017900040 MY APO	susan_cheung_1	prs.susan.cheung@gmail.com	

Remove/Transfer

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.

Add Access Right Remove/Transfer

Transfer/Revoke From: Susan CHEUNG---prs.susan.cheung@gmail.com(Supervisor) ▼


To: <<Revoke from User>>
LIU Kenny---prs.kenny.liu@gmail.com
Susan CHEUNG---prs.susan.cheung@gmail.com(Supervisor)

	HK No.	Name of Product	User Account
<input type="checkbox"/> ANP2016900032 PL0029/2016 PR0024/2016 HK63517 WALKTRHOUGH	susan_cheung_1	prs.susan.cheung@gmail.com	
<input type="checkbox"/> ANP2016900041 PL0038/2016 PR0030/2016 HK63522 TEST2016112301	susan_cheung_1	prs.susan.cheung@gmail.com	
<input type="checkbox"/> ANP2016900040 PL0035/2016 PR0029/2016 HK63518 TEST_2016112101	susan_cheung_1	prs.susan.cheung@gmail.com	
<input type="checkbox"/> ANP2017900040 MY APO	susan_cheung_1	prs.susan.cheung@gmail.com	

Remove/Transfer

Step 3:

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



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2018 14:34

- Online Notification
- My Product Search**
- + New Registration
- + Change of Registered Particulars

Remove/Transfer

Add Access Right

Transfer/Revoke From: Susan CHEUNG---prs.susan.cheung@gmail.com(Supervisor) ▼

To: LIU Kenny---prs.kenny.liu@gmail.com ▼

	Application ID	PL No.	PR No.	HK No.	Name of Product	User Account
<input type="checkbox"/>	ANP20169000032	PL0029/2016	PR0024/2016	HK63517	WALKTRHOUGH	susan_cheung_1 prs.susan.cheung@gmail.com
<input checked="" type="checkbox"/>	ANP20169000041	PL0038/2016	PR0030/2016	HK63522	TEST2016112301	susan_cheung_1 prs.susan.cheung@gmail.com
<input type="checkbox"/>	ANP20169000040	PL0035/2016	PR0029/2016	HK63518	TEST_2016112101	susan_cheung_1 prs.susan.cheung@gmail.com
<input type="checkbox"/>	ANP20179000040				MY APO	susan_cheung_1 prs.susan.cheung@gmail.com

Remove/Transfe

網頁訊息


Updated successfully.

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.



You are login as ORG TRIAL ONE TESTING LIMITED (TEST)
Login date and time
09.02.2021 14:33

- Online Notification**
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- Request to change name and/or address of the certificate holder
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + Printing Service
- + System
- Logout

ONLINE_NOTIFICATION_VIEW_01

Online Notification

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	21.01.2021 17:25:14	Application Payment Request	FACE CREAM	PL0001/2021	Paid
Open	21.01.2021 17:14:03	Screening Application	FACE CREAM	PL0001/2021	N/A
Open	06.11.2019 11:52:34	Application Payment Request	TEST OPEN FILE CASE 3	PL0024/2019	Paid
Open	05.09.2019 16:10:27	Screening Application	TEST OPEN FILE CASE 3	PL0024/2019	N/A
Open	04.09.2019 11:17:16	Evaluation Application	TEST 2017022401	PL0030/2017	N/A

Archived Notifications

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	28.01.2021 04:00:12	Application Effective Reminder	HK63536	DEMO ON 2017-01-19
Open	22.01.2021 09:47:20	Application Submitted Notification	HK63668	TEST 20145
Open	20.01.2021 11:50:56	Application Submitted Notification	HK63536	DEMO ON 2017-01-19

Archived Notifications

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals
Open	28.09.2019 02:06:59	Expired Product Notice	DEMO ON 2017.	1
Open	20.07.2019 02:05:10	Expired Product Notice	TEST OPEN FILE CASE	1
Open	08.07.2019 04:00:11	Renewal Final Reminder	DEMO ON 2017.	1

Archived Notifications

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	21.01.2021 15:49:10	Cancellation Registration Request Submitted Notification	HK63517	WALKTRHOUGH

Non Pharmaceutical Product Alert

No related notifications

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

Online Notification ONLINE_NOTIFICATION_VIEW_01

☒ Filter by Notification Date ☐ Filter by HK No. Back

From to

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_01

☒ Filter by Notification Date ☐ Filter by HK No. Back

From to

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:37:19	Application Clarification Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:34:49	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	27.11.2020 04:00:10	Application Effective Reminder	HK42660	CALCIUM UNISON TAB 300MG
Open	26.11.2020 14:45:02	Application Acknowledgement Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	26.11.2020 14:34:57	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

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

Online Notification ONLINE_NOTIFICATION_VIEW_01

☐ Filter by Notification Date ☒ Filter by HK No. Back

HK

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	21.08.2018 18:35:21	Application Approval Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:34:10	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:33:18	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX

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


2.3.1 New Product Registration Online Notification

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

Step 1:

- Click the menu item “Online Notification” in the menu on the left.

- Click the hyperlink “Open” to view the notification.



You are login as

Login date and time
28.01.2021 15:06

Online Notification

- My Product Search
- New Registration
- Change of Registered Particulars
- Renewal of Registration
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VOCIN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	BOURBON POWDER	PL0002/2020	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CALCIUM UNISON TAB 300MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CALCIUM UNISON TAB 300MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CALCIUM UNISON TAB 300MG

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 : [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 Control Division
Suites 2002-05, 20/F,
ALA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong,
Kowloon, Hong Kong

For enquiries, please call our hotline at (852) 3974 4175 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: 17.02.2015

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
<input checked="" type="checkbox"/> Application(s) for Product Registration 藥劑製品註冊申請 (HK\$1,100)	1	HK\$1,100

Ref. 檔號:
PL0181/2015

Drug Office
Department of Health

DEF COMPANY
D 18 HUNG HOI CENTER
255 KING'S ROAD
NORTH POINT HONG KONG

- The system will redirect to the new application payment pool.



You are login as **WONG David**
ABC COMPANY LIMITED
Login date and time
17.08.2018 15:08

- 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

New Application Payment

Print Ready to Pay


<input type="checkbox"/>	Application Received Date	PL No.	PR No.	Proposed Name of Product	Payment Status
<input type="checkbox"/>	31.05.2017 16:16	PL0070/2017		MY 20170531 1559	Ready for Application Payment
<input type="checkbox"/>	25.10.2017 14:34	PL0086/2017		MY 20170928 1652	Ready for Application Payment

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.



You are login as

Login date and time
28.01.2021 15:06

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal of Registration

+ Request to Cancel Product Registration

+ Payment

Application History

+ User Profile

+ System

Logout

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration
Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VIGIN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	BOURBON POWDER	PL0002/2020	N/A

CORP
Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

Renewal of Registration
Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request
Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CIPICIN PELLETTES FOR FORTY TWO 300MG

Non Pharmaceutical Product Alert
Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CECTECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CECTECTIN 500 CAP 500MG

Step 2:

- Click the “View Detail” button to view the application in detail.

The screenshot displays the user interface of the PHARMACEUTICALS REGISTRATION SYSTEM 2.0. On the left is a sidebar with a user profile section showing 'You are login as FONG Winnie', 'DEFG COMPANY', and the login date/time '17.08.2018 15:38'. Below this are several menu items: 'Online Notification' (highlighted), 'My Product Search', '+ New Registration', '+ Change of Registered Particulars', and '+ Renewal of Registration'. The main content area is titled 'Online Notification' with a red 'CORP_NOTIFICATION' label in the top right. Below the title is a search bar and a 'View Detail' button (highlighted with a red box) next to a 'Back' button. The main section is titled 'Application Clarification Notification' and contains the following text: 'Notification Date: 24.08.2017 18:06:20', 'Notification Letter: [ClarificationLetter.pdf](#)', 'Dear Certificate Holder,', and 'We want to inform you following application(s) have been evaluation failed. Please follow up attached clarification letter required information to reply application as soon as possible.' Below this text is a table with the following data:

Application Ref. No. ⬇	HK No. ⬇	Name of Product ⬇	Change Categories⬇	Application Status ⬇	Application Payment Status ⬇
CORP-HK63554-201750673	HK63554	TEST 20170221001	2,3	Application Evaluated	Not Necessary

At the bottom of the table, there is another 'View Detail' button (highlighted with a red box) and a 'Back' button.

- The system will redirect to the CORP application page.

CORP Application Status

Summary | e-Product File (e-PF) Change | DO Req. | Clarification Letter | Ack. Letter | CORP Change History | Ref. Material | Same Batch

Application Reference No.: CORP-HK63554-201750673 Application Status: Application Evaluated
Application Batch No.: CORP-HK63554-201750673 Application Type: Certificate holder initiated - New CORP application
HK No.: HK63554 Previous App. Reference No.:
Product Name: TEST 20170221001 DO Request Reference No.:
Application Received Date: 18.08.2017 Client Date: 18.08.2017
Proposed Effective Date: Application Form Image: No File Chosen
Hard Copy Received Date: Submission Acknowledgement: Justification (Urgent Application):
Applicant Username: winnie_fong

Category 2 - Label Under Evaluation

Particulars Proposed to Change Recall Required Cert. Reprint Required Evaluation Comment and Result

2.Label
2.1-Change in label Yes Not Required
Brief Description of Change and Reason: test
Satisfactory Unsatisfactory Acknowledged Withdrawn

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

Documents File Name	Remark	Screening Comment	Evaluation Comment
test3.pdf	The same file has already been uploaded in another location in this submission		

Change Categories Allowed for Amendment:

Category 3 - Package Insert Clarification Letter Sent

Particulars Proposed to Change Recall Required Cert. Reprint Required Evaluation Comment and Result

3.Package Insert
3.1-Change in package insert Yes Not Required
Brief Description of Change and Reason: test
Satisfactory Unsatisfactory Acknowledged Withdrawn

Supporting Documents:
3.1 Change in package insert
i. Proposed package insert with the change(s) underlined and highlighted *

Documents File Name	Remark	Screening Comment	Evaluation Comment
test3.pdf	The same file has already been uploaded in another location in this submission		

ii. Documents substantiating the proposed change(s) with the relevant sections highlighted *

Documents File Name	Remark	Screening Comment	Evaluation Comment
test3.pdf	The same file has already been uploaded in another location in this submission		

Change Categories Allowed for Amendment:


Reply Clarification Letter | Withdraw Application | Close

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.



You are login as

Login date and time
28.01.2021 15:06

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal of Registration

+ Request to Cancel Product Registration

+ Payment

Application History

+ User Profile

+ System

Logout

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VICIN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	BOURBON POWDER	PL0002/2020	N/A

CORP

Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 500MG

Renewal of Registration

Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request

Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CIPRIAT FREEZE-DRIED FOR FORTY TWO 400MG

Non Pharmaceutical Product Alert

Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CECTECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CECTECTIN 500 CAP 500MG

Step 2:

- Click the hyperlink “View Renewal Application Status” to view the application in detail.

The screenshot shows the 'Renewal of Registration' page. On the left is a sidebar with a user profile and navigation menu. The main content area has a header 'Renewal of Registration' and a sub-header 'RENEWAL_NOTIFICATION'. Below this is a 'Renewal Final Reminder' section, which is highlighted with a red box. It contains a notification date, a link to the reminder letter, and a table of products with their registration details and required information. A link 'View Renewal Application Status' is also present and highlighted with a red box.

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2018 15:44

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration
+ Interview

Renewal of Registration

RENEWAL_NOTIFICATION

Print Product List Back

Renewal Final Reminder

Notification Date: 20.03.2018 10:52:49

Notification Letter: [Renewal Final Reminder.pdf](#)

HK No.	PR No.	Name of Product	Required information
HK61844	PR0664/2012	PRODUCT NAME XXXX	
HK61840	PR0659/2012	PRODUCT NAME XXXX	
HK36789	PR0830/1992	PRODUCT NAME XXXX	BABE Requirement

[View Renewal Application Status](#)

Print Product List Back

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

The screenshot shows the 'Renewal of Registration' page. On the left is a sidebar with a user profile and navigation menu. The main content area has a header 'Renewal of Registration' and a sub-header 'RENEWAL_STATUS'. Below this is a 'Reply and Pay for Renewal of Registration' section, which is highlighted with a red box. It contains instructions for renewal, a table of products with their registration details and expiry dates, and buttons for 'Renew' and 'Not to Renew'. Below this is a 'Payment Completed' section, followed by an 'Issued e-Certificate' section, a 'Product Confirmed Not to Renew' section, and a 'Requires Further Action Before Product Renewal' section. The 'Requires Further Action Before Product Renewal' section is also highlighted with a red box and contains a table of products with their registration details and reasons for requiring further action.

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
27.07.2023 10:04

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration
Application Status
- Reply and Pay for Renewal of Registration
- Payment Completed
- Product Confirmed Not to Renew
- Requires Further Action Before Product Renewal
+ Submission of Other Post-registration Supplement
+ Interview
+ Request to Cancel Product Registration
+ Payment
Application History
+ User Profile
+ Printing Service
+ System
Logout

Renewal of Registration

RENEWAL_STATUS

Reply and Pay for Renewal of Registration

Please complete the renewal procedure at least 10 working days before the expiry date of the certificate. If you make online payment via PRS 2.0, please complete the relevant payment transaction at least 5 working days before the expiry date of the certificate.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 3974 4195 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

Renew Not to Renew

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/> HK37027	CEDAX CAP 400MG	15.09.2022	12.09.2023	Batch Five

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
--------	-----------------	--------------	------------------	-------------	----------------------	-----------

Issued e-Certificate

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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
--------	-----------------	--------------	------------------	-------------	---------------	-----------

Product Confirmed Not to Renew

Reinstate

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
--------	-----------------	------------	-------------	-----------

Requires Further Action Before Product Renewal

Please complete the renewal procedure at least 10 working days before the expiry date of the certificate. If you make online payment via PRS 2.0, please complete the relevant payment transaction at least 5 working days before the expiry date of the certificate.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 3974 4195 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

Not to Renew

HK No.	Name of Product	Reason	Expiry Date	Batch No.
<input type="checkbox"/> HK63572	TEST 2017011901	BABE list	23.08.2023	Batch Four
<input type="checkbox"/> HK36996	NULCER TAB 400MG	CORP Requirement	25.08.2023	Batch Four
<input type="checkbox"/> HK44460	FENSTAN TAB 500MG	CORP Requirement	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.

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VOON-300 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	BOURBON POWDER	PL0002/2020	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request


	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CALCIUM UNISON TAB 300MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CECTOTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CECTOTIN 500 CAP 500MG

Step 2:

- View the notification detail.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2018 15:51

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Interview
- + Request to Cancel

Online Notification

END_OF_PRODUCT_LIFE_NOTIFICATION

Back

Notification Date : 07.08.2018 17:40:25

Cancellation Request Submission Notification

Dear Sirs/Madams,

Cancellation of Drug/Product Registration:

HK No.	PR No.	Name of Product
HK63533	PR0034/2016	TEST 20161208

Thank you for your online application dated 07.08.2018 for cancellation of drug/product registration. Please return the original certificate to the Drug Office. The Department of Health is providing professional and executive support to the Pharmacy and Poisons Board and its Committee.

We acknowledge the receipt of your application and it is now being processed.


Back

2.3.5 Non Pharmaceutical Product Alert Online Notification

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

Step 1:

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



You are login as

Login date and time
28.01.2021 15:06

Online Notification

- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VIGIN 500 TAB 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	BOURBON POWDER	PL0002/2020	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM CHISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM CHISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM CHISON TAB 300MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request


	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CIPICIN FEECEL DRUG FOR FORTYING 300MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CECTECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CECTECTIN 500 CAP 500MG

Step 2:

- View the notification detail.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
17.08.2018 16:00

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Interview
- + Request to Cancel Product Registration

Online Notification Detail

Back

Renewal Pending Notification

Notification Date: 21.03.2016 16:43:10

Please be informed that the below product(s) does not fall within the meaning of pharmaceutical product and, for this reason, is exempt from registration control under the Pharmacy and Poisons Ordinance and its regulations. Registration of the product is therefore not renewed. The Department of Health is providing professional and executive support to the Pharmacy and Poisons Board and its Committees.

As the product is not pharmaceutical product, I wish to remind you that no promotional or advertising materials should carry any implication on the product for treating or preventing diseases. Otherwise, the product will fall within the meaning of pharmaceutical product and the sale of unregistered pharmaceutical product is an offence under the above Ordinance and its regulations.

HK No.	PR No.	Name of Product
HK47678	PR1402/2000	PRODUCT NAME XXXX

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 Product Search

Search Clear

HK No. HK [] - HK []

PR No. PR [] / [] - PR [] / []

PL No. PL [] / [] - PL [] / []

Product Name []

Active Ingredient(s) ☒ Contains All ☐ Contains Either One ☐ Exact Match

[]

Search Clear

Product Information						
Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	PR No.
1 to 1 of 1 rows						

New Application for Registration of Pharmaceutical Product										
Seq.	Application Ref. Number	PL No.	PR No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Submission Date	Last Updated By	Last Update Date
1 to 1 of 1 rows										

Change of Registered Particular(s) of Registered Pharmaceutical Product											
Seq.	HK No.	Application Ref. Number	Product Name	No. of Active Ingredient	Active Ingredient(s)	Application Type	Category	Status	Submission Date	Last Updated By	Last Update Date
1 to 1 of 1 rows											

Product Renewal								
Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Expiry Date	Last Updated By	Last Update Date
1 to 1 of 1 rows								

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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 influenzae 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.



You are login as Irene Chu
DEF COMPANY
Login date and time
17.03.2015 18:10

- Online Notification
- 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
- + System
- Logout

My Product Search

HK No.

HK

- HK

PR No.

PR

/

- PR

/

PL No.

PL 0000

/ 1994

- PL 3333

/ 2015

Product Name

Active Ingredient(s)

☒ Contains All
 ☐ Contains Either One
 ☐ Exact Match

Search

Clear

Master Product Information							
Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	PR No.	
<div>1 to 1 of 1 rows</div> <div>10</div>							


New Application Information										
Seq.	Application Ref. Number	PL No.	PR No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Submit Date	Last Update By	Last Update Date
<div>1 to 1 of 1 rows</div> <div>10</div>										

Change of Registered Product Information											
Seq.	HK No.	Application Ref. Number	Product Name	No. of Active Ingredient	Active Ingredient(s)	Application Type	Category	Status	Submit Date	Last Update By	Last Update Date
<div>1 to 1 of 1 rows</div> <div>10</div>											

Product Renewal Information								
Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Expiry Date	Last Update By	Last Update Date
<div>1 to 1 of 1 rows</div> <div>10</div>								

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.



You are login as ORG Trial One
TESTING LIMITED
Login date and time
23.01.2021 09:10

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal of Registration

+ Request to Cancel Product Registration

+ Payment

Application History

+ User Profile

+ System

Logout

My Product Search

Search Clear

HK No. HK - HK

PR No. PR 0060 / 1995 - PR 8888 / 2019

PL No. PL - PL

Product Name

Active Ingredient(s) ☒ Contains All ☐ Contains Either One ☐ Exact Match

Search Clear

Product Information						
Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	PR No.
1	HK41190	PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Active	PR0552/1996
2	HK42175	APT-INDOMETHACIN 25 CAP 25MG	1	C1.1 indomethacin 25mg/1capsule	Active	PR0822/1996
3	HK60366	DRUG NAME XXXX TAB 50MG	1	C1.1 acarbose 50mg/1tablet	Active	PR1211/2009

1 to 3 of 3 rows 10

New Application for Registration of Pharmaceutical Product

Seq.	Application Ref. Number	PL No.	PR No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Submission Date	Last Updated By	Last Update Date
1	HK41190-201857483			PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Application Under Screening	21/08/2018	Drug Office	21/08/2018
2	HK41190-201857485			PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	21/08/2018	Drug Office	21/08/2018
3	HK41190-202050013			PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	05/06/2020	Drug Office	12/01/2021
4	HK42175-201753699-02			APT-INDOMETHACIN 25 CAP 25MG	1	C1.1 indomethacin 25mg/1capsule	Certificate holder initiated - Response to clarification letter	18/04/2017	ORG Trial One	27/02/2019

1 to 4 of 4 rows 10

Change of Registered Particular(s) of Registered Pharmaceutical Product

Seq.	HK No.	Application Ref. Number	Product Name	No. of Active Ingredient	Active Ingredient(s)	Application Type	Category	Status	Submission Date	Last Updated By	Last Update Date
1	HK41190	CORP- HK41190-201857483	PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	5	Application Under Screening	21/08/2018	Drug Office	21/08/2018
2	HK41190	CORP- HK41190-201857485	PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	4	Application Evaluated	21/08/2018	Drug Office	21/08/2018
3	HK41190	CORP- HK41190-202050013	PRODUCT NAME XXXXX XXXX	3	C1.1 biodiastase 25mg/1tablet C1.2 dried aluminium hydroxide gel 192mg/1tablet C1.3 methosulfonium chloride 25mg/1tablet	Certificate holder initiated - New CORP application	3,4,7	Application Evaluated	05/06/2020	Drug Office	12/01/2021
4	HK42175	CORP- HK42175-201753699-02	APT-INDOMETHACIN 25 CAP 25MG	1	C1.1 indomethacin 25mg/1capsule	Certificate holder initiated - Response to clarification letter	1,2,3,4,5,6,7,8	Application Approved	18/04/2017	ORG Trial One	27/02/2019

1 to 4 of 4 rows 10

Product Renewal

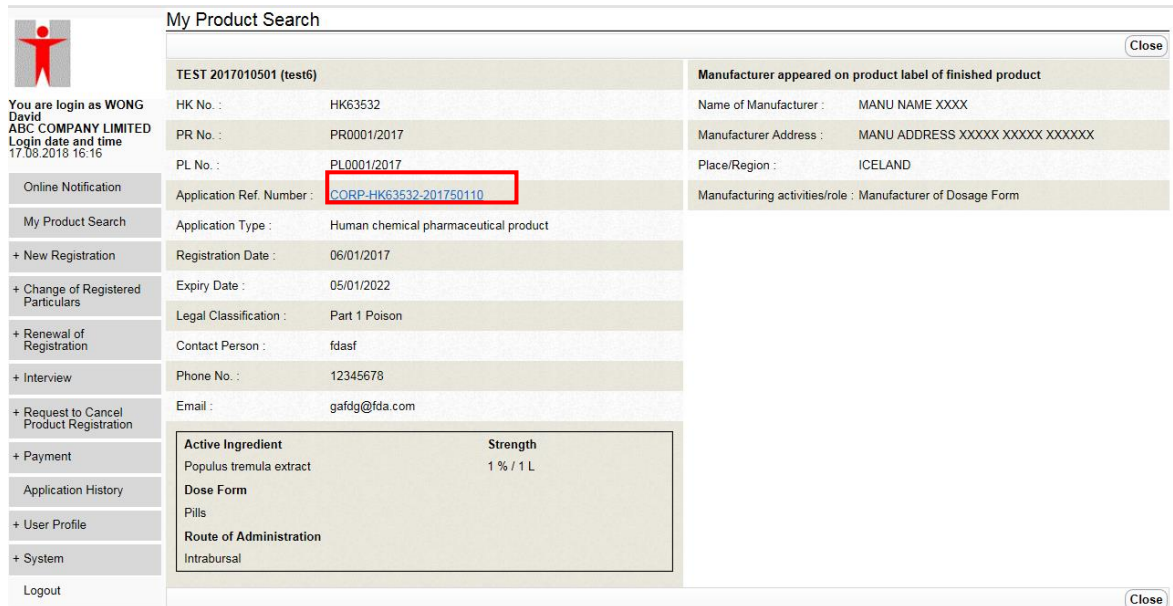
Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Expiry Date	Last Updated By	Last Update Date
1	HK60366	DRUG NAME XXXX TAB 50MG	1	C1.1 acarbose 50mg/1tablet	Pending for Reply	15/03/2021	Drug Office	27/01/2021

1 to 1 of 1 rows 10

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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.



My Product Search

TEST 2017010501 (test6)

HK No.: HK63532

PR No.: PR0001/2017

PL No.: PL0001/2017

Application Ref. Number: **CORP-HK63532-201750110**

Application Type: Human chemical pharmaceutical product

Registration Date: 06/01/2017

Expiry Date: 05/01/2022

Legal Classification: Part 1 Poison

Contact Person: fdasf

Phone No.: 12345678

Email: gaifdg@fda.com

Active Ingredient: Populus tremula extract

Strength: 1 % / 1 L

Dose Form: Pills

Route of Administration: Intrabursal

Manufacturer appeared on product label of finished product

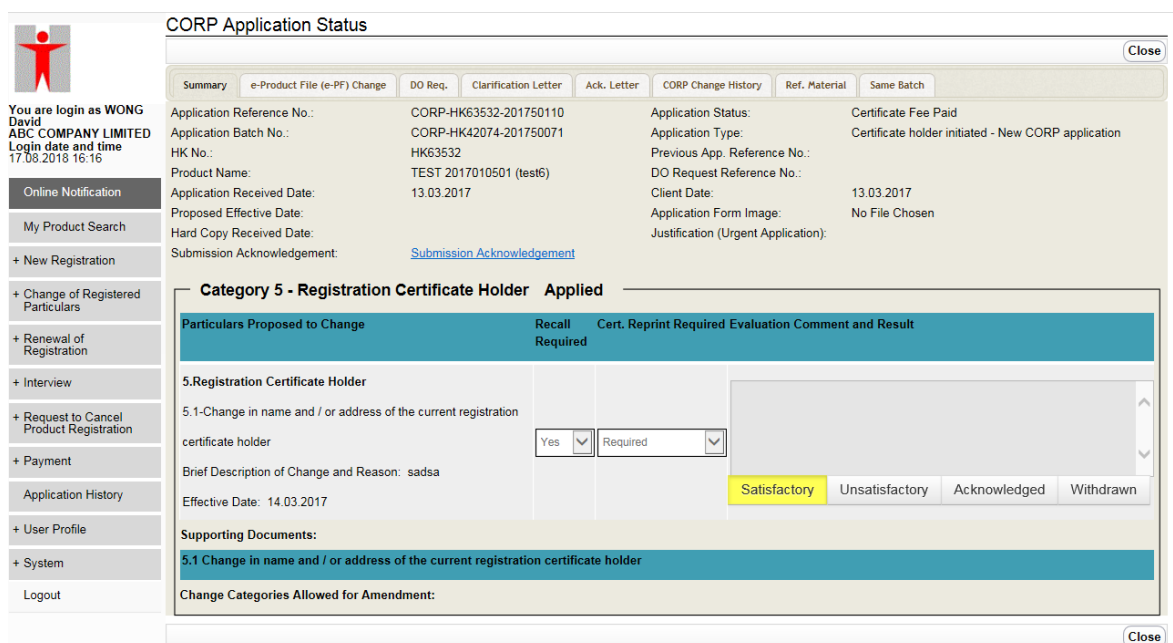
Name of Manufacturer: MANU NAME XXXX

Manufacturer Address: MANU ADDRESS XXXXX XXXXX XXXXXX

Place/Region: ICELAND

Manufacturing activities/role: Manufacturer of Dosage Form

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



CORP Application Status

Summary e-Product File (e-PF) Change DO Req. Clarification Letter Ack. Letter CORP Change History Ref. Material Same Batch

Application Reference No.: CORP-HK63532-201750110

Application Batch No.: CORP-HK42074-201750071

HK No.: HK63532

Product Name: TEST 2017010501 (test6)

Application Received Date: 13.03.2017

Proposed Effective Date:

Hard Copy Received Date:

Submission Acknowledgement: [Submission Acknowledgement](#)

Application Status: Certificate Fee Paid

Application Type: Certificate holder initiated - New CORP application

Previous App. Reference No.:

DO Request Reference No.:

Client Date: 13.03.2017

Application Form Image: No File Chosen

Justification (Urgent Application):

Category 5 - Registration Certificate Holder Applied

Particulars Proposed to Change Recall Cert. Reprint Required Evaluation Comment and Result

5.Registration Certificate Holder

5.1-Change in name and / or address of the current registration certificate holder

Brief Description of Change and Reason: sadsa

Effective Date: 14.03.2017

Supporting Documents:

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

Change Categories Allowed for Amendment:

2.5 NEW REGISTRATION

2.5.1 Initiate New Product Registration

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

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

No related notifications

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:44:04	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	05.06.2020 11:00:01	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX
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
Open	27.02.2019 11:52:23	Certificate Fee Notification	HK65135	CELECOXIB FARMOZ
Open	26.02.2019 15:12:46	Application Approval Notification	HK42175	APT-INDOMETHACIN 25 CAP 25MG
Open	21.08.2018 18:25:53	Application Clarification Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:20:50	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:19:47	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:07:37	Application Submitted Notification	HK37565	PRODUCT NAME XXXXX

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	EPILIM FREEZE-DRIED PDR FOR IV INJ 400MG

Non Pharmaceutical Product Alert


No related notifications

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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.



You are login as ORG Trial One
TESTING LIMITED
Login date and time
28.01.2021 11:20

- Online Notification
- My Product Search
- 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

Guidance

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 100 MB.
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): PL No.: 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):*

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name	Place
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="GERMANY"/>
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="UNITED KINGDOM"/>
<input type="text"/>	<input type="text" value="Please Select"/>

[Add More](#)

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*

Active Ingredient	Active Ingredient Appeared on Product Label
Component 11.* <input type="text" value="bisbentiamine"/>	<input type="text" value="bisbentiamine label"/>
2. <input type="text" value="None of the above"/>	<input type="text" value="New Ingredient Name"/>
3. <input type="text" value="Please Select"/>	<input type="text"/>
4. <input type="text" value="Please Select"/>	<input type="text"/>

[Add More](#)

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine
☐ ATP - gene therapy product
☐ ATP - somatic cell therapy product
☐ ATP - tissue engineered product

Guidance

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[Save](#) [Save and Exit](#) [Next](#)

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 Exit **Next**

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_02

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: 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

1.0.2 Dose Form (Applicable to Drug/Pharmaceutical Product Only)

Component Dose Form of product:*
1 Cream Add

1.0.3 Indication, Route(s) of Administration and Dosage

Indication:*
1 Indication of the Drug

Dosage:*
1 Dosage of the Drug Add

Component Route of administration*
1 Miscellaneous Add

Apply for Data Exclusivity/Description ☐

1.0.4 Container, Closure and Administrative Device(s), including description of material from which it is constructed

No. of Product Pack Size(s):* 2

1. Product Pack Size* 2 x 12's blister/box
(e.g.: 2 x 14's blister/box, 1000's bottle/box, 15g tube/box)

Component	Primary Container (container that is in direct contact with the product)	Proposed shelf life (months)*	Proposed storage conditions* (Temperature (°C) and Relative Humidity (RH))	Stability Report* Duration (Month) Start date	In-Use Stability Report
1	Packaging Material (e.g. glass, Alu/ Alu, HDPE)* Alu Type of container (e.g. vial, blister, bottle)* blister	24	Do not store over 25°C	24 10.05.2015	
				Upload No of File(s): 1	Upload No of File(s): 0

2. Product Pack Size* 2 x 48's blister/box
(e.g.: 2 x 14's blister/box, 1000's bottle/box, 15g tube/box)

Component	Primary Container (container that is in direct contact with the product)	Proposed shelf life (months)*	Proposed storage conditions* (Temperature (°C) and Relative Humidity (RH))	Stability Report* Duration (Month) Start date	In-Use Stability Report
1	Packaging Material (e.g. glass, Alu/ Alu, HDPE)* Alu Type of container (e.g. vial, blister, bottle)* blister	24	Do not store over 25°C	24 10.05.2015	
				Upload No of File(s): 1	Upload No of File(s): 0

Application History Guidance Back Save Save and Exit Next

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.

Guidance Back Save Save and Exit **Next**

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_03

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.: 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

1.0.5 Legal Status

1.0.6 Applicant Information

a. Username : winnie_fong
b. Email Address : prs.winnie.fong@gmail.com

1.0.6.1 Proposed Registration Certificate Holder

a. Name : DEFG COMPANY
b. Address :
Unit: 382 Floor: Block:
Building: PHLC
Street No.: Street Name:
Sub-district: SHEK KIP MEI
Area: KOWLOON

c. BRC Number: 00781432-000 Phone Number: (852) Fax Number: (852)

d. Contact Person for this Application
: John Ho Phone No.: 23192319 Position*: Administrator
Email*: john.ho@defcompany Fax No.*: 35234534

e. Business Type*:
☐ Manufacturer
☐ Importer
☒ Local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong
☐ Licensed wholesale dealer who has entered into a contract with the licensed manufacturer under which the licensed manufacturer is required to manufacture the pharmaceutical product or substance

1.0.6.2 Staff responsible for Pharmacovigilance

a. Name of Staff : Peter Lam
b. Contact Person HK Telephone No.: (852) 23192319 Position: Supervisor Email: john.ho@defcompany.
(24 hours)

Guidance Back Save Save and Exit Next

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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0
APPLICATION USER MANUAL

Application History

Guidance

Back

Save

Save and Exit

Next

New Product RegistrationNEW_PRODUCT_REGISTRATION_VIEW_04

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAMEPL No.:PR No.:HK No.:

Module 1Module 2Module 3Module 4Module 5

Page 1Page 2Page 3Page 4Page 5Page 6Page 7Page 8Page 9Application Form

1.0.7 Manufacturers

1.0.7.1.a Manufacturer appeared on product label of finished product*

Place/Region*:GERMANY

Name of Manufacturer*:MANU NAME xxxxxx

Chinese Name of Manufacturer:

Address*:MANU ADDR XXXXXX XXXXXX XXXXXX

Chinese Address:

GMP Certificate*:

Upload

No of File(s): 1

GMP Certificate Number*:GMP Cert No

GMP Certificate Expiry Date #:30.08.2022

Manufacturer Licence*:

Upload

No of File(s): 1

Manufacturer Licence Number*:MI Number

Manufacturer Licence Expiry Date #:

Manufacturing activities/role*

☒ Batch Release Manufacturer

☐ Manufacturer of Dosage Form

☐ Office

☐ Other

☐ Packing Manufacturer

☐ QC Testing

Add More

1.0.7.1.b All Other Manufacturer(s) involved in the preparation of the product/substance

☒ Yes☐ No

Manufacturing activities/role*

☐ Batch Release Manufacturer

☐ Manufacturer of Dosage Form

☐ Office

☐ Other

☐ Packing Manufacturer

☒ QC Testing

Add More

Place/Region*:UNITED KINGDOM

GMP Certificate*:

Upload

No of File(s): 0

GMP Certificate Number*:GMP Cert No

GMP Certificate Expiry Date #:

You are required to enter the expiration date of your licence or certificate in this box. If there is no expiration date indicated or expressed in any way on the licence or certificate, please leave this box blank.

Manufacturer Licence:

Upload

No of File(s): 0

Manufacturer Licence Number:

Manufacturer Licence Expiry Date #:

Name of Manufacturer*:MANU NAME xxxxxx

Address*:MANU ADDR XXXXXX XXXXXX XXXXXX

Chinese Name of Manufacturer:

Chinese Address:

1.0.7.1.c Official Batch Release for Blood Products and Vaccines (if applicable)

Add More

Application History

Guidance

Back

Save

Save and Exit

Next

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.

Guidance Back Save Save and Exit Next

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_05

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): ONLINE 20170712 PL No.: 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

1.0.8 Qualitative and Quantitative composition

1.0.8.1 Qualitative and Quantitative Composition in Terms of the Active Ingredient(s) and the Excipient(s) ?

Please select those excipients available under the drop down list
When input is complete, you are advised to use the "Export" function to export the inputted excipient list and save in your computer in .csv file format.
Next time when you have to amend the content of excipient list, you can use the "Import" function to retrieve the saved excipient list.

Please list the active ingredient(s) and the excipient(s) as stated in the Master Formula:

Component	Name of Active Ingredient(s)*	Quantity (Strength Value)*	Unit (Strength Unit)*	Dose Value*	Dose Unit*	Reference / Monograph Standard
1	Bordetella pertussis	test	% v/w	1	PRLS Data Conversion	USP

Additional Information
test Add

☐ This component does not have any excipient.

Excipient*	Quantity (Strength Value)*	Unit (Strength Unit)*	Dose Value*	Dose Unit*	Function	Reference / Monograph Standard
adipic acid	0.5	AHU	1	TEST		Please Sel

Import CSV Export as CSV Clean all Data Add Remove

1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicinal product?
* ☒ No ☐ Yes

1.0.8.3 Does the product contain human plasma-derived ingredients?
* ☒ No ☐ Yes, please fill in the following.

Guidance Back Save Save and Exit Next

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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.

Application History Guidance Back Save Save and Exit **Next**

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_06

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: 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

1.0.9 Other Marketing Authorization Applications

1.0.9.1 Is there another country/region where an authorization is granted for the same product?

* ☐ No ☒ Yes

1.0.9.2 If 1.0.9.1 is yes, are there any differences which have therapeutic indications, dosage, contraindications or side effects between this application and authorizations for the same product in other countries/regions (as specified in 1.0.9.4)

* ☒ No ☐ Yes

1.0.9.3 Is there another countries/regions where an authorization was refused / suspended / revoked by the competent authorities for the same product?

* ☒ No ☐ Yes

1.0.9.4 Please list marketing authorization application(s) for the same product in other country/region here :

Country/Region	Status	Date of Authorization	Product Name	Free Sale Certificate(FSC) attached	Authorization Number	Expire Date of FSC
GERMANY	Approved	01.08.2018	PRODUCT NAME	<input type="button" value="Upload"/>	<input type="text"/>	<input type="text"/>
				No of File(s): 1		
UNITED KINGDOM	Approved	01.08.2018	PRODUCT NAME	<input type="button" value="Upload"/>	<input type="text"/>	<input type="text"/>
				No of File(s): 1		

Application History Guidance Back Save Save and Exit Next

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.

Application History Guidance Back Save Save and Exit **Next**

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_07

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: 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

1.1.0 Annexed Documents/information/sample

- 1.* Prototype sales pack/outer and inner container labels (Reference for 1.0.4 of Page 2)
- 2.* Package insert (Reference for 1.0.3 of Page 2)
3. For pharmaceutical substance, please provide a sample for inspection. (Reference for 1.0.1.3 of Page 1)
- 4.* Photo or scanned image of the product samples
5. Photo or scanned image of extra component(s) included in the sales pack apart from the drug product and package insert, e.g., measuring cups/spoons, syringe, connectors, alcohol swabs, etc. (if applicable) (Reference for 1.0.4 of Page 2)
6. Information on the overseas legal status of the product.
- 7.* Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)
8. Authorization letter from the applicant authorizing a person/company to deal with the communication matters related to this application) (if applicable)
- 9.* Authorization letter from the manufacturer/marketing authorization holder authorizing the applicant to apply registration for its product.
- 10.* 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
- 11.* Documentary evidence showing the compliance with GMP by the labeled manufacturer and the manufacturer to be shown on the label issued by competent authorities.
(Manual submission of certified true copy(ies) is required). (Reference for 1.0.7 of Page 4)
12. An undertaking, given by the manufacturer(s) of the product/substance, to permit the premises where it is to be manufactured, and the operations carried on or to be carried on in the course of manufacturing it, to be inspected by or on behalf of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substance: Certification of Clinical Trial/Medicinal Test) Committee.
13. A declaration, given by the manufacturer of the product or substance, that, in relation to the manufacture of the product/substance any requirements imposed by or under the law of the country in which it is or is to be manufactured have been or will be complied with.
14. Flow chart indicating sequence and activities of the different sites involved in the manufacturing process, including testing site. (Reference for 1.0.7 of Page 4)

Prototype Sale Pack(s) List

Package Insert(s) List

Upload
No of File(s): 0

Upload
No of File(s): 1

Upload
No of File(s): 0

Upload
No of File(s): 0

Upload
No of File(s): 1

Upload
No of File(s): 0

Upload
No of File(s): 1

Manufacturer(s) List

Upload
No of File(s): 0

Upload
No of File(s): 0

Upload
No of File(s): 0

Application History Guidance Back Save Save and Exit Next

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

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

Application History Guidance Back Save Save and Exit Next

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_08

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: 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

1.1.0 Annexed Documents/information/sample

15. Detailed information regarding the manufacturer in respect of its manufacturing and quality control facilities and personnel. (Reference for 1.0.7 of Page 4)

16.* Master Formula (complete qualitative and quantitative composition of the drug product issued by the manufacturer) (Reference for 1.0.8 of Page 5)

17. Evidence of the source of animals, the nature of the animal tissues used in manufacturing and production process, showing compliance with one or more of the safety measures taken to minimize the risk of communicable diseases that can be transmitted to human, including but not limited to TSE. (Reference for 1.0.8 of Page 5)

18. Ph. Eur. Certificate(s) of suitability for TSE (if applicable) or evidence from the manufacturer showing compliance with the US, Australian or European guidelines with respect to minimization of the risk of communicable diseases as stated in Guidance Notes on Registration of Pharmaceutical products. (Reference for 1.0.8 of Page 5)

19. An undertaking from the manufacturer of the product to inform the applicant in case of any change in nature or source of materials (e.g., from chemically synthesized to animal/human origin or vice-versa) of active ingredient(s) or excipient(s) during the application process or after approval of registration has been granted. (Reference for 1.0.8 of Page 5)

20. An undertaking from the applicant to inform the Drug Office in case of any change in nature or source of materials (e.g., from chemically synthesized to animal/human origin or vice-versa) of active ingredient(s) or excipient(s) during the application process or after approval of registration has been granted. (Reference for 1.0.8 of Page 5)

21. Information on the sourcing, quality assurance aspects of plasma-derived products, including information such as but not limited to donor selection criteria, viral inactivation procedures with validation, and measures taken to minimize the risk of transmission of CJD by the blood products. (Reference for 1.0.8 of Page 5)

22. Copy of EMA Certificate for a Plasma Master File (PMF) (if applicable) (Reference for 1.0.8 of Page 5)

23.* Free sale certificate of the product issued by the country of origin (Manual submission of original or certified true copy(ies) is required). (Reference for 1.0.9 of Page 6)
(For NCE)
Official evidence of registration approval of the product (e.g. original or certified true copies of free sale certificates) in 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 and USA (Reference for 1.0.9.4 of Page 6)

24.* (For NCE)
Clinical and non-clinical overviews and quality overall summary

25. Information on clinical trial(s) performed in Hong Kong (Please provide clinical trial certificate no./application reference no.)

Upload No of File(s): 0

Upload No of File(s): 1
Evidence of the source of animals and/or human origin materials

Upload No of File(s): 0

Upload No of File(s): 0

List showing free sale certificate in other market(s)

Upload No of File(s): 1

Upload No of File(s): 0

Application History Guidance Back Save Save and Exit Next

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.

Guidance Back Save Save and Exit Next

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_09

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 300 MB.
File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necessary.

You are login as ORG Trial One
TESTING LIMITED
Login date and time
27.01.2021 15:08

Proposed Name of Product (English): PRODUCT ONE PL No.: 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

1.1.0 Annexed Documents/information/sample

26.* **(For NCE)**
Information about the experts who were responsible for writing the non-clinical and clinical overviews and quality overall summary UPLOAD
No of File(s): 0

27.*
For biological and vaccine products, please provide the protein sequence/schematic diagram of the active substance and details regarding the manufacturing process and process control of the active substance and the product (Reference for 1.0.8 of Page 5)

28.* **(For NCE)**
Description of risk-management System (Information on the EU Risk Management Plan (RMP) or US Risk evaluation and mitigation strategies (REMS) imposed on the product and the proposed RMP for Hong Kong. (Reference for 1.0.6 of Page 3) UPLOAD
No of File(s): 0

29.*
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) UPLOAD
No of File(s): 0

30.*
Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5) UPLOAD
No of File(s): 0

31.*
Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5) UPLOAD
No of File(s): 0

32.*
Stability report - real time and accelerated (please refer to testing conditions on Guidance Notes on Registration of Pharmaceutical Products) (Reference for 1.0.4 of Page 2) Stability Report(s) List

33.*
Certified true copy of manufacturers licence
(Manual submission of certified true copy(ies) is required) (Reference for 1.0.7 of Page 4) Manufacturer(s) List

34.
Clinical and scientific documentation substantiating the safety and efficacy of the product (except for generic product applications received on or after 1 OCT 2012 and their originator products have been registered in Hong Kong for over 8 years). UPLOAD
No of File(s): 0

35.*
Reputable documentary evidence to substantiate the content of package insert. Cross-referencing to documents should be made by referring to page number of the reference and the relevant parts of the reference document (s) shall be clearly highlighted. Please refer to the list of reputable references in the Guidance Notes on Registration of Pharmaceutical Products UPLOAD
No of File(s): 0

36.
Declaration from manufacturer on whether the different product name(s) listed in the dossier is identical to the product under application in all aspects. UPLOAD
No of File(s): 0

37.
For capsule dose forms, please provide documentary evidence to substantiate the quality of gelatin / vacant capsule in compliance with pharmacopoeial standard. UPLOAD
No of File(s): 0

38.
Bioequivalence (BE) data for anti-epileptic drugs and critical dose drugs / narrow therapeutic range drugs. UPLOAD
No of File(s): 0

39.*
Priority application supporting document(s). (Reference for Page 1)

40.* **(For NCE)**
Risk assessment report of elemental impurities in accordance with ICH Q3D UPLOAD
No of File(s): 0

1.1.1 Others, please specify
 UPLOAD
No of File(s): 0

Additional Information of Product
 Add

Guidance Back Save Save and Exit Next

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.

Guidance Back Save Save and Exit **Next**

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_MODULE_02

The maximum upload size of single file is 50MB, while the maximum total upload size per application 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.: PR No.: HK No.:
(CH3)

Module 1 Module 2 Module 3 Module 4 Module 5

2.1 Overall CTD Table of Contents of Modules 2-5

Remarks:

2.2 Introduction to Summary

Remarks:

2.3 Quality Overall Summary

Remarks:

2.3.S Drug Substance (name, manufacturer)

Remarks:

2.3.P Drug Product (name, dosage form)

Remarks:

2.3.A Appendices

Remarks:

2.3.R Regional Information

Remarks:

2.4 Nonclinical Overview

Remarks:

2.5 Clinical Overview

Remarks:

2.6.1 Introduction

Remarks:

2.6.2 Pharmacology Written Summary

Remarks:

2.6.3 Pharmacology Tabulated Summary

Remarks:

2.6.4 Pharmacokinetic Written Summary

Remarks:

2.6.5 Pharmacokinetic Tabulated Summary

Remarks:

2.6.6 Toxicology Written Summary

Remarks:

2.6.7 Toxicology Tabulated Summary

Remarks:

2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Method

Remarks:

2.7.2 Summary of Clinical Pharmacology Studies

Remarks:

2.7.3 Summary of Clinical Efficacy [indication]

Remarks:

2.7.4 Summary of Clinical Safety

Remarks:

2.7.5 References

Remarks:

2.7.6 Synopses of individual studies

Remarks:

Guidance

BackSaveSave and ExitNext

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 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.: PR No.: HK No.:
(CH3)

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:

3.2.S.1.2 Structure

Remarks:

3.2.S.1.3 General Properties

Remarks:

3.2.S.2.1 Manufacturer(s)

Remarks:

3.2.S.2.2 Description of Manufacturing Process and Process Controls

Remarks:

3.2.S.2.3 Control of Materials

Remarks:

3.2.S.2.4 Controls of Critical Steps and Intermediates

Remarks:

3.2.S.2.5 Process Validation and/or Evaluation

Remarks:

3.2.S.2.6 Manufacturing Process Development

Remarks:

3.2.S.3.1 Elucidation of Structure and other Characteristics

Remarks:

3.2.S.3.2 Impurities

Remarks:

3.2.S.4.1 Specification

Remarks:

3.2.S.4.2 Analytical Procedures

Remarks:

3.2.S.4.3 Validation of Analytical Procedures

Remarks:

3.2.S.4.4 Batch Analyses

Remarks:

3.2.S.4.5 Justification of Specification

Remarks:

3.2.S.6 Container Closure Systems

Remarks:

3.2.S.7.1 Stability Summary and Conclusions

Remarks:

3.2.S.7.2 Post Approval Stability Protocol and Stability Commitment

Remarks:

3.2.S.7.3 Stability Data

Remarks:

3.2.P.1 Description and Composition of the Drug Product

Remarks:

3.2.P.2 Pharmaceutical Development

Remarks:

3.2.P.3 Manufacture

Remarks:

3.2.P.3.1 Manufacturer(s)

Remarks:

3.2.P.3.2 Batch Formula

Remarks:

3.2.P.3.3 Description of Manufacturing Process and Process Controls

Remarks:

3.2.P.3.4 Controls of Critical Steps and Intermediates

Remarks:

3.2.P.3.5 Process Validation and/or Evaluation

Remarks:

3.2.P.4 Control of Excipients [name]

Remarks:

3.2.P.4.1 Specification(s)

Remarks:

3.2.P.4.2 Analytical Procedures

Remarks:

3.2.P.4.3 Validation of Analytical Procedures

Remarks:

3.2.P.4.4 Justification of Specifications

Remarks:

3.2.P.4.5 Excipients of Human or Animal Origin

Remarks:

3.2.P.4.6 Novel Excipients

Remarks:

3.2.P.5.1 Specification(s)

Remarks:

3.2.P.5.2 Analytical Procedures

Remarks:

3.2.P.5.3 Validation of Analytical Procedures

Remarks:

3.2.P.5.4 Batch Analyses

Remarks:

3.2.P.5.5 Characterization of Impurities

Remarks:

3.2.P.5.6 Justification of Specification(s)

Remarks:

3.2.P.6 Reference Standards or Material Intermediates

Remarks:

3.2.P.7 Container Closure System

Remarks:

3.2.P.8 Stability

Remarks:

3.2.P.8.1 Stability Summary and Conclusion

Remarks:

3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment

Remarks:

3.2.P.8.3 Stability Data

Remarks:

3.2.A.1 Facilities and Equipment [name,manufacturer]

Remarks:

3.2.A.2 Adventitious Agents Safety Evaluation [name,dosage,form,manufacturer]

Remarks:

3.2.A.3 Novel Excipients

Remarks:

3.2.R Regional Information

Remarks:

3.3 Literature references

Remarks:

Guidance

Back Save Save and Exit Next

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.

Guidance Back Save Save and Exit **Next**

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_MODULE_04

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.: PR No.: HK No.:
(CH3)

Module 1 Module 2 Module 3 **Module 4** Module 5

4.1 Module 4 Table of Contents

Remarks:

4.2.1.1 Primary Pharmacodynamics

Remarks:

4.2.1.2 Secondary Pharmacodynamics

Remarks:

4.2.1.3 Safety Pharmacology

Remarks:

4.2.1.4 Pharmacodynamic Drug Interactions

Remarks:

4.2.2.1 Analytical Methods and Validation Reports (if separate reports are available)

Remarks:

4.2.2.2 Absorption

Remarks:

4.2.2.3 Distribution

Remarks:

4.2.2.4 Metabolism

Remarks:

4.2.2.5 Excretion

Remarks:

4.2.2.6 Pharmacokinetic drug interactions (nonclinical)

Remarks:

4.2.2.7 Other pharmacokinetics studies

Remarks:

4.2.3.1 Single-Dose Toxicity (in order by species, by route)

Remarks:

4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive toxicokinetics evaluations)

Remarks:

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:

4.2.3.4.1 Long-term studies (in order by species; including range-finding studies that cannot appropriately be included under repeat-dose toxicity or pharmacokinetics)

Remarks:

4.2.3.4.2 Short- or medium-term studies (including range-finding studies that cannot appropriately be included under repeat-dose toxicity or pharmacokinetics)

Remarks:

4.2.3.4.3 Other studies

Remarks:

4.2.3.5 Reproductive and Development Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (if modified study designs are used, the following sub-headings should be modified accordingly.)

Remarks:

4.2.3.5.1 Fertility and early embryonic development

Remarks:

4.2.3.5.2 Embryo-fetal development

Remarks:

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

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

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

Guidance Back **Save** Save and Exit

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_MODULE_05

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 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.: PR No.: HK No.:

(CH3)

Module 1 Module 2 Module 3 Module 4 **Module 5**

5.1 Module 5 Table of Contents

Remarks:

5.2 Tabular Listing of All Clinical Studies

Remarks:

5.3.1.1 Bioavailability (BA) Study Reports

Remarks:

5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports

Remarks:

5.3.1.3 In Vitro - In Vivo Correlation Study Reports

Remarks:

5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies

Remarks:

5.3.2.1 Plasma Protein Binding Study Reports and Related Information

Remarks:

5.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies

Remarks:

5.3.2.3 Reports of Studies Using Other Human Biomaterials

Remarks:

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:

5.3.3.2 Patient PK and Initial Tolerability Study Reports and Related Information

Remarks:

5.3.3.3 Intrinsic Factor PK Study Reports and Related Information

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 More Than One Study (Integrated Summary of Safety Report)

Remarks:

5.3.5.4 Other Study Reports and Related Information (Special Pathogens and Immune Modulator Reports, Antiviral Reports)

Remarks:

5.3.6 Reports of Postmarketing Experience

Remarks:

5.3.7 Case Report Forms and Individual Patient Listings

Remarks:

5.4 Literature References

Remarks:

Application History

Guidance

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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.

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 100 MB.
File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necessary.

You are login as ORG Trial
One
TESTING LIMITED
Login date and time
26.01.2021 11:20

Proposed Name of Product (English): PL No.: 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):* ?

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name	Place
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="GERMANY"/>
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="UNITED KINGDOM"/>
<input type="text"/>	<input type="text" value="Please Select"/>

[Add More](#)

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*

Active Ingredient	Active Ingredient Appeared on Product Label
Component 1.1.* <input type="text" value="bisbentiamine"/>	<input type="text" value="bisbentiamine label"/>
2. <input type="text" value="None of the above"/>	<input type="text" value="New Ingredient Name"/>
3. <input type="text" value="Please Select"/>	<input type="text"/>
4. <input type="text" value="Please Select"/>	<input type="text"/>

[Add More](#)

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine
☐ ATP - gene therapy product
☐ ATP - somatic cell therapy product
☐ ATP - tissue engineered product

Guidance Save Save and Exit Next

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Step 16: Click the “Proceed to Submit” button.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

[Guidance](#) [Back](#) [Print](#) [Proceed To Submit](#)

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CDiDVD if necessary.

Proposed Name of Product (English): PRODUCT NAME PL No.: PR No.: HK No.: [FORM6_VIEW](#)

PHARMACY AND POISONS ORDINANCE (CHAPTER 138)
APPLICATION FORM FOR REGISTRATION OF A DRUG / PHARMACEUTICAL
PRODUCT / SUBSTANCE

Note: A specimen sales pack of the drug/product or sample of the substance and the relevant literature must be submitted together with the application. Supplementary documentation and supporting documents issued by the health authority in the country of origin should be submitted if required.

Name of the Drug / Product / Substance-* (*Delete as appropriate)
PRODUCT NAME

Dose Form / Package Size(s) :

Dose Form
Component 1
Package Size(s): Cream
Product Pack Size 2 x 12's blister/box
Product Pack Size 2 x 48's blister/box

Detailed Qualitative and Quantitative Composition :

Component 1

Name of Active Ingredient(s)	Quantity (Strength Value)	Unit (Strength Unit)	Dose Value	Dose Unit	Reference / Monograph Standard
1. bisbentamine	1.5	mg	1	tablet	EP
2. New Ingredient Name	200	mcg	1	tablet	

Indications:

1. Indication of the Drug

Registered and Marketed in Which Countries/Places : GERMANY
UNITED KINGDOM

Name of Applicant: ABC COMPANY LIMITED
Business Registration No.: 00671890-000
In What Capacity the Applicant Makes This Application: Importer

Business Address of Applicant: 382, 3, A, CHA KWO LING, KOWLOON
Tel No.: 23198414 (Contact Person:David Wong)
12345678 (Submitted By:WONG David)
Facsimile No.: 23198414 (Contact Person:David Wong)
Email Address: prs.david.wong@gmail.com (Contact Person:David Wong)
prs.david.wong@gmail.com (Submitted By:WONG David)

Name of Manufacturer:
Name of manufacturer appeared on product label of finished product: MANU NAME xxxxxx
Address of Manufacturer:
Address of manufacturer appeared on product label of finished product: MANU ADDR XXXXXX XXXXXX XXXXXX

All Company(ies) involved in the preparation of the product/substance

Name of Manufacturer	Address of Manufacturer
1. MANU NAME xxxxxx	MANU ADDR XXXXXX XXXXXX XXXXXX

DECLARATION OF APPLICANT

☐ I wish to apply for registration of the said pharmaceutical products under the Pharmacy and Poisons Ordinance. I hereby declare that, to the best of my knowledge and belief, the information given in this application is correct.

Name: WONG David **Position held:**

e-Cert Authentication:
Please select the e-Cert file, e.g. C:\cert.p12

e-Cert PIN:

For Office Use Only

Date Received	Legal Classification	Fees Paid	Registration Approved	Certificate Issued	Registration
					%

[Guidance](#) [Back](#) [Print](#) [Proceed To Submit](#)

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.

New Product Registration

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 100 MB.
File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necessary.

You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 11:20

Online Notification
My Product Search
- 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

Guidance

Proposed Name of Product (English): PL No.: 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):*

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name	Place
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="GERMANY"/>
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="UNITED KINGDOM"/>
<input type="text"/>	<input type="text" value="Please Select"/>

[Add More](#)

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*

Active Ingredient	Active Ingredient Appeared on Product Label
Component 1.1.* <input type="text" value="bisbentiamine"/>	<input type="text" value="bisbentiamine label"/>
2. <input type="text" value="None of the above"/>	<input type="text" value="New Ingredient Name"/>
3. <input type="text" value="Please Select"/>	<input type="text"/>
4. <input type="text" value="Please Select"/>	<input type="text"/>

[Add More](#)

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine
☐ ATP - gene therapy product
☐ ATP - somatic cell therapy product
☐ ATP - tissue engineered product

Guidance

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[Save](#) [Save and Exit](#) [Next](#)

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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

[Guidance](#) [Back](#) [Submit Application](#) [Print](#)

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: PR No.: HK No.: [FORM6_VIEW](#)

PHARMACY AND POISONS ORDINANCE (CHAPTER 138)

APPLICATION FORM FOR REGISTRATION OF A DRUG / PHARMACEUTICAL

PRODUCT / SUBSTANCE

Note: A specimen sales pack of the drug/product or sample of the substance and the relevant literature must be submitted together with the application. Supplementary documentation and supporting documents issued by the health authority in the country of origin should be submitted if required.

Name of the Drug / Product / Substance: * (*Delete as appropriate)
PRODUCT NAME

Dose Form / Package Size(s) :

Dose Form
Component 1
Package Size(s): Cream
Product Pack Size :2 x 12's blister/box
Product Pack Size :2 x 45's blister/box

Detailed Qualitative and Quantitative Composition :

Component 1

Name of Active Ingredient(s)	Quantity (Strength Value)	Unit (Strength Unit)	Dose Value	Dose Unit	Reference / Monograph Standard
1. bisbentamine	1.5	mg	1	tablet	EP
2. New Ingredient Name	200	mcg	1	tablet	

Indications:

1. Indication of the Drug

Registered and Marketed in Which Countries/Places : GERMANY
UNITED KINGDOM

Name of Applicant: ABC COMPANY LIMITED
Business Registration No.: 00671890-000
In What Capacity the Applicant Makes This Application: Importer

Business Address of Applicant: 382, 3, A, CHA KWO LING, KOWLOON
Tel No.: 23198414 (Contact Person:David Wong)
12345678 (Submitted By:WONG David)
Facsimile No.: 23198414 (Contact Person:David Wong)
Email Address: prs.david.wong@gmail.com (Contact Person:David Wong)
prs.david.wong@gmail.com (Submitted By:WONG David)

Name of Manufacturer:
Name of manufacturer appeared on product label of finished product: MANU NAME xxxxxx
Address of Manufacturer:
Address of manufacturer appeared on product label of finished product: MANU ADDR XXXXXX XXXXXX XXXXXX

All Company(ies) involved in the preparation of the product/substance

Name of Manufacturer	Address of Manufacturer
1. MANU NAME xxxxxx	MANU ADDR XXXXXX XXXXXX XXXXXX

DECLARATION OF APPLICANT

☒ I wish to apply for registration of the said pharmaceutical products under the Pharmacy and Poisons Ordinance. I hereby declare that, to the best of my knowledge and belief, the information given in this application is correct.

Name: WONG David **Position held:**

e-Cert Authentication: C:\cert.p12 [瀏覽...](#)
Please select the e-Cert file, e.g. C:\cert.p12

e-Cert PIN: ***

For Office Use Only

Date Received	Legal Classification	Fees Paid	Registration Approved	Certificate Issued	Registration
					%

[Guidance](#) [Back](#) [Submit Application](#) [Print](#)

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

Application ID:	ANP20189000154
Submission Date:	2018.08.17

Proposed Name of Product (English)	PL No.
PRODUCT NAME	PL0023/2018

The Drug Office acknowledges your on-line submission for application of new product registration. We will process your request and will provide response as soon as possible.

For enquiries, please call us quoting this reference number.

General 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, Sundays & Public Holidays)
Tel:	(852) 2319 8458
Email:	prs2_info@dh.gov.hk

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”



You are login as

Login date and time
28.01.2021 15:13

Online Notification

My Product Search

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

New Product Registration

NEW_PRODUCT_REGISTRATION_STATUS

New Submission
InitiateNew Product Registration

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	17.07.2018	ANP20189000108	PL0010/2018		TEST ECERT CASE1	1	Request for Outstanding Information	24.07.2018	No
2	31.07.2017	ANP20179000079	PL0082/2017		TEST LOGIN2	1	Request for Outstanding Information	22.06.2018	No
3	31.07.2017	ANP20179000078	PL0081/2017		TEST USER LOGIN 2	1	Request for Outstanding Information	14.11.2017	No

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	10.08.2018	ANP20189000153	TEST NCE 2	Pending
2	18.07.2018	ANP20189000132	TEST OPEN FILE CASE 3	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	10.08.2018	ANP20189000151	PL0022/2018		TEST NCE CASE	1	Application Submitted	15.08.2018	No
2	06.08.2018	ANP20189000133	PL0019/2018		TEST 2015	1	Screening	10.08.2018	No

New list added for new version:


Issued E-Certificate

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

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.



You are login as ORG Trial One

TESTING LIMITED

Login date and time
27.01.2021 10:22

Online Notification

My Product Search

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

New Product Registration

NEW_PRODUCT_REGISTRATION_STATUS

New Submission
InitiateNew Product Registration

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	27.01.2021	ANP20219000005			FACE CREAM		Pending		
2	26.01.2021	ANP20219000001			PRODUCT NAME		Pending		
3	01.03.2019	ANP20199000002			TEST DRUG 20190301		Pending		

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	27.01.2021	ANP20219000005	FACE CREAM	Pending
2	26.01.2021	ANP20219000001	PRODUCT NAME	Pending
3	01.03.2019	ANP20199000002	TEST DRUG 20190301	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	26.01.2021	ANP20219000004	PL0001/2021		PRODUCT NAME	1	Application Submitted	27.01.2021	No

New list added for new version:

Issued E-Certificate

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

Save Save and Exit Next

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 100 MB.
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): PL No.: 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):*

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name	Place
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="GERMANY"/>
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="UNITED KINGDOM"/>
<input type="text"/>	<input type="text" value="Please Select"/>

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*

Active Ingredient	Active Ingredient Appeared on Product Label
Component 1.1.* <input type="text" value="bisbentiamine"/>	<input type="text" value="bisbentiamine label"/>
2. <input type="text" value="None of the above"/>	<input type="text" value="New Ingredient Name"/>
3. <input type="text" value="Please Select"/>	<input type="text"/>
4. <input type="text" value="Please Select"/>	<input type="text"/>

1.0.1.3 Application Type: (please select one)*

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine
☐ ATP - gene therapy product
☐ ATP - somatic cell therapy product
☐ ATP - tissue engineered product


Guidance

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Save Save and Exit Next

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.



NEW_PRODUCT_REGISTRATION_STATUS

You are login as ORG Trial One
TESTING LIMITED
Login date and time
27.01.2021 10:22

Online Notification

My Product Search

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

New Product Registration

New Submission
[Initiate New Product Registration](#)

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
Not Submitted									
	Latest Draft Date	Application ID	Proposed Name of Product (English)				Application Status		
1	27.01.2021	ANP20219000005	FACE CREAM				Pending		
2	26.01.2021	ANP20219000001	PRODUCT NAME				Pending		
3	01.03.2019	ANP20199000002	TEST DRUG 20190301				Pending		
Application Submitted									
	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	26.01.2021	ANP20219000004	PL0001/2021		PRODUCT NAME	1	Application Submitted	27.01.2021	No

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New list added for new version:

Issued E-Certificate

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

Save Save and Exit Next

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 100 MB.
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): PL No.: 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):* PRODUCT NAME

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name: PRODUCT NAME Place: GERMANY

Name: PRODUCT NAME Place: UNITED KINGDOM

Name: Place: Please Select

Add More

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)* 1

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1.1.*	bisbentiamine	bisbentiamine label
2.	None of the above	New Ingredient Name
3.	Please Select	
4.	Please Select	

Add More

1.0.1.3 Application Type: (please select one)*

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine
☐ ATP - gene therapy product
☐ ATP - somatic cell therapy product
☐ ATP - tissue engineered product

Guidance

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Save Save and Exit Next

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’

Application History

Guidance

Next

Print

New Product RegistrationNEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAMEPL No.: PL0023/2018PR No.:HK No.:

Module 1Module 2Module 3Module 4Module 5

Page 1Page 2Page 3Page 4Page 5Page 6Page 7Page 8Page 9Application Form

☐ Priority Application

For priority applications, the following supporting documents 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☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):*

PRODUCT NAME?

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name: PRODUCT NAMEPlace: GERMANY

Name: PRODUCT NAMEPlace: UNITED KINGDOM

Name: Place: Please Select

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*1

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1 1. *	bisbentiamine	bisbentiamine Label
2.	None of the above New Ingredient Name	New Ingredient Name
3.	Please Select	
4.	Please Select	

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product

☒ Human chemical pharmaceutical product

☐ Human vaccine

☐ Pharmaceutical substance

☐ Veterinary biological pharmaceutical product

☐ Veterinary chemical pharmaceutical product

☐ Veterinary vaccine

Guidance

Edit Application

Next

Print

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

Application Version 1

CTD in PDF format
Application Submitted: [Application History.pdf](#)

Document List

Page 2

1. Product Pack Size: 6x10's blister/pack

Component	Duration (Month)	Stability Report Start date	In-Use Stability Report
1	24	08.01.2015	

[Stability Report.pdf](#)

2. Product Pack Size: 3x10's blister/pack

Component	Duration (Month)	Stability Report Start date	In-Use Stability Report
1	24	08.01.2015	

[Stability Report.pdf](#)

Page 4

1.0.7.1.a Manufacturer appeared on product
label of finished product
GMP Certificate of Manufacturer Appeared on
Product Label
[GMP.pdf](#)

Manufacturers Licence (ML) of Manufacturer
Appeared on Product Label
[ML.pdf](#)

1.0.7.1.b All Other Company(ies) involved in the
preparation of the product/substance
GMP Certificate of Other Manufacturer 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.pdf](#)

Authorization letter from the
manufacturer/marketing authorization holder
authorizing the applicant to apply registration for
its product.
[Manufacturer Authorization Letter.pdf](#)

An undertaking, given by the applicant to provide,
at any stage of registration, any information and/or
documents relating to the product/substance upon
request within the prescribed timeframe
[Product Information.pdf](#)

GMP Certificate of Manufacturer Appeared on
Product Label
[GMP.pdf](#)

GMP Certificate of Other Manufacturer 1
[GMP.pdf](#)

Page 8

Other Country/Region 1
[Free Sales Certificate.pdf](#)

Page 9

Specification of the product (showing compliance
with pharmacopoeias listed in the Guidance
Notes on Registration of Pharmaceutical
Products) (Reference for 1.0.8 of Page 5)
[Product Specification.pdf](#)

Method of analysis (detailed method of analysis
for all tests per finished product specifications)
(Reference for 1.0.8 of Page 5)
[Method of Analysis.pdf](#)

Certificate of analysis (showing results for all tests
per finished product specifications) (Reference for
1.0.8 of Page 5)
[Certificate of Analysis.pdf](#)

Reputable documentary evidence to substantiate
the content of package insert. Cross-referencing
to documents should be made by referring to
page number of the reference and the relevant
parts of the reference document(s) shall be clearly
highlighted. Please refer to the list of reputable
references in the Guidance Notes on Registration
of Pharmaceutical Products
[Evidence Document.pdf](#)

Manufacturers Licence (ML) of Manufacturer
Appeared on Product Label
[ML.pdf](#)

ML of Other Manufacturer 1
[ML.pdf](#)

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

New Product Registration Module 1 Page 1 - Submitted Application

Application Reference no.: ANP20169000003
PL no.: PL0004/2016 PR no.:
Version no.: 1
Submission Date: 07.03.2016

Priority Application

For Priority applications, the following supporting documents 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

1.0.1 Name Of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):

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):

	Ingredient	Labelled Ingredient
Component 1	a. <input type="text" value="CARDAMOM OIL"/>	<input type="text" value="CARDAMOM OIL"/>

1.0.1.3 Application Type:

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

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

Application Version 1

CTD in PDF format
Application Submitted: [Application History.pdf](#)

Document List

Page 2

1. Product Pack Size: 6x10's blister/pack

Component	Duration (Month)	Stability Report Start date	In-Use Stability Report
1	24	08.01.2015	

[Stability Report.pdf](#)

2. Product Pack Size: 3x10's blister/pack

Component	Duration (Month)	Stability Report Start date	In-Use Stability Report
1	24	08.01.2015	

[Stability Report.pdf](#)

Page 4

1.0.7.1.a Manufacturer appeared on product label of finished product
GMP Certificate of Manufacturer Appeared on Product Label
[GMP.pdf](#)

Manufacturers Licence (ML) of Manufacturer Appeared on Product Label
[ML.pdf](#)

1.0.7.1.b All Other Company(ies) involved in the preparation of the product/substance
GMP Certificate of Other Manufacturer 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.pdf](#)

Authorization letter from the manufacturer/marketing authorization holder authorizing the applicant to apply registration for its product.
[Manufacturer Authorization Letter.pdf](#)

An undertaking, given by the applicant to provide, at any stage of registration, any information and/or documents relating to the product/substance upon request within the prescribed timeframe
[Product Information.pdf](#)

GMP Certificate of Manufacturer Appeared on Product Label
[GMP.pdf](#)

GMP Certificate of Other Manufacturer 1
[GMP.pdf](#)

Page 8

Other Country/Region 1
[Free Sales Certificate.pdf](#)

Page 9

Specification of the product (showing compliance with pharmacopoeias listed in the Guidance Notes on Registration of Pharmaceutical Products) (Reference for 1.0.8 of Page 5)
[Product Specification.pdf](#)

Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)
[Method of Analysis.pdf](#)

Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)
[Certificate of Analysis.pdf](#)

Reputable documentary evidence to substantiate the content of package insert. Cross-referencing to documents should be made by referring to page number of the reference and the relevant parts of the reference document(s) shall be clearly highlighted. Please refer to the list of reputable references in the Guidance Notes on Registration of Pharmaceutical Products
[Evidence Document.pdf](#)

Manufacturers Licence (ML) of Manufacturer Appeared on Product Label
[ML.pdf](#)

ML of Other 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.

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VEGIN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	BOURBON POWDER	PL0002/2020	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 500MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1


Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CLOMIPRILET DRUG FOR FOR IV IN 500MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	DETECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	DETECTIN 500 CAP 500MG

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



You are login as

Login date and time
28.01.2021 15:06

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Certificate Payment Request	VIGON 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	PRODUCT NAME	PL0023/2018	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 500MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CELESTIN 500 CAP 500MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CETECOTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CETECOTIN 500 CAP 500MG

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 :

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.

Step 3: Click the “NOTIFICATION_PRINT.pdf” to view the notification in PDF format.

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 :

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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

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



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

(來函請註明此檔案號碼)
(IN REPLY PLEASE 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 other places

Section 1.0.8.1: Screening Comment

Assessment made By: Screen Officer

Signature of Assessment Officer: _____

Name (in BLOCK letters): Screen Officer

Post Title:

Date: 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 :

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
362 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.

Application History Guidance
Save Save and Exit Next

Applications Require Action
NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME
PL No.: PL0023/2018
PR No.:
HK No.:

Module 1

Module 2

Module 3

Module 4

Module 5

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Application Form

☐ Priority Application

For priority applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):*

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name: <input style="width: 150px;" type="text" value="PRODUCT NAME"/>	Place: <input style="width: 100px;" type="text" value="GERMANY"/>
Name: <input style="width: 150px;" type="text" value="PRODUCT NAME"/>	Place: <input style="width: 100px;" type="text" value="UNITED KINGDOM"/>
Name: <input style="width: 150px;" type="text"/>	Place: <input style="width: 100px;" type="text" value="Please Select"/>

[Add More](#)

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*

Active Ingredient	Active Ingredient Appeared on Product Label
Component 1.1. * <input style="width: 150px;" type="text" value="bisbentiamine"/>	<input style="width: 150px;" type="text" value="bisbentiamine Label"/>
2. <input style="width: 150px;" type="text" value="None of the above"/>	<input style="width: 150px;" type="text" value="New Ingredient Name"/>
3. <input style="width: 150px;" type="text" value="Please Select"/>	<input style="width: 150px;" type="text"/>
4. <input style="width: 150px;" type="text" value="Please Select"/>	<input style="width: 150px;" type="text"/>

[Add More](#)

1.0.1.3 Application Type: (please select one) *

- ☐ Human biological pharmaceutical product
- ☒ Human chemical pharmaceutical product
- ☐ Human vaccine
- ☐ Pharmaceutical substance
- ☐ Veterinary biological pharmaceutical product
- ☐ Veterinary chemical pharmaceutical product
- ☐ Veterinary vaccine

Comments for page Page 1

Section 1.0

☒ S ☐ U

Section 1.0.1.1

☐ S ☒ U

Section 1.0.1.2

☐ S ☒ U

Section 1.0.1.3

☐ S ☒ U


Application History Guidance
Save Save and Exit Next

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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL



New Product Registration

NEW_PRODUCT_REGISTRATION_STATUS

You are login as

InitiateNew Product Registration

Login date and time
27.01.2021 11:02

Online Notification

My Product Search

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

New Submission

InitiateNew Product Registration

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	06.04.2020	ANP20209000002	PL0023/2018		PRODUCT NAME	1	Request for Outstanding Information	20.11.2020	No
2	29.11.2019	ANP20199000004	PL0005/2019		CALMING RELIFE	2	Pending for Application Fee	04.12.2019	No

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	20.11.2020	ANP20209000006	TESTAAA	Pending
2	09.10.2020	ANP20209000005	OCTOBER UAT	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	16.12.2016	ANP20169000348	PL0975/2016	PR0012/2017	VOCIN 500 TABLETS 500MG	5	Issue Certificate	12.01.2021	Yes
2	24.10.2019	ANP20199000003	PL0003/2019	PR0005/2019	ADVANCE TYPE PRODUCT	4	Evaluation	12.01.2021	Yes
3	05.06.2020	ANP20209000004	PL0004/2020	PR0004/2020	JAVA 8 START	1	Issue Certificate	21.11.2020	Yes
4	03.11.2016	ANP20169000317	PL0886/2016	PR0717/2016	CETIZAL TABLETS 5MG	4	Withdraw Application Request	20.11.2020	Yes
5	23.06.2017	ANP20179000747	PL0270/2017	PR0260/2017	CILOSOL 100 TABLETS 100MG	2	Withdraw Application Request	20.11.2020	Yes
6	09.01.2019	ANP20179000769	PL0001/2019		SULSA 500 TABLETS 500MG	3	Screening	09.10.2020	No
7	12.05.2020	ANP20209000003	PL0003/2020	PR0003/2020	TEST2020	1	Issue Certificate	05.06.2020	Yes
8	09.03.2020	ANP20209000001	PL0001/2020	PR0002/2020	PURHEART PILL	2	Issue Certificate	06.04.2020	Yes
9	20.12.2019	ANP20169000308	PL0006/2019	PR0001/2020	LECETAM 250	3	Issue Certificate	31.01.2020	Yes
10	17.12.2018	ANP20179000740	PL0005/2018	PR0002/2019	VIVIR CREAM	3	Evaluation	14.06.2019	Yes
11	28.06.2017	ANP20169000306	PL0283/2017	PR0002/2018	MONTULAR 10 TABLETS 10MG	2	Issue Certificate	17.12.2018	Yes
12	16.12.2016	ANP20169000346	PL0974/2016	PR0011/2017	VOCIN 250 TABLETS 250MG	4	Evaluation	27.06.2017	Yes

2015 copyright | Important notices Last Revision Date: 02 Sep 2020 Version: 1.0.99 (PP)

[Application History](#) [Guidance](#)

[Save](#) [Save and Exit](#) [Next](#)

Applications Require Action

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
File upload is not allowed for modules 2 - 5, please submit the files to Drug Office via CD/DVD if necessary.

NEW_PRODUCT_REGISTRATION_VIEW_01

Proposed Name of Product (English): PRODUCT NAME

PL No.: PL0023/2018

PR No.:

HK No.:

Module 1

Module 2

Module 3

Module 4

Module 5

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Application Form

☐ Priority Application
 For priority applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):*

PRODUCT NAME ?

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name: PRODUCT NAME

Place: GERMANY

Name: PRODUCT NAME

Place: UNITED KINGDOM

Name:

Place: Please Select

[Add More](#)

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)* 1

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1. *	bisbentiamine	bisbentiamine Label
2.	None of the above New Ingredient Name	New Ingredient Name
3.	Please Select	
4.	Please Select	

[Add More](#)

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine

[Application History](#) [Guidance](#)

[Save](#) [Save and Exit](#) [Next](#)

Section 1.0

S U

Section 1.0.1.1

Please update the proposed names used in other places

S U

Section 1.0.1.2

S U

Section 1.0.1.3

S U

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

Application History Guidance Save Save and Exit Next

Applications Require Action NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: PL0023/2018 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):* PRODUCT NAME ?

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name	Place
PRODUCT NAME	GERMANY
PRODUCT NAME	UNITED KINGDOM
	Please Select

Add More

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)* 1

Component	Active Ingredient	Active Ingredient Appeared on Product Label
1. *	bisbentiamine	bisbentiamine Label
2.	None of the above New Ingredient Name	New Ingredient Name
3.	Please Select	
4.	Please Select	

Add More

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine

Comments for page Page 1

Section 1.0

Section 1.0.1.1

Please update the proposed names used in other places

Section 1.0.1.2

Section 1.0.1.3

Application History Guidance Save Save and Exit Next

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.

Application History Guidance Back Save Save and Exit Next

Applications Require Action NEW_PRODUCT_REGISTRATION_VIEW_03

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 (AP8) PL No.: PL1052/2015 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

1.0.5 Legal Status

1.0.6 Applicant Information

a. Username : CH6_ADMIN
b. Email Address : charles.lee@ch6.com.hk

1.0.6.1 Proposed Registration Certificate Holder

a. Name : CERT HOLDER 6
b. Address :
Unit: 044 Floor: 11 Block: A
Building: ABC Building
Street No.: 1 Street Name: ABC Street
Sub-district: SHEK KIP MEI
Area: KOWLOON

c. Phone Number: (852) Fax Number: (852)

d. Contact Person for this application*: John Ho Phone No.*: 23192319 Position*: Administrator
Email*: testing@hk.com Fax No.*: 35234534

e. Business Type*:
☐ Manufacturer
☐ Importer
☒ Local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong
☐ Licensed wholesale dealer who has entered into a contract with the licensed manufacturer under which the licensed manufacturer is required to manufacture the pharmaceutical product or substance

Comments for page Page 3

Section 1.0.5

Section 1.0.6.1

Section 1.0.6.2

1.0.6.2 Person responsible for Pharmacovigilance

a. Name of Person : Peter Lam
b. Contact Person HK Telephone No. : 852 23192319 Position : Supervisor Email : testing@hk.com (24 hours)

Application History Guidance Back Save Save and Exit Next

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

Application History Guidance Back Save Save and Exit Next

Applications Require Action NEW_PRODUCT_REGISTRATION_VIEW_03

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 (AP8) PL No.: PL1052/2015 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

1.0.5 Legal Status

1.0.6 Applicant Information

a. Username : CH6_ADMIN
b. Email Address : charles.lee@ch6.com.hk

1.0.6.1 Proposed Registration Certificate Holder

a. Name : CERT HOLDER 6
b. Address :
Unit: 044 Floor: 11 Block: A
Building: ABC Building
Street No.: 1 Street Name: ABC Street
Sub-district: SHEK KIP MEI
Area: KOWLOON

c. Phone Number: (852) Fax Number: (852)

d. Contact Person for this application*: John Ho Phone No.*: 23192319 Position*: Administrator
Email*: testing@hk.com Fax No.*: 35234534

e. Business Type*:
☐ Manufacturer
☐ Importer
☒ Local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong
☐ Licensed wholesale dealer who has entered into a contract with the licensed manufacturer under which the licensed manufacturer is required to manufacture the pharmaceutical product or substance

1.0.6.2 Person responsible for Pharmacovigilance

a. Name of Person : Peter Lam
b. Contact Person HK Telephone No. : 852 23192319 Position : Supervisor Email : testing@hk.com (24 hours)

Application History Guidance Back Save Save and Exit Next

Step 5: Click the “Proceed to Submit” button.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

[Application History](#) [Guidance](#) [Back](#) [Print](#) [Proceed To Submit](#)

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: PL0023/2018 PR No.: HK No.: FORM6_VIEW

PHARMACY AND POISONS ORDINANCE (CHAPTER 138)

APPLICATION FORM FOR REGISTRATION OF A DRUG / PHARMACEUTICAL

PRODUCT / SUBSTANCE

Note: A specimen sales pack of the drug/product or sample of the substance and the relevant literature must be submitted together with the application. Supplementary documentation and supporting documents issued by the health authority in the country of origin should be submitted if required.

Name of the Drug / Product / Substance (Delete as appropriate)
PRODUCT NAME

Dose Form / Package Size(s) :

Dose Form
Component 1
Package Size(s): Cream
Product Pack Size :2 x 12's blister/box
Product Pack Size :2 x 48's blister/box

Detailed Qualitative and Quantitative Composition :

Component 1

Name of Active Ingredient(s)	Quantity (Strength Value)	Unit (Strength Unit)	Dose Value	Dose Unit	Reference / Monograph Standard
1. bisbentamine	1.5	mg	1	tablet	EP
2. New Ingredient Name	200	mcg	1	tablet	

Indications:

1. Indication of the Drug

Registered and Marketed in Which Countries/Places : GERMANY
UNITED KINGDOM

Name of Applicant: ABC COMPANY LIMITED
Business Registration No.: 00671890-000
In What Capacity the Applicant Makes This Application: Importer

Business Address of Applicant: 382, 3, A, CHA KWO LING, KOWLOON
Tel No.: 23198414 (Contact Person:David Wong)
12345678 (Submitted By:WONG David)
Facsimile No.: 23198414 (Contact Person:David Wong)
Email Address: prs.david.wong@gmail.com (Contact Person:David Wong)
prs.david.wong@gmail.com (Submitted By:WONG David)

Name of Manufacturer:
Name of manufacturer appeared on product label of finished product: MANU NAME xxxxxx
Address of Manufacturer:
Address of manufacturer appeared on product label of finished product: MANU ADDR XXXXXX XXXXXX XXXXXX

All Company(ies) involved in the preparation of the product/substance

Name of Manufacturer	Address of Manufacturer
1. MANU NAME xxxxxx	MANU ADDR XXXXXX XXXXXX XXXXXX

DECLARATION OF APPLICANT

☐ I wish to apply for registration of the said pharmaceutical products under the Pharmacy and Poisons Ordinance. I hereby declare that, to the best of my knowledge and belief, the information given in this application is correct.

Name: WONG David **Position held:**

e-Cert Authentication:

Please select the e-Cert file, e.g. C:\cert.p12

e-Cert PIN:

For Office Use Only

Date Received	Legal Classification	Fees Paid	Registration Approved	Certificate Issued	Registration
					%

[Guidance](#) [Back](#) [Print](#) [Proceed To Submit](#)

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

Application History Guidance Next Print

New Product Registration NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: PL0023/2018 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 applications, the following supporting documents 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 ☒ New Chemical Entity (NCE)

1.0.1 Name of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English):* ?

b. Proposed Name of Product (Chinese), if any:

c. Names / Proposed Names Used in Other Places

Name	Place
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="GERMANY"/>
<input type="text" value="PRODUCT NAME"/>	<input type="text" value="UNITED KINGDOM"/>
<input type="text"/>	<input type="text" value="Please Select"/>

1.0.1.2 Name of Active Substance(s) / Ingredient(s) (Please list below)

No. of Component(s)*

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1 1. *	<input type="text" value="bisbentiamine"/>	<input type="text" value="bisbentiamine Label"/>
2.	<input type="text" value="None of the above"/>	<input type="text" value="New Ingredient Name"/>
3.	<input type="text" value="Please Select"/>	<input type="text"/>
4.	<input type="text" value="Please Select"/>	<input type="text"/>

1.0.1.3 Application Type: (please select one) *

☐ Human biological pharmaceutical product
☒ Human chemical pharmaceutical product
☐ Human vaccine
☐ Pharmaceutical substance
☐ Veterinary biological pharmaceutical product
☐ Veterinary chemical pharmaceutical product
☐ Veterinary vaccine

Guidance Edit Application Next Print

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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL

[Application History](#) [Guidance](#) [Back](#) [Print](#) [Proceed To Submit](#)

The maximum upload size of single file is 1MB, while the maximum total upload size per application is 10MB.
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): PRODUCT NAME PL No.: PL0023/2018 PR No.: HK No.: FORM6_VIEW

PHARMACY AND POISONS ORDINANCE (CHAPTER 138)

APPLICATION FORM FOR REGISTRATION OF A DRUG / PHARMACEUTICAL

PRODUCT / SUBSTANCE

Note: A specimen sales pack of the drug/product or sample of the substance and the relevant literature must be submitted together with the application. Supplementary documentation and supporting documents issued by the health authority in the country of origin should be submitted if required.

Name of the Drug / Product / Substance: * (*Delete as appropriate)
PRODUCT NAME

Dose Form / Package Size(s):

Dose Form
Component 1
Package Size(s): Cream
Product Pack Size 2 x 12's blister/box
Product Pack Size 2 x 48's blister/box

Detailed Qualitative and Quantitative Composition:

Component 1

Name of Active Ingredient(s)	Quantity (Strength Value)	Unit (Strength Unit)	Dose Value	Dose Unit	Reference / Monograph Standard
1. bisbentamine	1.5	mg	1	tablet	EP
2. New Ingredient Name	200	mcg	1	tablet	

Indications:

1. Indication of the Drug

Registered and Marketed in Which Countries/Places: GERMANY
UNITED KINGDOM

Name of Applicant: ABC COMPANY LIMITED
Business Registration No.: 00671890-000
In What Capacity the Applicant Makes This Application: Importer

Business Address of Applicant: 382, 3, A, CHA KWO LING, KOWLOON
Tel No.: 23198414 (Contact Person: David Wong)
12345678 (Submitted By: WONG David)
Facsimile No.: 23198414 (Contact Person: David Wong)
Email Address: prs.david.wong@gmail.com (Contact Person: David Wong)
prs.david.wong@gmail.com (Submitted By: WONG David)

Name of Manufacturer:
Name of manufacturer appeared on product label of finished product: MANU NAME xxxxxx
Address of Manufacturer:
Address of manufacturer appeared on product label of finished product: MANU ADDR XXXXXX XXXXXX XXXXXX

All Company(ies) involved in the preparation of the product/substance

Name of Manufacturer	Address of Manufacturer
1. MANU NAME xxxxxx	MANU ADDR XXXXXX XXXXXX XXXXXX

DECLARATION OF APPLICANT

☒ I wish to apply for registration of the said pharmaceutical products under the Pharmacy and Poisons Ordinance. I hereby declare that, to the best of my knowledge and belief, the information given in this application is correct.

Name: WONG David **Position held:**

e-Cert Authentication:
C:\cert.p12 瀏覽
Please select the e-Cert file (eg. Cert.p12)
e-Cert PIN: ***

For Office Use Only

Date Received	Legal Classification	Fees Paid	Registration Approved	Certificate Issued	Registration
					%

[Guidance](#) [Back](#) [Submit Application](#) [Print](#)

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

Application ID: ANP20189000154
Submission Date: 2018.08.17

Proposed Name of Product (English)	PL No.
PRODUCT NAME	PL0023/2018

The Drug Office acknowledges your on-line submission for application of new product registration. We will process your request and will provide response as soon as possible.

For enquiries, please call us quoting this reference number.


General 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, Sundays & Public Holidays)

Tel: (852) 2319 8458
Email: prs2_info@dh.gov.hk

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.



You are login as
Login date and time
28.01.2021 15:06

- Online Notification**
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Application Payment Request	VEDIN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	PRODUCT NAME	PL0023/2018	N/A

CORP

Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 500MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 500MG

Renewal of Registration

Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1


Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CALCIUM UNISON TAB 500MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	OSTEOTIN 600 CAP 600MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	OSTEOTIN 600 CAP 600MG

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



You are login as

Login date and time
28.01.2021 15:06

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

ONLINE_NOTIFICATION_VIEW_01

Online Notification

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Application Payment Request	VECTIN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	PRODUCT NAME	PL0023/2018	N/A

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	EPILIMY RELECCORIED FOR FOR TV 100 400MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	OSTECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	OSTECTIN 500 CAP 500MG

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

ONLINE_NOTIFICATION_VIEW_01

Online Notification

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 :

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
352 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
<input checked="" type="checkbox"/> 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友邦九龍大樓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
(Link / 網址: https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp)

Step 3: Click the “GO” button for application payment.

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Notification Date :	30.01.2015 01:05:14
PL No. :	PL1052/2015
PR No. :	-
HK No. :	-
Proposed Name of Product (English) :	Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6)
Notification Detail :	NOTIFICATION_PRINT.pdf
Attachment(s) :	

1. Go To Application Payment :

2. In alternative to (1), 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 prs_enquiry@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 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.

New Application Payment

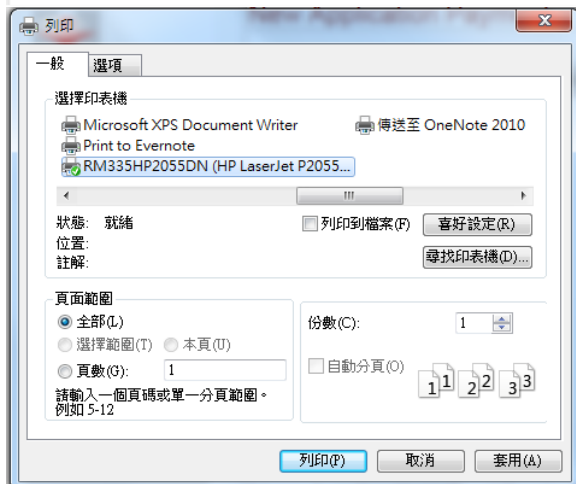
Print Ready to Pay

<input type="checkbox"/>	Application Received Date	PL No.	PR No.	Proposed Name of Product	Payment Status
<input type="checkbox"/>	31.05.2017 16:16	PL0070/2017		MY 20170531 1559	Ready for Application Payment

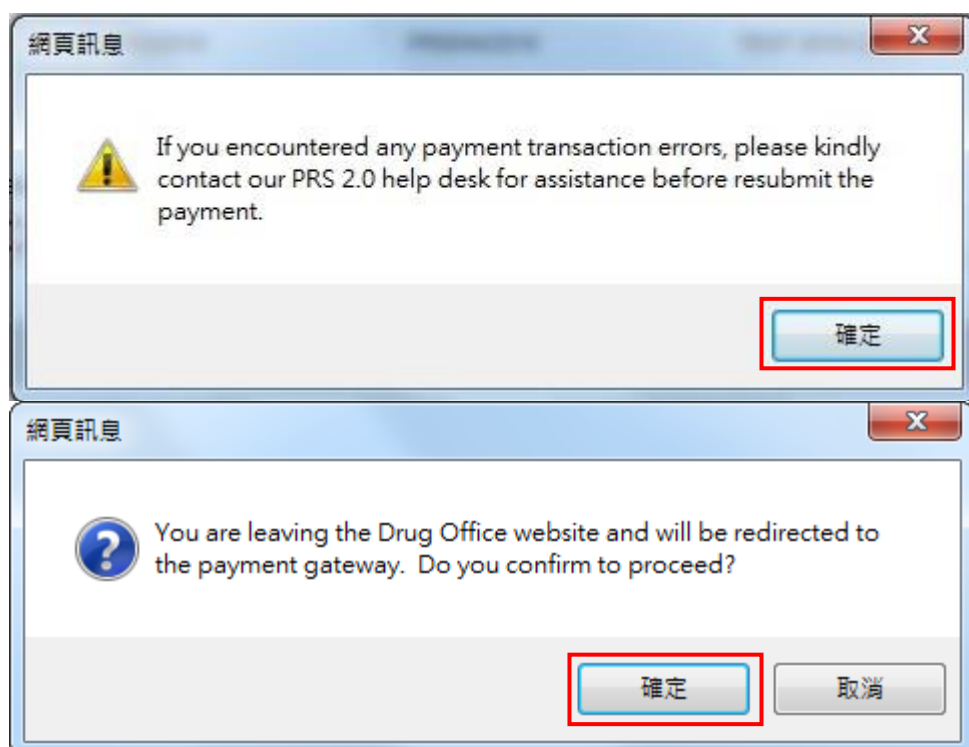
New Application Payment

Print Ready to Pay

<input type="checkbox"/>	Application Received Date	PL No.	PR No.	Proposed Name of Product	Payment Status
<input type="checkbox"/>	31.05.2017 16:16	PL0070/2017		MY 20170531 1559	Ready for Application Payment



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	DH Drug Office
Transaction Date	29-03-2023
Transaction Reference Number	DHPRS-202303291025-94191
Total Amount	HKD\$ 1,370.00
Payment Method*	<input type="radio"/> FPS <input type="radio"/> JCB <input type="radio"/> mastercard <input type="radio"/> VISA <input type="radio"/> UnionPay 银联 <input type="radio"/> PPS 繳費靈

Cancel Payment **Pay**

- Please take note of the transaction reference number or PRINT this page for making enquiry on the payment status when necessary.
- After pressing the 'Pay' button, please DO NOT leave this e-service until you receive the acknowledgement page, otherwise your transaction 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.

HONG KONG

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 Product Registration

[Print Receipt](#) [Close](#)

Payment Reference No.: DHPRS-201907261629-14197

Payment Method: Cash

Type of Payment: Application Fee

Transaction Time: 16.01.2020 11:20:30

Application Received Date	Reference No.	PR No.	Product Name
25.07.2019 15:33	ANP20199000015	PR0014/2019	TESTBBC

The Drug Office acknowledges the receipt of your payment of HK\$1,100.00 for certificate fee regarding the above product(s). We will process your application and will provide response as soon as possible.

Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)

Tel: (852) 3974 4175

Email: prs2_info@dh.gov.hk

[Print Receipt](#) [Close](#)

Name of Company

公司名稱

CERT HOLDER 6

Payment Date

繳費日期

30.1.2015

Payment Reference No: DHPRS-201501300213-90574

付款編號:

EGIS Reference No: A201501300000043

EGIS編號:

Payment Method: PPS

付款方法:

Payment Amount: HK\$1,100.00

付款金額:

Payment Reference No: DHPRS-201501300213-90574

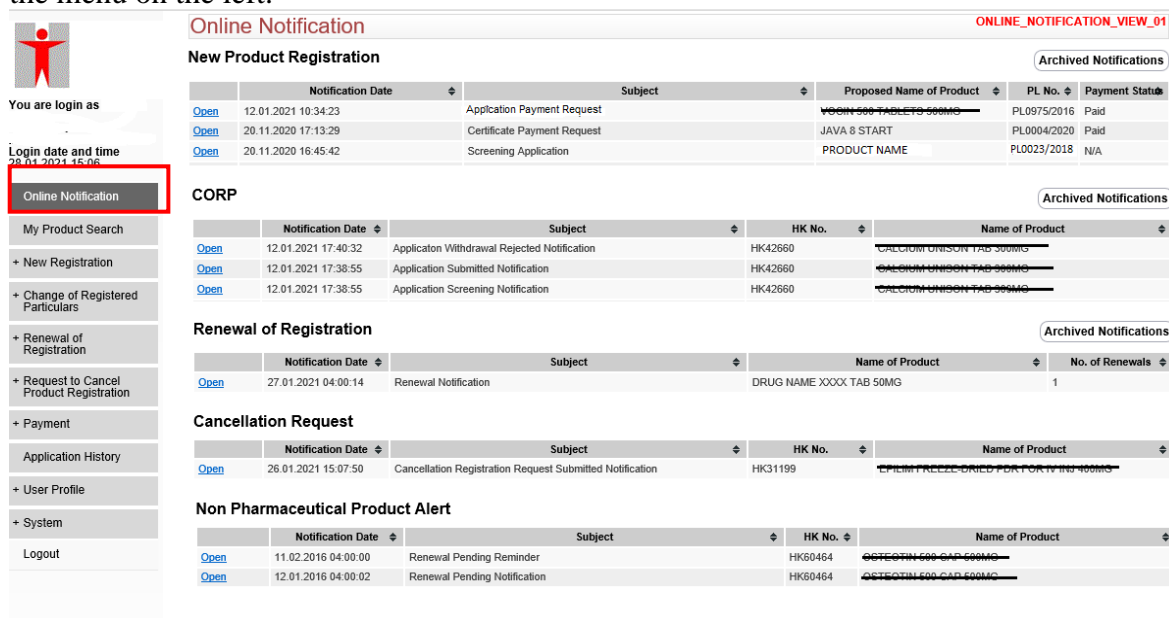
付款編號:

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 Release Tablets 1.5 mg (AP8)(CH6)	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.



Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Application Payment Request	VEEN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	PRODUCT NAME	PL0023/2018	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

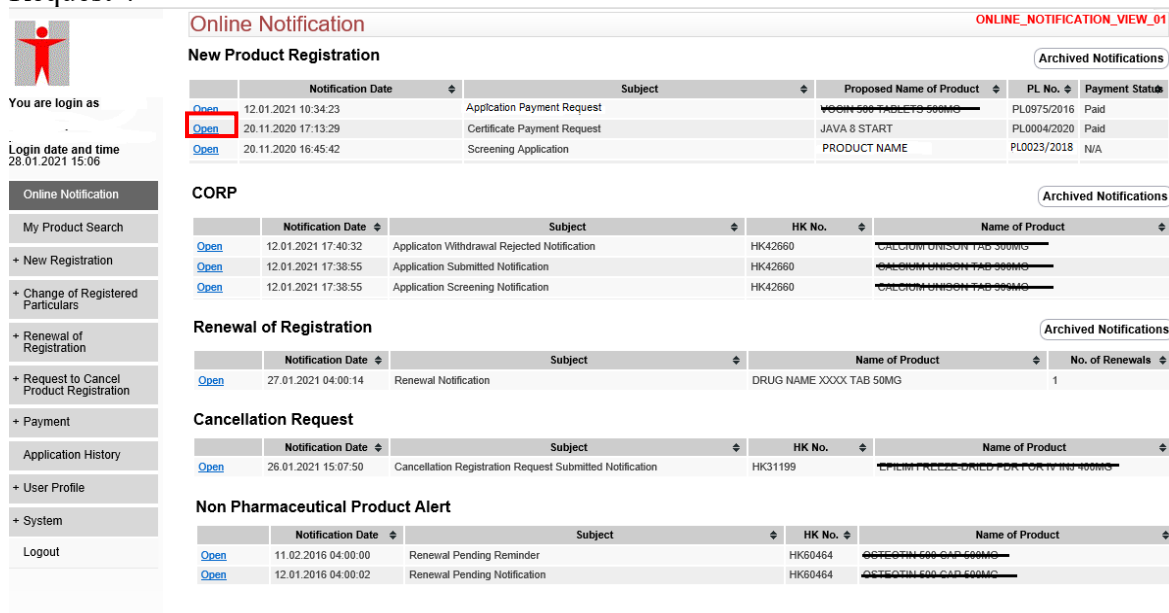
Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CELENT RELECO-DRUG FOR FOR TV 100MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CETECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CETECTIN 500 CAP 500MG

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



Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	12.01.2021 10:34:23	Application Payment Request	VEEN 500 TABLETS 500MG	PL0975/2016	Paid
Open	20.11.2020 17:13:29	Certificate Payment Request	JAVA 8 START	PL0004/2020	Paid
Open	20.11.2020 16:45:42	Screening Application	PRODUCT NAME	PL0023/2018	N/A

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:40:32	Application Withdrawal Rejected Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Submitted Notification	HK42660	CALCIUM UNISON TAB 300MG
Open	12.01.2021 17:38:55	Application Screening Notification	HK42660	CALCIUM UNISON TAB 300MG

Renewal of Registration Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1


Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	CELENT RELECO-DRUG FOR FOR TV 100MG

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	11.02.2016 04:00:00	Renewal Pending Reminder	HK60464	CETECTIN 500 CAP 500MG
Open	12.01.2016 04:00:02	Renewal Pending Notification	HK60464	CETECTIN 500 CAP 500MG

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



You are login as **WONG David**
ABC COMPANY LIMITED
Login date and time
16.01.2020 11:13

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- Request to change name and/or address of the certificate holder
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + Printing Service
- + System
- Logout

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Notification Date :17.08.2018 15:01:28

PL No. :PL0031/2017

PR No. :PR0038/2017

HK No. :HK63573

Proposed Name of Product (English) :TEST 2016022701

Notification Detail :[Cert. Payment Notification.pdf](#)

Attachment(s) :

1. Go To Certificate Payment :

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 Control Division
Suites 2002-05, 20/F,
AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong,
Kowloon, Hong Kong

For enquiries, please call our hotline at (852) 3974 4175 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
<input checked="" type="checkbox"/> Certificate(s) of Product Registration 藥劑製品註冊證明書 (HK\$1,370)	1	HK\$1,370
Ref. 檔號: PR0002/2015		

Drug Office
Department of Health

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 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衛生署藥物辦公室繳款處收。地址為香港九龍南昌街382號公共衛生檢測中心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
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
(Link / 網址: https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp)

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「藥劑製品註冊證書」、「證書的複本」、「更改註冊詳情」、「臨床試驗／藥物測試證書」及「影印服務」，請填妥丙部。

C. Certificate(s) Collection Method

丙：領取證書方法

Please tick your preferred collection method:

請選擇領取證書方法並在適當的空格內刷：

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

☐ 我／我等欲以郵遞方式領取證書

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書

Company Stamp:

公司印鑑：

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



You are login as **WONG David**
ABC COMPANY LIMITED
Login date and time
20.08.2018 14:04

- 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

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Notification Date : 17.08.2018 15:01:28

PL No. : PL0031/2017

PR No. : PR0038/2017

HK No. : -

Proposed Name of Product (English) : TEST 2016022701

Notification Detail : [Cert_Payment_Notification.pdf](#)

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 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.

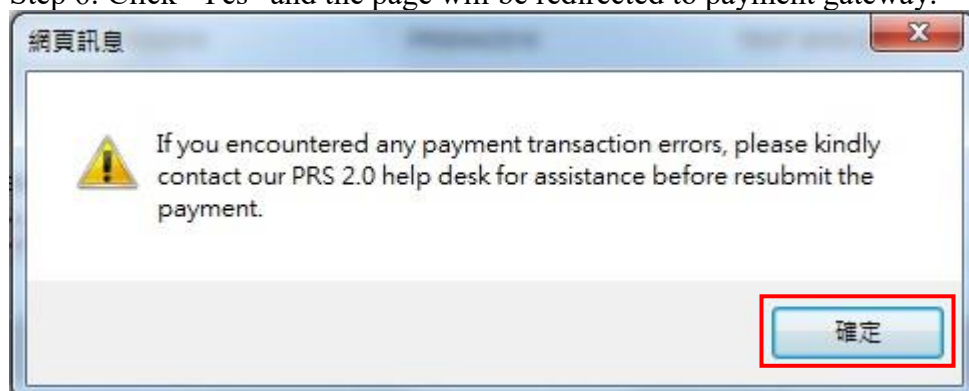
Step 5: Select single/multiple application, then choose the certificate collection method (received by post or collect in person in Drug Office), and then click the “Ready to Pay” button.

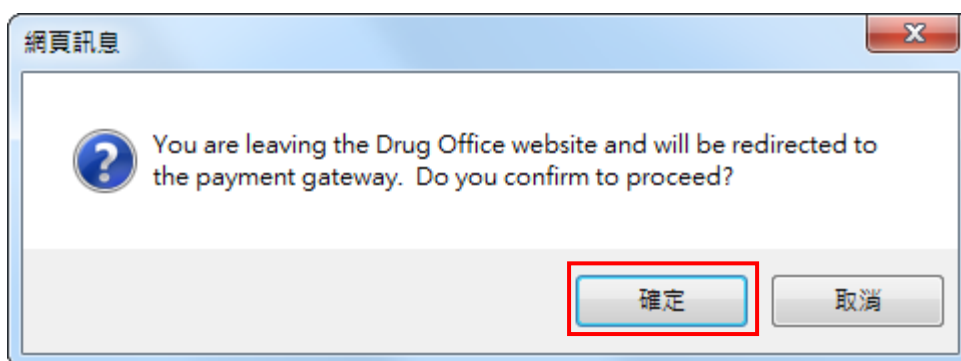
New Application Certificate Payment
Ready to Pay

	Application Received Date	PR No.	PL No.	Proposed Name of Product	Payment Status
<input style="border: 2px solid red;" type="checkbox"/>	19.01.2017 10:52	PL0004/2017	PR0006/2017	TEST 2017011901	Ready for Certificate Payment

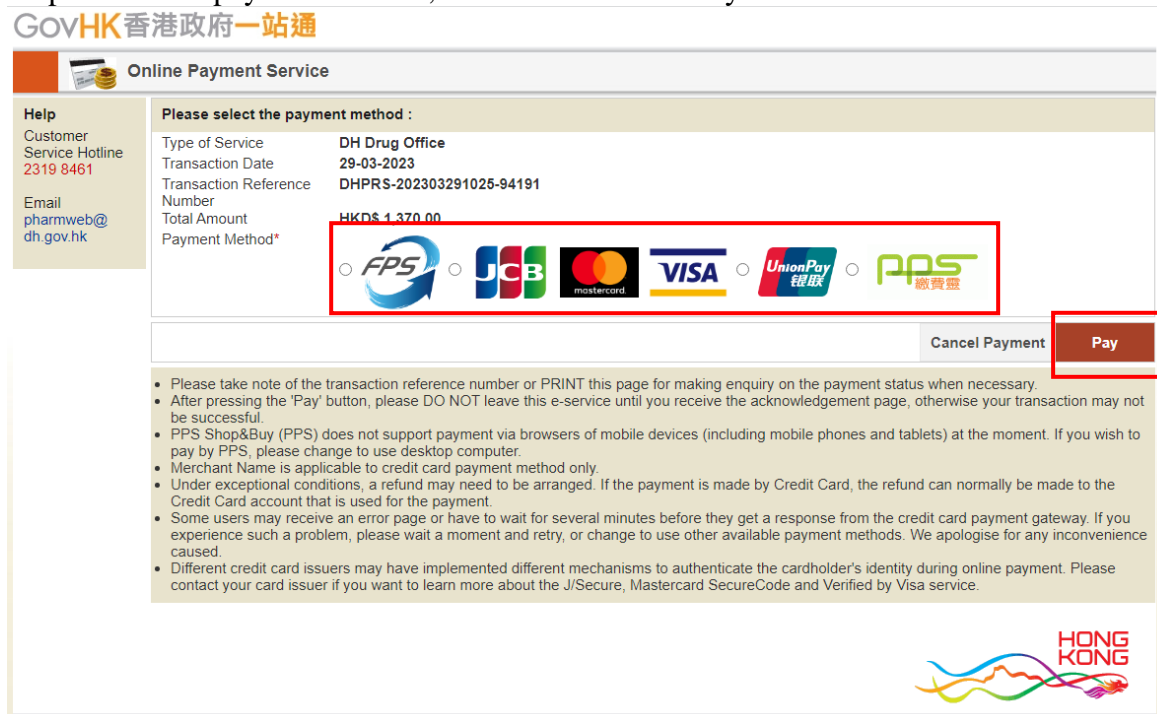
Certificate Collection: ☐ Received By Post ☐ Collect in Person in Drug Office

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.



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 Product Registration

[Print Receipt](#) [Close](#)

Payment Reference No.: DHPRS-201501300534-90575
EGIS Reference No.: A201501300000026
Payment Method: PPS
Type of Payment: Certificate Fee
Transaction Time: 30.01.2015 05:36:24
Delivery Method: Collect in Person in Drug Office
Certificate Collection Date: 06.02.2015

Application Received Date	Reference No.	PR No.	Product Name
29.01.2015 14:02	ANP20159000003	PR0002/2015	Indapamide-Trial Prolonged Release Tablets 1.5mg (AP8)(CH6)

The Drug Office acknowledges the receipt of your payment of HK\$1,370.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.

Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)
Tel: (852) 23198458
Email: prs2_info@dh.gov.hk

[Print Receipt](#) [Close](#)

Name of Company

公司名稱

CERT HOLDER 6

Payment Date

繳費日期

30.1.2015

Payment Reference No: DHPRS-201501300534-90575

付款編號:

EGIS Reference No: A201501300000026

EGIS編號:

Payment Method: PPS

付款方法:

Payment Amount: HK\$1,370.00

付款金額:

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

☒ 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.



You are login as ORG Trial One
TESTING LIMITED
Login date and time
27.01.2021 09:43

- Online Notification
- My Product Search
- 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

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Archived Notifications

No related notifications

CORP

Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:44:04	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	05.06.2020 11:00:01	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX
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	EPIILIM FREEZE-DRIED PDR FOR IV INJ 400MG
Open	27.02.2019 11:52:23	Certificate Fee Notification	HK55135	CELECOXIB FARMOZ
Open	26.02.2019 15:12:46	Application Approval Notification	HK42175	APT-INDOMETHACIN 25 CAP 25MG
Open	21.08.2018 18:25:53	Application Clarification Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:20:50	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:19:47	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:07:37	Application Submitted Notification	HK37565	PRODUCT NAME XXXXX

Renewal of Registration

Archived Notifications

	Notification Date	Subject	Name of Product	No. of Renewals
Open	27.01.2021 04:00:14	Renewal Notification	DRUG NAME XXXX TAB 50MG	1

Cancellation Request


	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	EPIILIM FREEZE-DRIED PDR FOR IV INJ 400MG

Non Pharmaceutical Product Alert

No related notifications

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



You are login as ORG Trial One
TESTING LIMITED
Login date and time
27.01.2021 10:22

- Online Notification
- My Product Search
- 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

New Product Registration Withdrawal

Withdraw application

	Application Date	PL No.	PR No.	Proposed Name of Product (English)	Application Status
<input type="checkbox"/>	2021.01.26	PL0001/2021		PRODUCT NAME	Application Submitted
<input type="checkbox"/>	2021.01.26			PRODUCT NAME	Pending
<input type="checkbox"/>	2019.03.01			TEST DRUG 20190301	Pending

Withdraw application

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Step 3: Input the reason (s) of withdrawal and click “Save” button to proceed the withdrawal request. Click ‘Cancel’ to cancel the withdrawal request.

Application Date	PL No.	PR No.	Proposed Name of Product (English)	Application Status
2018.07.18	PL0019/2018		TEST 2015	Screening

Date of Withdrawal Request : 20.08.2018

Reason(s) of Withdrawal :


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 here

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”.




You are login as ORG Trial One
TESTING LIMITED
Login date and time
27.01.2021 10:22

- Online Notification
- My Product Search
- 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

New Product Registration Withdrawal

<input type="checkbox"/>	Application Date	PL No.	PR No.	Proposed Name of Product (English)	Application Status
<input type="checkbox"/>	2021.01.26	PL0001/2021		PRODUCT NAME	Application Submitted
<input type="checkbox"/>	2021.01.26			PRODUCT NAME	Pending
<input type="checkbox"/>	2019.03.01			TEST DRUG 20190301	Pending

2015 copyright | Important notices Last Revision Date: 02 Sep 2020 Version: 1.0.99 (PP)



NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as ORG Trial One
TESTING LIMITED
Login date and time
20.08.2018 14:24

- Online Notification
- My Product Search
- New Registration**
- Initiate New Product Registration Application
- Application Status
- Action Required
- Not Submitted
- Application Submitted
- Withdraw application
- + Change of Registered Particulars
- + Renewal of Registration
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Submission
[Initiate New Product Registration](#)

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	17.07.2018	ANP20189000108	PL0010/2018		TEST ECERT CASE1	1	Withdraw Application Request	20.08.2018	No
2	31.07.2017	ANP20179000079	PL0082/2017		TEST LOGIN2	1	Request for Outstanding Information	22.06.2018	No
3	31.07.2017	ANP20179000078	PL0081/2017		TEST USER LOGIN 2	1	Request for Outstanding Information	14.11.2017	No


Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	10.08.2018	ANP20189000153	TEST NCE 2	Pending
2	18.07.2018	ANP20189000132	TEST OPEN FILE CASE 3	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	06.08.2018	ANP20189000133	PL0019/2018		TEST 2015	1	Withdraw Application Request	20.08.2018	No
2	10.08.2018	ANP20189000151	PL0022/2018		TEST NCE CASE	1	Application Submitted	15.08.2018	No
3	24.02.2017	ANP20179000023	PL0030/2017	PR0036/2017	TEST 2017022401	1	Evaluation	31.07.2018	Yes

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



Total Number of Application Records:1

Application History

You are login as

Login date and time
20.08.2018 15:46

- 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

New Product Registration

Application Date	PL No.	PR No.	HK No.	Name of Product	Payment Status	Status	Last Updated Date
06.08.2018	PL0019/2018			TEST 2015	No	Withdraw Application Approved	06.08.2018

Change of Registered Particulars

Application Date	Ref No.	HK No.	Name of Product	Change Categories	Payment Status	Status	Last Updated Date
23.05.2018	CORP-HK56673-201851497	HK56673	VICK-CLONAZEPAM TAB 2MG	5	Certificate Fee Paid	Application Withdrawn	23.06.2018

Renewal of Registration

Expiry Date	HK No.	Name of Product	Application Status	Last Updated Date


Termination of Product Registration

Application Date	Ref No.	HK No.	Name of Product	Status	Last Updated Date

Interview

Application Date	Subject	Application	Status

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



You are login as

Login date and time
17.08.2018 13:44

- 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

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	20.08.2018 15:45:31	Confirmation for withdrawal	TEST 2015	PL0019/2018	N/A
Open	14.11.2017 11:06:22	Application Payment Request	TEST USER LOGIN 2	PL0081/2017	Unpaid
Open	03.04.2017 10:47:03	Application Payment Request	TEST 2017022401	PL0030/2017	Paid

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	07.08.2018 17:35:15	Application Screening Notification	HK63517	WALKTRHOUGH
Open	07.08.2018 09:52:51	Application Submitted Notification	HK63517	WALKTRHOUGH

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals
Open	29.06.2018 04:20:28	Renewal Notification	APQ-LEVETIRACETAM TAB 500MG	1
Open	23.06.2018 02:13:33	Expired Product Notice	VICK-CLONAZEPAM TAB 2MG	1

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
--	-------------------	---------	--------	-----------------

Interview

	Notification Date	Subject
--	-------------------	---------

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
--	-------------------	---------	--------	-----------------



You are login as

Login date and time
20.08.2018 15:46

- 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

Online Notification
ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Notification Date : 20.08.2018 15:45:31

PL No. : PL0019/2018

PR No. : -

HK No. : -

Proposed Name of Product (English) : TEST 2015

Notification Detail :

Attachment(s) :

The withdrawal application has been confirmed.

1. Back To Application :

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.

Applicant will receive the confirmation of withdrawal letter by post.

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



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: 98765432
詢問處 Enquiries: (852) 23198458
傳真號碼 Faxline No: (852) 28034962
本署檔號 Our Ref.: DH DO PRIE/8-15/2
(來函請註明此檔案號碼)
(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)
Justification for urgent application

☐ I know I have already submitted another CORP application under the same category/sub-category which is under processing.
Justification for same category/sub-category application

*Application Received Date: 26.01.2021
*Client Date: 26.01.2021

Certificate Holder Name:
TESTING LIMITED


Initiate CORP Application [Add Product] [Remove Product] [Select from all product]

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

Particulars Proposed to Change	Brief Description of Change and Reason
+ 1 Specification	
+ 2 Label	
+ 3 Package Insert	
+ 4 Manufacturer	
+ 5 Registration Certificate Holder	
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)	
+ 7 Excipients	
+ 8 Indication / Dosage / Route of Administration	
+ 9 Other	<input type="checkbox"/>

[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.



You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 11:20

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application**
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particulars (CORP) Application

Step 1: Selection of Products and Change Categories Back Next

☐ Urgent Application (subject to decision by Drug Office)
Justification for urgent application

☐ I know I have already submitted another CORP application under the same category/sub-category which is under processing.
Justification for same category/sub-category application

*Application Received Date: 26.01.2021
*Client Date: 26.01.2021

Certificate Holder Name:
TESTING LIMITED

☐ HK No. Product Name


Add Product Remove Product Select from all product

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

Particulars Proposed to Change	Brief Description of Change and Reason
+ 1 Specification	
+ 2 Label	
+ 3 Package Insert	
+ 4 Manufacturer	
+ 5 Registration Certificate Holder	
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)	
+ 7 Excipients	
+ 8 Indication / Dosage / Route of Administration	
+ 9 Other <input type="checkbox"/>	<input type="text"/>

Back Next

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



You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 11:20

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application**
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particulars (CORP) Application

Step 1: Selection of Products and Change Categories Back Next

☐ Urgent Application (subject to decision by Drug Office)
Justification for urgent application

☐ I know I have already submitted another CORP application under the same category/sub-category which is under processing.
Justification for same category/sub-category application

*Application Received Date: 26.01.2021
*Client Date: 26.01.2021

Certificate Holder Name:
TESTING LIMITED

☐ HK No. Product Name

Add Product Remove Product Select from all product

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

Particulars Proposed to Change	Brief Description of Change and Reason
+ 1 Specification	
+ 2 Label	
+ 3 Package Insert	
+ 4 Manufacturer	
+ 5 Registration Certificate Holder	
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)	
+ 7 Excipients	
+ 8 Indication / Dosage / Route of Administration	
+ 9 Other <input type="checkbox"/>	<input type="text"/>

Back Next

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

<input type="checkbox"/>	HK No.	Product Name
<input type="checkbox"/>	HK37565	PRODUCT NAME XXXXX
<input type="checkbox"/>	HK41190	PRODUCT NAME XXXXX XXXX

Confirm Cancel

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

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

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

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

Change of Registered Particulars (CORP) Application

Step 1: Selection of Products and Change Categories [Back] [Next]

☒ Urgent Application (subject to decision by Drug Office)

Justification for urgent application

☐ I know I have already submitted another CORP application under the same category/sub-category which is under processing.

Justification for same category/sub-category application

Certificate Holder Name: TESTING LIMITED

HK No.	Product Name
<input checked="" type="checkbox"/> HK37565	PRODUCT NAME XXXXX
<input checked="" type="checkbox"/> HK41190	PRODUCT NAME XXXXX XXXX

Add Product Remove Product Select from all product

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

Particulars Proposed to Change	Brief Description of Change and Reason
+ 1 Specification	
+ 2 Label	
+ 3 Package Insert	
+ 4 Manufacturer	
+ 5 Registration Certificate Holder	
+ 5.1 Change in name and / or address of the current registration certificate holder	<input checked="" type="checkbox"/> change company location
+ 5.2 Change in new registration certificate holder	<input type="checkbox"/>
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)	
+ 7 Excipients	
+ 8 Indication / Dosage / Route of Administration	
+ 9 Other	<input type="checkbox"/>

[Back] [Next]

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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 select all active product(s) 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.

Change of Registered Particulars (CORP) Application

Step 2: Uploading Documents with Proposed Changes Highlighted, and Other Supporting Documents Close Back Delete Save & Close Next

For uploading Clean Copy of Supporting Documents, please refer to Step 3

You are login as VMG
EST USER1
HEAMAN COMPANY
Login date and time
7.12.2021 10:47

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 07.12.2021

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK63722	PRODUCT_20211116	<input type="radio"/> 1 week after approval <input checked="" type="radio"/> 1 year after approval

***Remarks**

- For CORP application submitted on or after 1 December 2021, the available options for the effective date proposed by the applicant would only include 1 week or 1 year after approval.
- Applicants can apply for change of implementation date (CIMP) subsequent to the approval of CORP, and for each approved CORP, the applicant can apply for CIMP no more than twice.
- CORP shall be implemented within 2 years after approval.

† This requirement applies to CORP approved on or after 1 December 2021.

Change Category and Supporting Documents. (Only relevant supporting documents will be processed)

Please upload Declaration Letter if no highlighted Copy
The recommendation resolution of scanning for the supporting document is 360dpi

i. Letter summarising the proposed changes

Remark	Documents File Name
<input type="checkbox"/> Add File Remove File	UPLOAD No File Chosen

ii. Proposed label(s) with the change(s) underlined or highlighted*

Remark	Documents File Name
<input type="checkbox"/> # Please specify the name of the Uploaded File in "Remark". (if applicable) Add File Remove File	UPLOAD No File Chosen

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

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

Change of Registered Particulars (CORP) Application

Step 2: Uploading Highlighted Copy of Supporting Documents Close Back Delete Save & Close Next

For uploading Clean Copy of Supporting Documents, please refer to Step 3

You are login as CHAN
Kim
HONG KONG RED CROSS
BLOOD TRANSFUSION
SERVICE
Login date and time
01.08.2018 18:11

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 20.07.2018

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK44456	MONOFIX-VF HUMAN FACTOR IX FOR INJ 500IU	<input checked="" type="radio"/> Expected Date: <input type="text"/> <input type="radio"/> Days after approval: <input type="text"/>
2	HK46073	INTRAGAM P NORMAL IMMUNOGLOBULIN INJ 6%	
3	HK58570	ALBUMEX 5 INF 12.5G/250ML	
4	HK58571	ALBUMEX 20 INF 10G/50ML	

Change Category and Supporting Documents. (Only relevant supporting documents will be processed)

Please upload Declaration Letter if no highlighted Copy
The recommendation resolution of scanning for the supporting document is 360dpi

5 Registration Certificate Holder

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


i. Copy of the Certification of Incorporation on the Change of Name (for incorporated company only)

Remark	Documents File Name
<input type="checkbox"/> Add File Remove File	Upload No File Chosen


Close Back Delete Save & Close Next

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

Proposed Effective Date

☒ Expected Date: 

☐ Days after approval

 Jan 2015 

Su	Mo	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

Done

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:

☒ Days after approval:

31

32

33

34

35

36

37

38

39

40

41

42

43

44

45

46

47

48

49

50

51

52

53

54

55

56

57

58

59

60

Documents File Name

Upload

No File Chosen

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 File Name	The same file has already been uploaded in another location in this submission #
# Please specify the name of the Uploaded File in "Remark". (if applicable)		
<input type="checkbox"/>	<input type="text" value="test20170702.pdf"/> <input type="button" value="Upload"/>	<input type="checkbox"/>


3 Package Insert

3.1 Change in package insert

i. Proposed package insert with the change(s) underlined and highlighted*

Remark	Documents File Name	The same file has already been uploaded in another location in this submission #
# Please specify the name of the Uploaded File in "Remark". (if applicable)		
<input type="checkbox"/>	<input type="text" value="Same as test20170702.pdf"/> <input type="button" value="Upload"/>	<input checked="" type="checkbox"/>

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.



You are login as CHAN Kim
HONG KONG RED CROSS
BLOOD TRANSFUSION
SERVICE
Login date and time
01.08.2018 18:11

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application**
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Submission of Other Post-registration Supplement

Change of Registered Particulars (CORP) Application

Step 2: Uploading Highlighted Copy of Supporting Documents
For uploading Clean Copy of Supporting Documents, please refer to Step 3

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 20.07.2018

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK44456	MONOFIX-VF HUMAN FACTOR IX FOR INJ 500IU	<input checked="" type="radio"/> Expected Date: <input type="text"/> <input type="radio"/> Days after approval: <input type="text"/>
2	HK46073	INTRAGAM P NORMAL IMMUNOGLOBULIN INJ 6%	
3	HK58570	ALBUMEX 5 INF 12.5G/250ML	
4	HK58571	ALBUMEX 20 INF 10G/50ML	

Change Category and Supporting Documents. (Only relevant supporting documents will be processed)

Please upload Declaration Letter if no highlighted Copy
The recommendation resolution of scanning for the supporting document is 360dpi

5 Registration Certificate Holder

5.1 Change in name and / or address of the current registration certificate holder
i. Copy of the Certification of Incorporation on the Change of Name (for incorporated company only)

Remark	Documents File Name	The same file has already been uploaded in another location in this submission #
<input type="checkbox"/>	<input type="text" value="test20170702.pdf"/> <input type="button" value="Upload"/>	<input type="checkbox"/>

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 Particulars (CORP) Application
Step 3: Change Product Particulars

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 21.08.2018

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK37565	PRODUCT NAME XXXXX	
2	HK41190	PRODUCT NAME XXXXX XXXX	

1.0.6.1 Proposed Registration Certificate Holder

a. Name: TESTING LIMITED

b. Address:

Unit: Room 301

Floor: 3/F

Block:

Building: Public Health Laboratory Centre

Street No.:

Street Name: 382 Nam Cheong Street

Sub-district: SHEK KIP MEI

Area: Kowloon

c. Phone Number: Fax Number:

d.

Contact Person for this Application*: Trial Phone No.*: 23198414

Position*: Trial Email*: trial@test.com

e. Business Type*:

☐ Licensed manufacturer

☒ Licensed wholesale dealer

☐ Local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong

☐ Licensed wholesale dealer who has entered into a contract with the licensed manufacturer under which the licensed manufacturer is required to manufacture the pharmaceutical product or substance

1.0.6.2 Staff responsible for Pharmacovigilance

a. Name of Staff: Trial One

b. Contact Person HK Telephone No.: 852 23198414 Position: Trial Email: trial@test.com (24 hours)

1.1.0 Annexed Documents/information/sample

* 7 Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)

UPLOAD
No of File(s): 1

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 Particulars (CORP) Application

Application Summary

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 21.08.2018

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK37565	PRODUCT NAME XXXXX	
2	HK41190	PRODUCT NAME XXXXX XXXX	

Change Category:

Particulars Proposed to Change	Brief Description of Change and Reason
5.1 Change in name and / or address of the current registration certificate holder	change company location

Supporting Documents:

5 Registration Certificate Holder

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

I. Copy of the Certification of Incorporation on the Change of Name (for incorporated company only)

Remark	Documents File Name
	No File Chosen

DECLARATION

☐ **DECLARATION BY THE APPLICANT:** I hereby declare that to the best of my knowledge and belief that the information given in this application is correct and all the changes have been identified and are being applied for the approval to change the registered particular(s).

The product / substance

☐ is supplied to the Department of Health via tender or direct purchase agreements.
☐ is not supplied to the Department of Health via tender or direct purchase agreements.

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.

Change of Registered Particulars (CORP) Application
Acknowledgement

Thank you for using our service. Your application has been submitted to the Drug Office.
Application submitted should be subjected to our final approval.
For enquiries, please call us quoting this reference number.

General 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, Sundays & Public Holidays)
Tel: (852) 2319 8458
Email: prs2_info@dh.gov.hk

Application Received Date: 21.08.2018

Product Selected:

	HK No.	PR No.	PL No.	Product Name	Application Reference No.	Proposed Effective Date
1	HK37565	PR0568/1993		PRODUCT NAME XXXXX	CORP-HK37565-201857482	
2	HK41190	PR0552/1996		PRODUCT NAME XXXXX XXXX	CORP-HK41190-201857483	

Change Category:

Particulars Proposed to Change	Brief Description of Change and Reason
5.1 Change in name and / or address of the current registration certificate holder	change company location

Supporting Documents:
5 Registration Certificate Holder
5.1 Change in name and / or address of the current registration certificate holder
i. Copy of the Certification of Incorporation on the Change of Name (for incorporated company only)

Remark	Documents File Name
	No File Chosen

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



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: (852) 2319 8458

詢問處 Enquiries: (852) 2319 8458

21 August 2018

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. Your application has 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

Your application has 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 Proposed to Change	Change Reason
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.

The application status page will be displayed for review.



You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 11:20

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application
- Application Status**
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particulars (CORP) Application

Please be reminded that for approved application(s), you are required to submit application(s) for change of implementation date 5 working days before the effective date, if necessary.

New Submission

[Initiate New CORP Application](#)

Action Required

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated	Not Necessary

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX XXXX	3,4,7	Application Evaluated	Not Necessary
2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
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
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
5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary
6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
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

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New List added

Issued E-Certificate

Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	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.

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

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL



You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 11:20

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particulars (CORP) Application

Please be reminded that for approved application(s), you are required to submit application(s) for change of implementation date 5 working days before the effective date, if necessary.

New Submission

[Initiate New CORP Application](#)

Action Required

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated	Not Necessary

Not Submitted


	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX XXXX	3,4,7	Application Evaluated	Not Necessary
2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
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
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
5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary
6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
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

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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:



You are login as ORG Trial One
TESTING LIMITED
Login date and time
21.08.2018 18:26

- Online Notification
- My Product Search
- + New Registration
- 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

CORP Application Status

[Reply Clarification Letter](#) [Withdraw Application](#) [Close](#)

Summary e-Product File (e-PF) Change DO Req. Clarification Letter Ack. Letter CORP Change History Ref. Material Same Batch

Application Reference No.: CORP-HK41190-201857485 Application Status: Application Evaluated
Application Batch No.: CORP-HK41190-201857485 Application Type: Certificate holder initiated - New CORP application
HK No.: HK41190 Previous App. Reference No.:
Product Name: PRODUCT NAME XXXXX XXXX DO Request Reference No.:
Application Received Date: 21.08.2018 Client Date: 21.08.2018
Proposed Effective Date: Application Form Image: No File Chosen
Hard Copy Received Date: Justification (Urgent Application):
Submission Acknowledgement: [Submission Acknowledgement](#)
Applicant Username: joelun

Category 4 - Manufacturer Clarification Letter Sent

Particulars Proposed to Change	Recall Required	Cert. Reprint Required	Evaluation Comment and Result
4.Manufacturer			Please reply
4.1-Change in name and / or address of the current manufacturer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Required	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Required	
Brief Description of Change and Reason: test			
<div>Satisfactory Unsatisfactory Acknowledged Withdrawn</div>			
Supporting Documents:			
4.1 Change in name and / or address of the current manufacturer			
i. Proposed label with the change(s) underlined or highlighted *			
Documents File Name	Remark	Screening Comment	Evaluation Comment
test20170702.pdf <input type="checkbox"/> The same file has already been uploaded in another location in this submission			
Change Categories Allowed for Amendment:			

[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)
Justification for urgent application:

*Application Received Date: 21.08.2018
*Client Date: 21.08.2018

Justification for changing the batch :

Certificate Holder Name: TESTING LIMITED

HK No.	Product Name
<input checked="" type="checkbox"/> HK41190	PRODUCT NAME XXXXX XXXX


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

Particulars Proposed to Change		Brief Description of Change and Reason
+ 1 Specification		
+ 2 Label		
+ 3 Package Insert		
+ 4 Manufacturer		
+ 4.1 Change in name and / or address of the current manufacturer	<input checked="" type="checkbox"/>	test
+ 4.2 Change in new manufacturer	<input type="checkbox"/>	
+ 5 Registration Certificate Holder		
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)		
+ 7 Excipients		
+ 8 Indication / Dosage / Route of Administration		
+ 9 Other	<input type="checkbox"/>	

[Back] [Next]

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



Change of Registered Particulars (CORP) Application

CORP_APPLICATION_STATUS

Please be reminded that for approved application(s), you are required to submit application(s) for change of implementation date 5 working days before the effective date, if necessary.

New Submission

[Initiate New CORP Application](#)

You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 11:20

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Action Required

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated	Not Necessary

Not Submitted


	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX XXXX	3,4,7	Application Evaluated	Not Necessary
2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
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
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
5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary
6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
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

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



CORP Application Status

CORP_APPLICATION_STATUS

[Continue Application](#) [Delete Application](#) [Close](#)

You are login as ORG Trial One
TESTING LIMITED
Login date and time
21.08.2018 18:26

- Online Notification
- My Product Search
- + New Registration
- 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

Summary | e-Product File (e-PF) Change | DO Req. | Clarification Letter | Ack. Letter | CORP Change History | Ref. Material | Same Batch

Application Reference No.: CORP-HK37565-201857484
Application Batch No.: CORP-HK37565-201857484
HK No.: HK37565
Product Name: PRODUCT NAME XXXXX
Application Received Date: 21.08.2018
Proposed Effective Date:
Hard Copy Received Date:

Application Status: Application Saved
Application Type: Certificate holder initiated - New CORP application
Previous App. Reference No.:
DO Request Reference No.:
Client Date: 21.08.2018
Application Form Image: No File Chosen
Justification (Urgent Application):


Category 3 - Package Insert Initiated

Particulars Proposed to Change	Recall Required	Cert. Reprint Required	Evaluation Comment and Result
3.Package Insert			
3.1-Change in package insert	Yes <input type="checkbox"/>	Not Required <input type="checkbox"/>	
Brief Description of Change and Reason: tets			
<div style="display: flex; justify-content: space-around;"> Satisfactory Unsatisfactory Acknowledged Withdrawn </div>			
Supporting Documents:			
3.1 Change in package insert			
Change Categories Allowed for Amendment:			

[Continue Application](#) [Delete Application](#) [Close](#)

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:



You are login as ORG Trial One
TESTING LIMITED
Login date and time
21.08.2018 18:26

Change of Registered Particulars (CORP) Application

Step 1: Selection of Products and Change Categories Back Next

☐ Urgent Application (subject to decision by Drug Office)
Justification for urgent application

*Application Received Date: 21.08.2018
*Client Date: 21.08.2018

Certificate Holder Name:
TESTING LIMITED

Online Notification

My Product Search

+ New Registration

- 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

☐ HK No. Product Name

☒ PRODUCT NAME XXXXX


Add Product Remove Product Select from all product

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

Particulars Proposed to Change		Brief Description of Change and Reason
+ 1 Specification		
+ 2 Label		
+ 3 Package Insert		
+ 3.1 Change in package insert	<input checked="" type="checkbox"/>	change P1
+ 3.2 Addition of package insert	<input type="checkbox"/>	
+ 4 Manufacturer		
+ 5 Registration Certificate Holder		
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)		
+ 7 Excipients		
+ 8 Indication / Dosage / Route of Administration		
+ 9 Other	<input type="checkbox"/>	

Back Next

3) Application Submitted



You are login as ORG Trial
One
TESTING LIMITED
Login date and time
26.01.2021 11:20

- Online Notification
- My Product Search
- + New Registration
- Change of Registered Particulars
- Initiate CORP Application
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particulars (CORP) Application

CORP_APPLICATION_STATUS

Please be reminded that for approved application(s), you are required to submit application(s) for change of implementation date 5 working days before the effective date, if necessary.

New Submission

[Initiate New CORP Application](#)

Action Required

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	21.08.2018	CORP-HK41190-201857485	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated	Not Necessary

Not Submitted


	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	26.01.2021	CORP-HK37565-202150005	CORP-HK37565-202150005	HK37565	PRODUCT NAME XXXXX	1	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	05.06.2020	CORP-HK41190-202050013	CORP-HK41190-202050013	HK41190	PRODUCT NAME XXXXX XXXX	3,4,7	Application Evaluated	Not Necessary
2	03.10.2019	CORP-HK37565-201857484	CORP-HK37565-201857484	HK37565	PRODUCT NAME XXXXX	3	Application Under Screening	Not Necessary
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
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
5	21.08.2018	CORP-HK37565-201857482	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening	Not Necessary
6	21.08.2018	CORP-HK37565-201857482	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening	Not Necessary
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

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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:



You are login as ORG Trial
One
TESTING LIMITED
Login date and time
21.08.2018 18:35

- Online Notification
- My Product Search
- + New Registration
- 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

CORP Application Status

[Change Effective Date](#) [Close](#)

Summary
e-Product File (e-PF) Change
DO Req.
Clarification Letter
Ack. Letter
CORP Change History
Ref. Material
Same Batch

Application Reference No.: CORP-HK41190-201857486

Application Batch No.: CORP-HK41190-201857486

HK No.: HK41190

Product Name: PRODUCT NAME XXXXX XXXX

Application Received Date: 21.08.2018

Proposed Effective Date: 31.08.2018

Hard Copy Received Date: [Submission Acknowledgement](#)

Submission Acknowledgement: [Submission Acknowledgement](#)

Applicant Username: joelun

Application Status: Application Approved

Application Type: Certificate holder initiated - New CORP application

Previous App. Reference No.: DO Request Reference No.: 21.08.2018

Client Date: 21.08.2018

Application Form Image: No File Chosen

Justification (Urgent Application):

Category 1 - Specification Approved

Particulars Proposed to Change	Recall Required	Cert. Reprint Required	Evaluation Comment and Result
1.Specification 1.1-Change in specifications of the product Brief Description of Change and Reason: change label Effective Date: 31.08.2018	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Not Required <input checked="" type="checkbox"/>	<div style="display: flex; justify-content: space-between;"> Satisfactory Unsatisfactory Acknowledged Withdrawn </div>

Supporting Documents:

1.1 Change in specifications of the product

i. Proposed specifications with the change(s) underlined or highlighted *

Documents File Name	Remark	Screening Comment	Evaluation Comment
test20170702.pdf	<input type="checkbox"/> The same file has already been uploaded in another location in this submission		

Change Categories Allowed for Amendment:

[Change Effective 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)

Justification for urgent application

*Application Received Date: 21.08.2018

*Client Date: 21.08.2018

Justification for changing the batch :

Certificate Holder Name: TESTING LIMITED

Previous Approval Letter : No File Chosen

HK No.	Product Name
<input checked="" type="checkbox"/> HK41190	PRODUCT NAME XXXXX XXXX

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

Particulars Proposed to Change	Change Justification	New effective date
+ 1 Specification	<input type="text"/>	31.08.2018
+ 2 Label		
+ 3 Package Insert		
+ 4 Manufacturer		
+ 5 Registration Certificate Holder		
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)		
+ 7 Excipients		
+ 8 Indication / Dosage / Route of Administration		
+ 9 Other	<input type="checkbox"/>	

[Back] [Next]

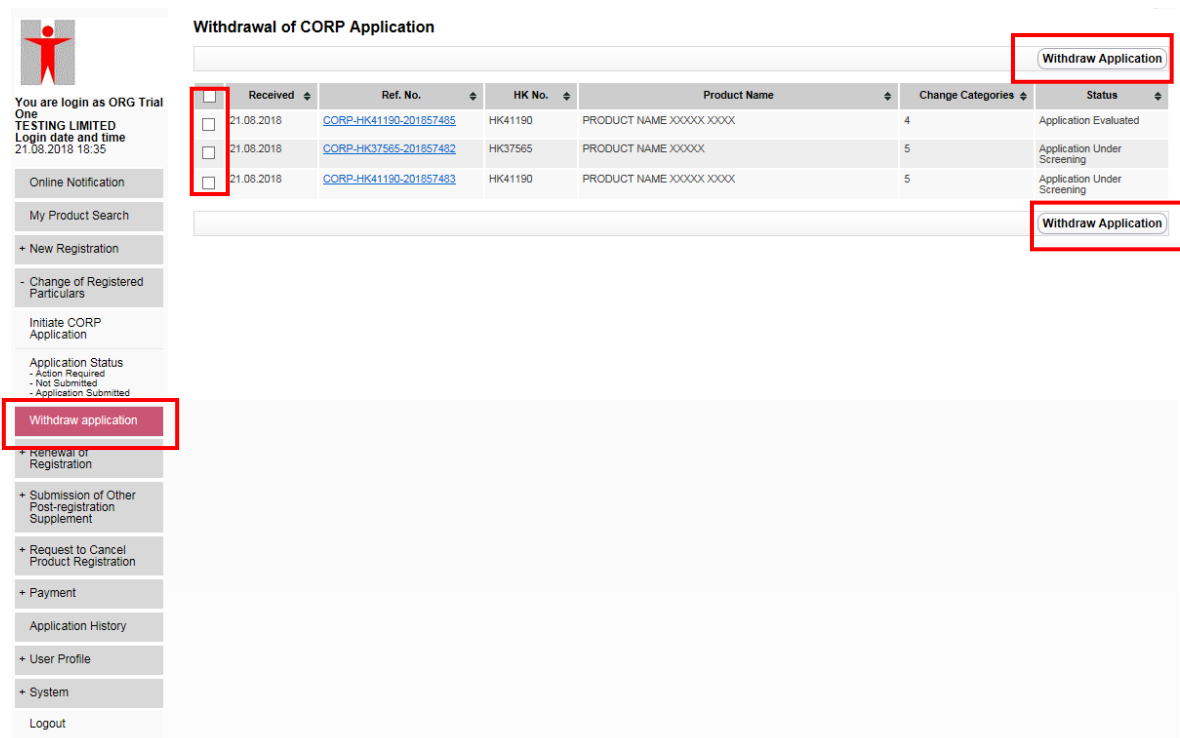
Other than effective date, all information of product particulars is not allowed to change in the application of change in effective date.

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.



Withdrawal of CORP Application

You are login as **ORG Trial One**
TESTING LIMITED
Login date and time
21.08.2018 18:35

Online Notification

My Product Search

+ New Registration

- 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

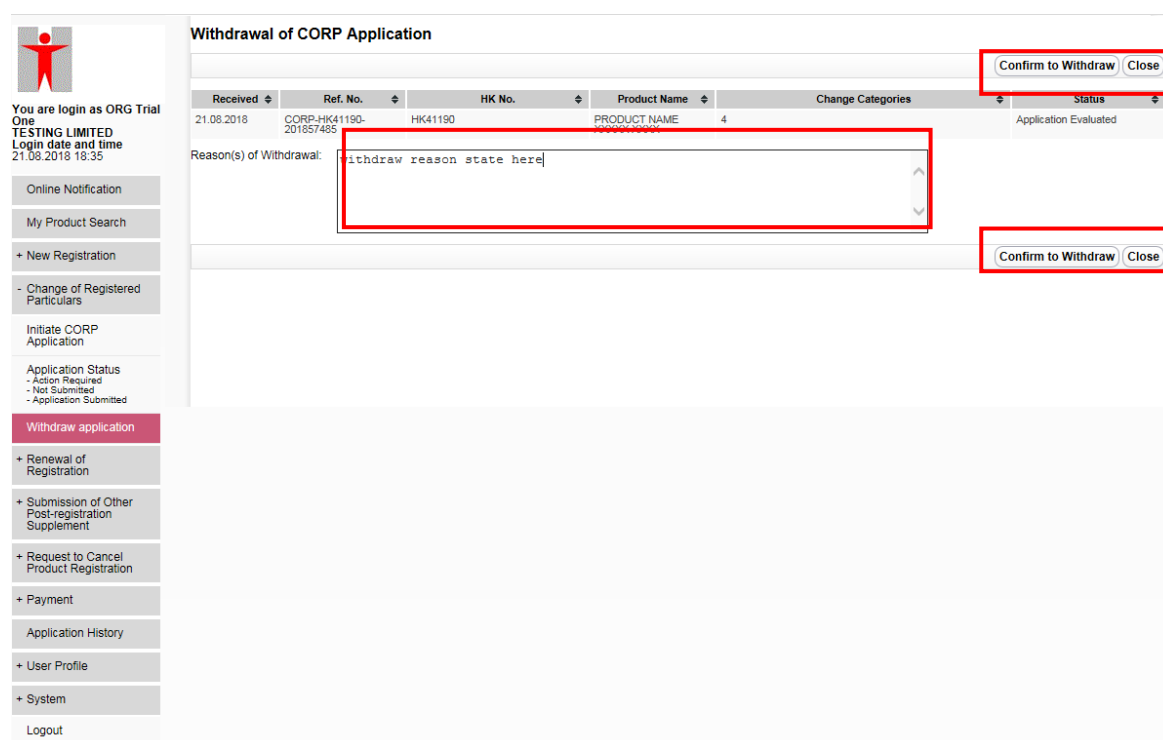
+ System

Logout

Received	Ref. No.	HK No.	Product Name	Change Categories	Status	
<input type="checkbox"/>	21.08.2018	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated
<input type="checkbox"/>	21.08.2018	CORP-HK37565-201857482	HK37565	PRODUCT NAME XXXXX	5	Application Under Screening
<input type="checkbox"/>	21.08.2018	CORP-HK41190-201857483	HK41190	PRODUCT NAME XXXXX XXXX	5	Application Under Screening

Withdraw Application

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



Withdrawal of CORP Application

You are login as **ORG Trial One**
TESTING LIMITED
Login date and time
21.08.2018 18:35

Online Notification

My Product Search

+ New Registration

- 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

Received	Ref. No.	HK No.	Product Name	Change Categories	Status	
<input checked="" type="checkbox"/>	21.08.2018	CORP-HK41190-201857485	HK41190	PRODUCT NAME XXXXX XXXX	4	Application Evaluated

Reason(s) of Withdrawal:

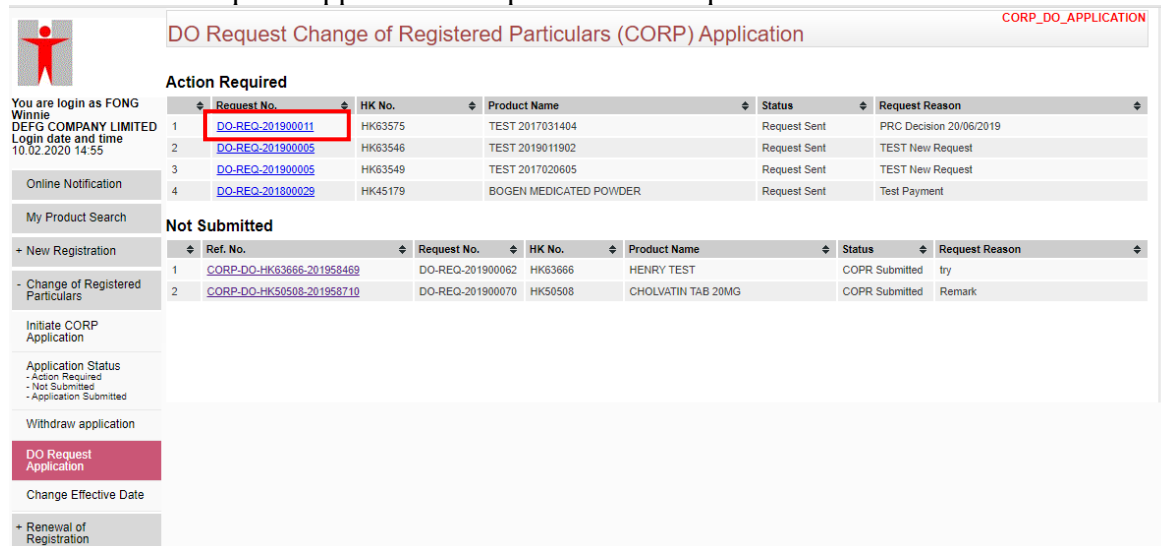
Confirm to Withdraw Close

Confirm to Withdraw Close

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

Click the DO Request Application to open the DO Request Pool



DO Request Change of Registered Particulars (CORP) Application CORP_DO_APPLICATION

Action Required

	Request No.	HK No.	Product Name	Status	Request Reason
1	DO-REQ-201900011	HK63575	TEST 2017031404	Request Sent	PRC Decision 20/06/2019
2	DO-REQ-201900005	HK63546	TEST 2019011902	Request Sent	TEST New Request
3	DO-REQ-201900005	HK63549	TEST 2017020605	Request Sent	TEST New Request
4	DO-REQ-201800029	HK45179	BOGEN MEDICATED POWDER	Request Sent	Test Payment

Not Submitted

	Ref. No.	Request No.	HK No.	Product Name	Status	Request Reason
1	CORP-DO-HK63666-201958469	DO-REQ-201900062	HK63666	HENRY TEST	COPR Submitted	Try
2	CORP-DO-HK50508-201958710	DO-REQ-201900070	HK50508	CHOLVATIN TAB 20MG	COPR Submitted	Remark

Navigation Sidebar:

- You are login as FONG Winnie
- DEFG COMPANY LIMITED
- Login date and time 10.02.2020 14:55
- Online Notification
- My Product Search
- New Registration
- Change of Registered Particulars
- Initiate CORP Application
- Application Status
 - Action Required
 - Not Submitted
 - Application Submitted
- Withdraw application
- DO Request Application**
- Change Effective Date
- Renewal of Registration

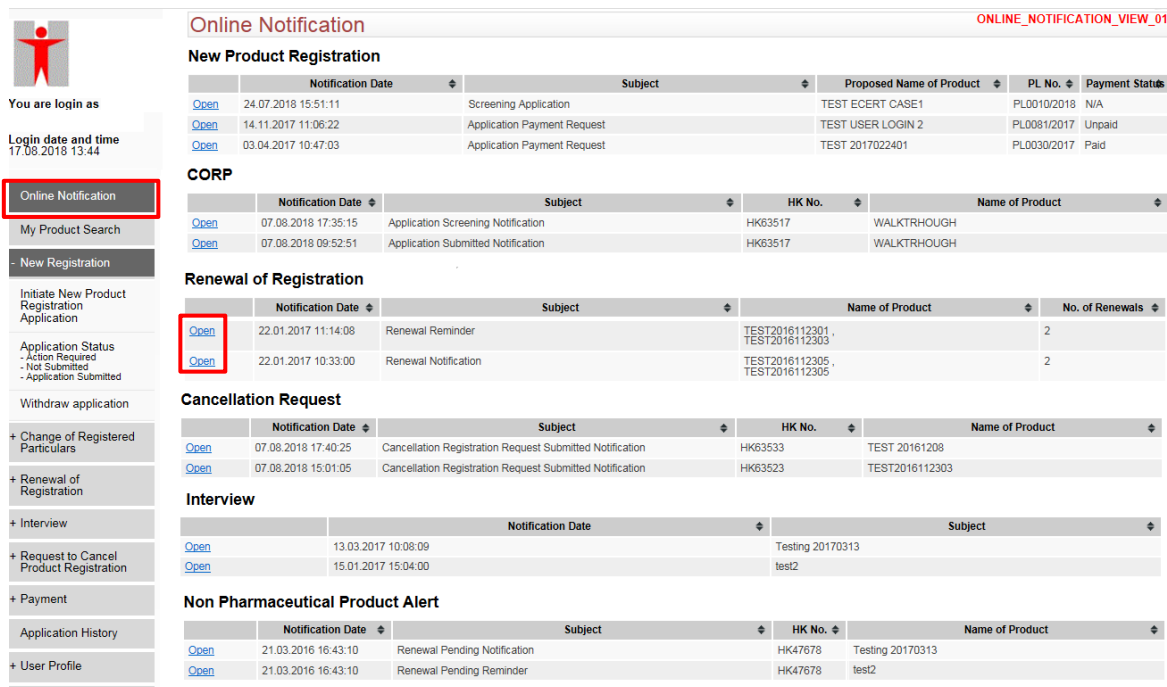
Click the Request No from the Action Required to initiate a CORP to reply this request or Continue the application

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.



Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	24.07.2018 15:51:11	Screening Application	TEST ECERT CASE1	PL0010/2018	N/A
Open	14.11.2017 11:06:22	Application Payment Request	TEST USER LOGIN 2	PL0081/2017	Unpaid
Open	03.04.2017 10:47:03	Application Payment Request	TEST 2017022401	PL0030/2017	Paid

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	07.08.2018 17:35:15	Application Screening Notification	HK63517	WALKTRHOUGH
Open	07.08.2018 09:52:51	Application Submitted Notification	HK63517	WALKTRHOUGH

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals
Open	22.01.2017 11:14:08	Renewal Reminder	TEST2016112301 , TEST2016112303	2
Open	22.01.2017 10:33:00	Renewal Notification	TEST2016112305 , TEST2016112305	2

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	07.08.2018 17:40:25	Cancellation Registration Request Submitted Notification	HK63533	TEST 20161208
Open	07.08.2018 15:01:05	Cancellation Registration Request Submitted Notification	HK63523	TEST2016112303

Interview

	Notification Date	Subject
Open	13.03.2017 10:08:09	Testing 20170313
Open	15.01.2017 15:04:00	test2


Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product
Open	21.03.2016 16:43:10	Renewal Pending Notification	HK47678	Testing 20170313
Open	21.03.2016 16:43:10	Renewal Pending Reminder	HK47678	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).
- 3. 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.



You are login as ORG Trial One
TESTING LIMITED
Login date and time
21.08.2018 18:44

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL_NOTIFICATION

Renewal of Registration

[Print Manual Renewal Form](#) [Back](#)

Renewal Notification

Notification Date: 26.04.2016 04:00:02

HK No. ▾	PR No. ▾	Name of Product ▾	Required information ▾
HK41190	PR0552/1996	PRODUCT NAME XXXXX XXXX	
View Renewal Application Status			

[Print Manual Renewal Form](#) [Back](#)

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.

Renewal of Registration RENEWAL_STATUS

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/> HK36996	PRODUCT NAME XXXX XXXX	28.06.2018	25.06.2018	Batch Four

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK36995	PRODUCT NAME XXXX	22.08.2018	25.08.2018	25.08.2023		Batch Four

Product Confirmed Not to Renew

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.
<input type="checkbox"/> HK44475	PRODUCT NAME XXXX XXXX	BABE list	10.03.2019	Batch Two
<input type="checkbox"/> HK43560	PRODUCT NAME XXXX	PICS requirement	04.09.2018	Batch Five

New list added for new version:

Issued e-Certificate

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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch 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.

Renewal of Registration RENEWAL_STATUS

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.08.2018 16:50

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
- Renewal of Registration
Application Status
- Reply and Pay for Renewal of Registration
- Payment Completed
- Product Confirmed Not to Renew
- Requires Further Action Before Product Renewal
+ Interview
+ Request to Cancel Product Registration
+ Payment
Application History
+ User Profile
+ System
Logout

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/> HK36995	PRODUCT NAME XXXX XXXX	28.06.2018	25.08.2018	Batch Four

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK36995	PRODUCT NAME XXXX	22.08.2018	25.08.2018	25.08.2023		Batch Four

Product Confirmed Not to Renew

Reinstate

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
--------	-----------------	------------	-------------	-----------

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.
<input type="checkbox"/> HK44475	PRODUCT NAME XXXX XXXX	BABE list	10.03.2019	Batch Two
<input type="checkbox"/> HK43560	PRODUCT NAME XXXX	PICS requirement	04.09.2018	Batch Five

New list added for new version:

Issued e-Certificate


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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
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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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0 APPLICATION USER MANUAL



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
27.07.2023 12:09

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + Printing Service
- + System
- Logout

ATTENTION :

If unable to open the online payment service page, please enable the TLS1.1 and TLS1.2 from the Internet Option > advance setting.

If the error message PAY-E-0001 does appear and Kaspersky Internet Security software installed on you device, please refer to [online payment service FAQ Question 1](#).

RENEWAL_PROCESS_STATUS

Renewal of Registration

Pay for Renewal Certificate

Certificate Holder	HK No.	PR No.	Name of Product
ABC COMPANY LIMITED	HK37027	PR0335/1993	CEDAX CAP 400MG

No. of Product(s): 1

Fee type: Application Fee of Pharmaceutical Product Renewal

Payment Amount: HK\$ 575.0

Certificate Collect: ☒ e-Certificate


Recipient*: ☒ susan_cheung_1
☐ david_wong

*Select only one recipient. The e-Certificate will be available for download on the day after the last expiry date of registration.

☒ Before proceeding to the 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.

☒ By submitting this application, consent is given to the Pharmacy & Poisons Board of Hong Kong to arrange the name of product, name and address of certificate holder, name and address of the manufacturer, registration number, name of active ingredients, name of excipients, date of registration, package insert and product pack size provided in this application to be displayed on the website of the Board. For enquiries, please contact the Drug Evaluation and Import/Export Control Division of the Drug Office (Phone No. 3974 4175).

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



Online Payment Service

Help

Customer Service Hotline
2319 8461


Email
pharmweb@dh.gov.hk

Please select the payment method :

Type of Service DH Drug Office
Transaction Date 29-03-2023
Transaction Reference DHPRS-202303291025-94191
Number
Total Amount HKD\$ 1,370.00
Payment Method*

☐ FPS ☐ JCB ☐ Mastercard ☐ VISA ☐ UnionPay 銀聯 ☐ PPS 繳費靈


- 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 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.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL



You are login as WONG Javid
ABC COMPANY LIMITED
Login date and time
24.08.2018 16:50

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL PAYMENT
Print Receipt
Close

Renewal

Payment Reference No.: DHPRS-201808241655-91732

EGIS Reference No.: C201808242001297

Type of Payment: Renewal

Transaction Time: 24.08.2018 16:56:30

Delivery Method: Collect in Person in Drug Office

HK No.	Product Name	Expiry Date
HK36896	PRODUCT NAME XXXX.XXXX	25.08.2018

The Drug Office acknowledges the receipt of your payment of HK\$575.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.

The certificate(s) will be ready for collection on / after 07.09.2018

Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)

Tel: (852) 23198458
Email: prs2_info@dh.gov.hk

Print Receipt
Close

Click the “Print Receipt” button:

Payment Receipt of Renewal

Name of Company	Payment Date
公司名稱	繳費日期
BAUSCH & LOMB (HK) LTD	13.06.2019

Payment Reference No: DHPRS-201906131525-14151

付款編號:

Receipt Reference No:

收據編號:

Cheque No: 123

支票編號:

Payment Method: Cheque

付款方法:

Payment Amount: HK\$575.00

付款金額:

Payment Receipt of Renewal

Name of Company BAUSCH & LOMB (HK) LTD


公司名稱

Payment Reference No: DHPRS-201906131525-14151

付款編號:

Name of Product 製品/物質名稱	HK Reg. No 香港註冊號碼	Expiry Date 屆滿日期
1 "S.T." NATURAL TEARS EYE DROPS	HK58956	03.10.2019

The payment of renewal of registration is completed.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.08.2018 16:50

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL_STATUS

Renewal of Registration

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

Renew Not to Renew					
<input type="checkbox"/>	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/>	HK36996	PRODUCT NAME XXXX XXXX	28.06.2018	25.06.2018	Batch Four

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK36995	PRODUCT NAME XXXX	22.08.2018	25.08.2018	25.08.2023		Batch Four

Product Confirmed Not to Renew

Reinstate					
<input type="checkbox"/>	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
<input type="checkbox"/>	HK44475	PRODUCT NAME XXXX XXXX			
<input type="checkbox"/>	HK43560	PRODUCT NAME XXXX			

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

<input type="checkbox"/>	HK No.	Name of Product	Reason	Expiry Date	Batch No.
<input type="checkbox"/>	HK44475	PRODUCT NAME XXXX XXXX	BABE list	10.03.2019	Batch Two
<input type="checkbox"/>	HK43560	PRODUCT NAME XXXX	PICS requirement	04.09.2018	Batch Five

New list added for new version

Issued e-Certificate


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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
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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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.08.2018 16:50

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- Application Status**
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL_STATUS

Renewal of Registration

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/> HK36996	PRODUCT NAME XXXX XXXX	28.06.2018	25.08.2018	Batch Four

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK36995	PRODUCT NAME XXXX	22.08.2018	25.08.2018	25.08.2023		Batch Four

Product Confirmed Not to Renew

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
<input type="checkbox"/> HK44475	PRODUCT NAME XXXX XXXX		10.03.2019	Batch Two
<input type="checkbox"/> HK43560	PRODUCT NAME XXXX		04.09.2018	Batch Five


Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.
<input type="checkbox"/> HK44475	PRODUCT NAME XXXX XXXX	BABE list	10.03.2019	Batch Two
<input type="checkbox"/> HK43560	PRODUCT NAME XXXX	PICS requirement	04.09.2018	Batch Five

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
27.07.2023 12:09

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- Application Status**
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + Printing Service
- + System
- Logout

RENEWAL_PROCESS_STATUS

Renewal of Registration

Pay for Renewal Certificate

[Renew Product](#)
[Print Notification of Payment](#)
[Back](#)

Certificate Holder	HK No.	PR No.	Name of Product
ABC COMPANY LIMITED	HK37027	PR0335/1993	CEDAX CAP 400MG

No. of Product(s): 1

Fee type: Application Fee of Pharmaceutical Product Renewal

Payment Amount: HK\$ 575.0

Certificate Collect: ☒ e-Certificate

Recipient*: ☒ susan_cheung_1
☐ david_wong

*Select only one recipient. The e-Certificate will be available for download on the day after the last expiry date of registration.

☒ Before proceeding to the 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.


☒ By submitting this application, consent is given to the Pharmacy & Poisons Board of Hong Kong to arrange the name of product, name and address of certificate holder, name and address of the manufacturer, registration number, name of active ingredients, name of excipients, date of registration, package insert and product pack size provided in this application to be displayed on the website of the Board. For enquiries, please contact the Drug Evaluation and Import/Export Control Division of the Drug Office (Phone No: 3974 4175).

[Renew Product](#)
[Print Notification of Payment](#)
[Back](#)

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.08.2018 16:50

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
 - Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Renewal of Registration

RENEWAL_STATUS

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/> HK36996	PRODUCT NAME XXXX XXXX	28.06.2018	25.08.2018	Batch Four

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK36995	PRODUCT NAME XXXX	22.08.2018	25.08.2018	25.08.2023		Batch Four

Product Confirmed Not to Renew

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.
<input type="checkbox"/> HK44475	PRODUCT NAME XXXX XXXX	BABE list	10.03.2019	Batch Two
<input type="checkbox"/> HK43560	PRODUCT NAME XXXX	PICS requirement	04.09.2018	Batch Five



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
11.01.2018 17:20

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
 - Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
 - + Submission of Other Post-registration Supplement
 - + Interview
 - + Request to Cancel Product Registration
 - + Payment
 - Application History
 - + User Profile
 - + System
 - Logout

Renewal of Registration

RENEWAL_STATUS

Product(s) have been successfully set to not renew

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/> HK56272	AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB		14.02.2018	Batch One
<input type="checkbox"/> HK61778	AMLODIPINE TABLETS 10MG (HETERO)		26.02.2018	Batch One

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK56375	ACET 120MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two
HK56376	ACET 160MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two

Product Confirmed Not to Renew

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
<input type="checkbox"/> HK61779	AMLODIPINE TABLETS 5MG (HETERO)	31.01.2018	26.02.2018	Batch One

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.

New list added for new version

Issued e-Certificate


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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
--------	-----------------	--------------	------------------	-------------	---------------	-----------

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
11.01.2018 17:20

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
 - Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL_STATUS

Renewal of Registration

• Product(s) have been successfully set to not renew

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/>	HK56272	AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB		14.02.2018	Batch One
<input type="checkbox"/>	HK61778	AMLODIPINE TABLETS 10MG (HETERO)		26.02.2018	Batch One

Renew
Not to Renew

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK56375	ACET 120MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two
HK56376	ACET 160MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two

Product Confirmed Not to Renew

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
<input type="checkbox"/>	HK61779	AMLODIPINE TABLETS 5MG (HETERO)	31.01.2018	26.02.2018	Batch One

Reinstate

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).


HK No.	Name of Product	Reason	Expiry Date	Batch No.
--------	-----------------	--------	-------------	-----------

New list added for new version

Issued e-Certificate

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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
--------	-----------------	--------------	------------------	-------------	---------------	-----------



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
11.01.2018 17:20

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL_STATUS

Renewal of Registration

• Product(s) have been successfully set to not renew

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.	Renew	Not to Renew
<input type="checkbox"/> HK56272	AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB		14.02.2018	Batch One		
<input type="checkbox"/> HK61778	AMLODIPINE TABLETS 10MG (HETERO)		26.02.2018	Batch One		

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK56375	ACET 120MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two
HK56376	ACET 160MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two

Product Confirmed Not to Renew

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.	Reinstate
<input type="checkbox"/> HK61779	AMLODIPINE TABLETS 5MG (HETERO)	31.01.2018	26.02.2018	Batch One	

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.
--------	-----------------	--------	-------------	-----------

New list added for new version

Issued e-Certificate

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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
--------	-----------------	--------------	------------------	-------------	---------------	-----------

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
11.01.2018 17:20

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- Renewal of Registration
- + Application Status
 - Reply and Pay for Renewal of Registration
 - Payment Completed
 - Product Confirmed Not to Renew
 - Requires Further Action Before Product Renewal
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

RENEWAL_STATUS

Renewal of Registration

• Product(s) have been successfully set to not renew

Reply and Pay for Renewal of Registration

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
<input type="checkbox"/>	HK56272	AMERICAN HEALTH ABC PLUS WITH LUTEIN TAB		14.02.2018	Batch One
<input type="checkbox"/>	HK61778	AMLODIPINE TABLETS 10MG (HETERO)		26.02.2018	Batch One

[Renew](#) [Not to Renew](#)

Payment Completed

HK No.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	Cert Collection Date	Batch No.
HK56375	ACET 120MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two
HK56376	ACET 160MG SUPP	30.01.2018	14.03.2018	14.03.2023		Batch Two

Product Confirmed Not to Renew

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
<input type="checkbox"/>	HK61779	AMLODIPINE TABLETS 5MG (HETERO)	31.01.2018	26.02.2018	Batch One

[Reinstate](#)

Requires Further Action Before Product Renewal

Please complete the renewal procedure 10 working days before the expiry date of the product certificate and complete the relevant payment transaction before 5 working days.
In case certificate holder(s) cannot renew certificate(s) in due course, please contact our IT colleagues of PRS2.0 help desk at 2319 8414 during office hours.
Note: Working days do not include Saturday / Sunday / holiday(s).

HK No.	Name of Product	Reason	Expiry Date	Batch No.
--------	-----------------	--------	-------------	-----------

New list added for new version Issued e-Certificate

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.	Name of Product	Payment Date	Last Expiry Date	Expiry Date	e-Certificate	Batch No.
--------	-----------------	--------------	------------------	-------------	---------------	-----------

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”.

You are login as Charles Lee from CERT HOLDER 6
Login date is 27.11.2014 12:50

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal Registration

+ Other Post-registration Supplement

+ Interview

+ Request to Cancel Product Registration

- Payment

Payment Pool

Payment History

Application History

+ User Profile

+ System

Logout

Payment History

New Product Registration Total Number of Payment Records: 0

PR No.	Name of Product	Payment Date	Amount(HK\$)	Payment Ref No.
--------	-----------------	--------------	--------------	-----------------

Change of Registered Particulars Application Total Number of Payment Records: 0

HK No.	Name of Product	Payment Date	Amount(HK\$)	Payment Ref No.
--------	-----------------	--------------	--------------	-----------------

Renewal of Registration Total Number of Payment Records: 3

HK No.	Name of Product	Payment Date	Amount(HK\$)	Payment Ref No.
HK00863	INDAPAMIDE-TRIAL PROLONGED RELEASE TABLETS 1.5MG (MP2-2)(CH6)	27.11.2014	575.0	DHPRS-201411271258-90514
HK00861	ULTIBRO BREEZEHALER (MP1-2)(CH6)	27.11.2014	575.0	DHPRS-201411271258-90514
HK00869	GRACIAL TABLET (MPS-2)(CH6)	27.11.2014	575.0	DHPRS-201411271252-90513

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

You are login as Charles Lee from CERT HOLDER 6
Login date is 27.11.2014 12:50

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal Registration

+ Other Post-registration Supplement

+ Interview

+ Request to Cancel Product Registration

- Payment

Payment Pool

Payment History

Application History

+ User Profile

+ System

Logout

Renewal

RENEWAL_PAYMENT Print Receipt Print Close

Payment Reference No.: DHPRS-201411271258-90514

Type of Payment: Renewal

Transaction Time: 27.11.2014 12:59:15

HK No.	Product Name	Expiry Date
HK00863	INDAPAMIDE-TRIAL PROLONGED RELEASE TABLETS 1.5MG (MP2-2)(CH6)	01.02.2015
HK00861	ULTIBRO BREEZEHALER (MP1-2)(CH6)	01.02.2015

The Drug Office acknowledges your payment of HK\$1,150.00 for certificate fee regarding the above proposed product(s). We will process your request and will provide response as soon as possible.

The certificate(s) will be ready for collection on / after 01.01.2015

Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)

Tel: (852) 23198458
Email: pharmgeneral@dh.gov.hk

Print Receipt Print Close

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.



You are login as Charles Lee from CERT HOLDER 6
Login date is 27.11.2014 12:50

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal Registration
- + Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History**
- + User Profile
- + System
- Logout

Application History

New Product Registration

Total Number of Application Records:0

Application Date	PL No.	PR No.	HK No.	Name of Product	Payment Status	Status	Last Action Date
------------------	--------	--------	--------	-----------------	----------------	--------	------------------

Change of Registered Particulars

Total Number of Application Records:1

Application Date	Ref No.	HK No.	Name of Product	Change Categories	Payment Status	Status	Last Action Date
17.09.2014	CORP-HK00870-201450296	HK00870	3B CAPSULES (MP6-1)(CH6)	1	Not Necessary	Application Withdrawn	27.11.2014

Renewal of Registration

Total Number of Application Records:3

Expiry Date	HK No.	Name of Product	Application Status	Last Action Date
01.02.2015	HK00863	INDAPAMIDE-TRIAL PROLONGED RELEASE TABLETS 1.5MG (MP2-2)(CH6)	Paid	27.11.2014
01.02.2015	HK00861	ULTIBRO BREEZEHALER (MP1-2)(CH6)	Paid	27.11.2014
01.02.2015	HK00869	GRACIAL TABLET (MP5-2)(CH6)	Paid	27.11.2014

Termination of application of Product Application

Total Number of Application Records:0

Application Date	Ref No.	HK No.	Name of Product	Status	Last Action Date
------------------	---------	--------	-----------------	--------	------------------

Ongoing Request Application

Total Number of Application Records:1

Application Date	Request Type	Ref No.	HK No.	Name of Product	Status	Last Action Date
26.11.2014	BABE	BABE-HK00866-2014100070	HK00866	CEPPRA TABLET 1000MG (MP4-1)(CH6)	Report Accepted	26.11.2014

Interview

Total Number of Application Records:0

Application Date	Subject	Application	Status
------------------	---------	-------------	--------

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 Cancel Product Registrations [Close] [Next]

Step 1: Enter Product for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product

*HK No.	Product Name	Expiry Date	Other Issue
<input type="text"/>			

* Effective Date :

* Reason(s) of Product Cancellation :

* Request letter for Cancellation of Product Registration : (Please manual submit original letter and registration cert) **UPLOAD** No file chosen

Contact Information for Product Cancellation :

* Contact Person : * Phone No. : * Email :

* Address :

Unit :

Floor :

Block :

Building :

Street No. :

Street Name :

Sub-district : Please Select

Area : Please Select

[Close] [Next]

Step 2:

- Click the button “Select Product”, a dialog box is shown.

Request to Cancel Product Registrations [Close] [Next]

Step 1: Enter Product for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product

*HK No.	Product Name	Expiry Date	Other Issue
<input type="text"/>			

* Effective Date :

* Reason(s) of Product Cancellation :

* Request letter for Cancellation of Product Registration : (Please manual submit original letter and registration cert) **UPLOAD** No file chosen

Contact Information for Product Cancellation :

* Contact Person : * Phone No. : * Email :

* Address :

Unit :

Floor :

Block :

Building :

Street No. :

Street Name :

Sub-district : Please Select

Area : Please Select

[Close] [Next]

Step 3:

- Select a product and then click the button “Confirm”.

Request to Cancel Product Registrations

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration
+ Submission of Other Post-registration Supplement
+ Interview
+ Request to Cancel Product Registration
Initiate EOL Application
Application Status
- Not Submitted
- Application Submitted
Withdraw application
+ Payment
Application History
+ User Profile

Step 1: Enter Product(s) for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product

*HK No. :
*Effective Date :
*Reason(s) of Product Cancellation :
Contact Information for
* Contact Person :
* Address :
Unit :
Floor :
Block :
Building :
Street No. :
Street Name :
Sub-district :
Area :

Product List

HK No.	Product Name
<input type="radio"/> HK40870	2-4-2 OINTMENT (TEST)
<input type="radio"/> HK40981	CALCIUMFOLINAT EBEWE INJ 200MG (TEST)
<input type="radio"/> HK40985	CPC VITAMIN B1 TAB 100MG (TEST)
<input type="radio"/> HK41004	MEYSALIOL SPRAY (TEST)
<input type="radio"/> HK41016	VITAMIN E CAP 400IU (TEST)
<input type="radio"/> HK41018	PIROCAM INJ 20MG/ML (TEST)
<input type="radio"/> HK41025	TRANSBRONCHO TAB 30MG (TEST)
<input type="radio"/> HK41026	PAINSTOP INJ 25MG/ML (TEST)
<input type="radio"/> HK41441	ALLERSAN TAB
<input type="radio"/> HK42074	3TC ORAL SOLUTION 10MG/ML (TEST)
<input type="radio"/> HK49574	ALBOL SUPER-CAL 600MG + VIT D3 TAB
<input type="radio"/> HK55147	0.3% POTASSIUM CHLORIDE AND 0.9% SODIUM CHLORIDE IV INF (THAI OTSUKA)
<input type="radio"/> HK55411	0.15% POTASSIUM CHLORIDE AND 0.9% SODIUM CHLORIDE IV INF (THAI OTSUKA)
<input type="radio"/> HK58139	PROMERIS DUO SPOT-ON FOR EXTRA LARGE DOGS (40.1 - 50KG) (VET)
<input checked="" type="radio"/> HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)
<input type="radio"/> HK59168	DURAMUNE ADULT C4 VACCINE (VET)
<input type="radio"/> HK60366	ACARBOSE TAB 50MG (HANGZHOU ZHONG MEI)
<input type="radio"/> HK60817	ALENDRONATE SANDOZ TAB 70MG
<input type="radio"/> HK61163	XGEVA SOLUTION FOR INJECTION 120MG
<input type="radio"/> HK63482	OMEPRAZOLE NORMON POWDER FOR SOLUTION FOR INFUSION 40MG
<input type="radio"/> HK63505	TEST 1127

Confirm Cancel

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 Cancel Product Registrations

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration
+ Submission of Other Post-registration Supplement
+ Interview
+ Request to Cancel Product Registration
Initiate EOL Application
Application Status
- Not Submitted
- Application Submitted
Withdraw application
+ Payment
Application History
+ User Profile

Step 1: Enter Product(s) for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product


*HK No.	Product Name	Expiry Date	Other Issue
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	27.07.2019	Recent Notification(s) on Change of Registered Product

* Effective Date :
* Reason(s) of Product Cancellation :
Contact Information for Product Cancellation :
Contact Person : seaman.cai * Phone No. : 11223344 * Email : seaman@abc.com
Address :
Unit : 382
Floor : 3
Block : A
Building : CHA LEUNG BUILDING
Street No. :
Street Name :
Sub-district : CHA KWO LING
Area : Please Select

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
15.10.2018 11:07

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal of Registration

+ Submission of Other Post-registration Supplement

+ Interview

- Request to Cancel Product Registration

Initiate EOL Application

Application Status
- Not Submitted
- Application Submitted

Withdraw application


Request to Cancel Product Registrations

Close **Next**

Step 1: Enter Product for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product

*HK No.	Product Name	Expiry Date	Other Issue

* Effective Date: 

* Reason(s) of Product Cancellation :

* Request letter for Cancellation of Product Registration : **UPLOAD**
(Please manual submit original letter and registration cert) No file chosen

Contact Information for Product Cancellation :

* Contact Person : * Phone No. : * Email :

* Address :

Unit :

Floor :

Block :

Building :


Street No. :

Street Name :

Sub-district :

Area :

Close **Next**



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

Online Notification

My Product Search

+ New Registration

+ Change of Registered Particulars

+ Renewal of Registration

+ Submission of Other Post-registration Supplement

+ Interview

- Request to Cancel Product Registration

Initiate EOL Application

Application Status
- Not Submitted
- Application Submitted

Withdraw application


Request to Cancel Product Registrations

Close **Next**

Step 1: Enter Product(s) for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product

*HK No.	Product Name	Expiry Date	Other Issue
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	27.07.2019	Recent Notification(s) on Change of Registered Product

* Effective Date: 

* Reason(s) of Product Cancellation : This product is no longer produce

Contact Information for Product Cancellation :

* Contact Person : * Phone No. : * Email :

* Address :

Unit :

Floor :

Block :

Building :

Street No. :

Street Name :

Sub-district :

Area :


Close **Next**

Step 6:

- Click “Next” to save the information.

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL



You are login as **WONG David**
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- Initiate EOL Application**
- Application Status
 - Not Submitted
 - Application Submitted

Request to Cancel Product Registrations

Close Next

Step 1: Enter Product(s) for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

Select Product

*HK No.	Product Name	Expiry Date	Other Issue
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	27.07.2019	Recent Notification(s) on Change of Registered Product

* Effective Date : 14.10.2016

* Reason(s) of Product Cancellation :
This product is no longer produce

Contact Information for Product Cancellation :

* Contact Person : seaman.cai * Phone No. : 11223344 * Email : seaman@abc.com


* Address :
Unit : 382
Floor : 3
Block : A
Building : CHA LEUNG BUILDING
Street No. :
Street Name :
Sub-district : CHA KWO LING
Area : Please Select

網頁訊息
Are you sure to save?
確定 取消

Close Next

Step 7:

- Verify the information inputted in page 1.
- Indicate return product registration certificate to Drug Office.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- Request to Cancel Product Registration
- Initiate EOL Application
- Application Status

Request to Cancel Product Registrations

Back Save Confirm & Submit

Step 2: Indicate the Return of Registration Certificate, and Confirm Submission of Your Request of Cancellation of Product Registration.

HK No.	Product Name	Return Registration Certification to Drug Office
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	<input checked="" type="checkbox"/>

If "Return Registration Certificate to Drug Office" is checked, Drug Office will start to process your request when the registration certificate is received.

Effective Date: 14.10.2016

Reason(s) of Product Cancellation: This product is no longer produce

Contact Information for Product Cancellation:

Contact Person : seaman.cai Phone No. : 11223344 Email : seaman@abc.com


Address :
Unit : 382
Floor : 3
Block : A
Building : CHA LEUNG BUILDING
Street No. :
Street Name :
Sub-district : CHA KWO LING
Area :

Warning:The cancellation of registered product is subject to approval by Drug Office.The cancellation of product registration cannot be revoked after the approval of cancellation by Drug Office.

Back Save Confirm & Submit

Scenario 1: Return registration certificate to Drug Office.

- Check the checkbox.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- Request to Cancel Product Registration
- Initiate EOL Application
- Application Status

Request to Cancel Product Registrations

Back Save Confirm & Submit

Step 2: Indicate the Return of Registration Certificate, and Confirm Submission of Your Request of Cancellation of Product Registration.

HK No.	Product Name	Return Registration Certification to Drug Office
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	<input checked="" type="checkbox"/>

If "Return Registration Certificate to Drug Office" is checked, Drug Office will start to process your request when the registration certificate is received.

Effective Date: 14.10.2016

Reason(s) of Product Cancellation: This product is no longer produce

Contact Information for Product Cancellation:

Contact Person : seaman.cai Phone No. : 11223344 Email : seaman@abc.com


Address :
Unit : 382
Floor : 3
Block : A
Building : CHA LEUNG BUILDING
Street No. :
Street Name :
Sub-district : CHA KWO LING
Area :

Warning:The cancellation of registered product is subject to approval by Drug Office.The cancellation of product registration cannot be revoked after the approval of cancellation by Drug Office.

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- Request to Cancel Product Registration
- Initiate EOL Application**
- Application Status
- Not Submitted
- Application Submitted
- Withdraw application

Request to Cancel Product Registrations

Back Save Confirm & Submit

Step 2: Indicate the Return of Registration Certificate, and Confirm Submission of Your Request of Cancellation of Product Registration.

HK No.	Product Name	Return Registration Certification to Drug Office
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	<input type="checkbox"/>

If "Return Registration Certificate to Drug Office" is checked, Drug Office will start to process your request when the registration certificate is received.

If "Return Registration Certificate to Drug Office" is unchecked, please provide reason(s).
The certificate is missing.

Effective Date: 14.10.2016

Reason(s) of Product Cancellation: This product is no longer produce

Contact Information for Product Cancellation:

Contact Person : seaman.cai Phone No. : 11223344 Email : seaman@abc.com


Address :
Unit : 382
Floor : 3
Block : A
Building : CHA LEUNG BUILDING
Street No. :
Street Name :
Sub-district : CHA KWO LING
Area :

Warning:The cancellation of registered product is subject to approval by Drug Office.The cancellation of product registration cannot be revoked after the approval of cancellation by Drug Office.

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.



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
14.10.2016 11:24

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- Request to Cancel Product Registration
- Initiate EOL Application**
- Application Status
- Not Submitted
- Application Submitted
- Withdraw application

Request to Cancel Product Registrations

Back Save Confirm & Submit

Step 2: Indicate the Return of Registration Certificate, and Confirm Submission of Your Request of Cancellation of Product Registration.

HK No.	Product Name	Return Registration Certification to Drug Office
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)	<input type="checkbox"/>

If "Return Registration Certificate to Drug Office" is checked, Drug Office will start to process your request when the registration certificate is received.

If "Return Registration Certificate to Drug Office" is unchecked, please provide reason(s).
The certificate is missing.

Effective Date: 14.10.2016

Reason(s) of Product Cancellation: This product is no longer produce

Contact Information for Product Cancellation:

Contact Person : seaman.cai Phone No. : 11223344 Email : seaman@abc.com

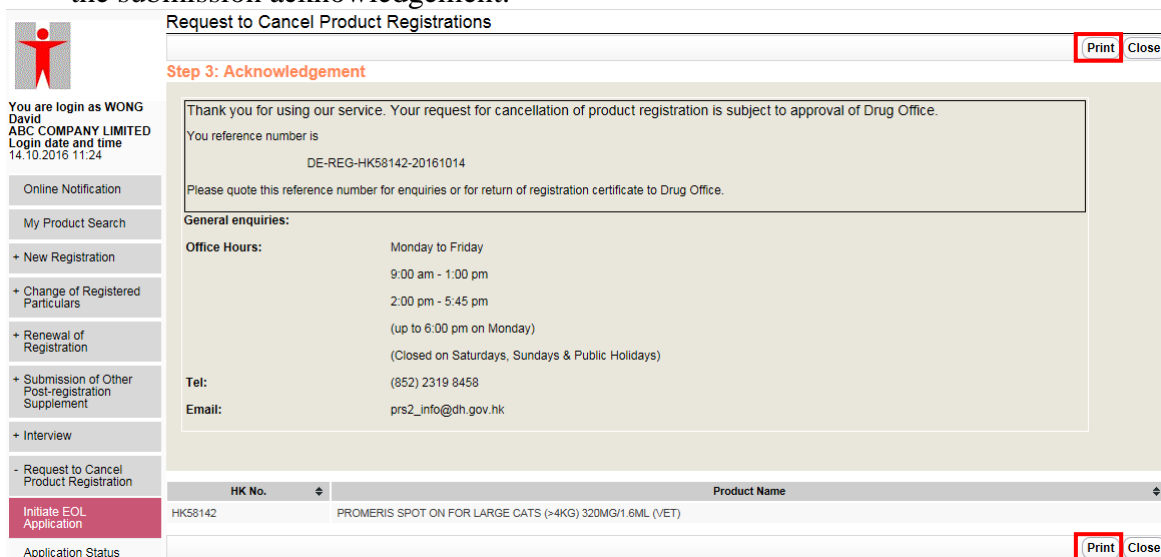
Address :
Unit : 382
Floor : 3
Block : A
Building : CHA LEUNG BUILDING
Street No. :
Street Name :
Sub-district : CHA KWO LING
Area :

Warning:The cancellation of registered product is subject to approval by Drug Office.The cancellation of product registration cannot be revoked after the approval of cancellation by Drug Office.

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 Product Registrations Print Close

Step 3: Acknowledgement

Thank you for using our service. Your request for cancellation of product registration is subject to approval of Drug Office.

You reference number is
DE-REG-HK58142-20161014

Please quote this reference number for enquiries or for return of registration certificate to Drug Office.

General 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, Sundays & Public Holidays)

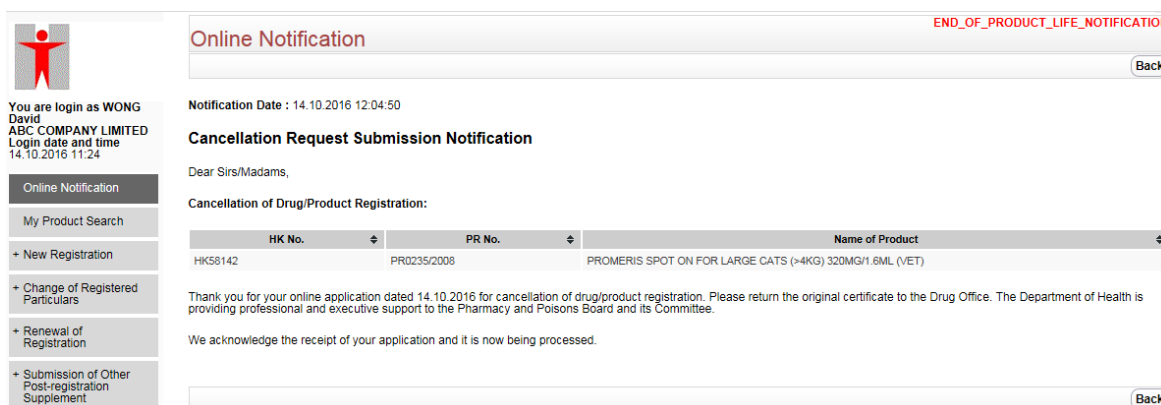
Tel: (852) 2319 8458
Email: prs2_info@dh.gov.hk

HK No.	Product Name
HK58142	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)

Print Close

Step 10:

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



Online Notification END_OF_PRODUCT_LIFE_NOTIFICATION Back

Notification Date : 14.10.2016 12:04:50

Cancellation Request Submission Notification

Dear Sirs/Madams,

Cancellation of Drug/Product Registration:

HK No.	PR No.	Name of Product
HK58142	PR0235/2008	PROMERIS SPOT ON FOR LARGE CATS (>4KG) 320MG/1.6ML (VET)

Thank you for your online application dated 14.10.2016 for cancellation of drug/product registration. Please return the original certificate to the Drug Office. The Department of Health is providing professional and executive support to the Pharmacy and Poisons Board and its Committee.

We acknowledge the receipt of your application and it is now being processed.

Back

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.

Request to Cancel Product Registrations EOL_APPLICATION_STATUS

New Submission
[Initiate new EOL Application](#)

Not Submitted

	Last Draft Date	Ref No.	HK No.	Product Name
1	07.08.2018	DE-REG-HK63521-20180807	HK63521	TEST2016112305
2	21.06.2017	DE-REG-HK63482-20170621	HK63482	TEST2016112303

Application Submitted

	Date Received	Ref No.	HK No.	Product Name	Status
1	24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX	Cancellation Request Submitted

Request to Cancel Product Registration

[Initiate EOL Application](#)

Application Status - Not Submitted - Application Submitted

[Withdraw application](#)

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.

The screenshot shows the 'EOL Application Withdrawal' interface. On the left is a sidebar menu with the user's login information: 'You are login as WONG David', 'ABC COMPANY LIMITED', and 'Login date and time 24.08.2018 17:51'. The menu items include 'Online Notification', 'My Product Search', '+ New Registration', '+ Change of Registered Particulars', '+ Renewal of Registration', '+ Interview', '- Request to Cancel Product Registration' (highlighted with a red box), 'Initiate EOL Application', 'Application Status' (with sub-items 'Not Submitted' and 'Application Submitted'), 'Withdraw application' (highlighted with a red box), and '+ Payment'. The main area is titled 'EOL Application Withdrawal' and contains a table with columns: 'Date Received', 'Ref No.', 'HK No.', 'Product Name', and 'Status'. There are two rows of data. The first row has a checkbox, '24.08.2018', 'DE-REG-HK36995-20180824', 'HK36995', 'PRODUCT NAME XXXX', and 'Cancellation Request Submitted'. The second row has a checkbox, '07.08.2018', 'DE-REG-HK63533-20180807', 'HK63533', 'TEST 20161208', and 'Cancellation Request Submitted'. A 'Withdraw Application' button is located at the top right and bottom right of the table area.

	Date Received	Ref No.	HK No.	Product Name	Status
<input type="checkbox"/>	24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX	Cancellation Request Submitted
<input type="checkbox"/>	07.08.2018	DE-REG-HK63533-20180807	HK63533	TEST 20161208	Cancellation Request Submitted

Step 2:

- Select the application(s) for withdrawal and click the button “Withdraw Application”.

This screenshot is identical to the previous one, but with additional red highlights. The 'Withdraw Application' button at the top right is highlighted with a red box. The entire table area, including the two data rows, is highlighted with a red border. The 'Withdraw Application' button at the bottom right is also highlighted with a red box. The sidebar menu remains the same, with 'Request to Cancel Product Registration' and 'Withdraw application' highlighted.

	Date Received	Ref No.	HK No.	Product Name	Status
<input type="checkbox"/>	24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX	Cancellation Request Submitted
<input type="checkbox"/>	07.08.2018	DE-REG-HK63533-20180807	HK63533	TEST 20161208	Cancellation Request Submitted

Step 3:

- Input the reason(s) of withdrawal and click the button “Confirm to Withdraw”.

EOL Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.08.2018 17:51

Online Notification
My Product Search
+ New Registration

Date Received	Ref No.	HK No.	Product Name	Status
24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX	Cancellation Request Submitted

Reason(s) of Withdrawal :

Confirm to Withdraw Close

Step 4:

- Click the button “OK” to confirm withdrawal.

EOL Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.08.2018 17:51

Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration
+ Interview
- Request to Cancel

Date Received	Ref No.	HK No.	Product Name	Status
24.08.2018	DE-REG-HK36995-20180824	HK36995	PRODUCT NAME XXXX	Cancellation Request Submitted

* Reason(s) of Withdrawal :
Reason

Are you sure to save?

確定 取消

Confirm to Withdraw Close

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.

ATTENTION :
If unable to open the online payment service page, please enable the TLS1.1 and TLS1.2 from the Internet Option > advance setting.
If the error message PAY-E-0001 does appear and Kaspersky Internet Security software installed on you device, please refer to [online payment service FAQ Question 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 Registration
+ Change of Registered Particulars
+ Renewal of Registration
+ Submission of Other Post-registration Supplement
+ Interview
+ Request to Cancel Product Registration
- Payment
Payment Pool
Payment History
Application History
+ User Profile
+ Printing Service
+ System
Logout

New Application Payment

<input type="checkbox"/>	Application Received Date	PL No.	PR No.	Proposed Name of Product	Payment Status
					Ready to Pay

New Application Certificate Payment

Certificate Collection : ☐ e-Certificate

Recipient : ☐ vmg_user3
☐ vmg_user1
*Select only one recipient.

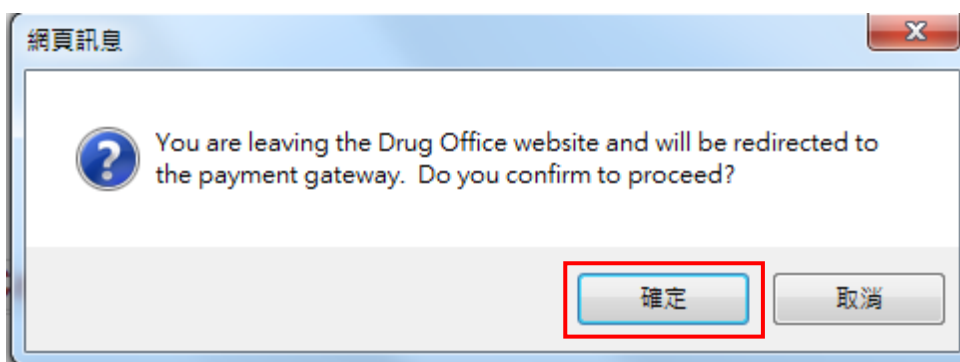
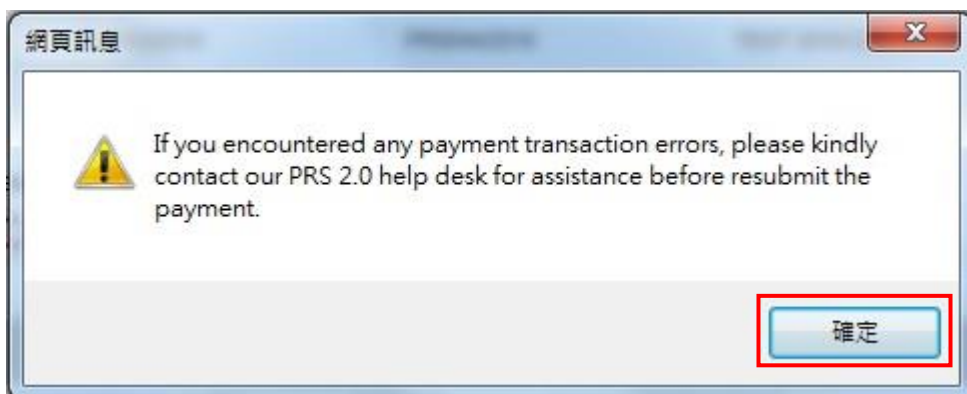
CORP Updated Certificate Payment

<input type="checkbox"/>	Application Received Date	Reference No.	HK No.	Name of Product	Change Categories	Payment Status
						Ready to Pay

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, JCB, UnionPay, FPS or PPS) and press 'Pay' to proceed. Press 'Cancel payment' if you want to cancel the payment and back to payment pool.

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	DH Drug Office
Transaction Date	29-03-2023
Transaction Reference Number	DHPRS-202303291025-94191
Total Amount	HKD\$ 1,370.00
Payment Method*	<input type="radio"/> FPS <input type="radio"/> JCB <input type="radio"/> mastercard <input type="radio"/> VISA <input type="radio"/> UnionPay 銀聯 <input type="radio"/> PPS 繳費靈


• 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.

HONG KONG

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:

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

APPLICATION USER MANUAL



You are login as WONG Javid
ABC COMPANY LIMITED
Login date and time
27.08.2018 09:08

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Interview
- + Request to Cancel Product Registration
- Payment
- Payment Pool**
- Payment History

New Product Registration

Print Receipt Close

Payment Reference No.: DHPRS-201808270916-91733
EGIS Reference No.: C201808272000707
Payment Method: JCB
Type of Payment: Certificate Fee
Transaction Time: 27.08.2018 09:16:40
Delivery Method: Received By Post

Application Received Date	Reference No.	PR No.	Product Name
27.02.2017 10:22	ANP20179000024	PR0038/2017	TEST 2016022701

The Drug Office acknowledges the receipt of your payment of HK\$1,370.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.

Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)

Tel: (852) 23198458
Email: prs2_info@dh.gov.hk

Print Receipt Close

The print out payment receipt is follow:

Payment Receipt of Change of Registered Particulars	
Name of Company	Payment Date
公司名稱 3 MED MEDICAL SUPPLIES CO	繳費日期 26.08.2022
Payment Reference No: DHPRS-202208261522-93716	
付款編號:	
EGIS Reference No: C202208265000807	
EGIS編號:	
Payment Method: JCB	
付款方法:	
Payment Amount: HK\$155.00	
付款金額:	

For Office use
certificate(s) collected on _____

Company Stamp:
公司印鑑: _____

Certificate(s) Collection Method
領取證明書方法

The issued e-Certificate(s) can be downloaded in PRS 2.0 from at least 3 working days from the date of payment made or effective date, whichever is later.

已發出的電子證明書可在繳交費用或生效日期(以較遲者為準)後最少 3 個工作天起在PRS2.0 內下載。

2.9.2 Payment History

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

Payment History

New Product Registration Total Number of Payment Records: 2

PR No.	Name of Product	Payment Date	Amount(HKS)	Payment Ref No.
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

Change of Registered Particulars Application Total Number of Payment Records: 1

HK No.	Name of Product	Payment Date	Amount(HKS)	Payment Ref No.
HK63552	TEST ATTACH	16.11.2017	155.0	DHPRS-201711161525-13744

Renewal of Registration Total Number of Payment Records: 1

HK No.	Name of Product	Payment Date	Amount(HKS)	Payment Ref No.
HK36996	PRODUCT NAME XXXX XXXX	24.08.2018	575.0	DHPRS-201808241655-91732

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:

New Product Registration Print Receipt Close

Payment Reference No.: DHPRS-201412091902-90540
EGIS Reference No.: A201412090000618
Payment Method: PPS
Type of Payment: Certificate Fee
Transaction Time: 29.01.2015 22:10:57
Delivery Method: Collect in Person in Drug Office
Certificate Collection Date: 09.12.2014

Application Received Date	Reference No.	PR No.	Product Name
09.12.2014 17:55	ANP20149000189	PR0103/2014	HP TEST 1209 NCE

The Drug Office acknowledges the receipt of your payment of HK\$1,370.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.
Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)
Tel: (852) 23198458
Email: prs2_info@dh.gov.hk

Print Receipt Close

Change of Registered Particular:

Change of Registered ParticularPrint ReceiptClose

Payment Reference No.: DHPRS-201803201138-13842
EGIS Reference No.:
Payment Method: Cash
Transaction Time: 27.08.2018 09:53:09
Delivery Method: Received By Post

Application Received Date	Reference No.	HK No.	Product Name	Change Categories	Payment Status
20.03.2018 00:00	CORP-HK63567-201851387	HK63567	TEST 20161226 01	5	Certificate Fee Paid

The Drug Office acknowledges the receipt of your payment of HK\$155.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.

Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)
Tel: (852) 23198458
Email: prs2_info@dh.gov.hk

Print ReceiptClose

Renewal:

RenewalRENEWAL_PAYMENTPrint ReceiptClose

Payment Reference No.: DHPRS-201808241655-91732
EGIS Reference No.: C201808242001297
Type of Payment: Renewal
Transaction Time: 24.08.2018 16:56:30
Delivery Method: Collect in Person in Drug Office

HK No.	Product Name	Expiry Date
HK36996	PRODUCT NAME XXXX XXXX	25.08.2018

The Drug Office acknowledges the receipt of your payment of HK\$575.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.

The certificate(s) will be ready for collection on / after 07.09.2018


Please kindly quote the above Payment Reference Number for enquiries.

General 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, Sundays & Public Holidays)
Tel: (852) 23198458
Email: prs2_info@dh.gov.hk

Print ReceiptClose

2.10 APPLICATION HISTORY

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



You are login as ORG Trial One
TESTING LIMITED
Login date and time
26.01.2021 15:42

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Request to Cancel Product Registration
- + Payment
- Application History**
- + User Profile
- + System
- Logout

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration Archived Notifications

No related notifications

CORP Archived Notifications

	Notification Date	Subject	HK No.	Name of Product
Open	12.01.2021 17:44:04	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	05.06.2020 11:00:01	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX
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	EPIILIM FREEZE-DRIED PDR FOR IV INJ 400MG
Open	27.02.2019 11:52:23	Certificate Fee Notification	HK65135	CELECOXIB FARMOZ
Open	26.02.2019 15:12:46	Application Approval Notification	HK42175	APT-INDOMETHACIN 25 CAP 25MG
Open	21.08.2018 18:25:53	Application Clarification Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:20:50	Application Screening Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:19:47	Application Submitted Notification	HK41190	PRODUCT NAME XXXXX XXXX
Open	21.08.2018 18:07:37	Application Submitted Notification	HK37565	PRODUCT NAME XXXXX

Renewal of Registration Archived Notifications

No related notifications

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product
Open	26.01.2021 15:07:50	Cancellation Registration Request Submitted Notification	HK31199	EPIILIM FREEZE-DRIED PDR FOR IV INJ 400MG

Non Pharmaceutical Product Alert

No related notifications

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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 ***