APPLICATION USER MANUAL

FOR THE

PHARMACEUTICALS REGISTRATION SYSTEM 2.0

(PRS 2.0)

OF THE

DEPARTMENT OF HEALTH

Version: 1.1.18

Jul 2023

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

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1. SYSTEM REQUIREMENT

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

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

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

1.1.2 New Operating Systems and Browsers

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

1.1.3 File Upload Size Limitation

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

Application	Application Type	Scope	Single File Max. Size	Total File Size Max. Size
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)

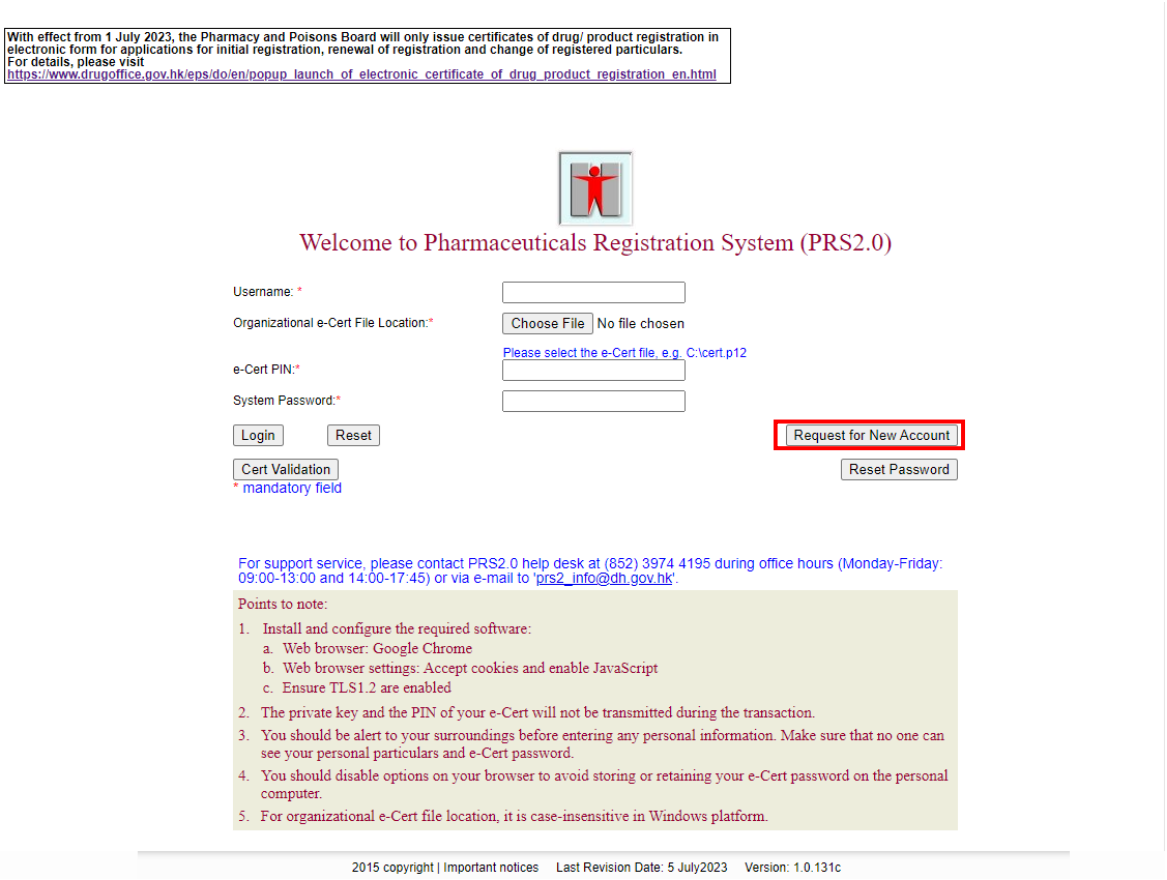
2.1 USER REGISTRATION

2.1.1 New User Registration

Step 1:

- Type the following link into the web browser and click the button “Request for New Account”.

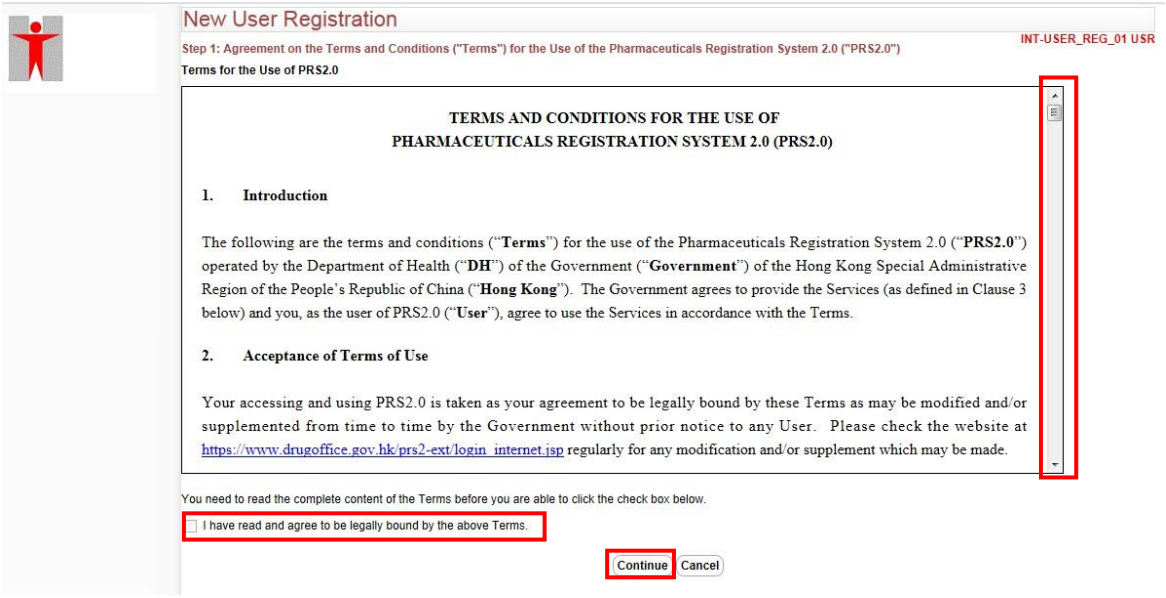
  https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp



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.



Step 3:

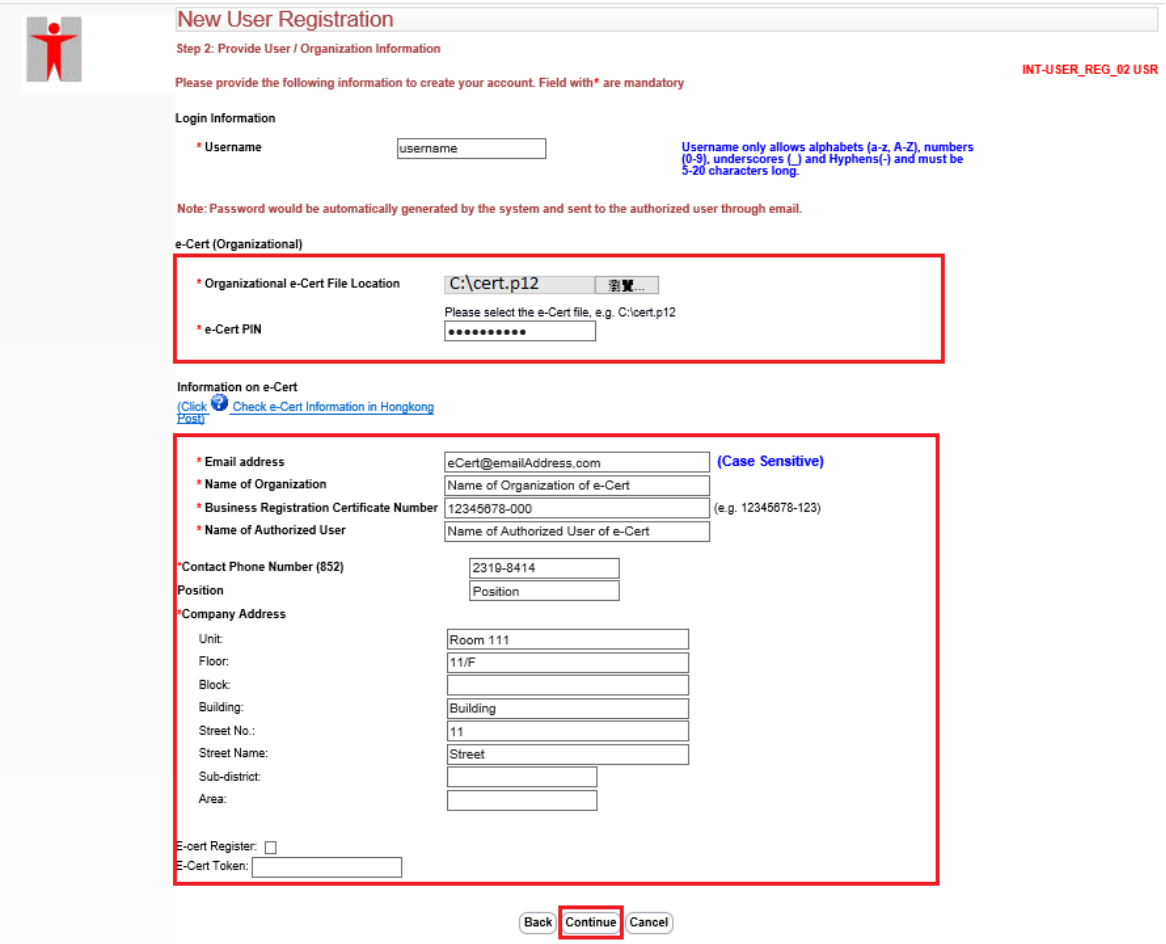
- Type the user name under the “Login Information” section. Please note the username only allows alphabets (a-z, A-Z), numbers (0-9), underscores (_) and hyphens (-) and must be 5-20 characters long.

- Type the full path of the e-cert file location for the organizational e-cert and enter the e-cert PIN.

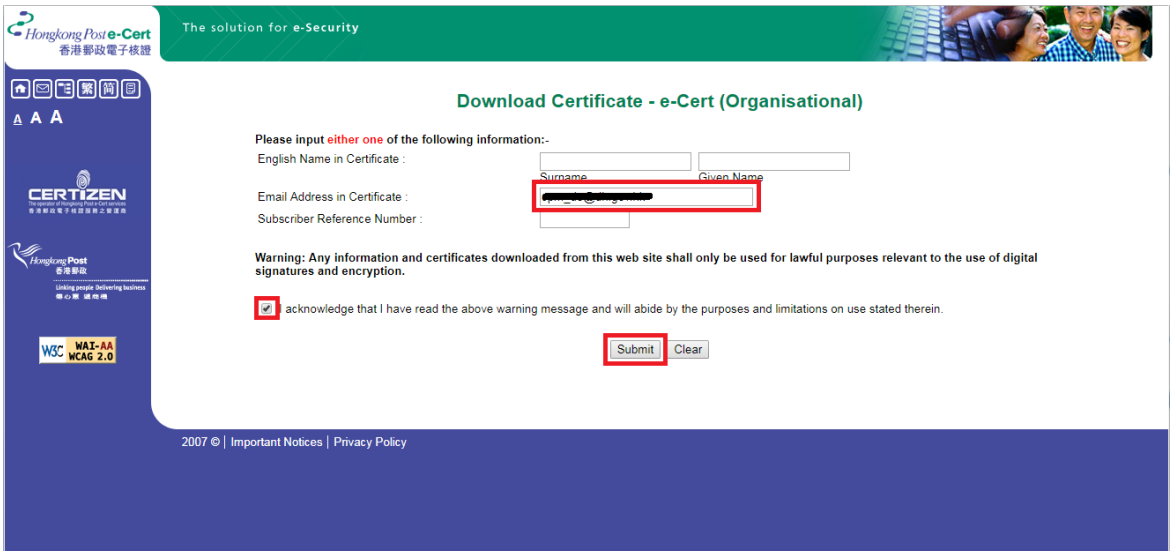
- Enter the section on “Information on e-cert”. The items with asterisks (*) are mandatory fields.

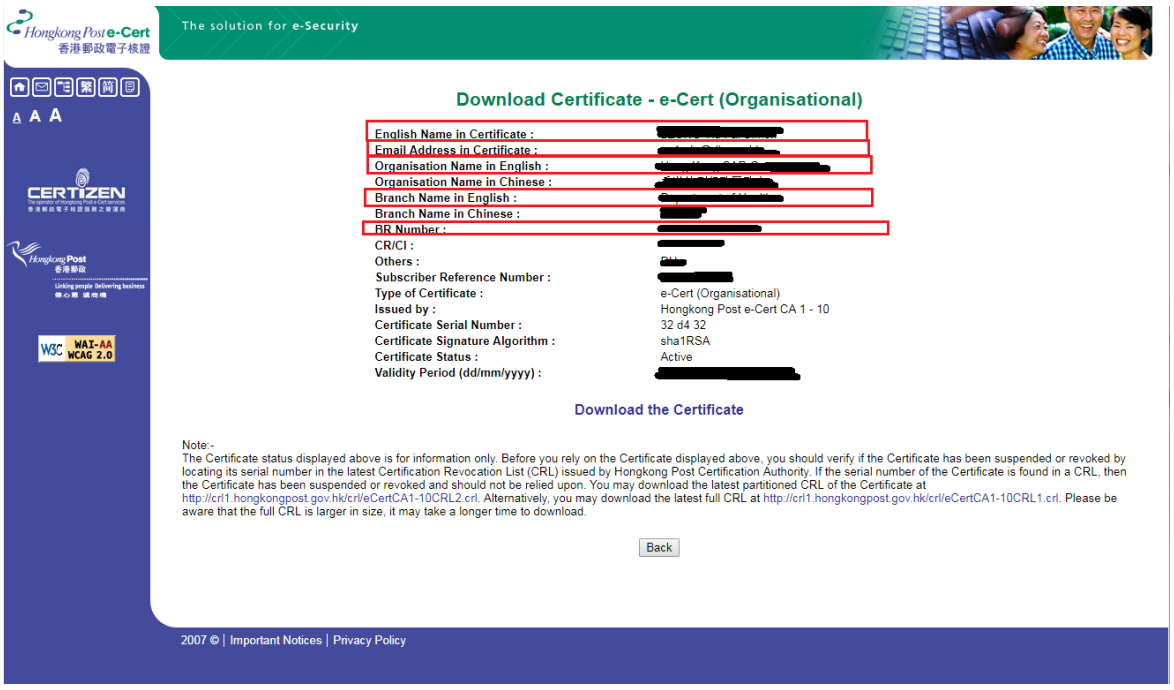
- Enter the Contact Phone Number

- Click “Continue” to proceed.



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.

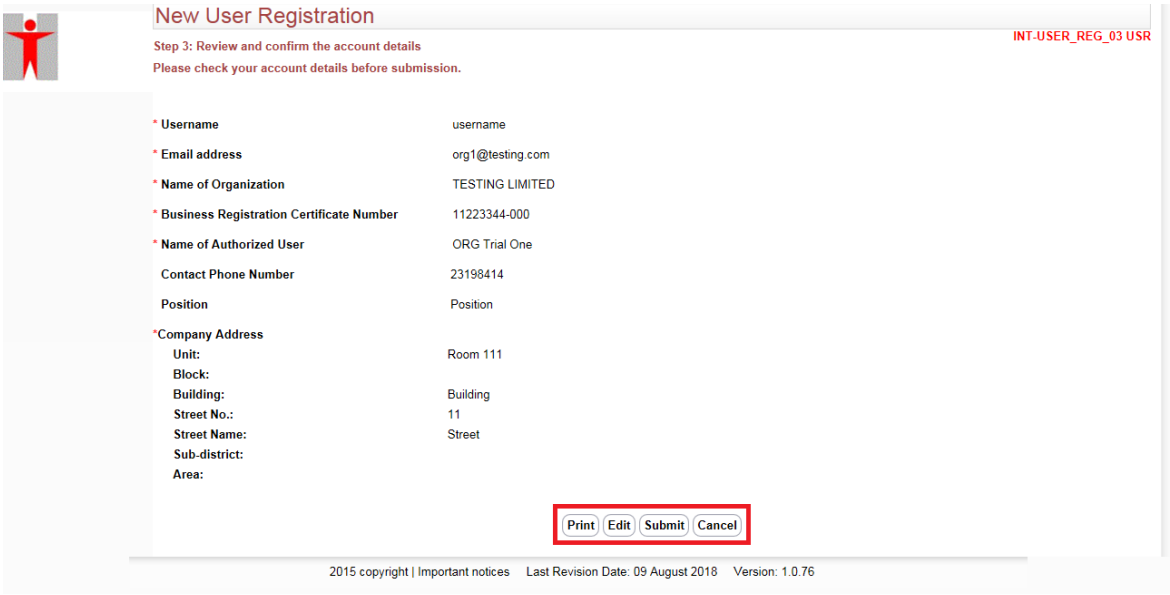




Note: If Branch Name in English is exist, please fill the Branch Name in English into Name of Organization

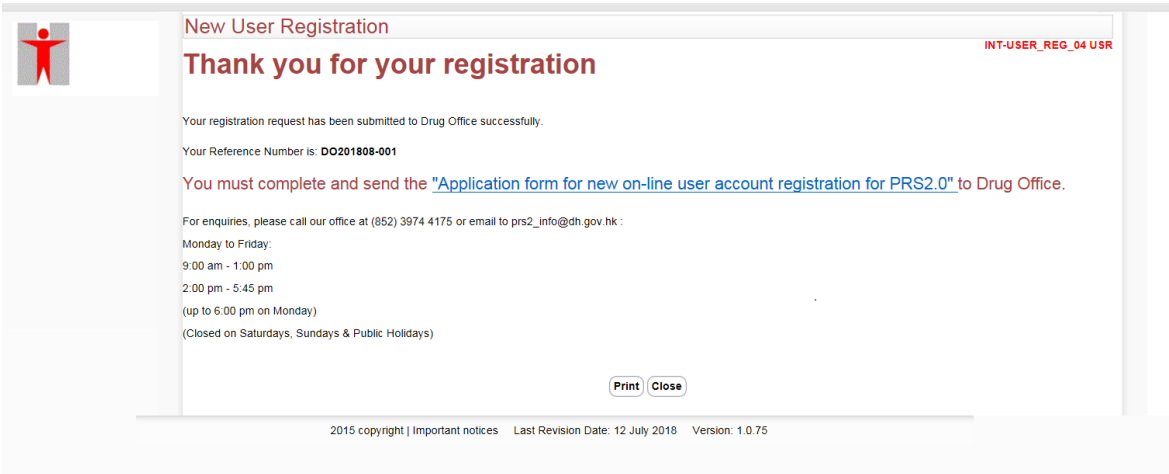
Step 4:

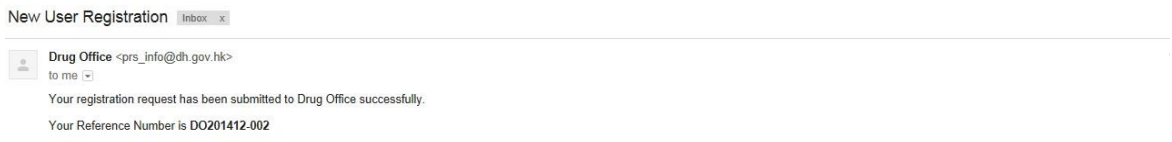
- The user will then be redirected to the summary page.
- Click “Submit” to confirm the information to be sent to Drug Office and proceed to the next step.
- Click “Print” to print the summary screen.
- Click “Edit” to edit the information.
- Click “Cancel” to cancel the registration.



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 Inbox x

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

Your registration request has been submitted to Drug Office successfully.

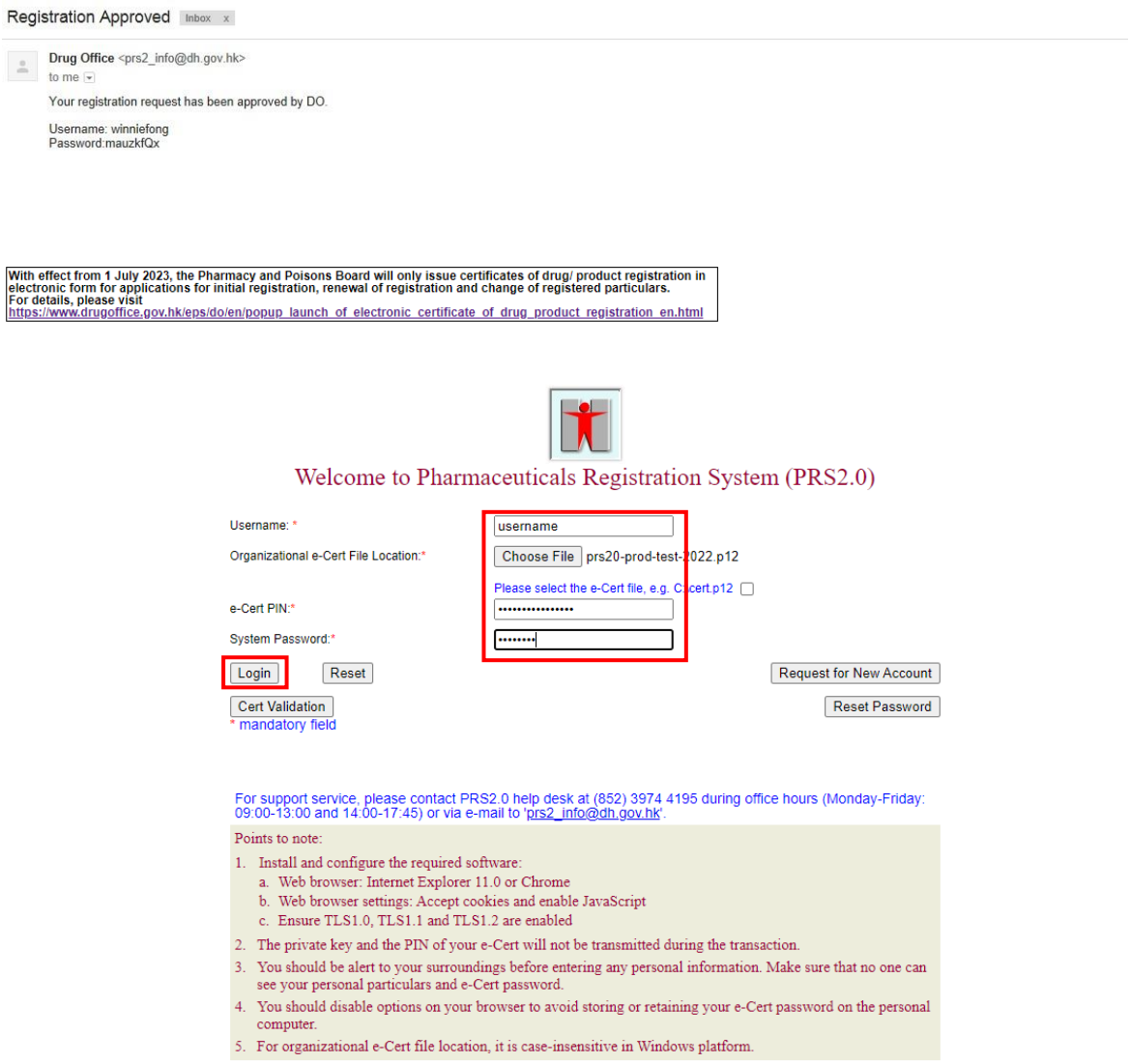
Your Reference Number is **DO201412-002**

2.1.2 Received Registration Approved Email

Step 1:

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

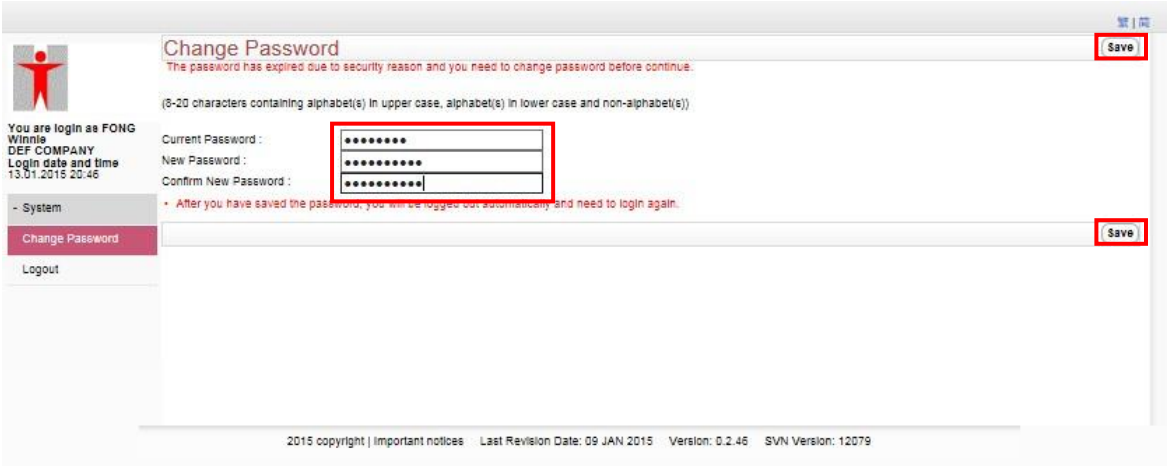
https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp



Step 2:

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



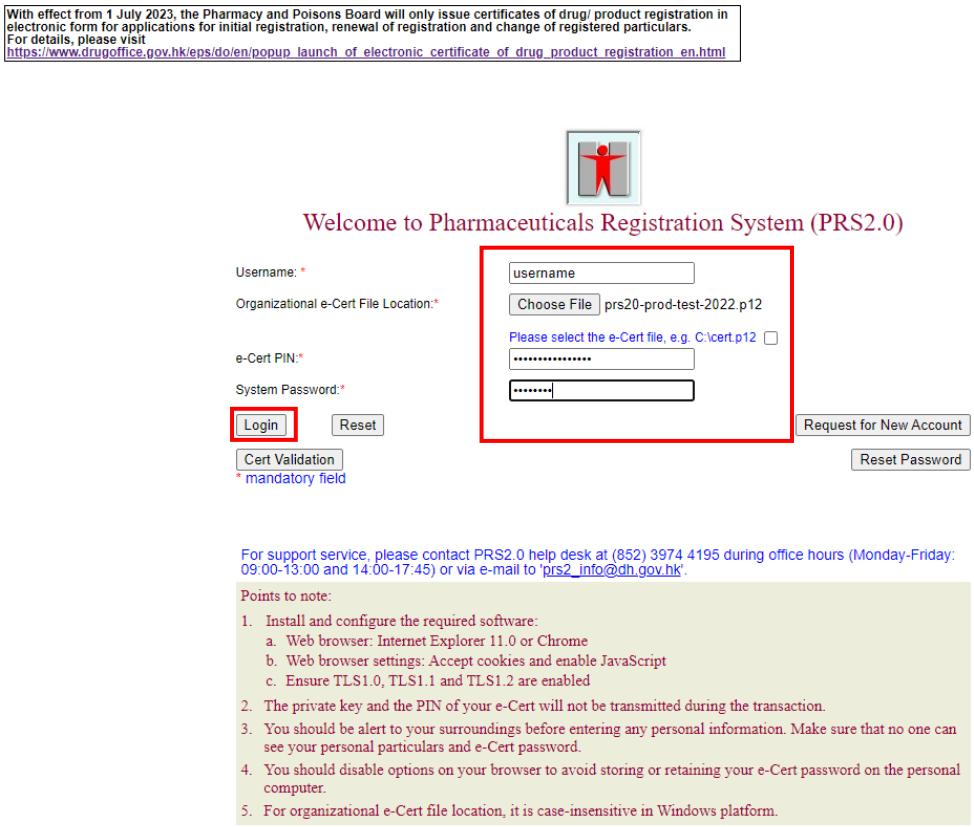
Step 3:

- 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.

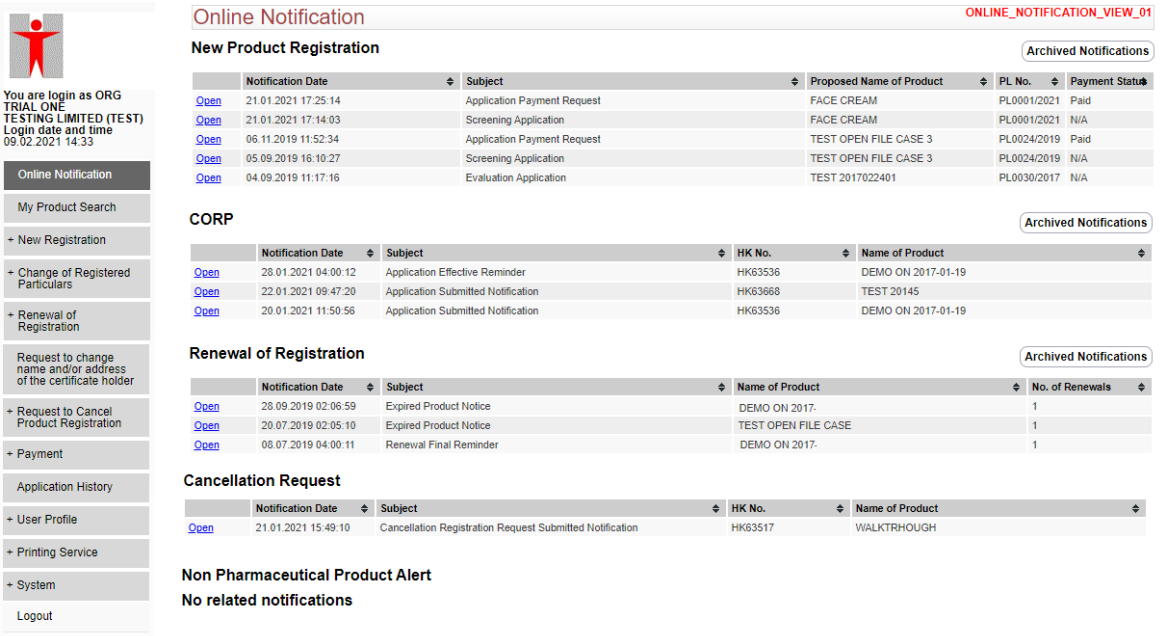
  https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/forget_password.html

- Click “Login” to proceed.



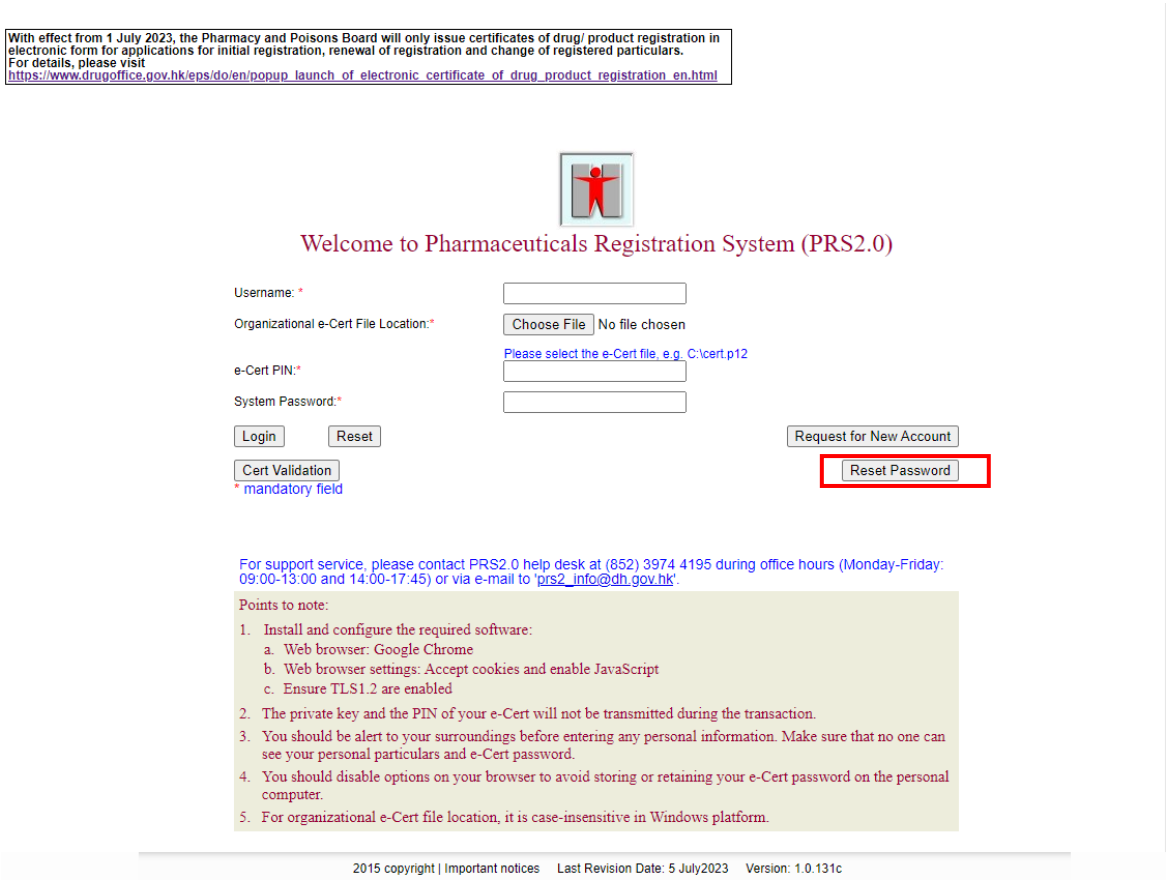
Step 4:

- 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.

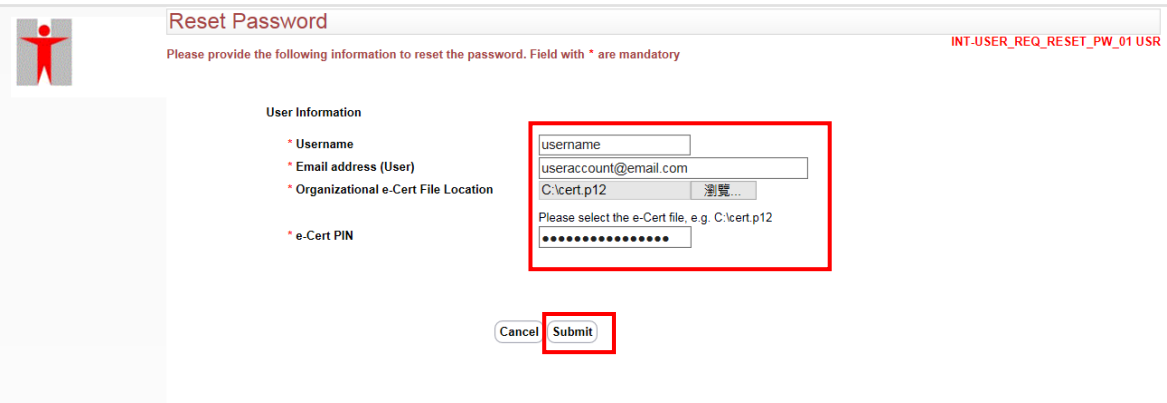


2.1.2.1 Request Reset Password

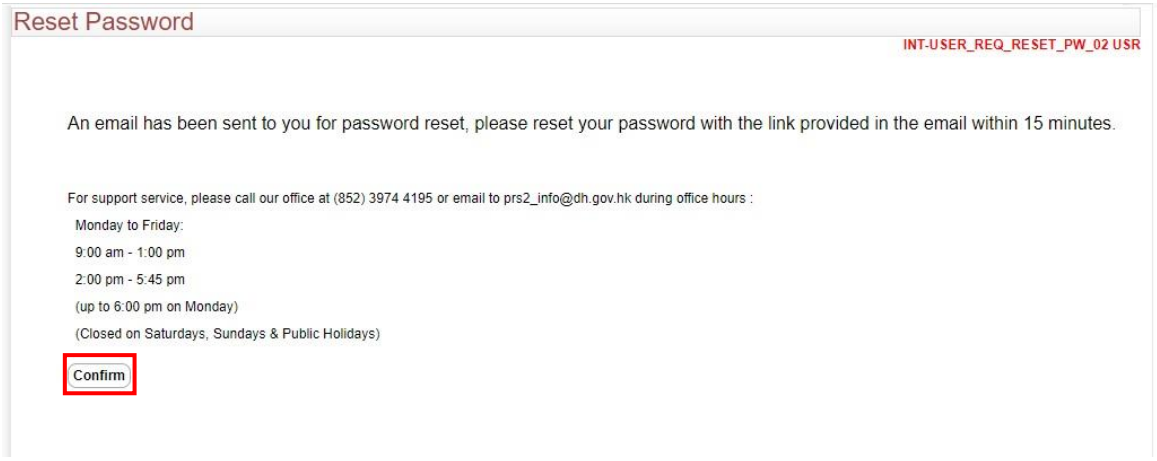
Step 1: Click Reset Password to request reset password



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

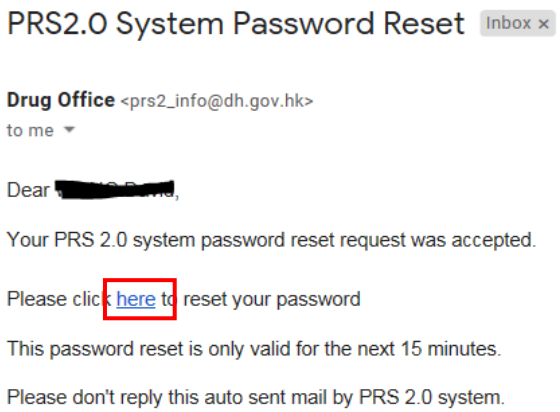


Step 3: A reset password email will be sent to your registered email

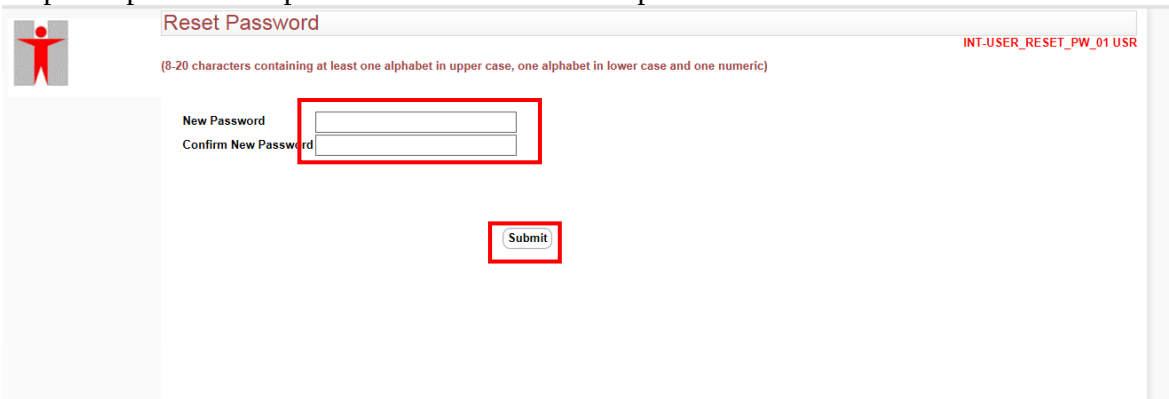


2.1.3 Reset Password

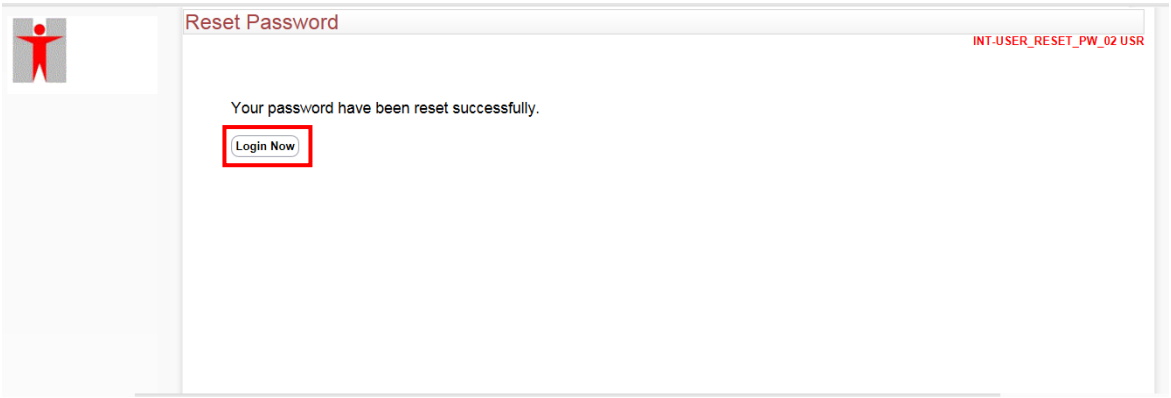
Step 1: Open the reset password email and click here



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

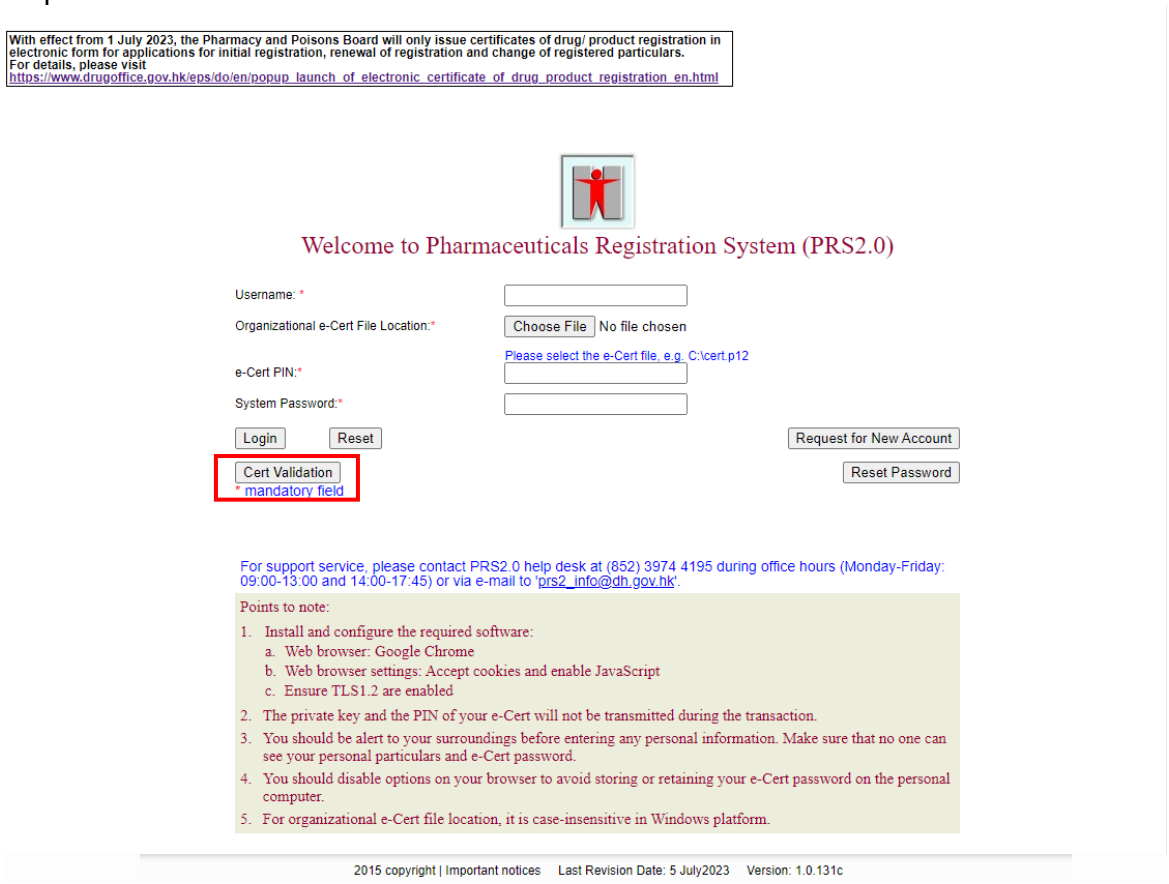


Step 3: Click Login Now to go to login page and use the new password to login

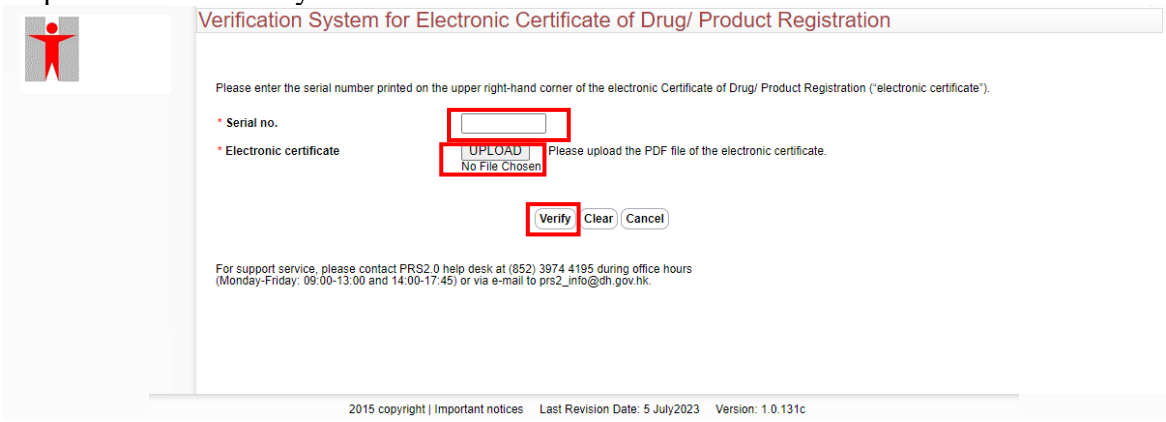


2.1.4 Product E-Cert Validation

Step1: Click the Cert Validation button.

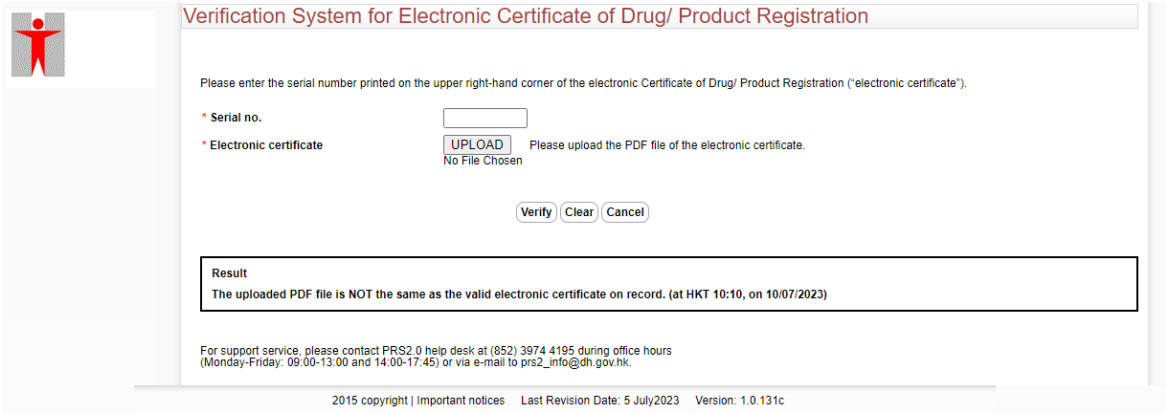


Step2: Enter the Serial No. of the Product e-cert (right hand corner)
Step3: Upload the E-cert file
Step4: Click the 'Verify' button



If the E-Cert is Valid

If the E-Cert is not Valid

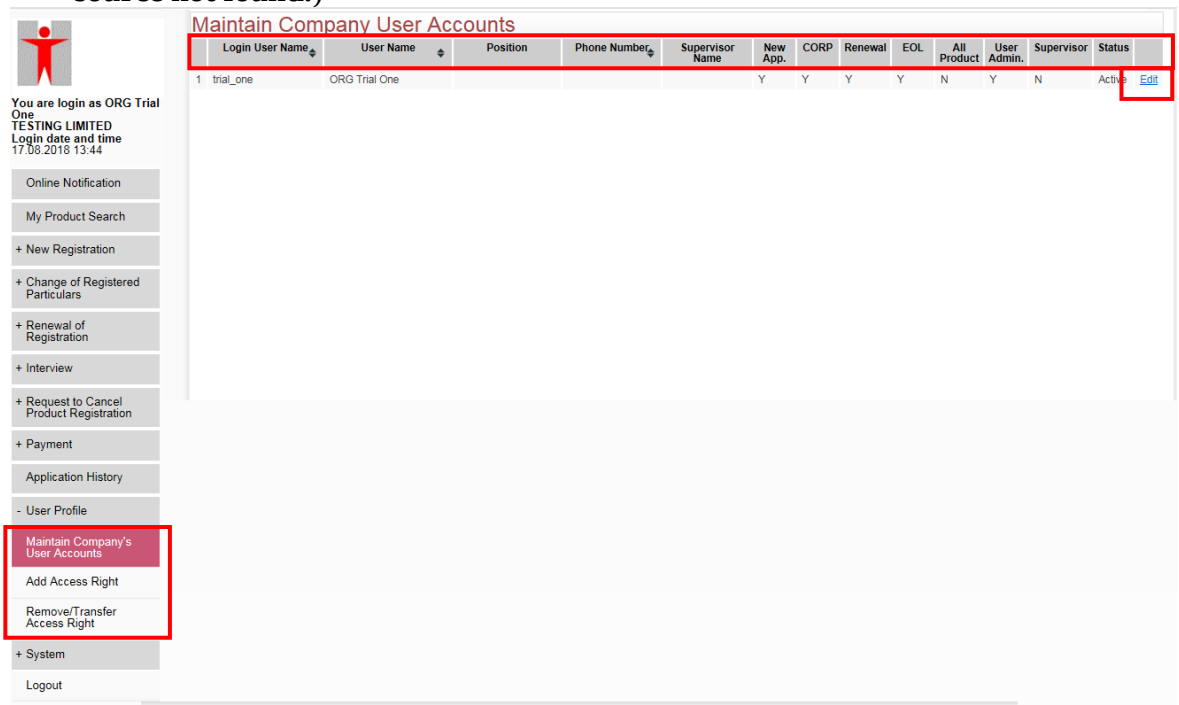


2.2 USER PROFILE

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

2.2.1 Maintain Company's User Accounts

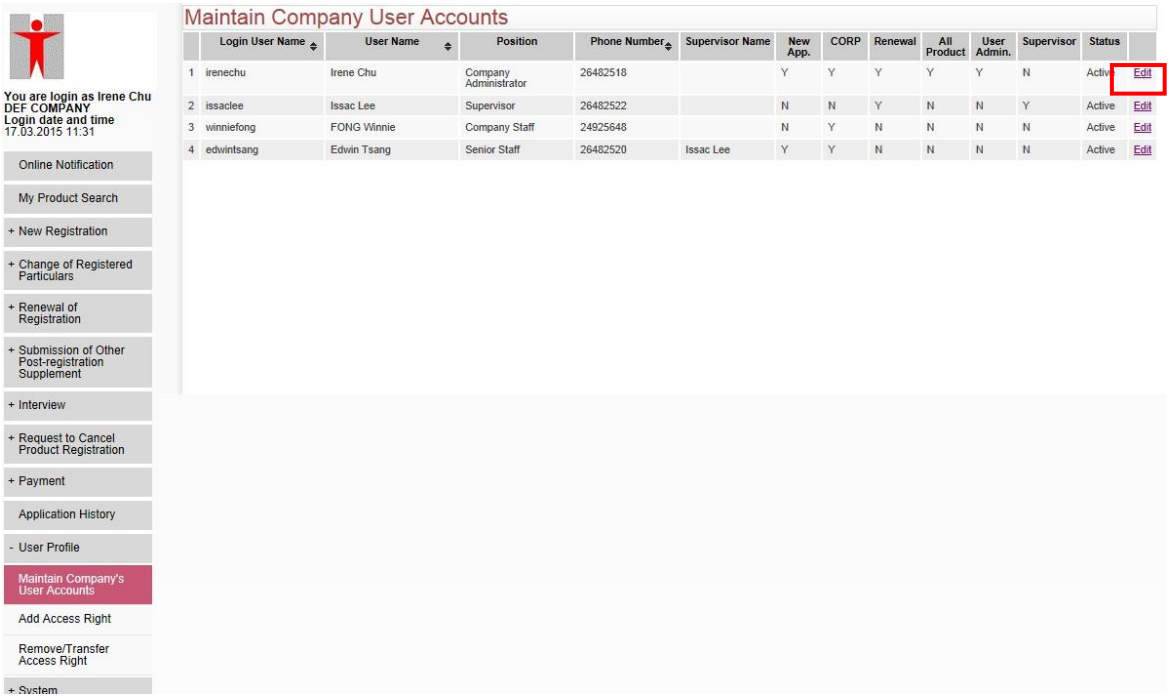
- Click the menu item “Maintain Company’s User Accounts” under “User Profile” in the menu on the left.
- “Position” describes the position of the users in the company.
- “Supervisor Name” indicates the supervisor of a particular user.
- “New App.”, “CORP” and “Renewal” indicate the application submission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



2.2.1.1 Edit user account profile

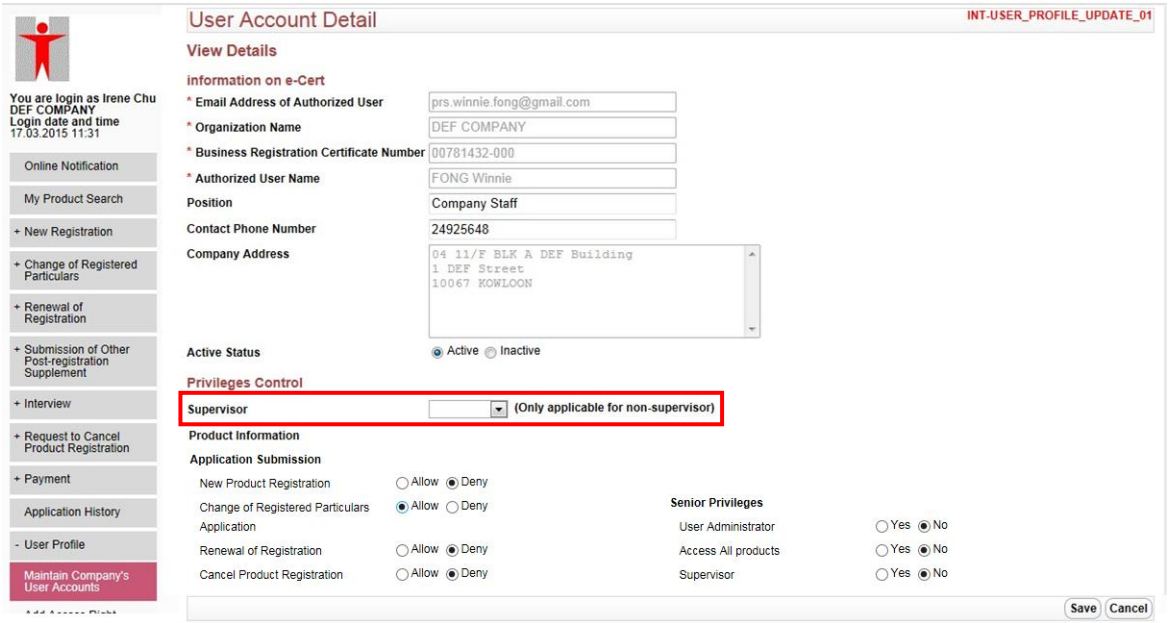
Step 1:

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

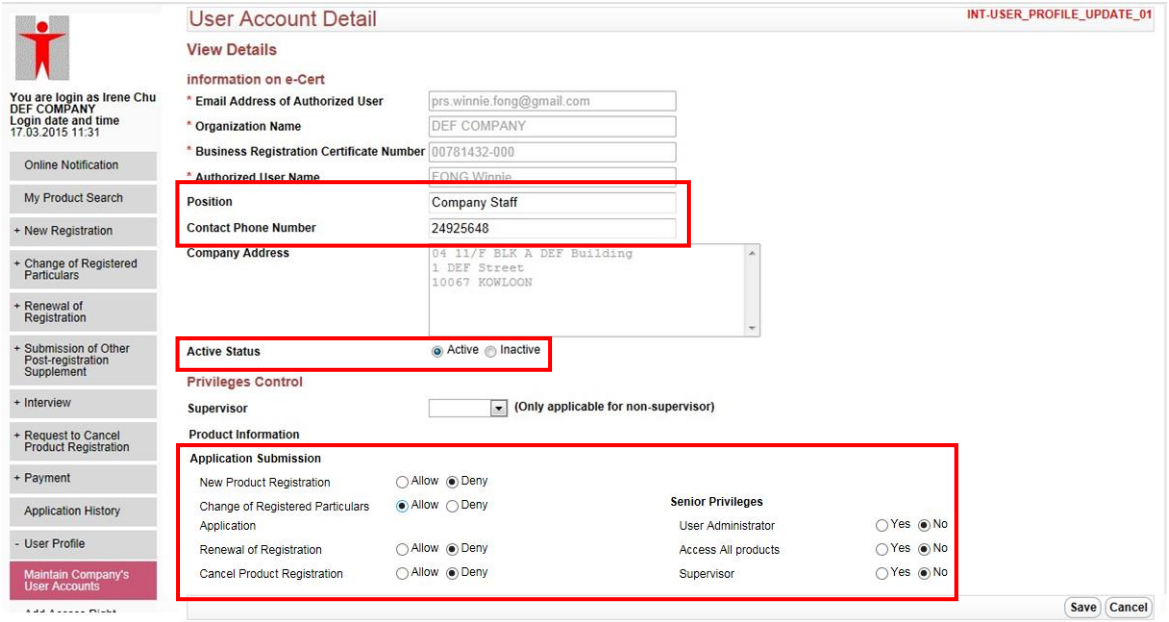


Step 2:

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

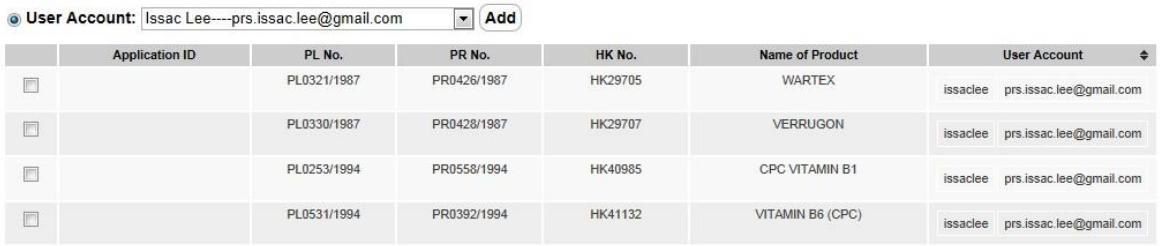


Scenario 1:
Administrator can edit the basic information of the staff, including the position, contact phone number and the active status of the user. (Note that the phone number cannot be blank) The privileges on accessing new application, CORP, and renewal senior privileges functions of his staff can also be amended.



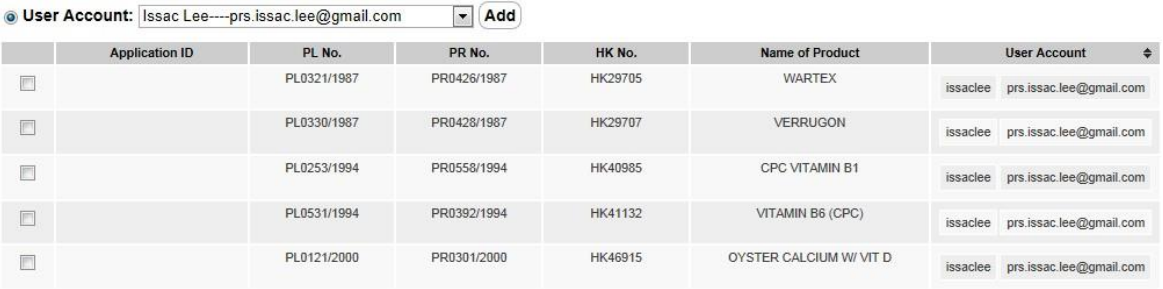
Scenario 2:
Administrator can assign supervisor to a particular staff. The "Supervisor" privilege allows user to control access rights of products of staff under his supervision in the company. (Assign Issac Lee as the supervisor of Winnie Fong in the following example)

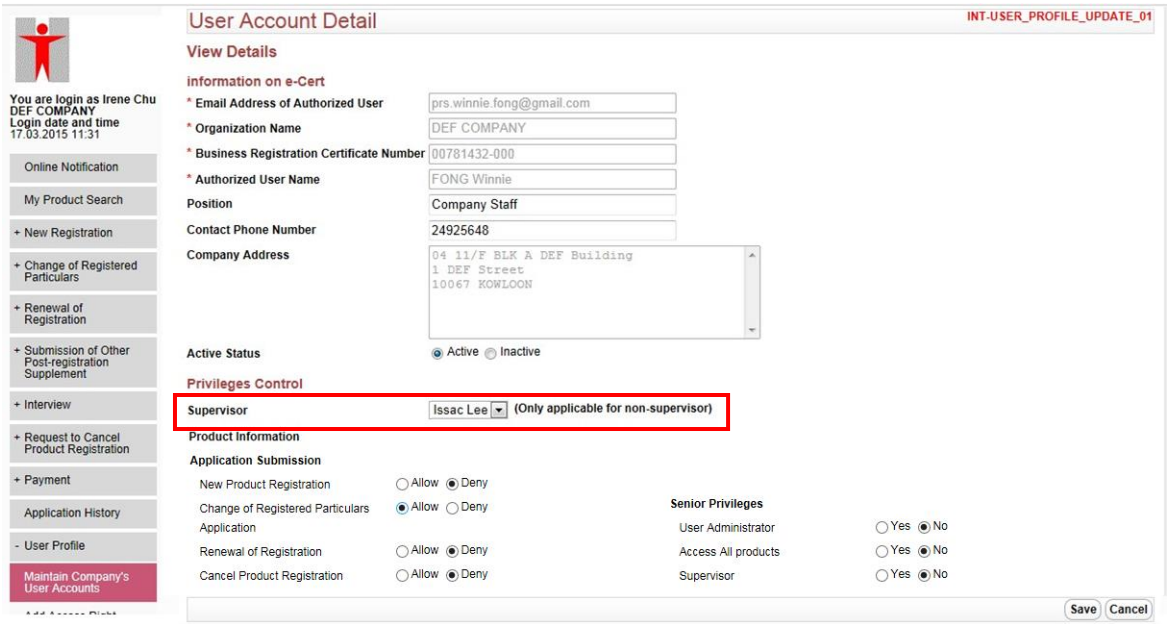
Issac's access rights of products before assignment:



Winnie's access rights of products before assignment:

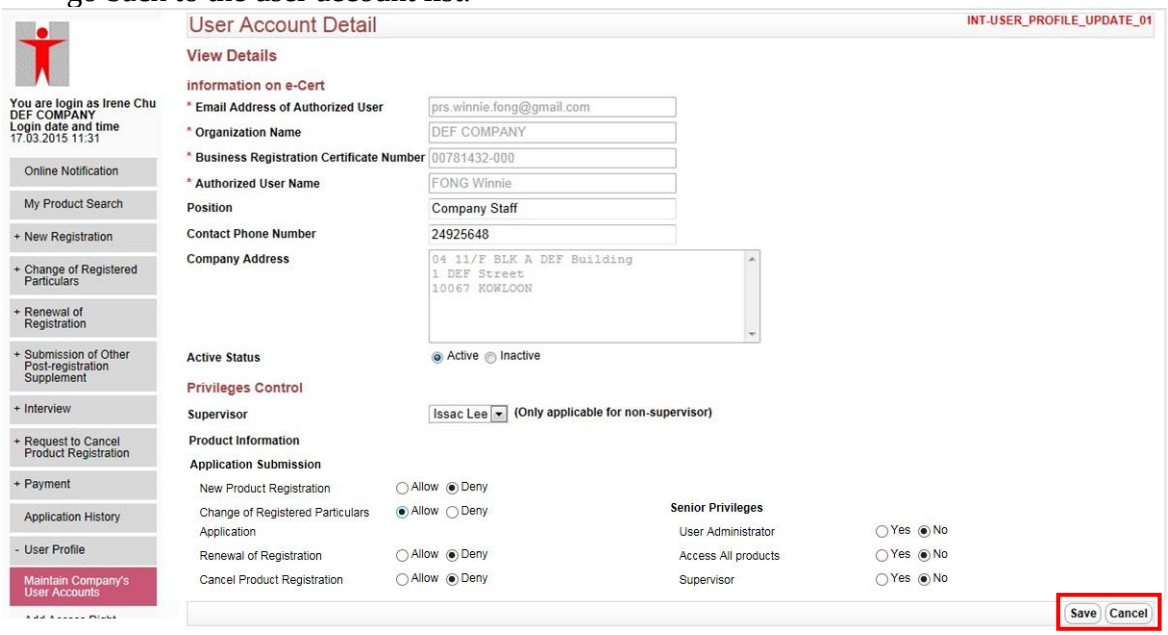
Issac's access rights of products after assignment:




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
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 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

Step 3:

- Click “Save” to save the updated profile or click “Cancel” to revoke the changes and go back to the user account list.

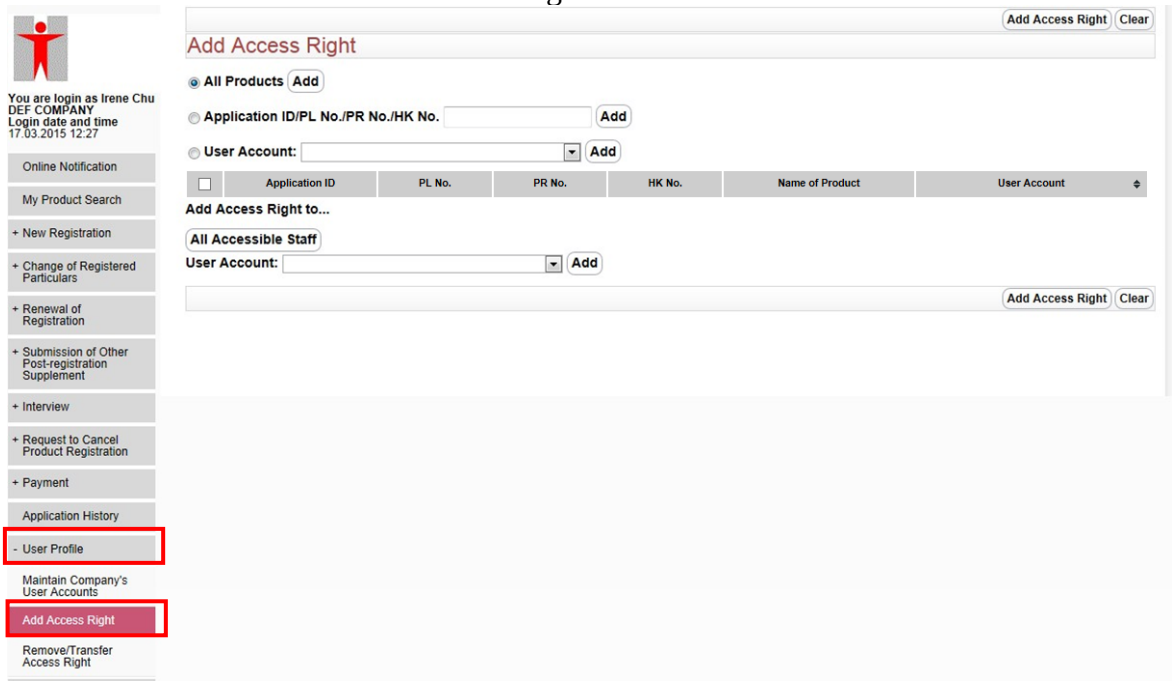


2.2.2 Add Access Right

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.



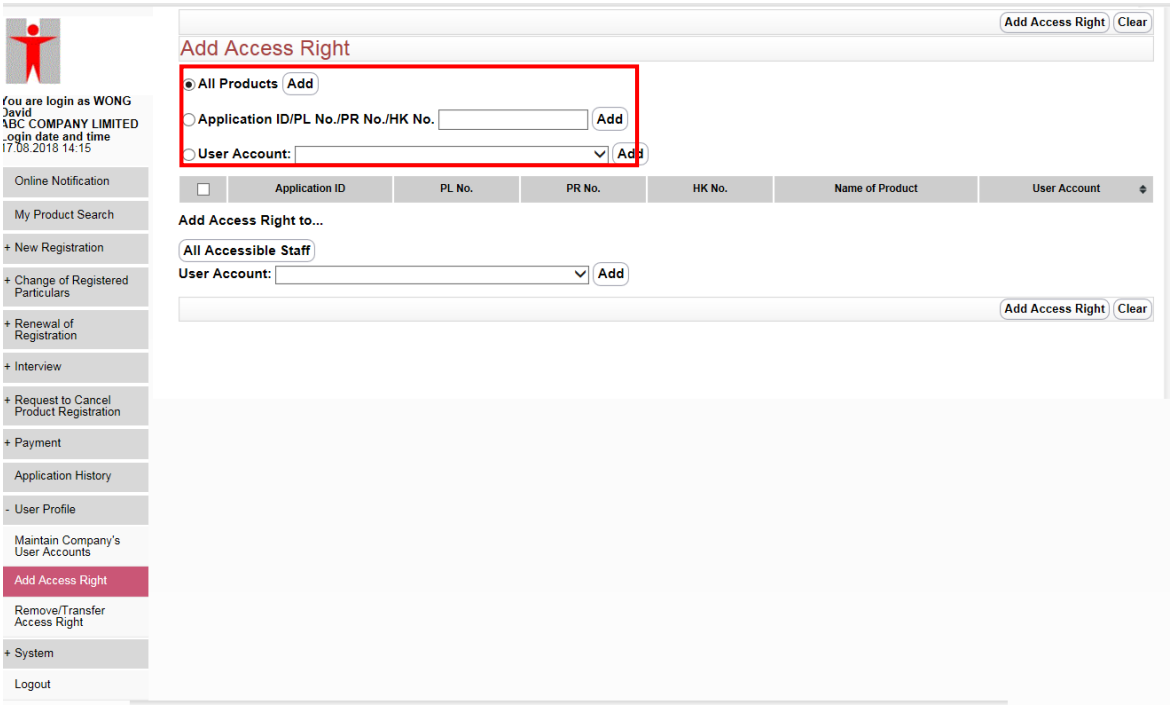
Step 2:

- 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.

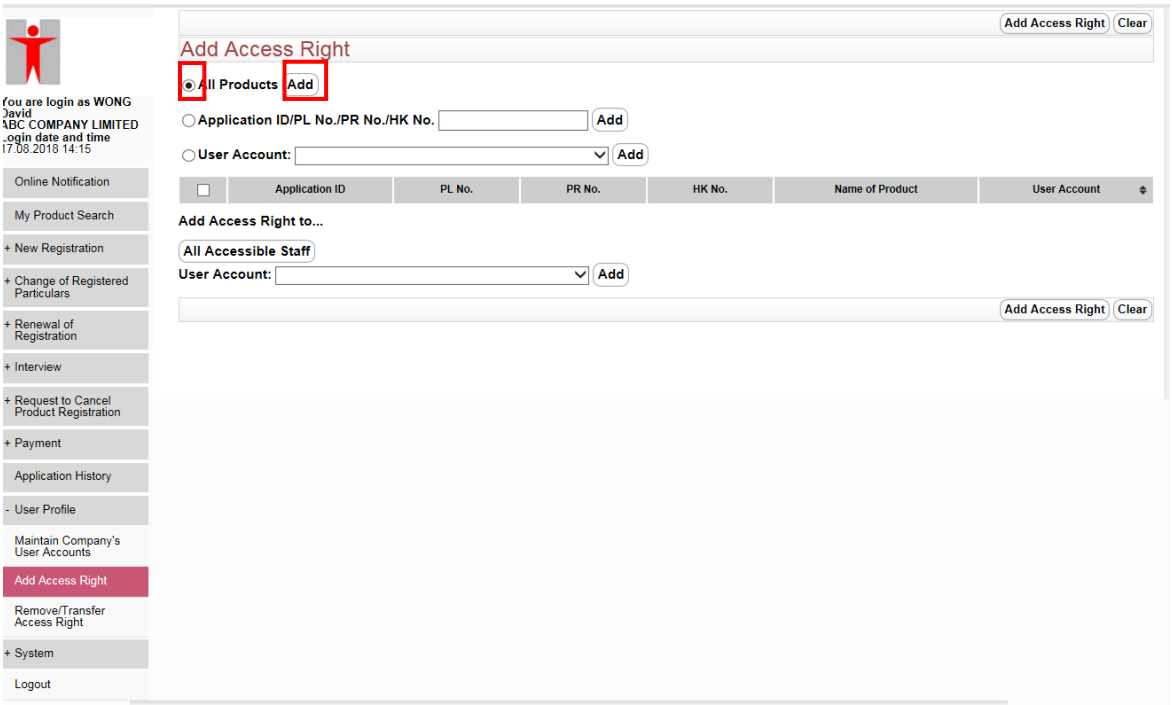
- Under 'Add Access Right to..', select the user account from the dropdown for a specific staff or click 'all accessible staff' for all staff under his supervision.

- After that, click "Add Access Right" to update the changes or click "Clear" to reload the page.

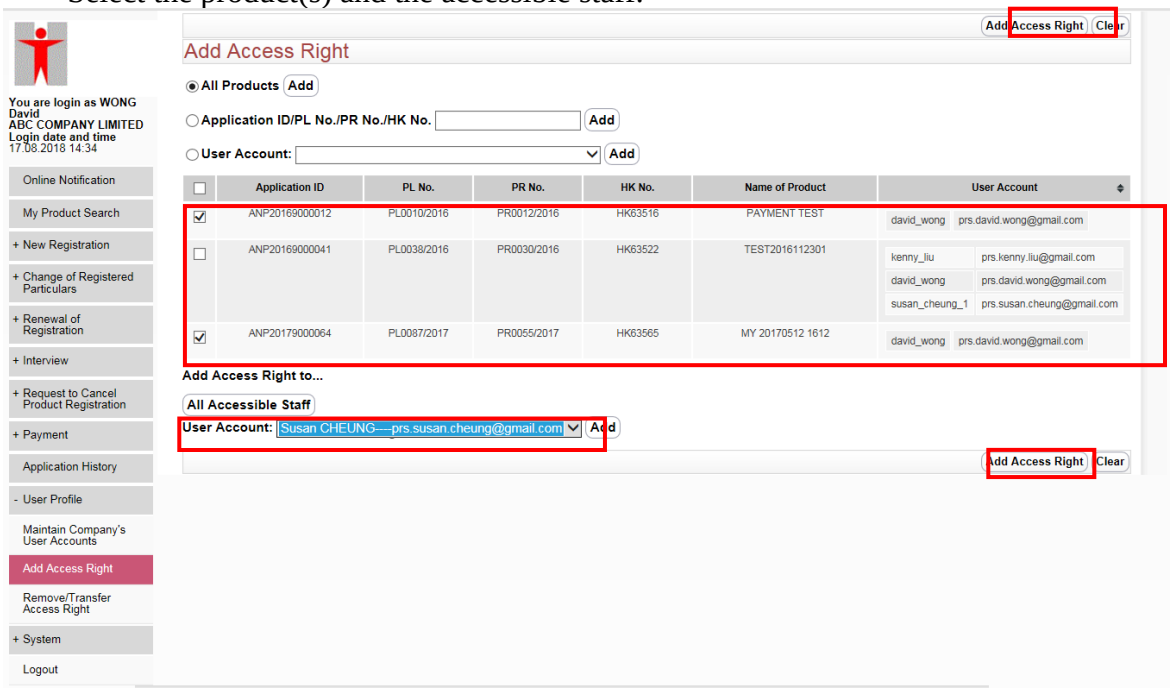


Scenario 1:
Select from all product(s) and access right of product(s) to a particular user (in this scenario assigning product HK-63516 and HK-63525 to staff Susan Cheung):

- Select All Products and click the “Add” button.



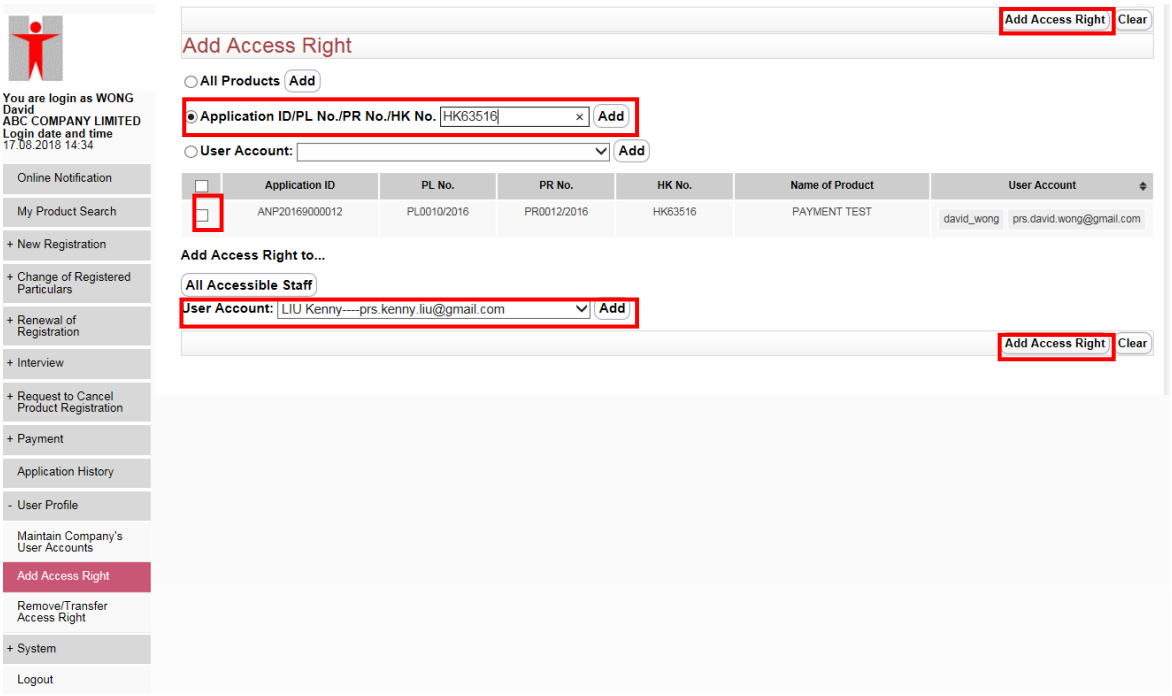
- Select the product(s) and the accessible staff.



Scenario 2:
Assign access right of product(s) to a particular user (in this scenario assigning product HK-63516 to staff Kenny Liu):

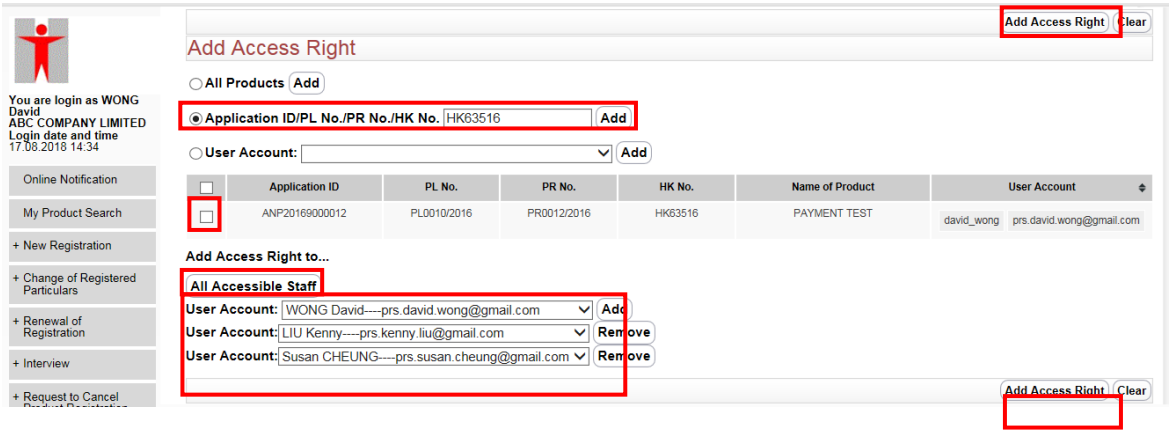
- Select “Application ID /PL No. /HK No.”.

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



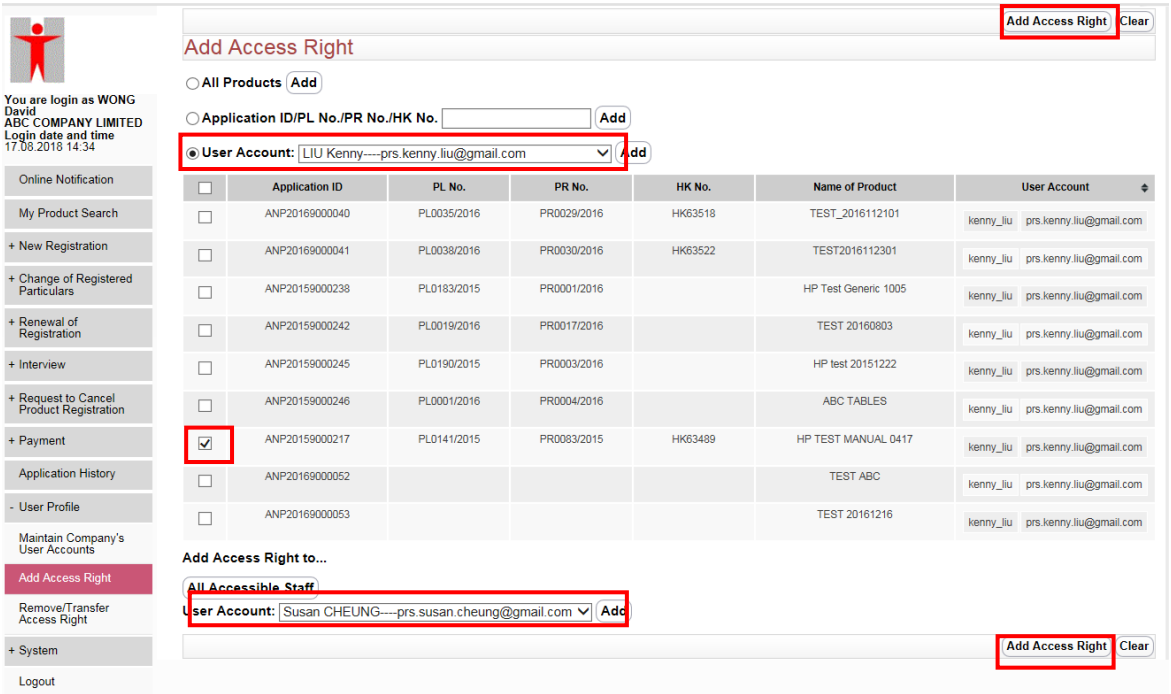
Scenario 3:
Assign access right of product(s) to all users (in this scenario assigning product HK-63516 to all staff):

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



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.



Step 3:

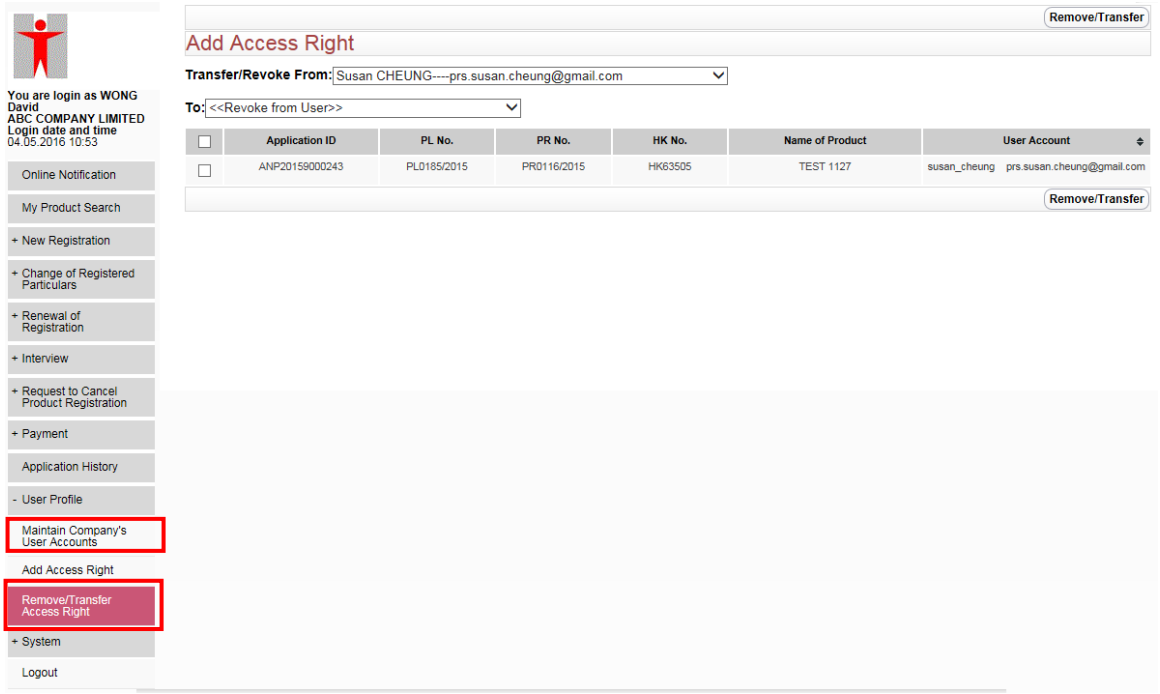
- After clicking the “Add Access Right” button to update the changes or click “Clear” to reload the page, the following dialogue box will come up.

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:

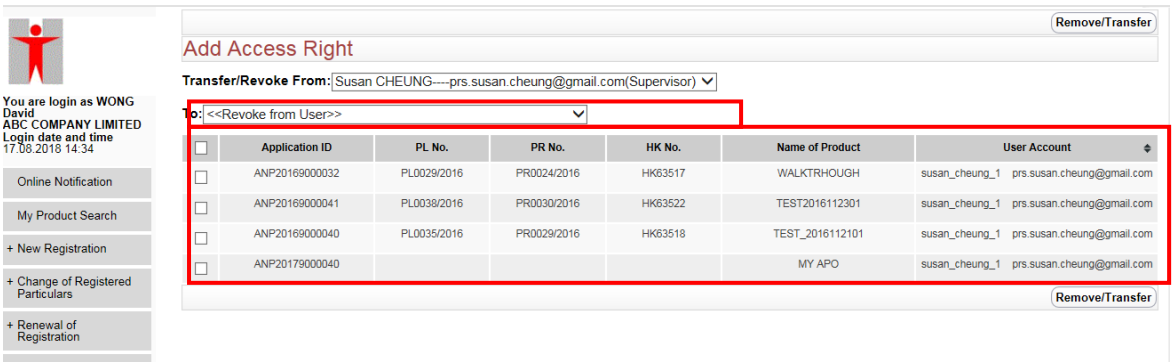
- Click the menu item "Remove/Transfer Access Right" under "User Profile"in the menu on the left.



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

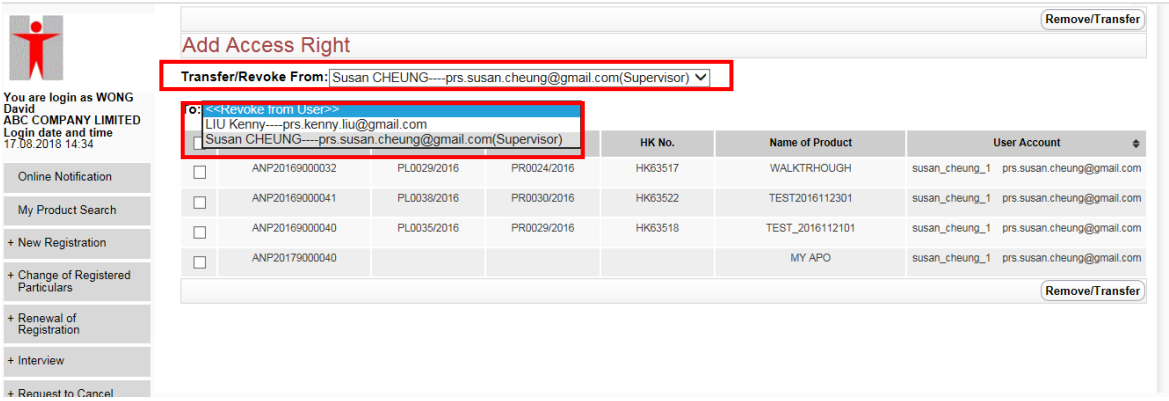


Step 3:

- 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).

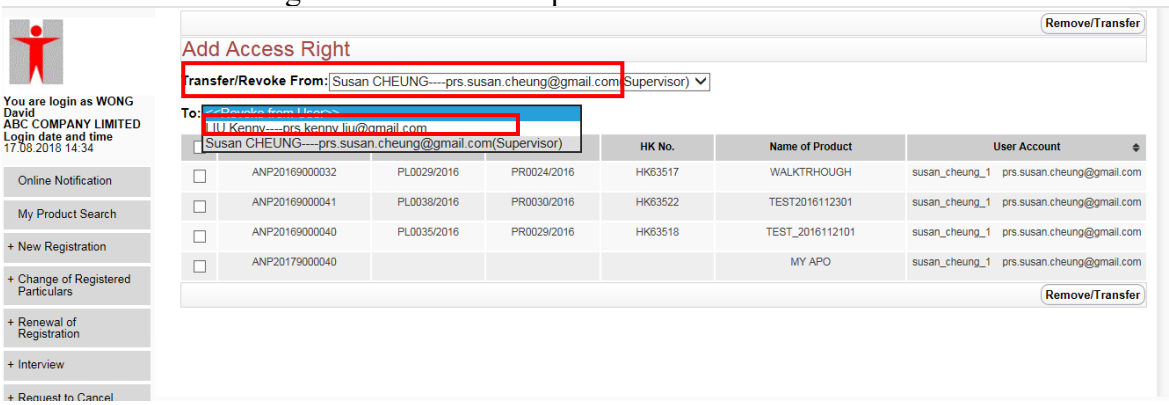
Scenario 1:
To revoke product access right from particular user (in this scenario revoke the access right of the selected product from staff Susan CHEUNG).

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

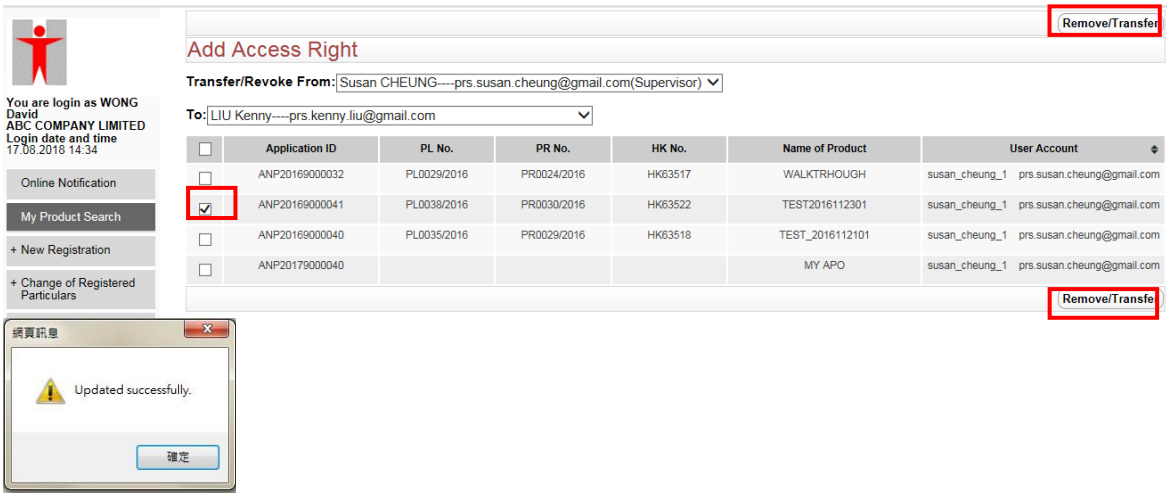


Scenario 2:
To transfer the access right of the product between staff (in this scenario transfer the access right of the selected product from staff Susan CHEUNG to Kenny LIU).

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



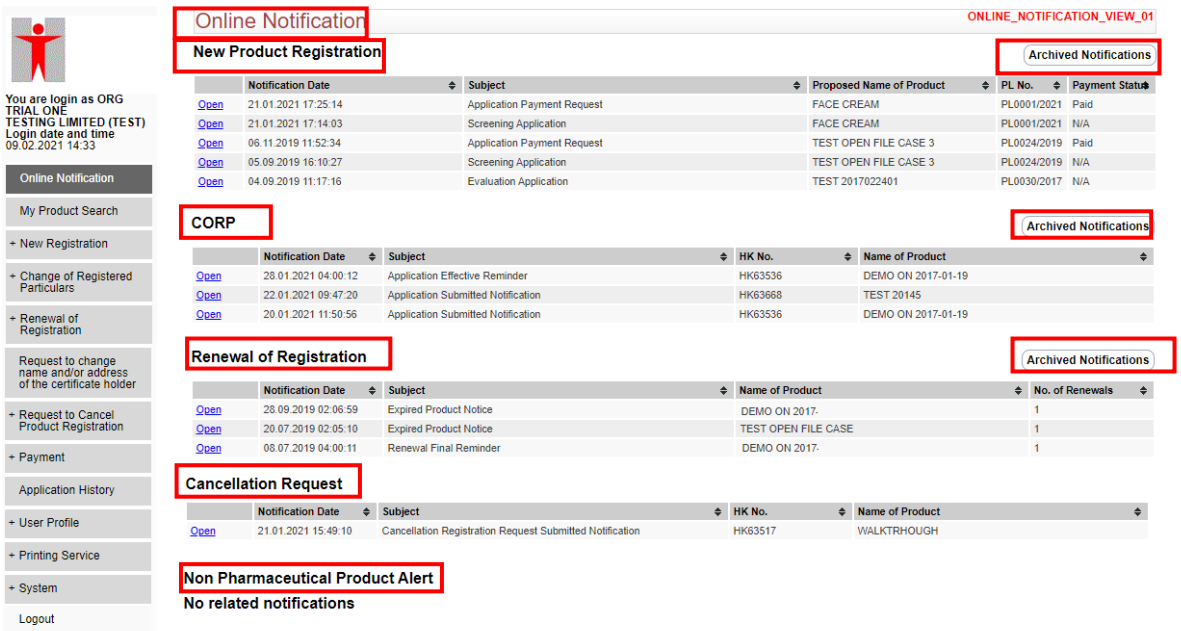
Step 3:
- Select the product(s).
- Click "Remove/Transfer" to update the changes.



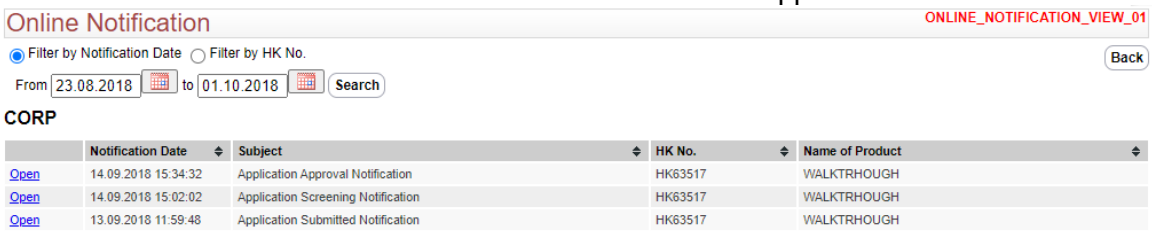
2.3 ONLINE NOTIFICATION

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.



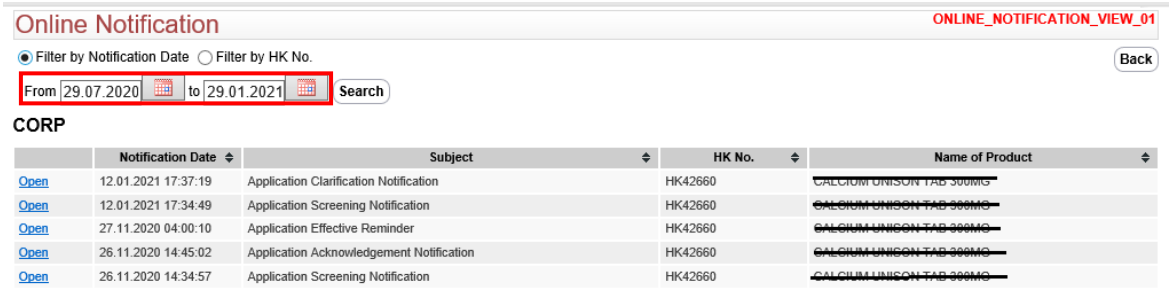
After click the Archived Notifications Button. The archived application will be shown.



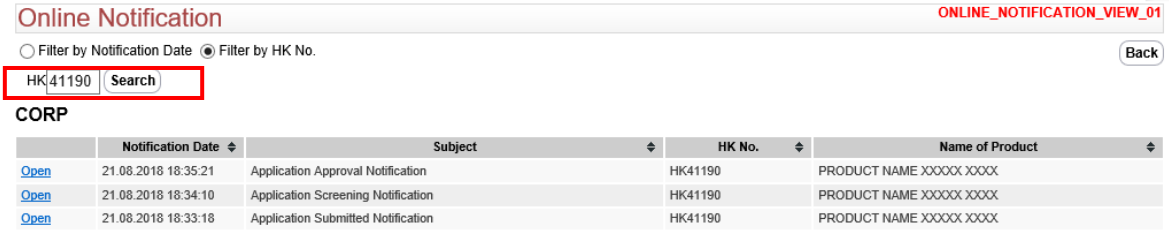
The online notifications for different modules will be shown in the respective section in this manual.

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.



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



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

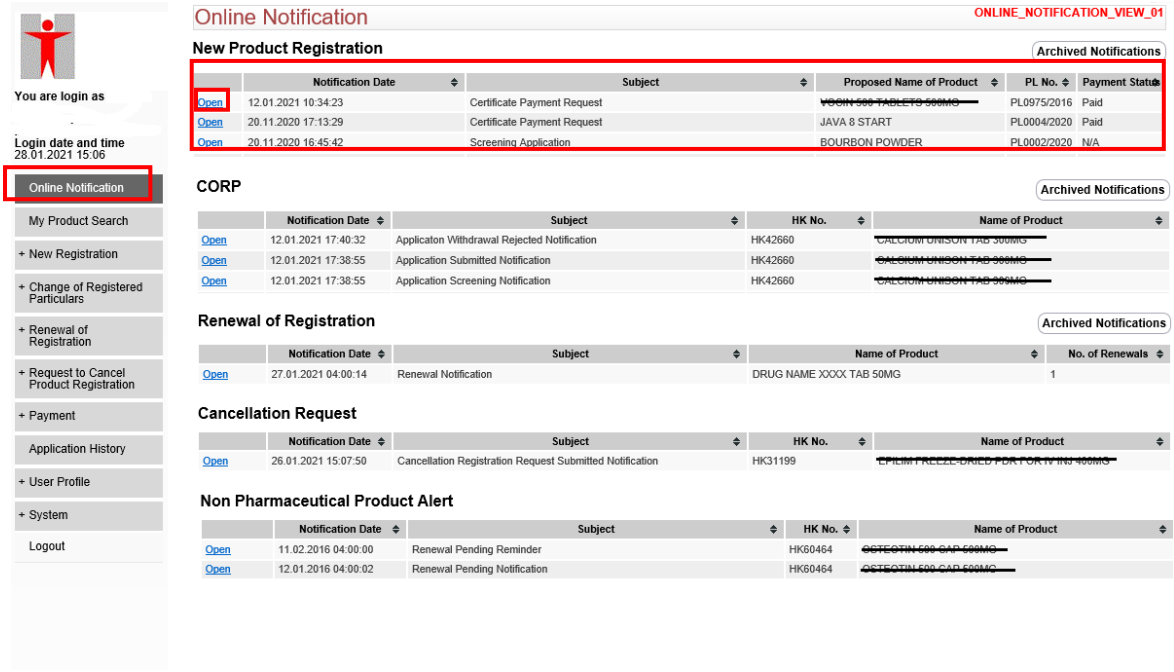
2.3.1 New Product Registration Online Notification

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

Step 1:

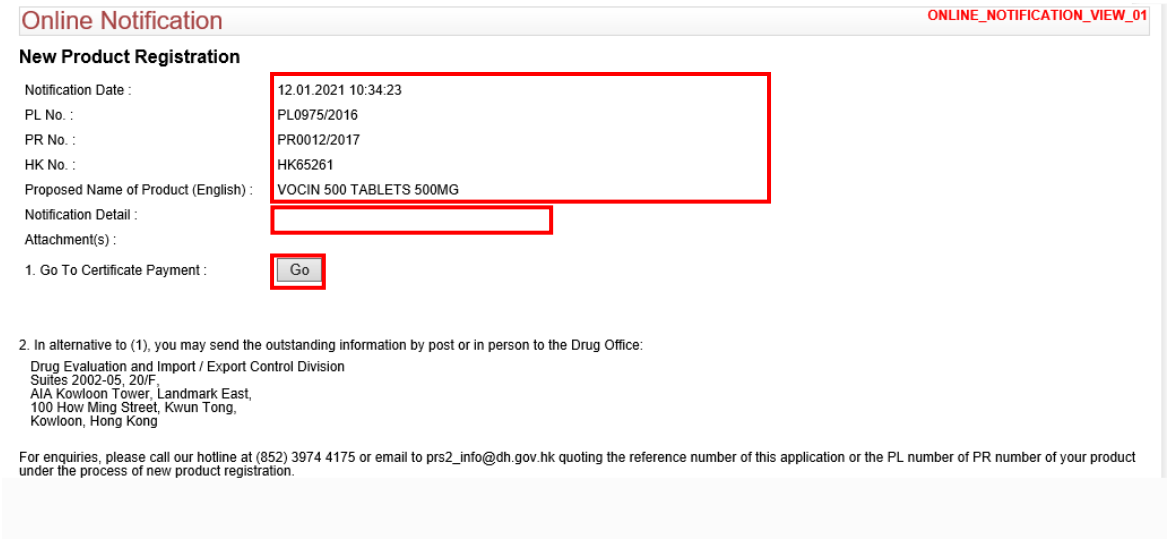
- Click the menu item "Online Notification" in the menu on the left.

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



Step 2:

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



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：

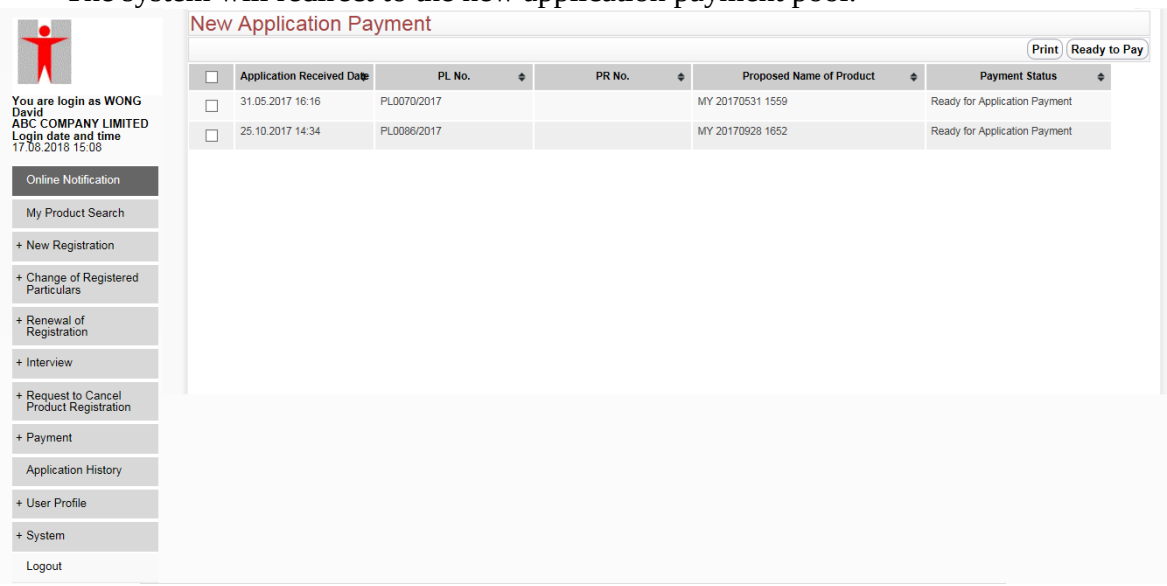
	Number 數量	Total Fee 總費用
[x] **Application(s) for Product Registration** 藥劑製品註冊申請 **(HK$1,100)**	1	HK$1,100

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.

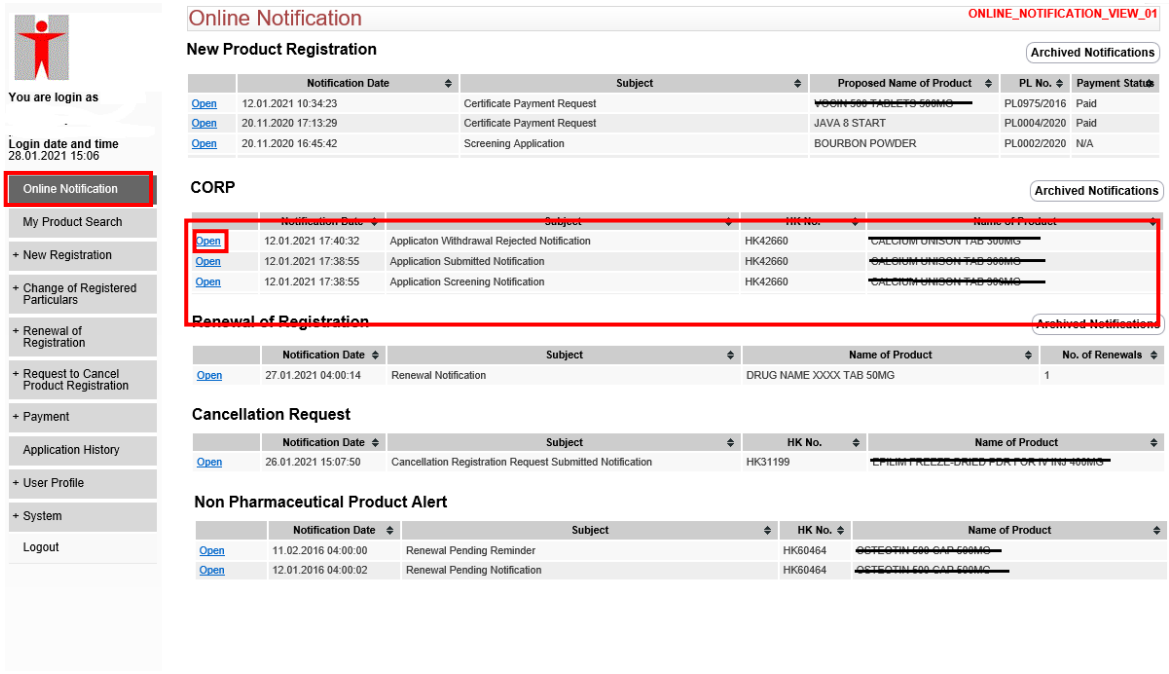


2.3.2 CORP Online Notification

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

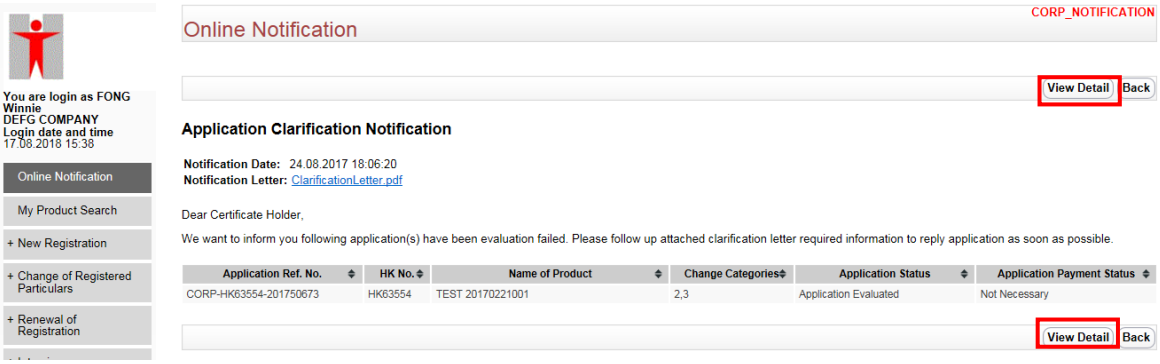
Step 1:

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

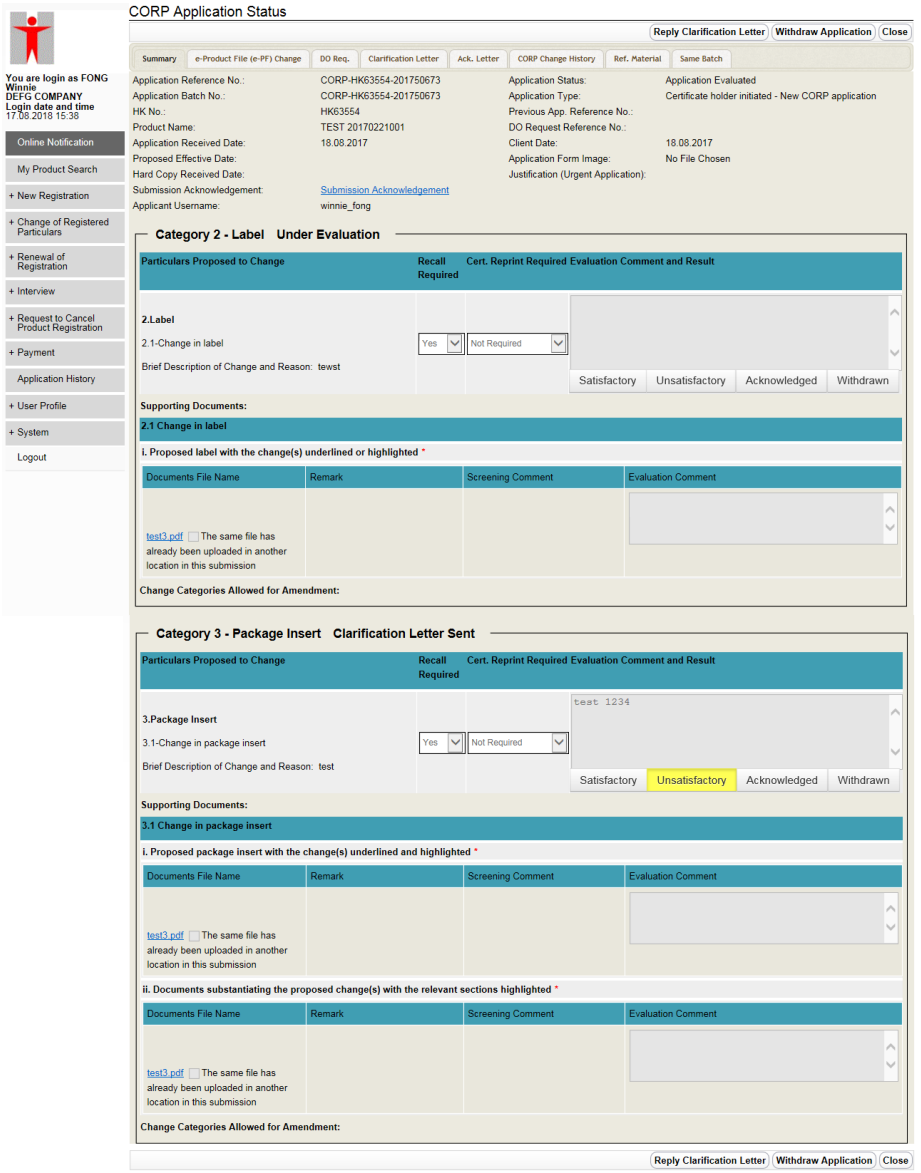


Step 2:

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



- The system will redirect to the CORP application page.

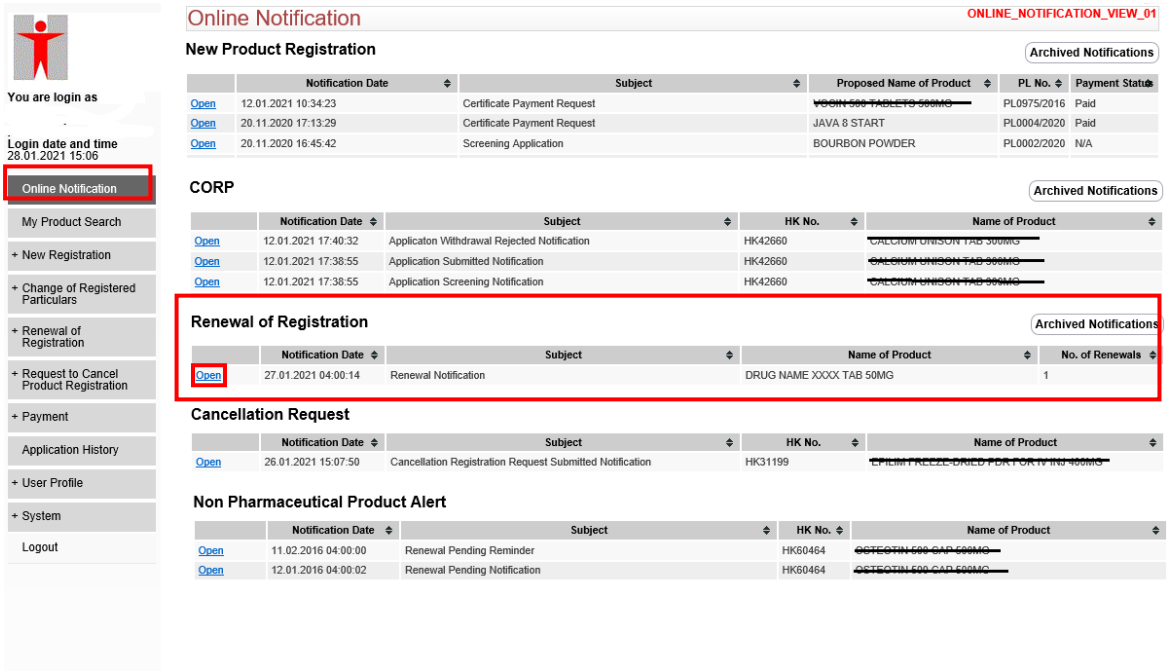


2.3.3 Renewal of Registration Online Notification

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

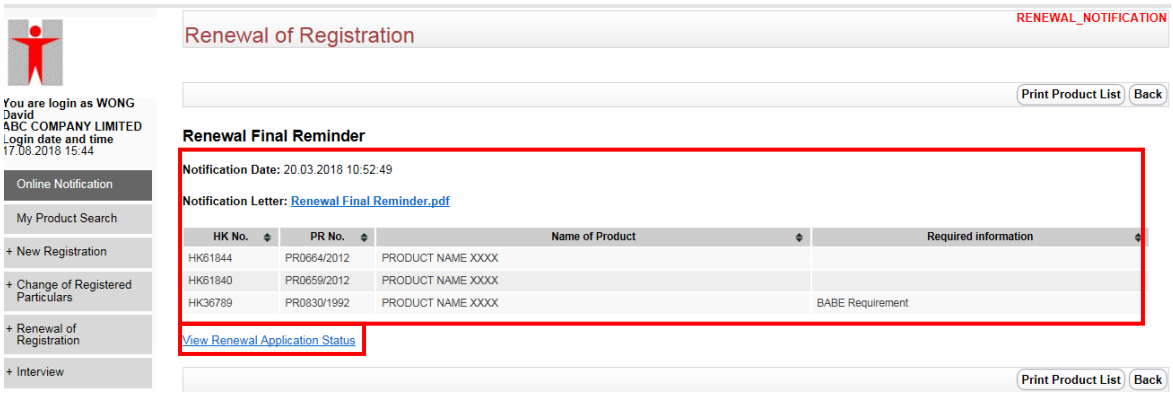
Step 1:

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

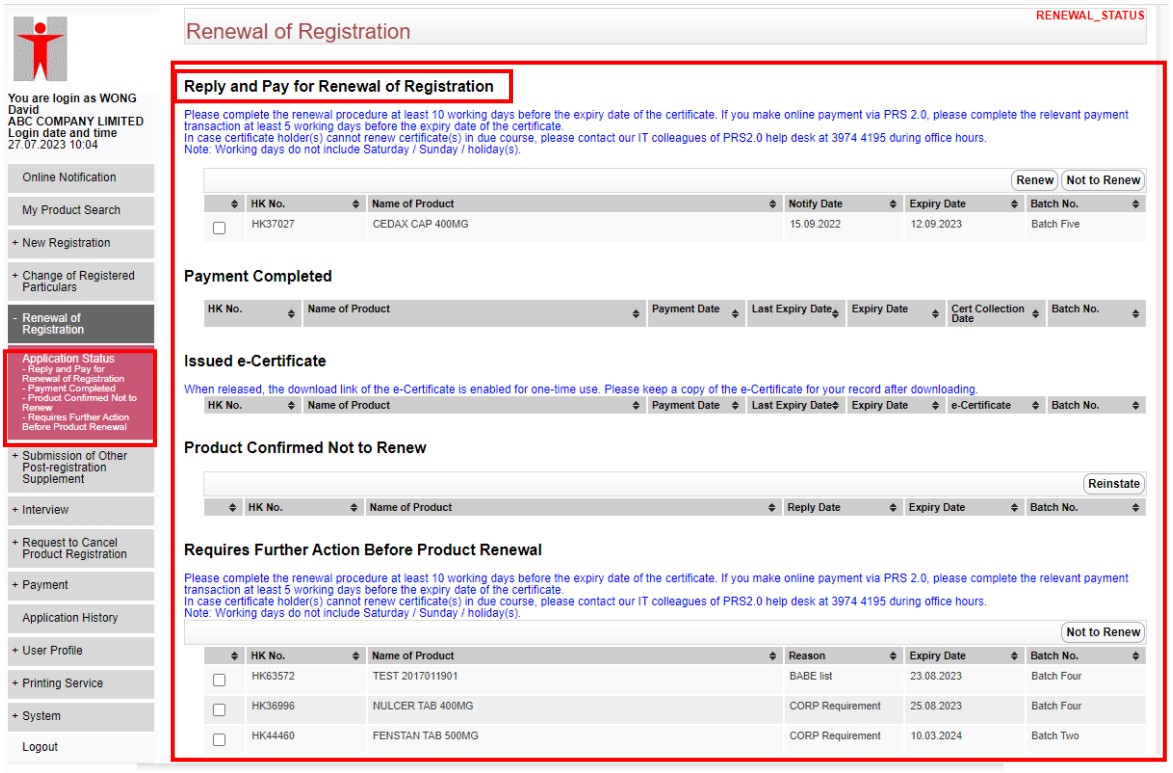

You are login as
Login date and time
28.01.2021 15:06
Online Notification
My Product Search
+ New Registration
+ Change of Registered Particulars
+ Renewal of Registration
+ Request to Cancel Product Registration
+ Payment
Application History
+ User Profile
+ System
Logout
Online Notification
ONLINE_NOTIFICATION_VIEW_01
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
PL0975/2016
Paid
20.11.2020 17:13:29
Certificate Payment Request
JAVA 8 START
PL0004/2020
Paid
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
12.01.2021 17:40:32
Applicaton Withdrawal Rejected Notification
HK42660
12.01.2021 17:38:55
Application Submitted Notification
HK42660
12.01.2021 17:38:55
Application Screening Notification
HK42660
Renewal of Registration
Archived Notifications
Notification Date
Subject
Name of Product
No. of Renewals
27.01.2021 04:00:14
Renewal Notification
DRUG NAME XXXX TAB 50MG
1
Cancellation Request
Notification Date
Subject
HK No.
Name of Product
26.01.2021 15:07:50
Cancellation Registration Request Submitted Notification
HK31199
Non Pharmaceutical Product Alert
Notification Date
Subject
HK No.
Name of Product
11.02.2016 04:00:00
Renewal Pending Reminder
HK60464
12.01.2016 04:00:02
Renewal Pending Notification
HK60464

Step 2:

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



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

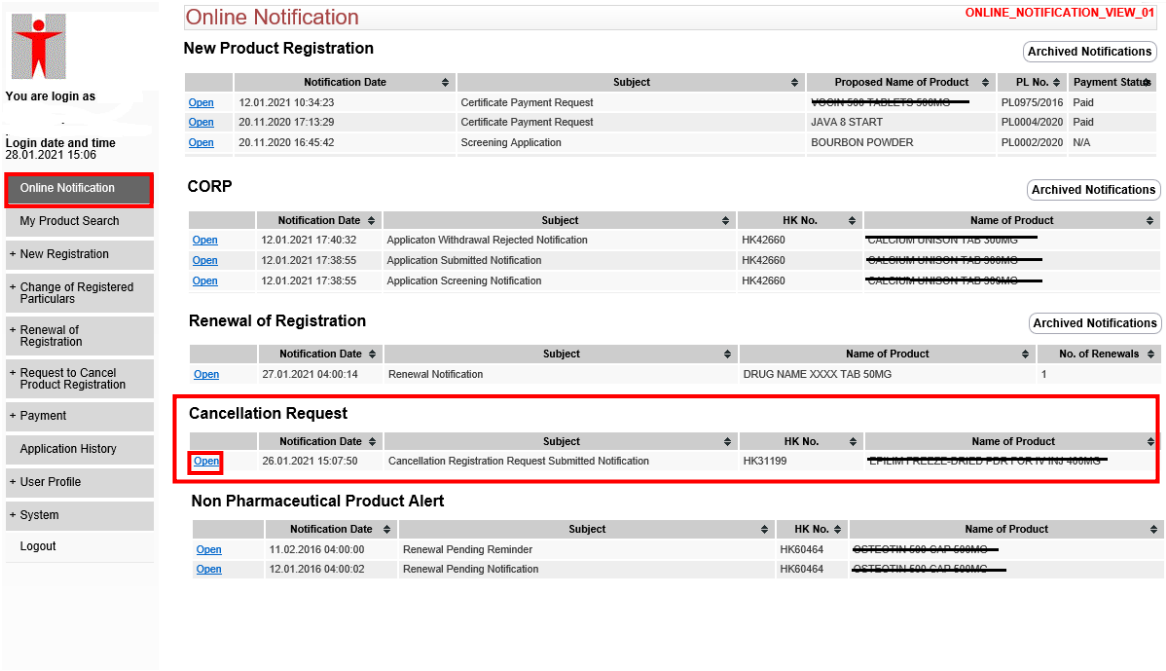


2.3.4 Cancellation Request Online Notification

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

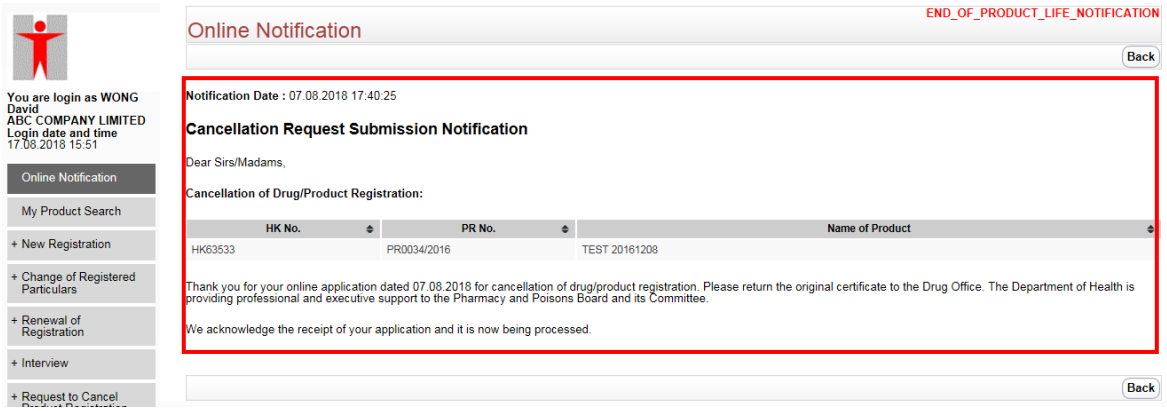
Step 1:

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



Step 2:

- View the notification detail.

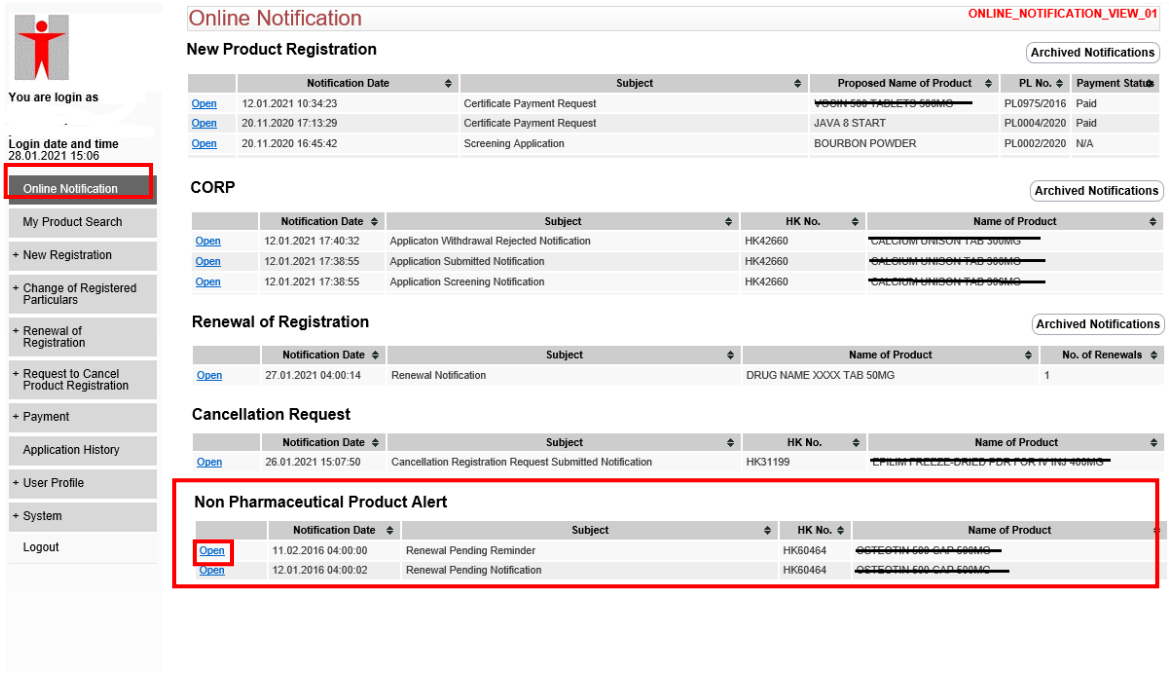


2.3.5 Non Pharmaceutical Product Alert Online Notification

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

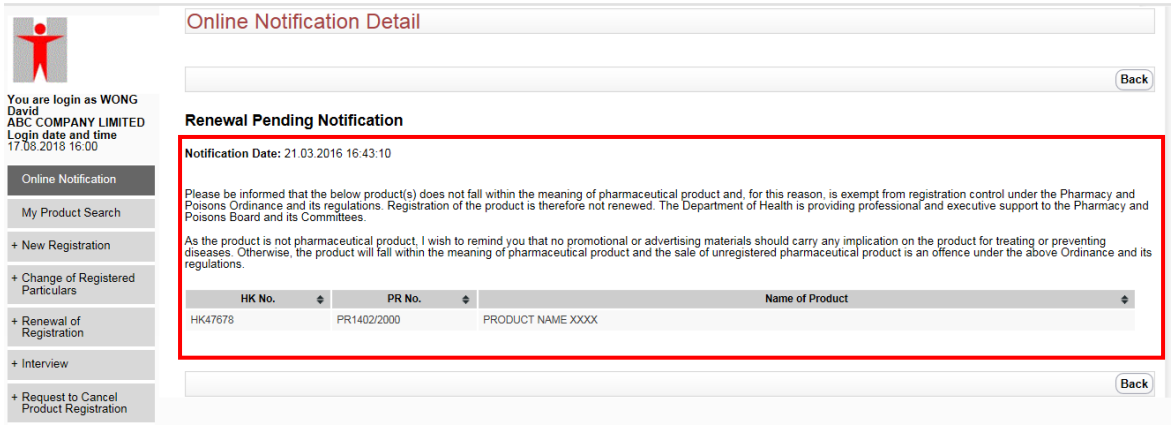
Step 1:

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



Step 2:

- View the notification detail.



2.4 MY PRODUCT SEARCH

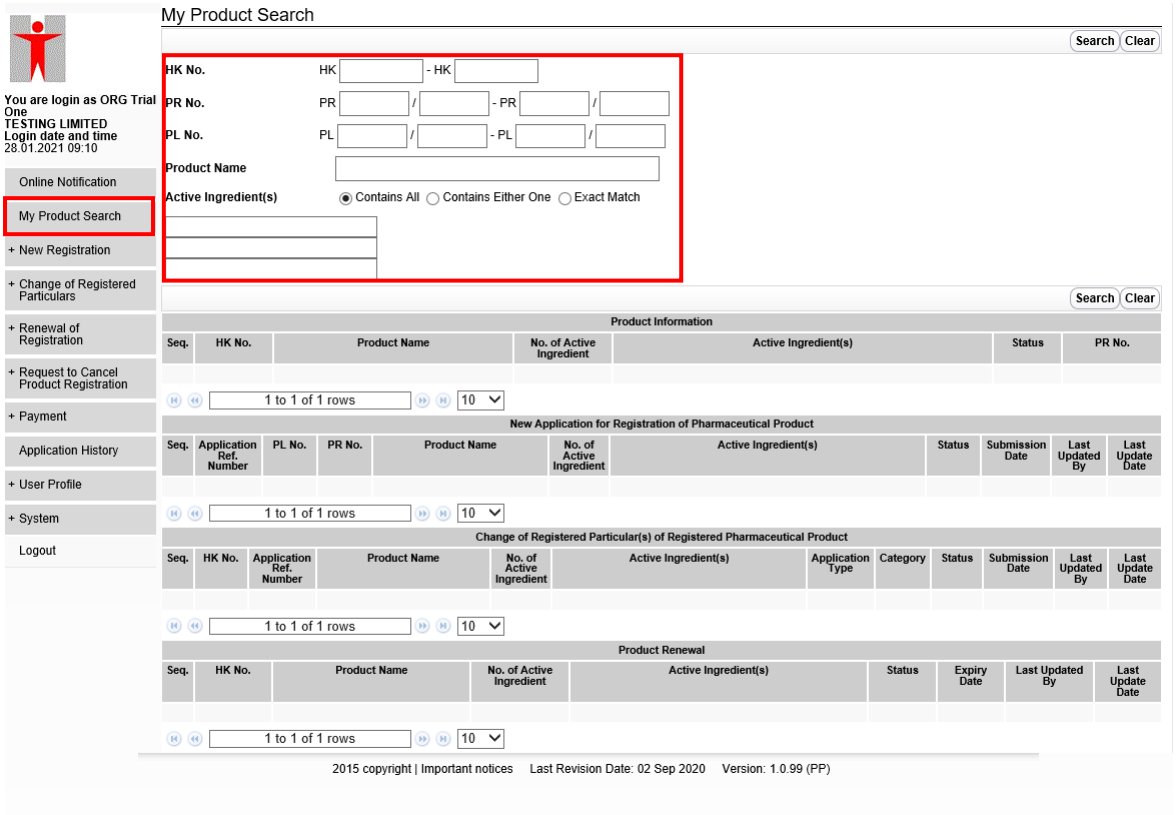
My Product Search function allows user to search four categories of information under his access control base on different searching criteria:

- 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.

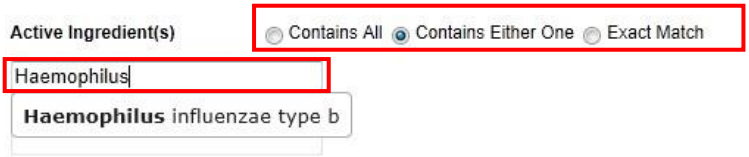
- Input the searching criteria, including range of HK No., range of PR No. (e.g. PR 0060/2015), range of PL No. (e.g. PL 0001/2015), the keyword of product name or the active ingredient(s) of the product (any of these).



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.



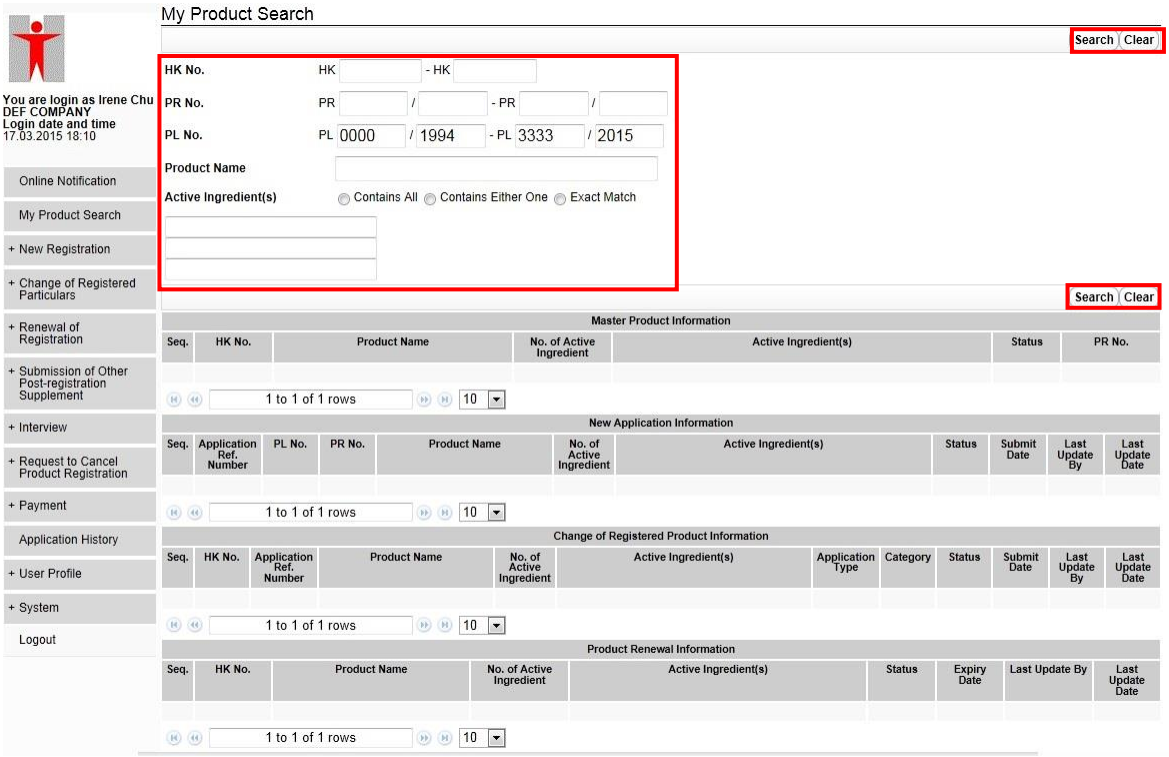
- For “Contains All”, system will only search the product(s) which contains all of the below ingredient(s) (maximum 3 ingredients).

- 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).

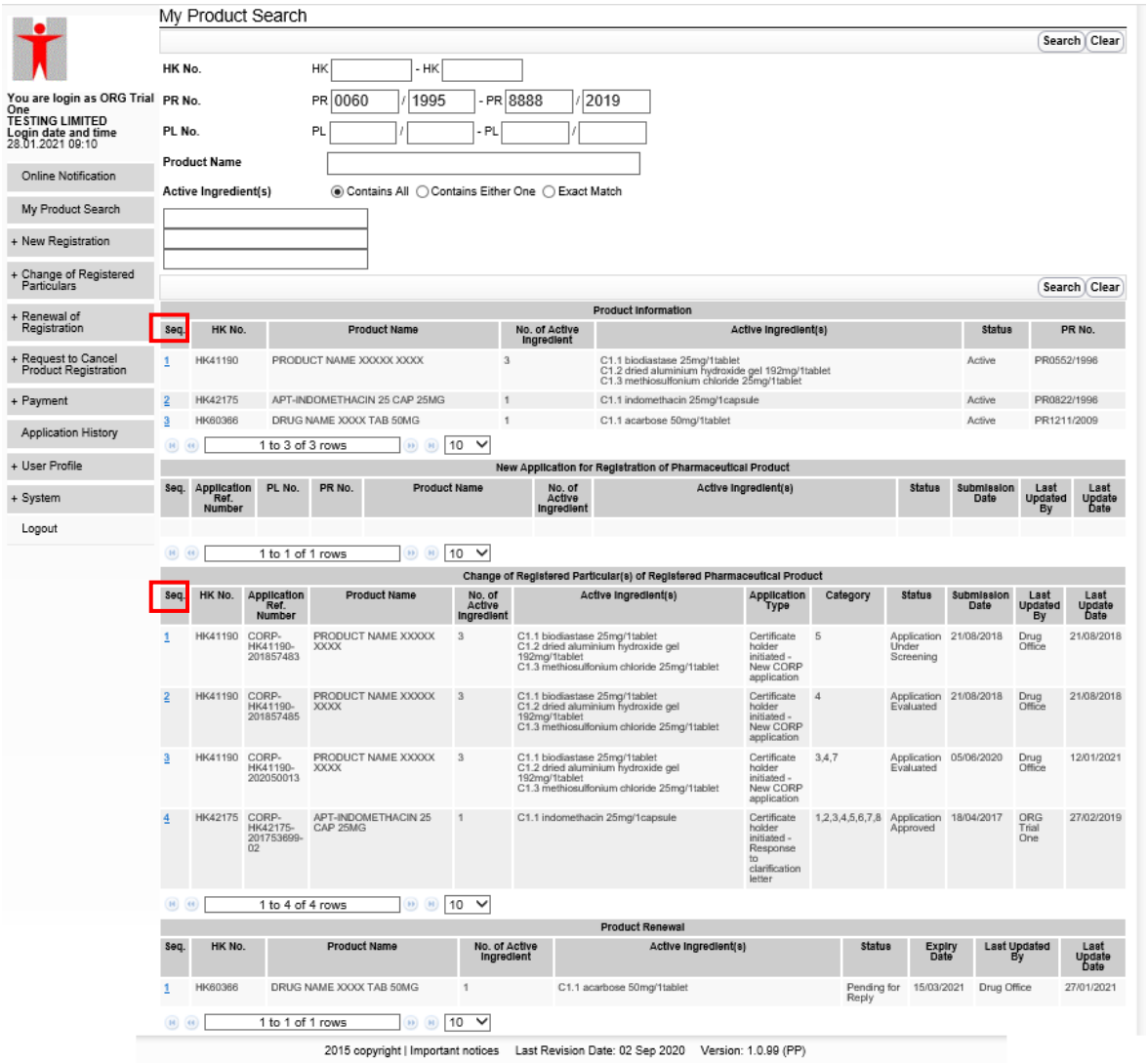
Step 3:

- Click the button “Search” to search, based on the searching criteria, or click the button “Clear” to remove all the searching criteria.



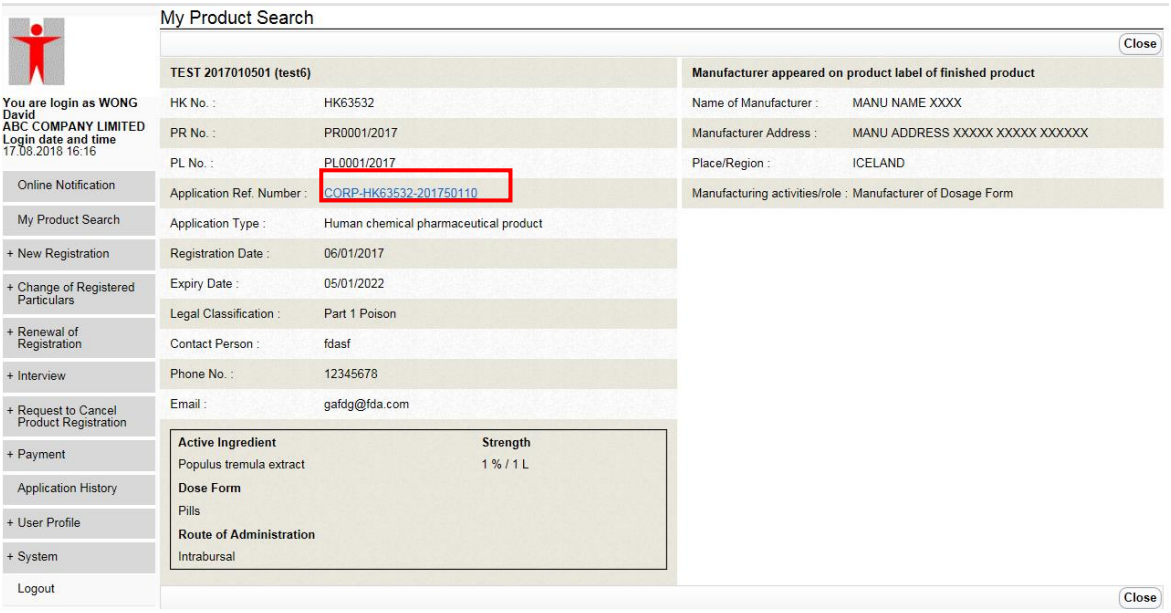
Step 4:

- 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.

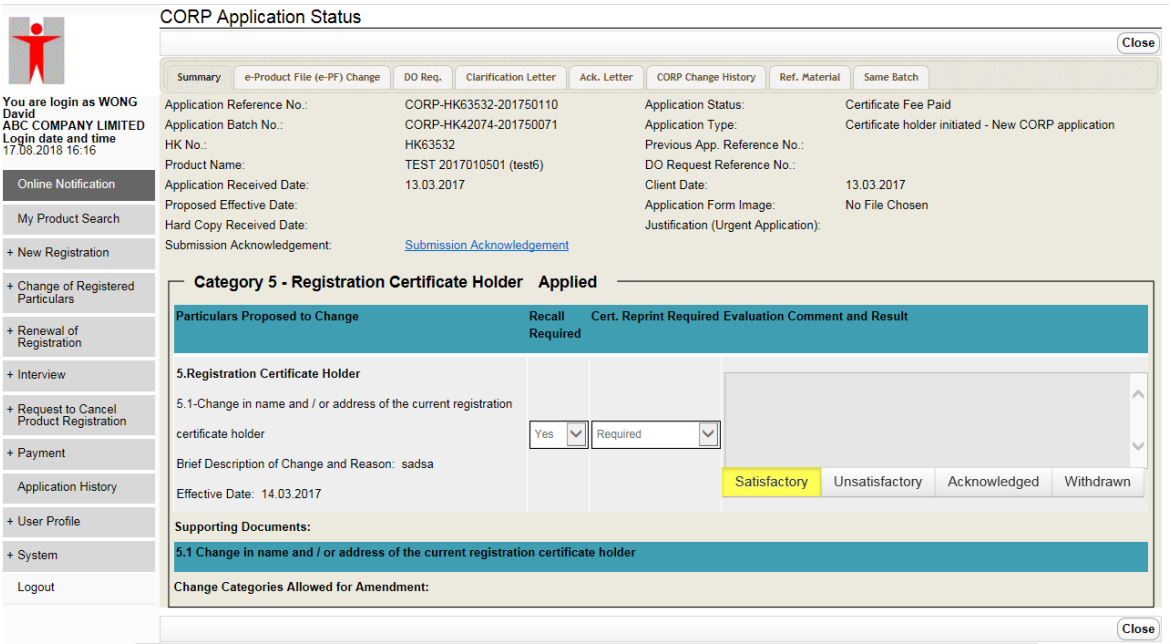


Step 5:

- 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.



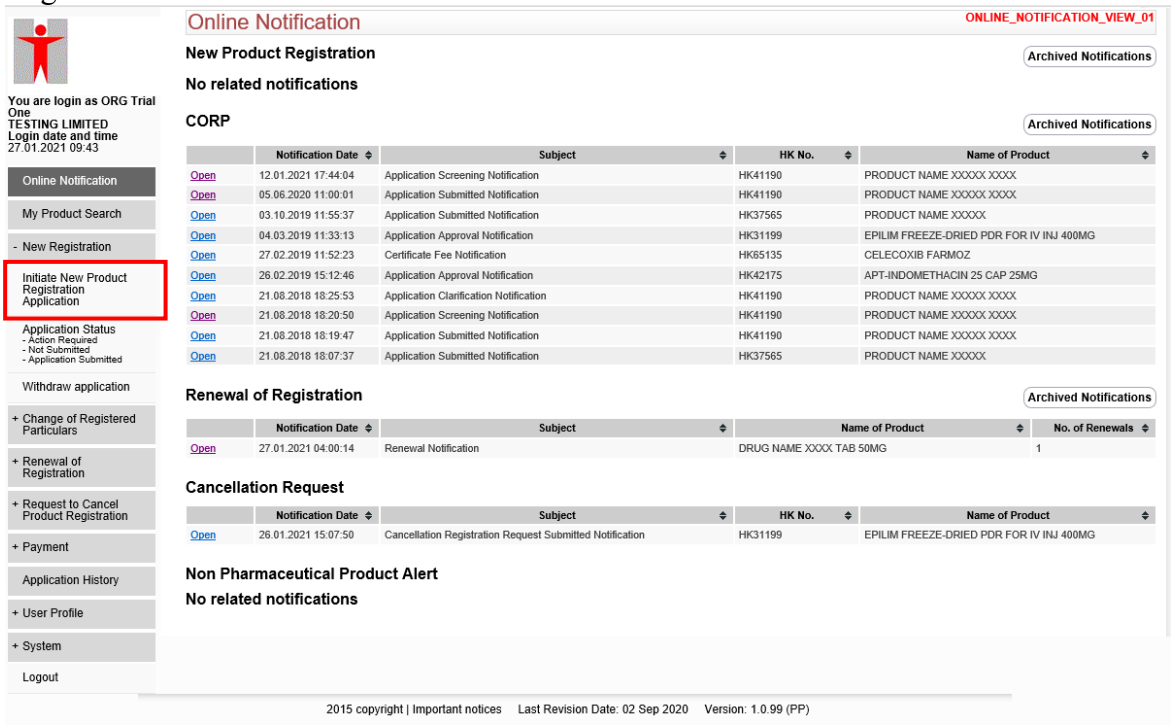
- The system will redirect to the corresponding application detail page.



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.



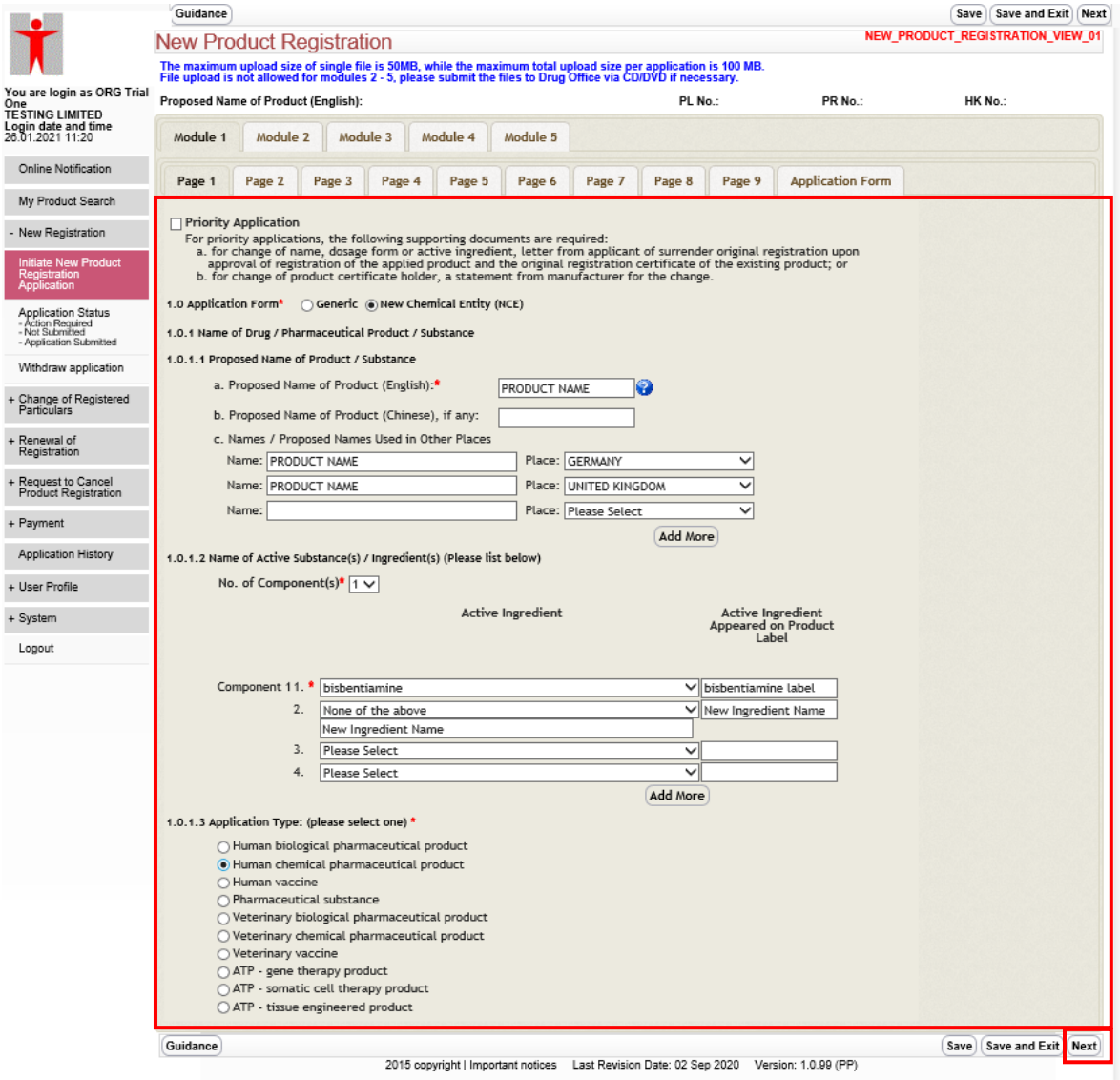
Step 2: The page is redirected to new application module in CTD format. It contains 5 modules:

- 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.

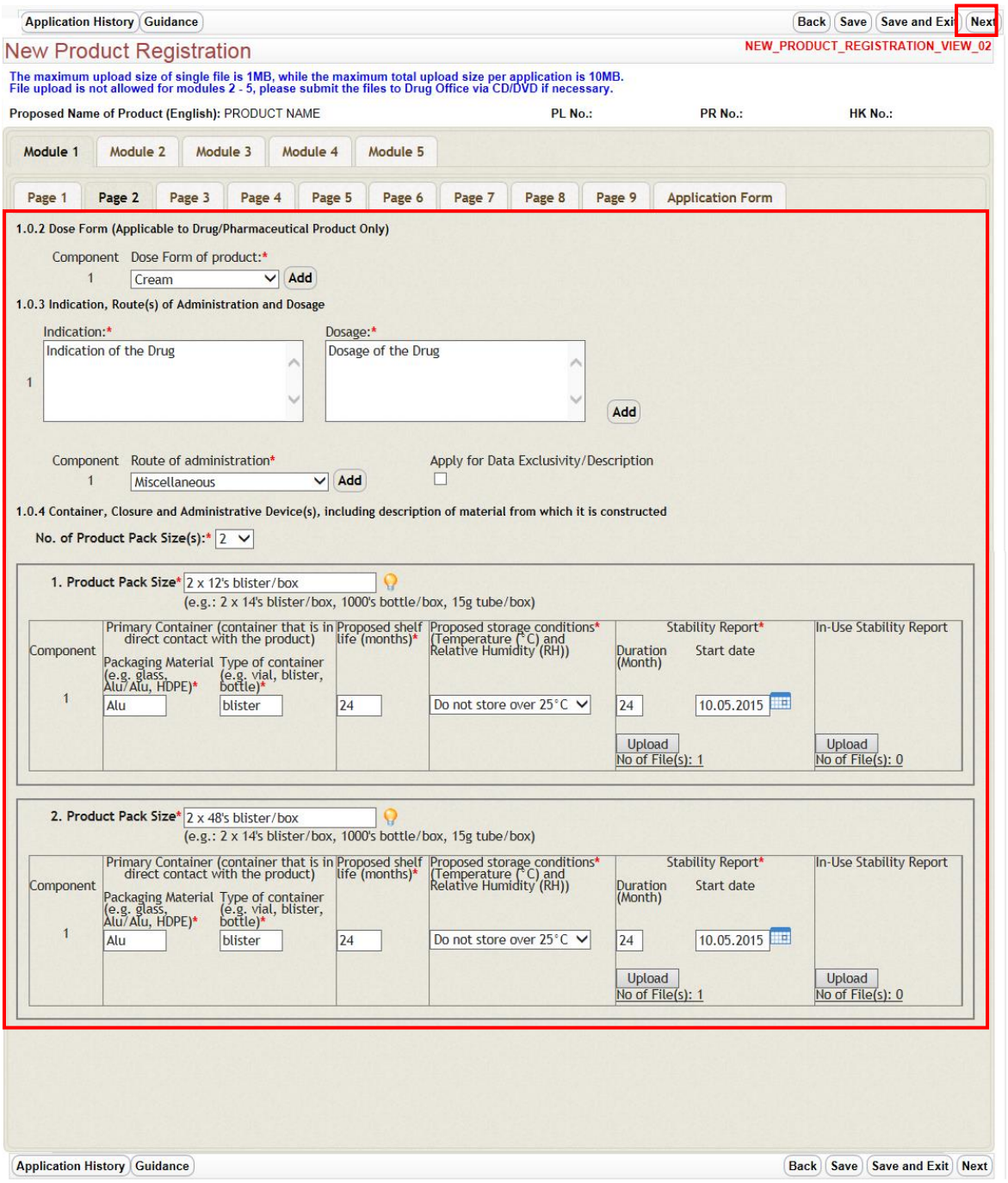
- Select the application form (generic or NCE).
- Enter the proposed name of product. (in Capital letters)
- Input the name / proposed name used in other place and select the place.
- Select the no of component (Maximum: 5) and select the active ingredient, at least one component with 1 active ingredient is required.

- Select the application type.



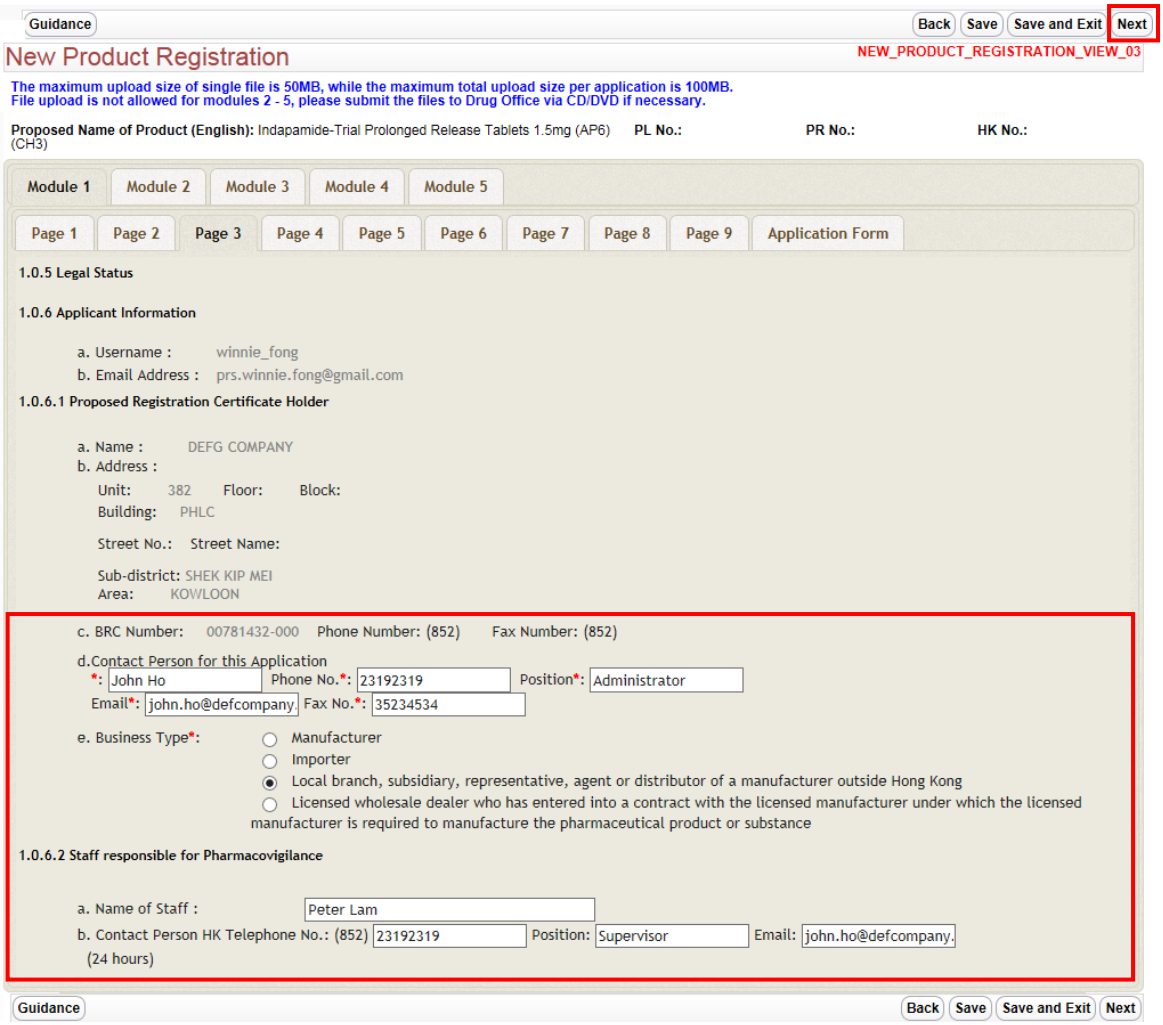
Step 3: Filling in CTD Module 1 Page 2 and click the “Next” button.

- 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.



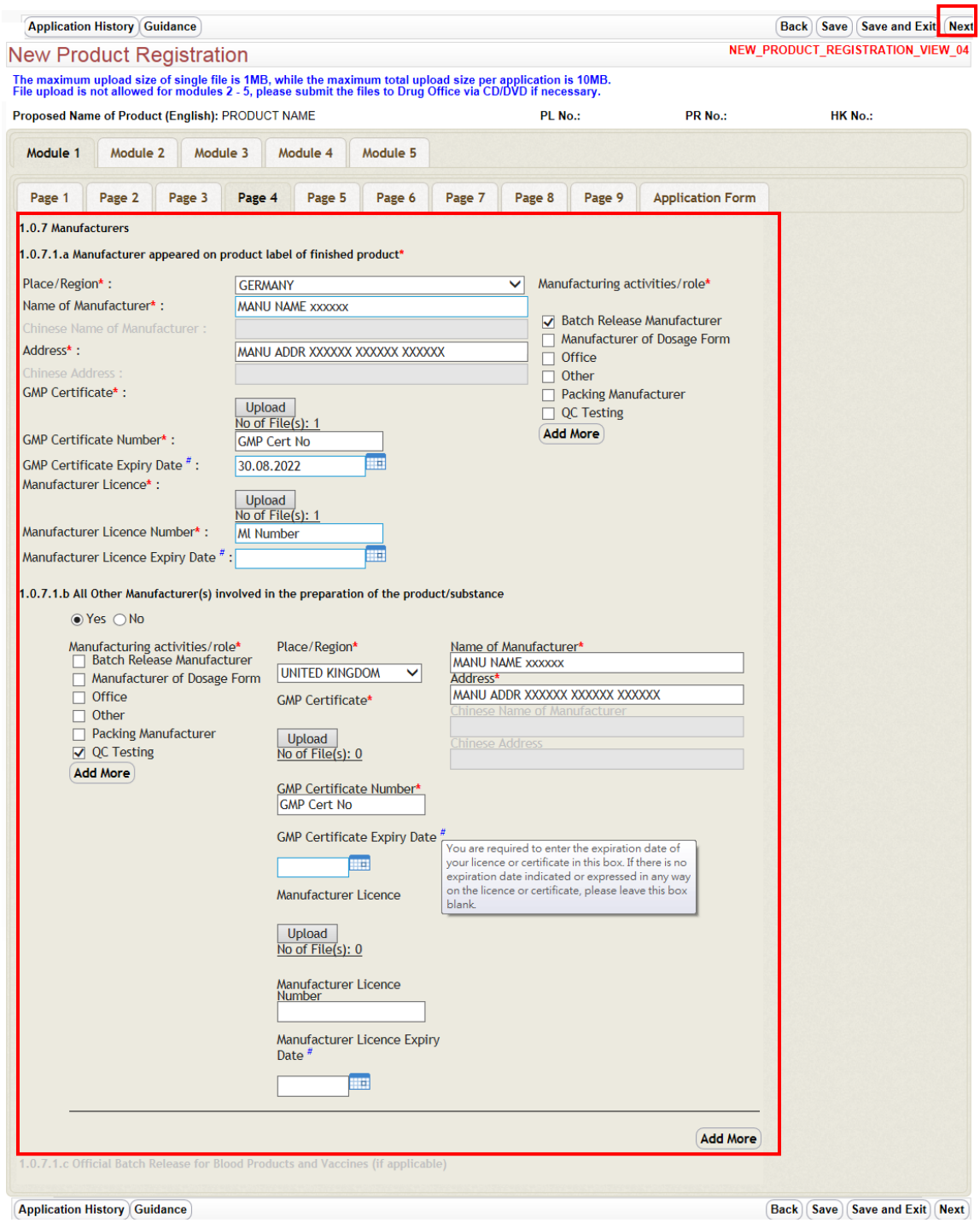
Step 4: Filling in CTD Module 1 Page 3 and click the “Next” button.

- 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.



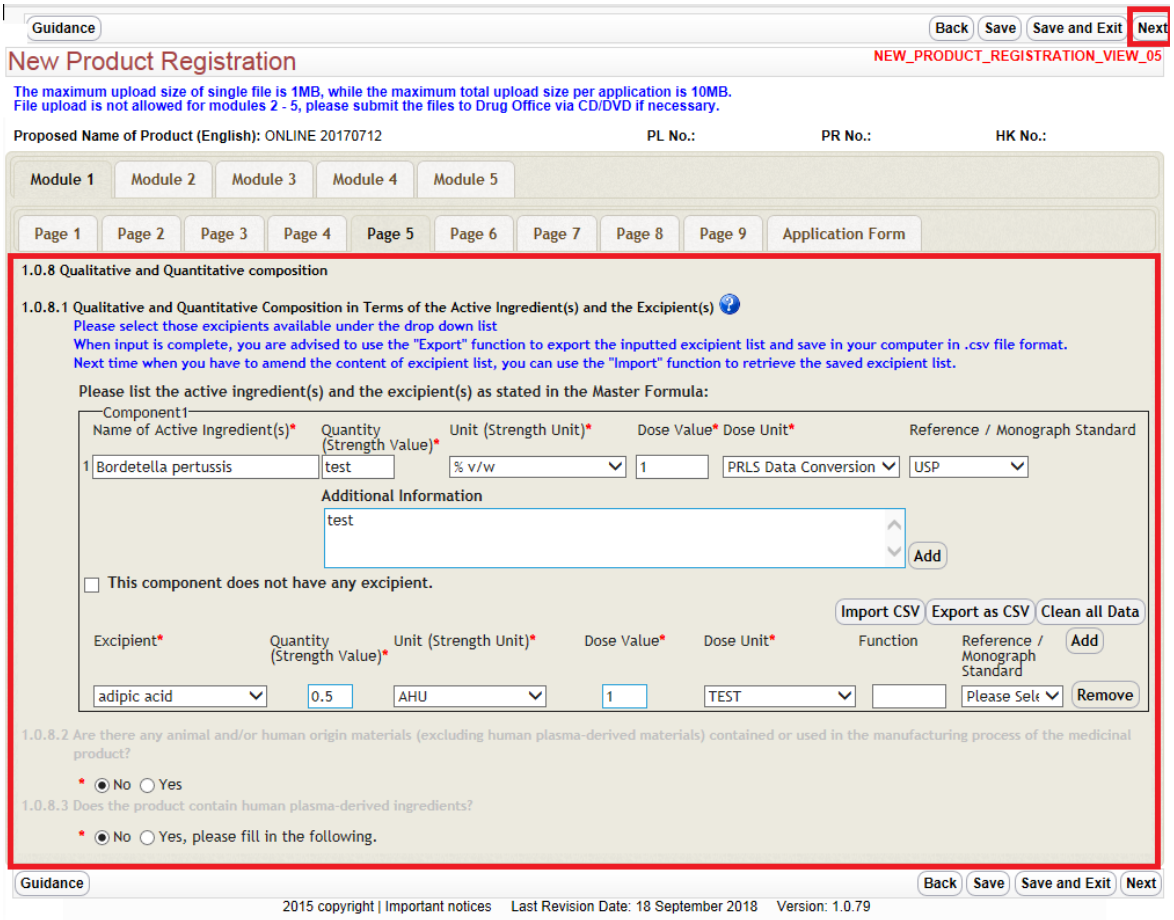
Step 5: Filling in CTD Module 1 Page 4 and click the “Next” button.

- 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.


Application History
Guidance
Back
Save
Save and Exit
Next
New Product Registration
NEW_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 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
1.0.7 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
Add More
1.0.7.1.c Official Batch Release for Blood Products and Vaccines (if applicable)
Application History
Guidance
Back
Save
Save and Exit
Next

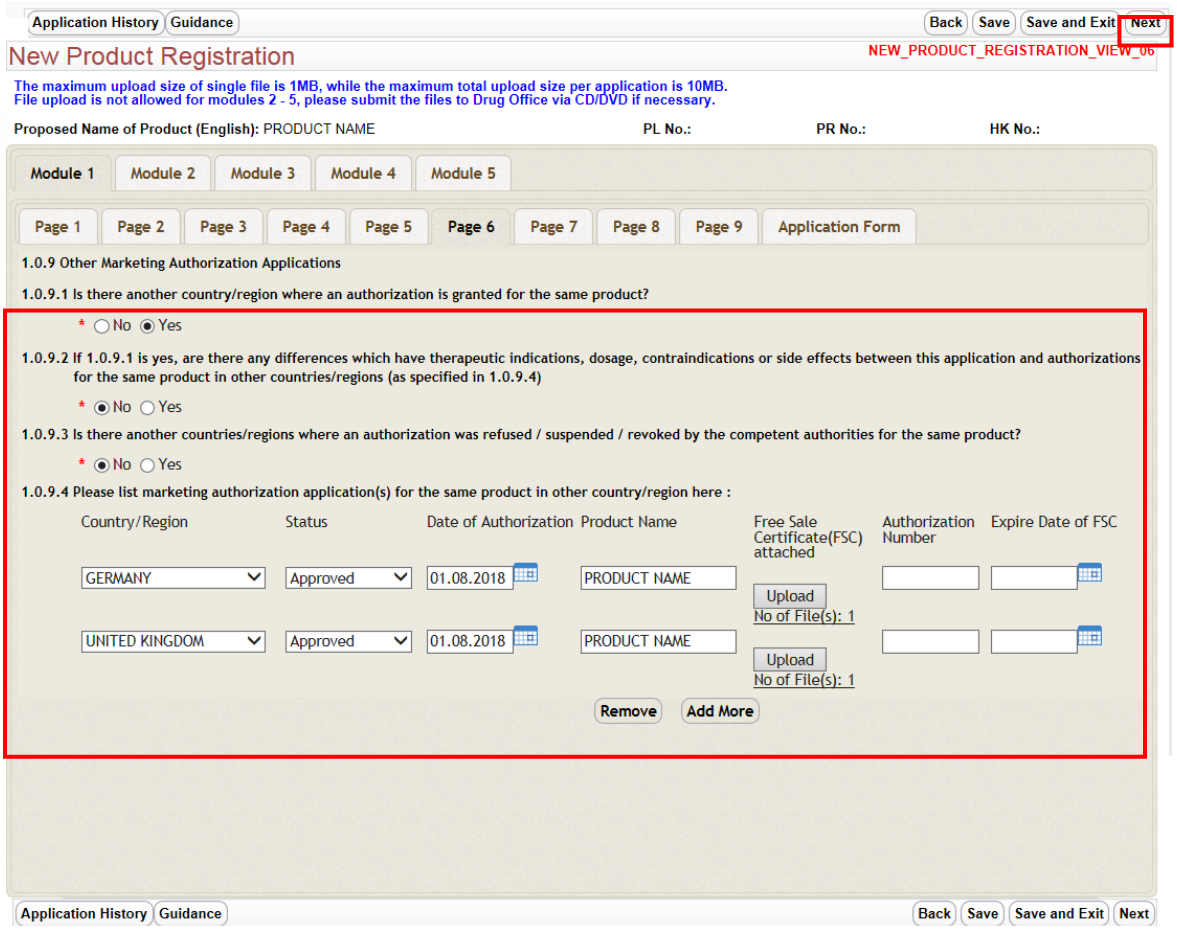
Step 6: Filling in CTD Module 1 Page 5 and click the “Next” button.

- 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.



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.



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

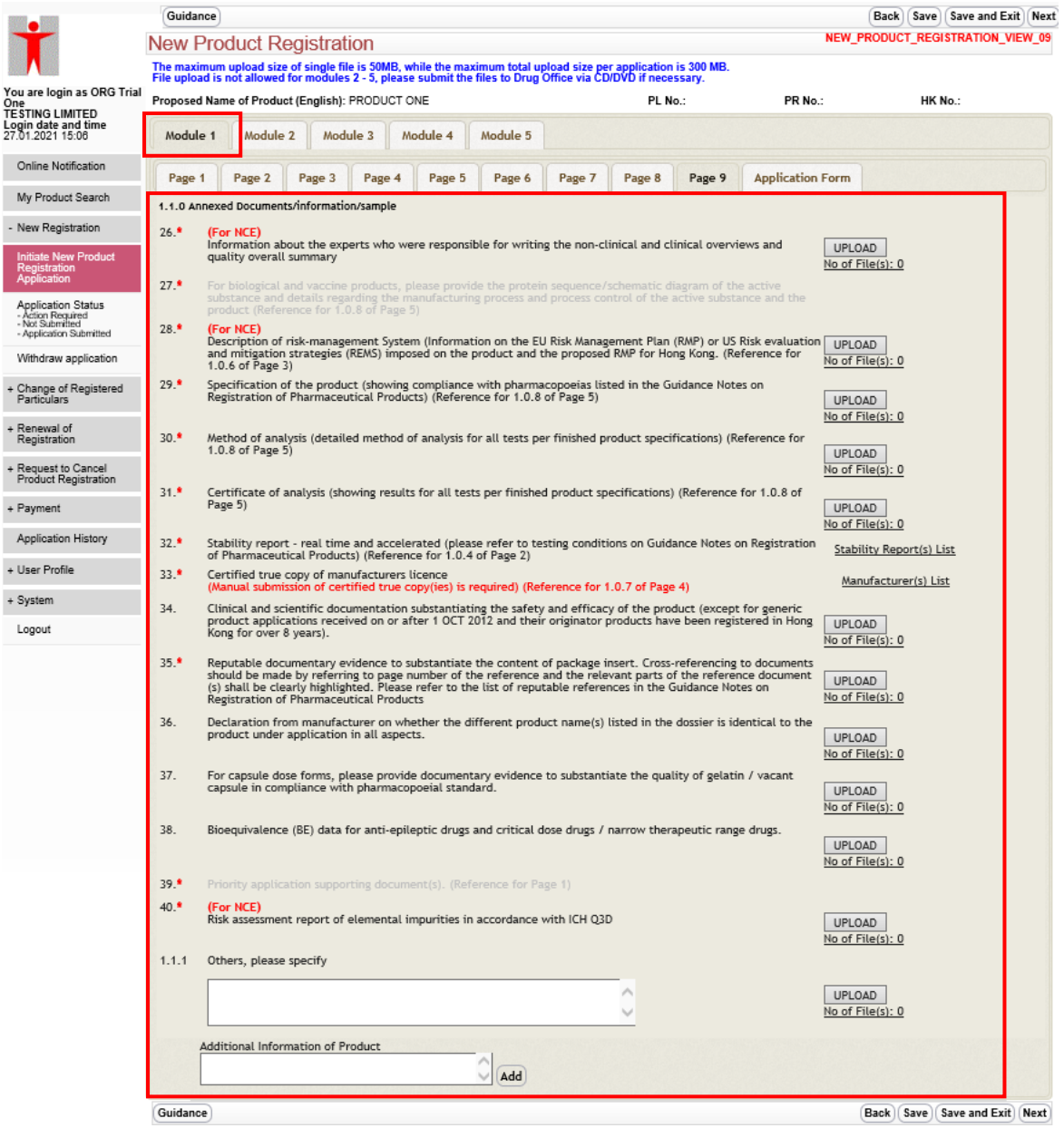
- Upload the requested file(s) accordingly. For each file list, multiple files can be uploaded.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.

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.

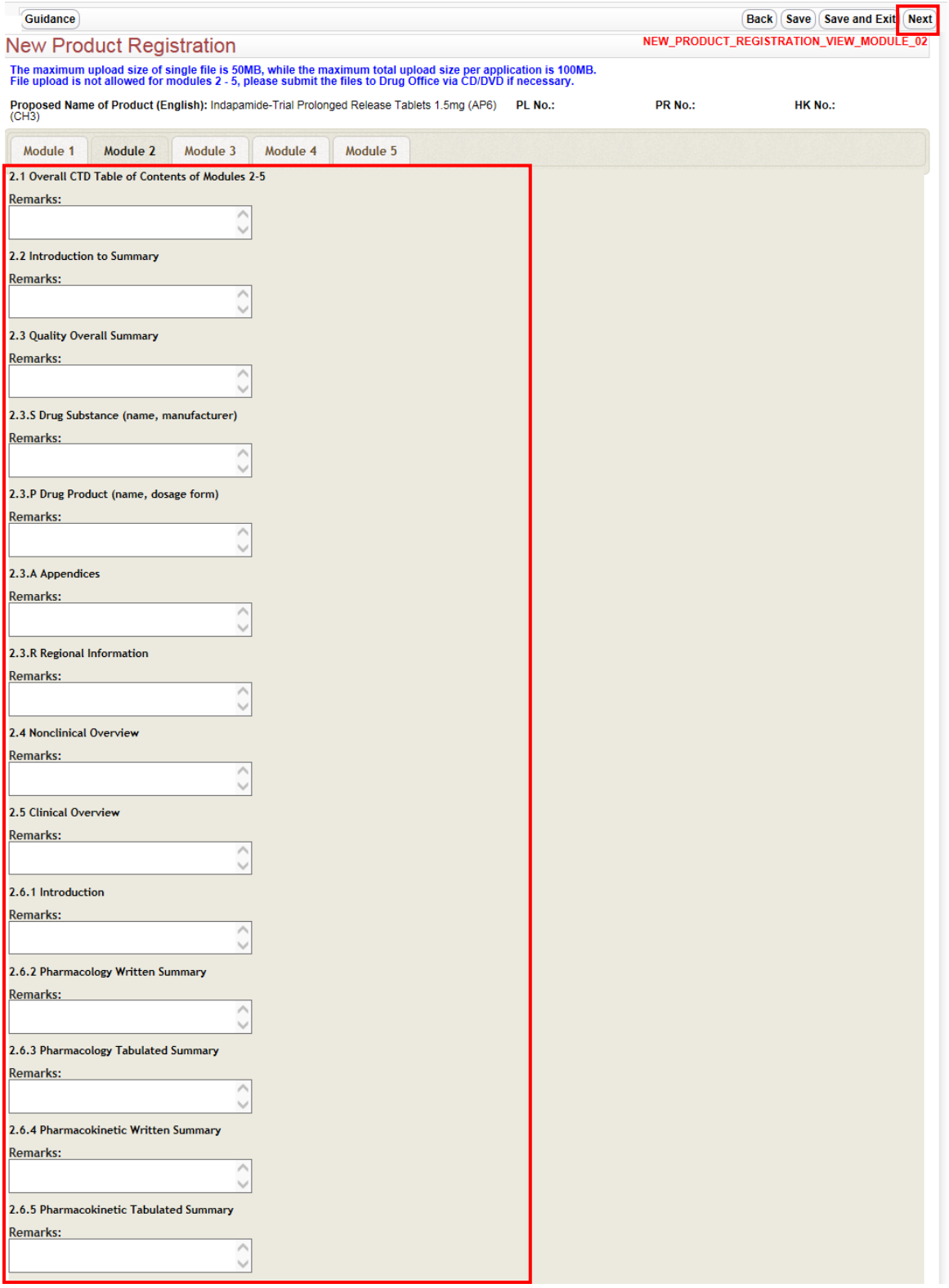
Step 10: Filling in CTD Module 1 Page 9 and click the “Module 2” tab. Modules 2 to 5 are specific modules and are not mandatory for a generic product.

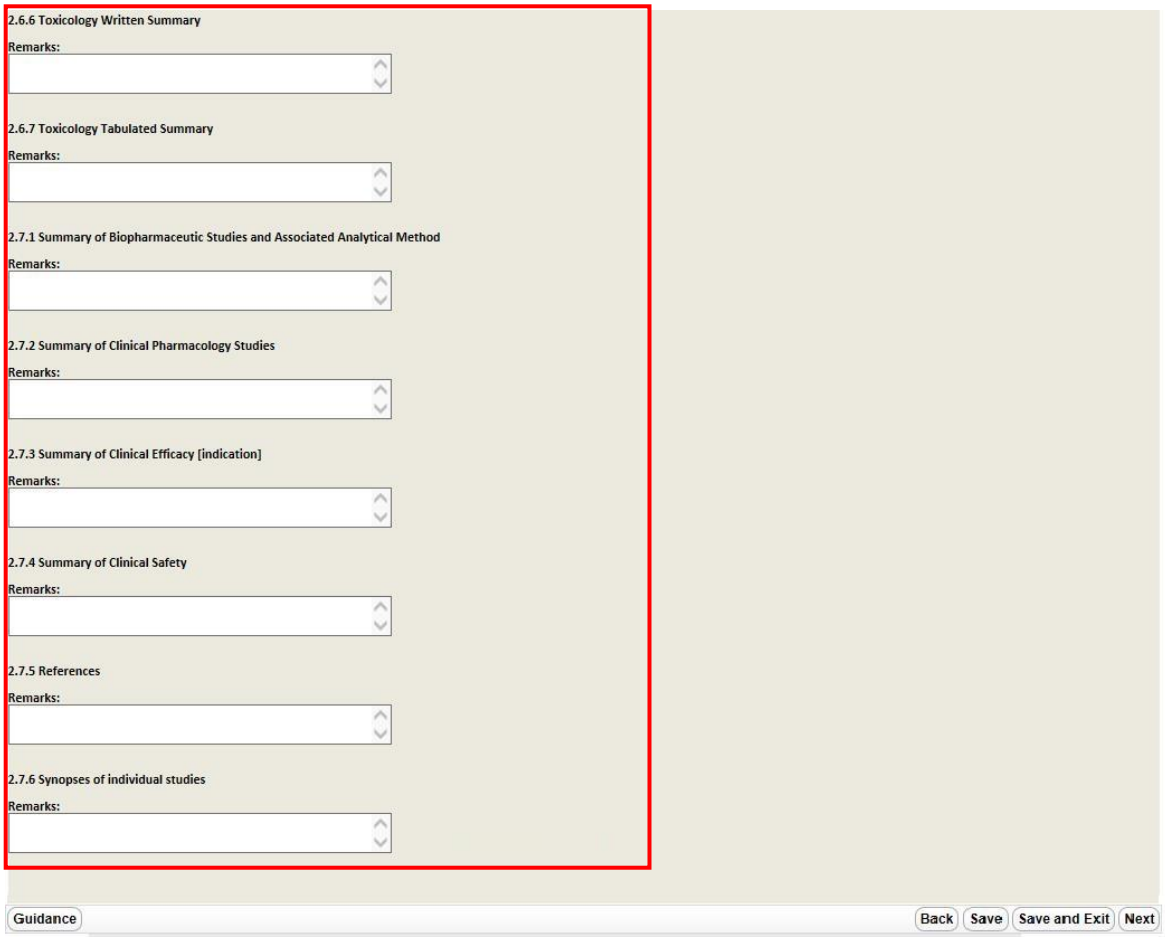
- Upload the requested file(s) accordingly. For each file list, multiple files can be uploaded.
- Note: Asterisk (*) items are mandatory fields to the submission of the application form.



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

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




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
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Save
Save and Exit
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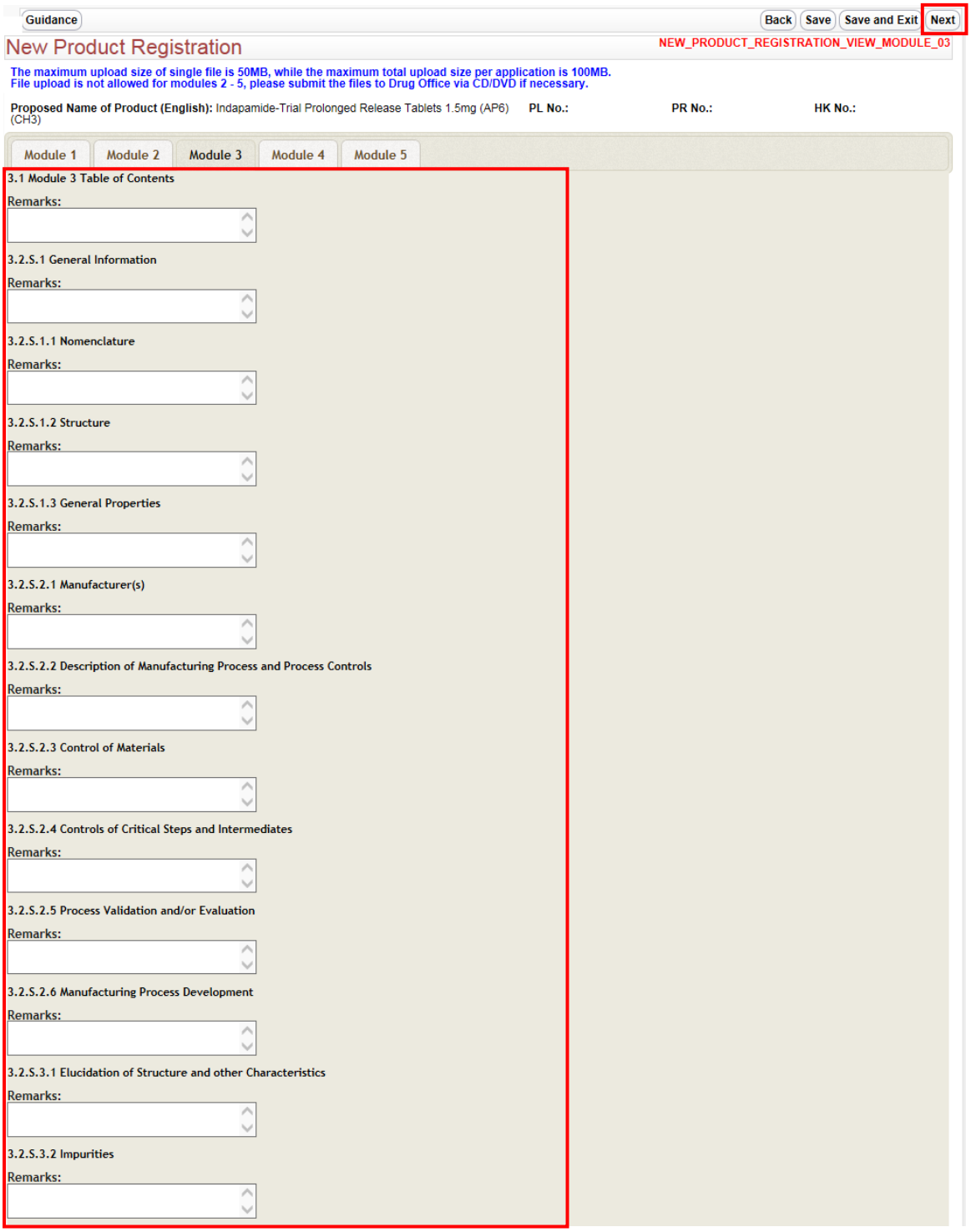
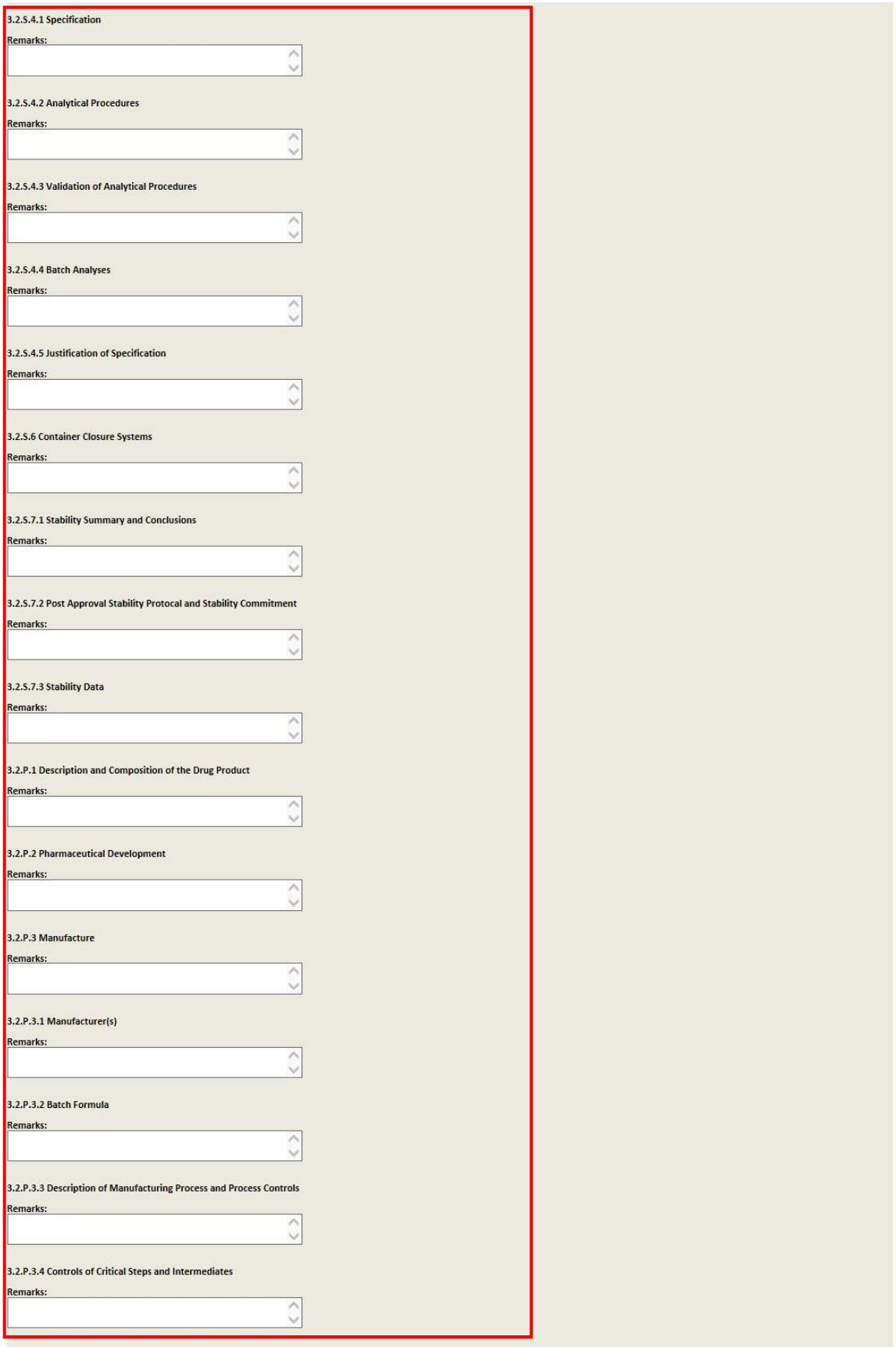
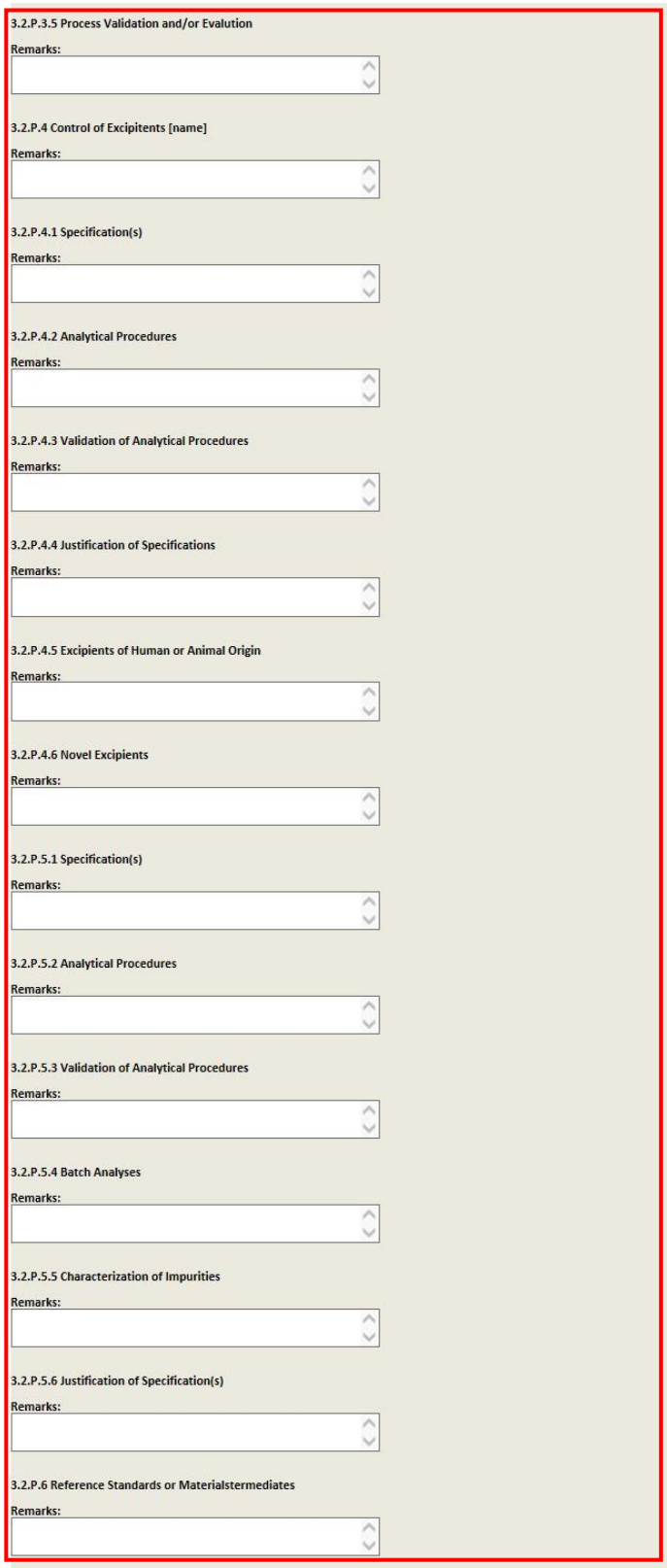
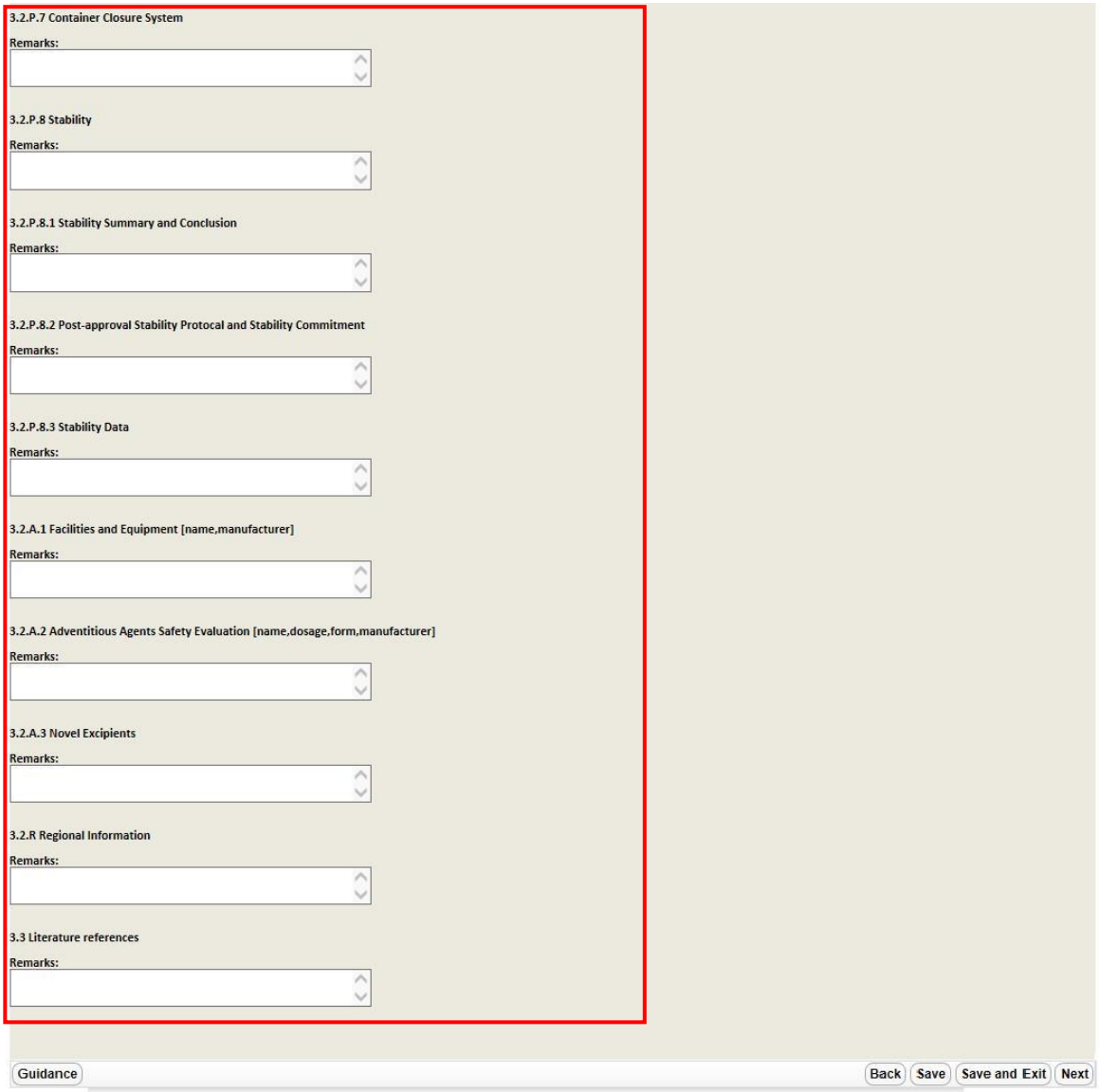
Step 12: Filling in CTD Module 3 and click the “Next” button.

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




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 Protocal 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 Evalution
Remarks:
3.2.P.4 Control of Excipitents [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 Materialstermediates
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 Protocal 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
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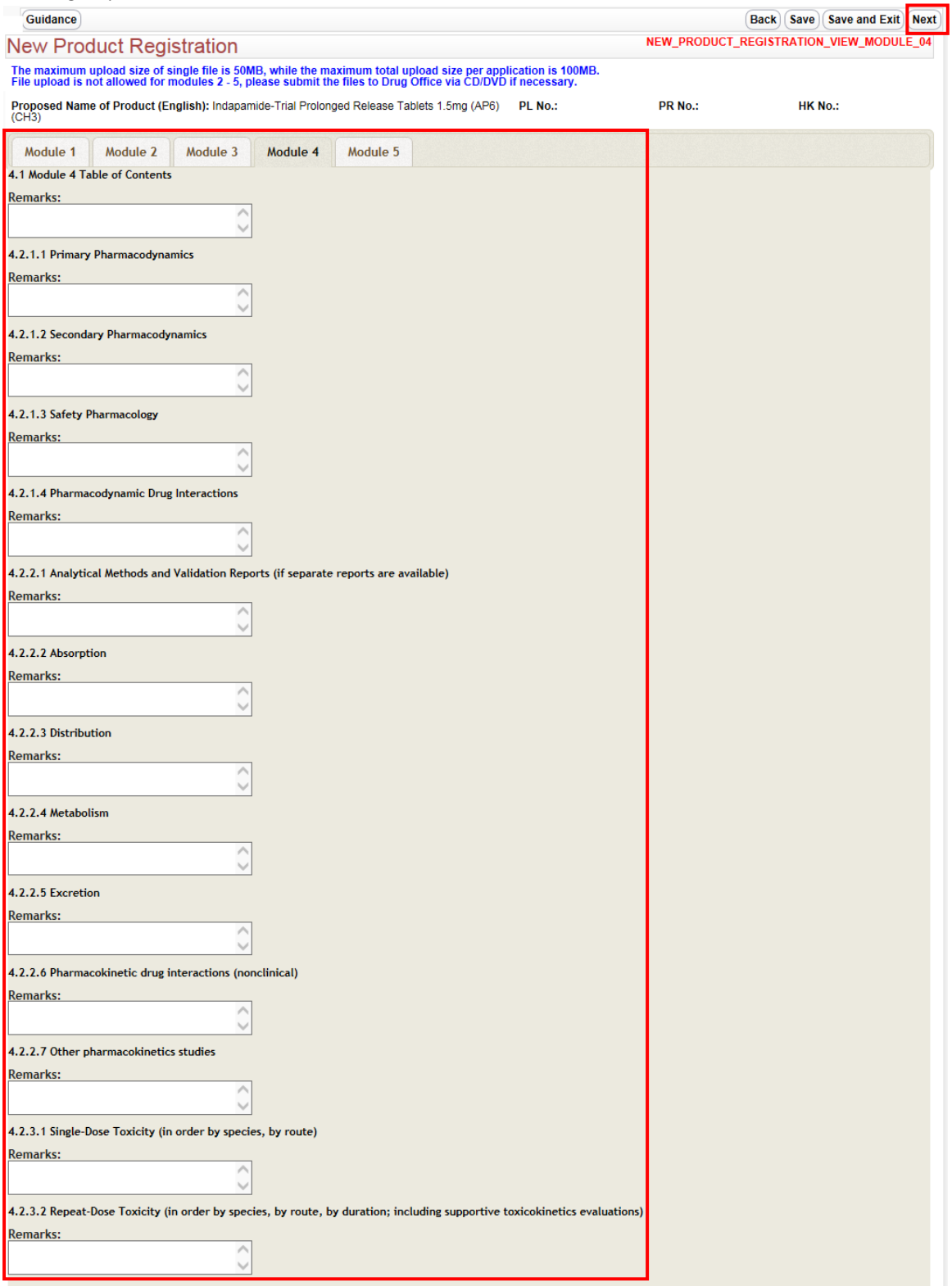
Step 13: Filling in CTD Module 4 and click the “Next” button.

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



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 Developmental 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

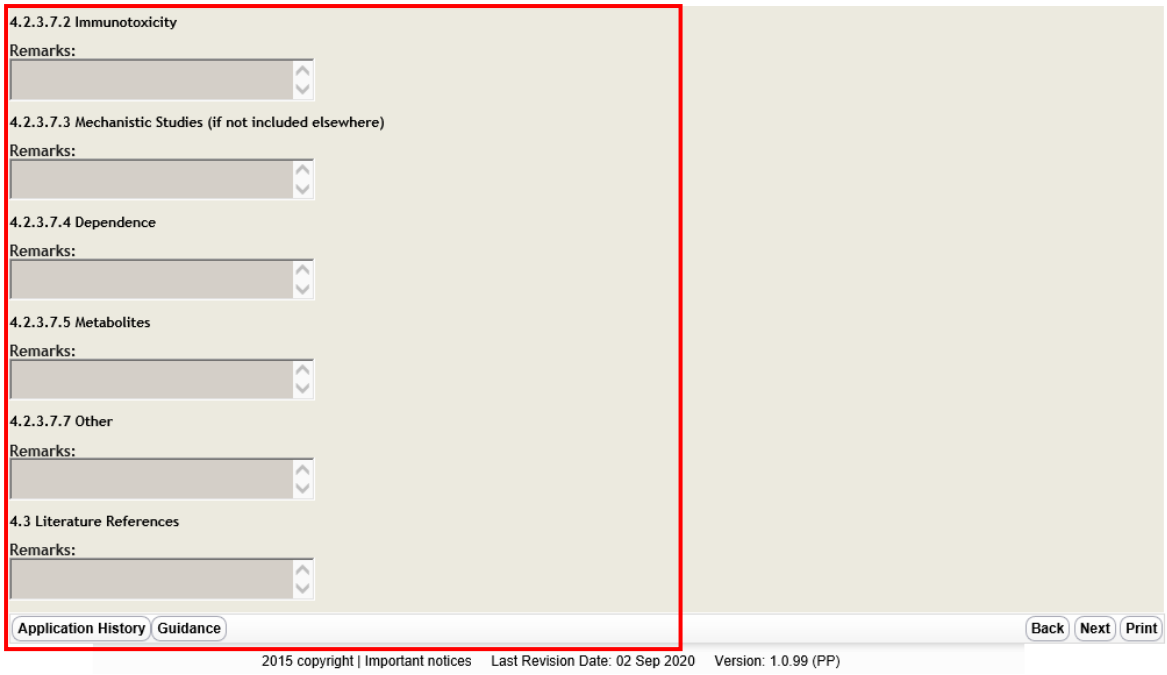
Remarks:

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:
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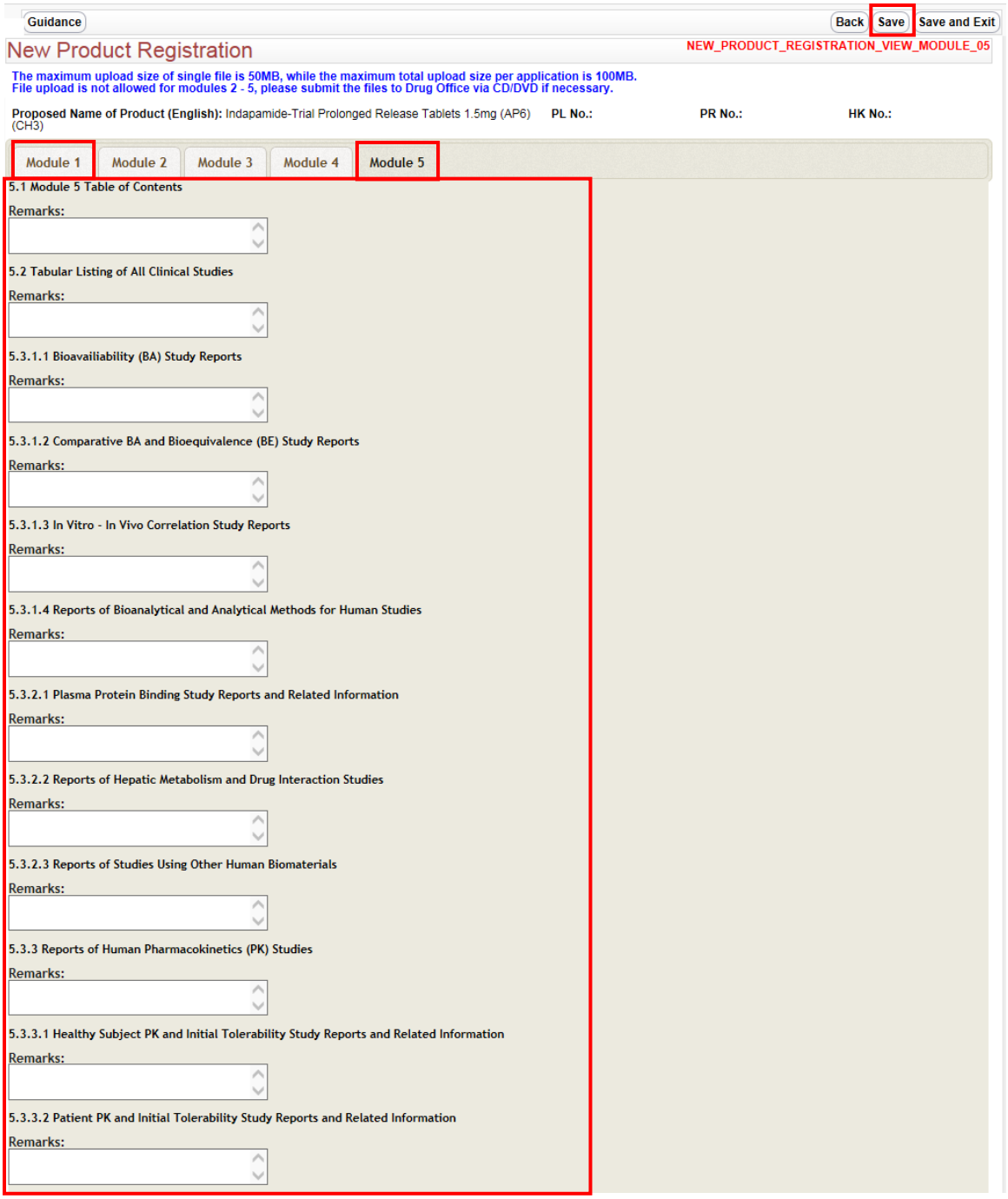
Last Revision Date: 02 Sep 2020
Version: 1.0.99 (PP)

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.




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
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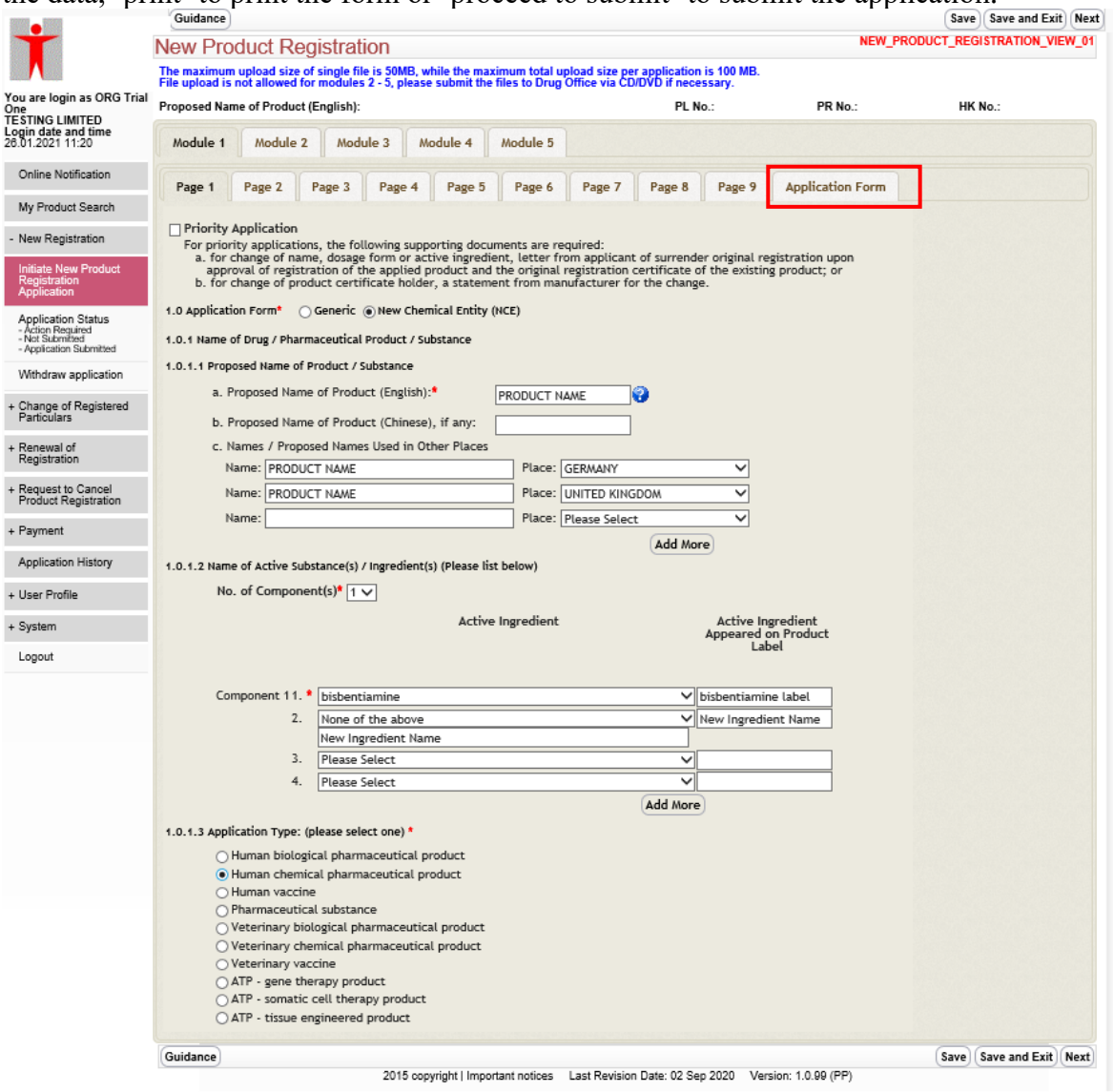
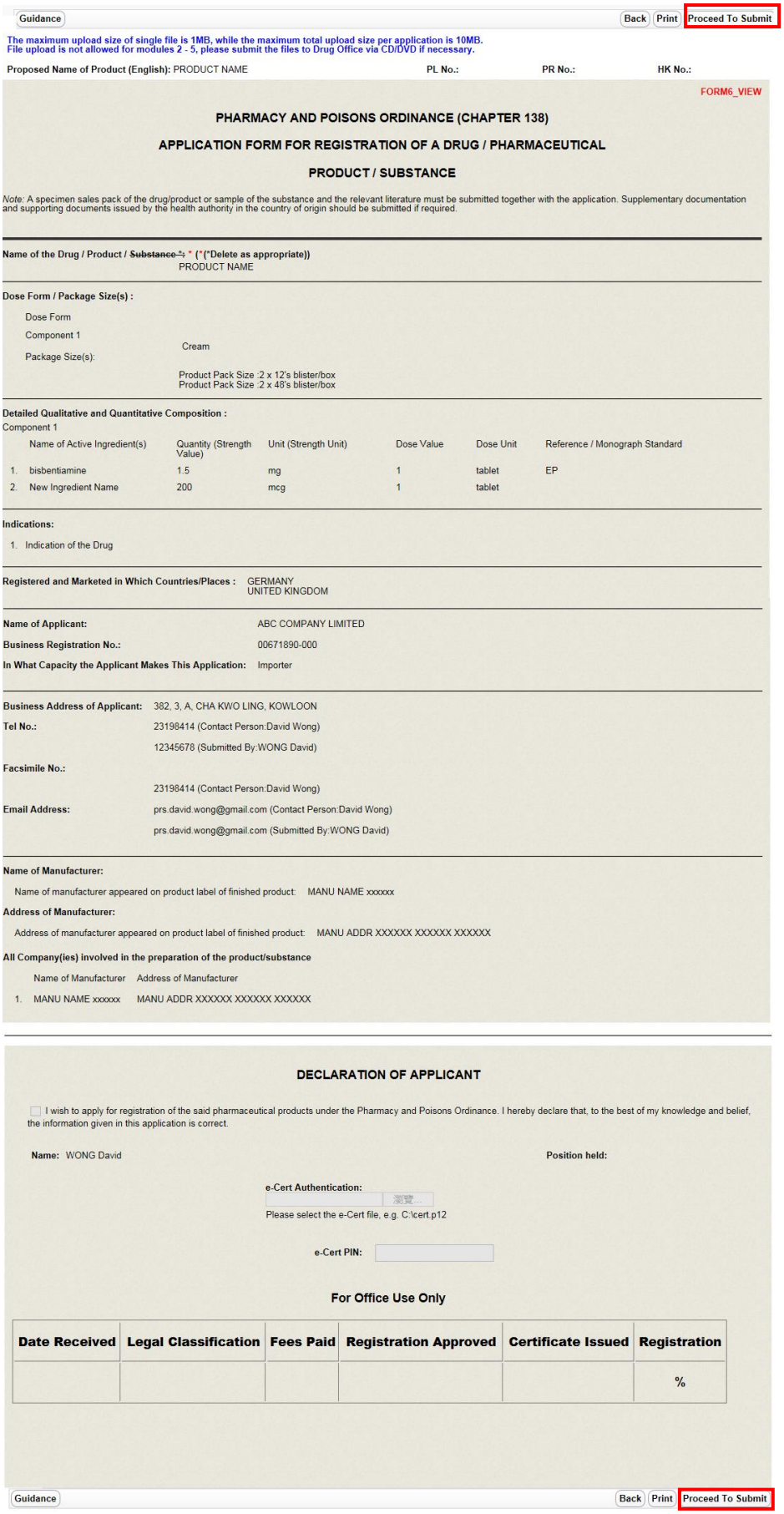
Last Revision Date: 02 Sep 2020
Version: 1.0.99 (PP)

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



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



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.:** **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 Cream
Package Size(s): 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.	bisbentiamine	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: 瀏覽...
Please select the e-Cert file, e.g. C:\cert.p12

e-Cert PIN:

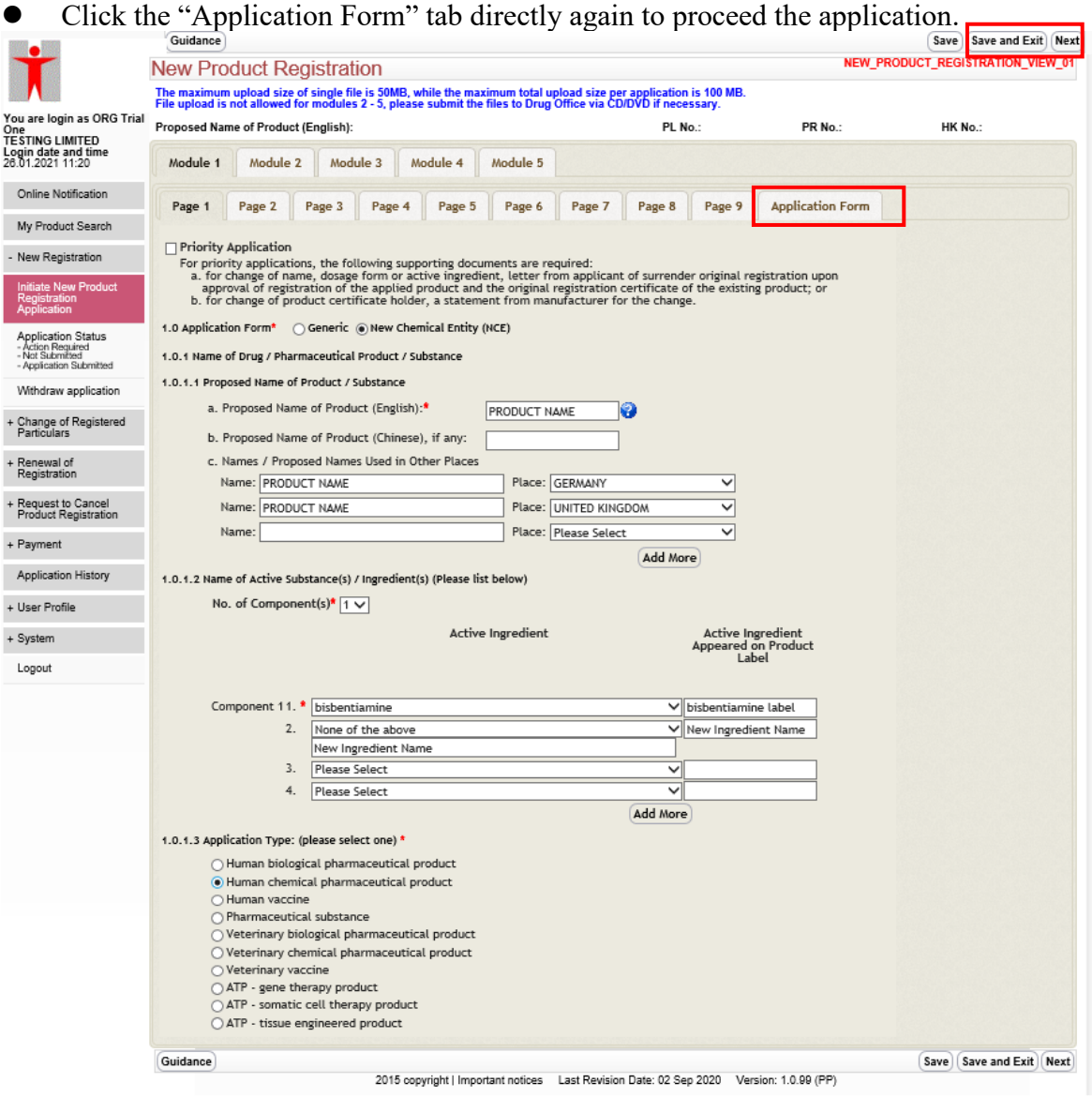
For Office Use Only

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

Guidance | Back | 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.



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.


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
Cream
Package Size(s):
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. bisbentiamine 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
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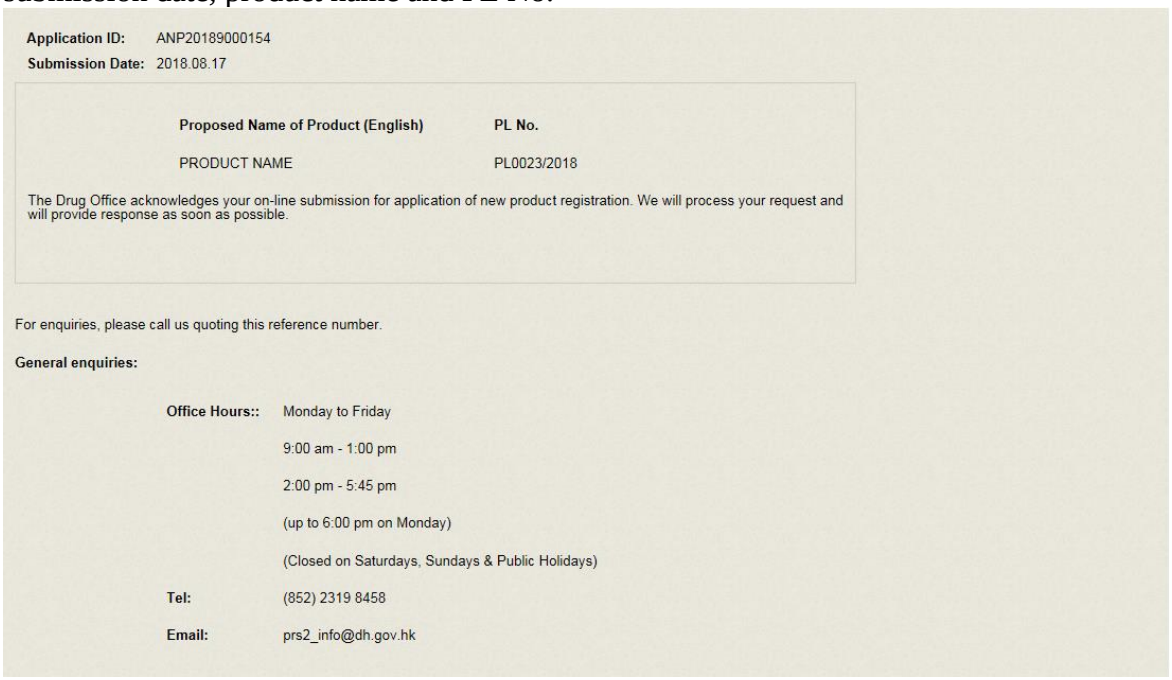
Submit Application
Print

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



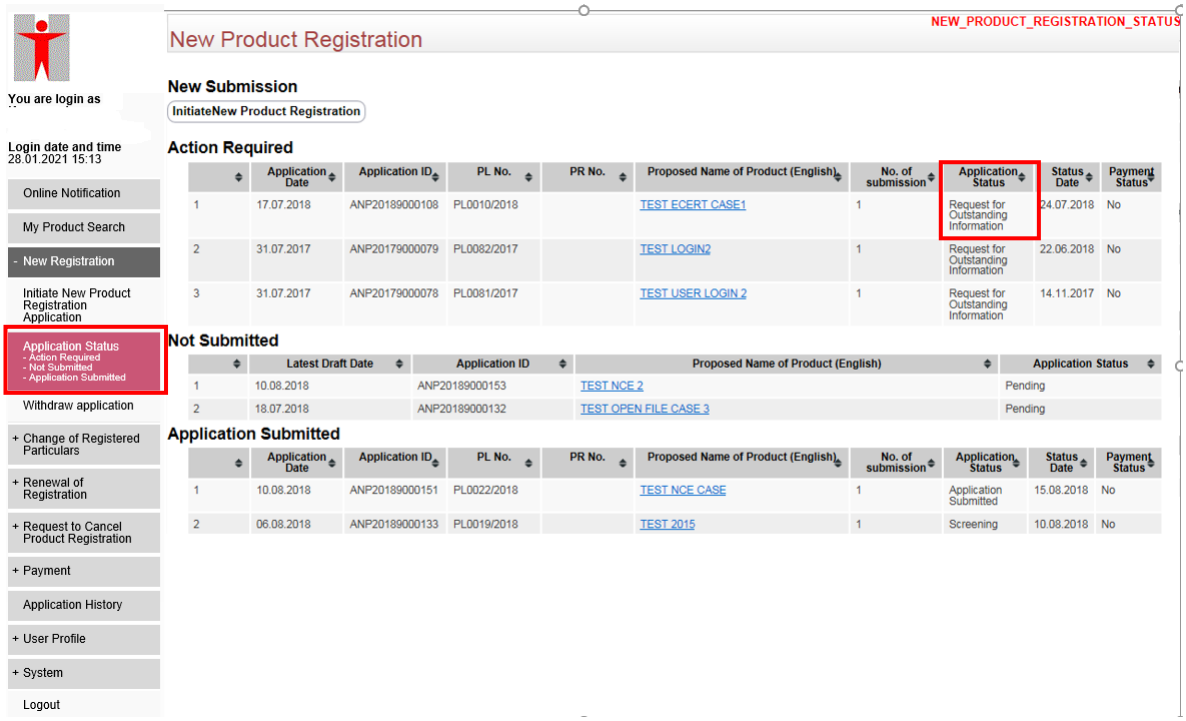
2.5.2 Application Status

- Click the menu item “Application Status” under “New Registration” in the menu on the left.

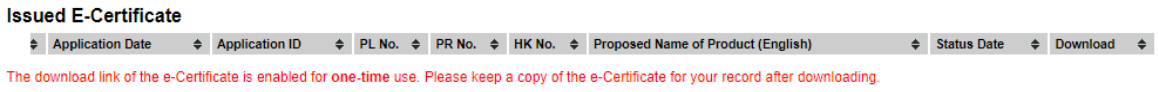
There are 3 pools:

- 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”

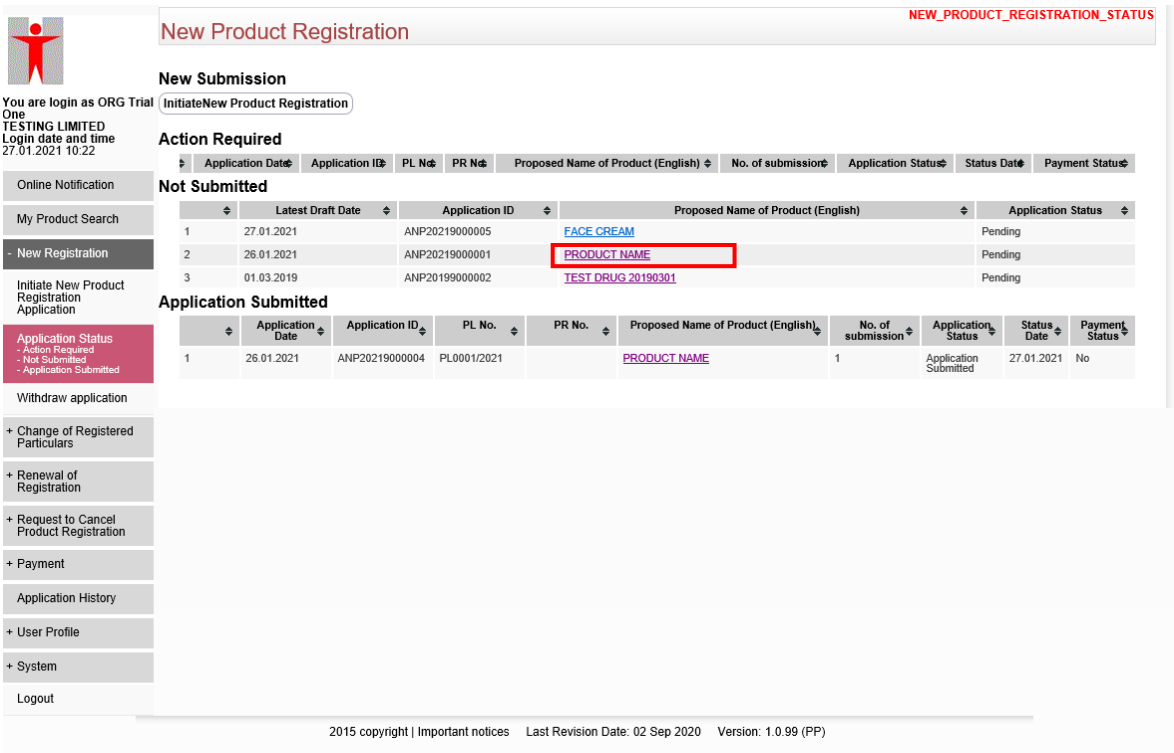


New list added for new version:

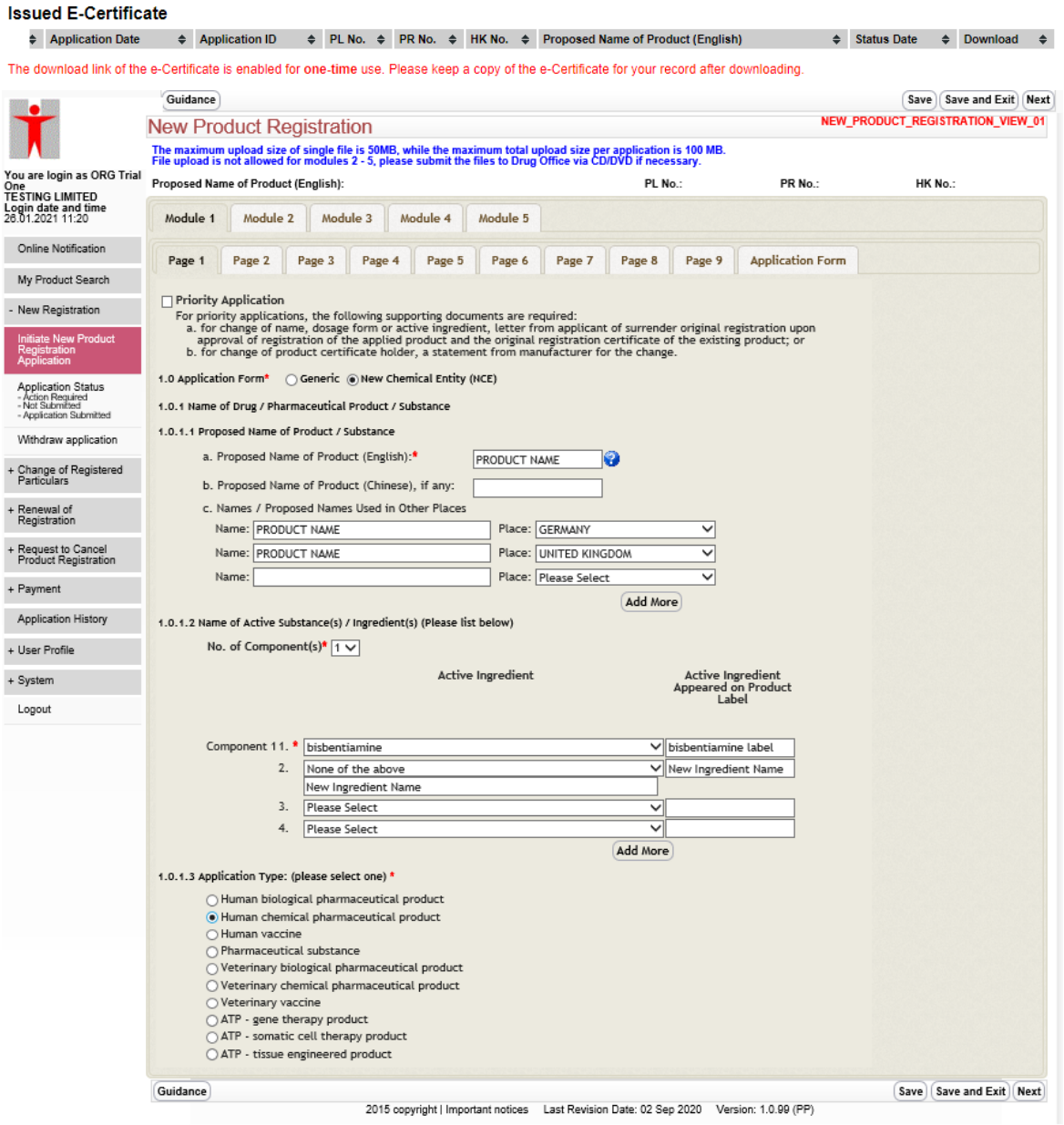


2.5.2.1 Not Submitted:

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

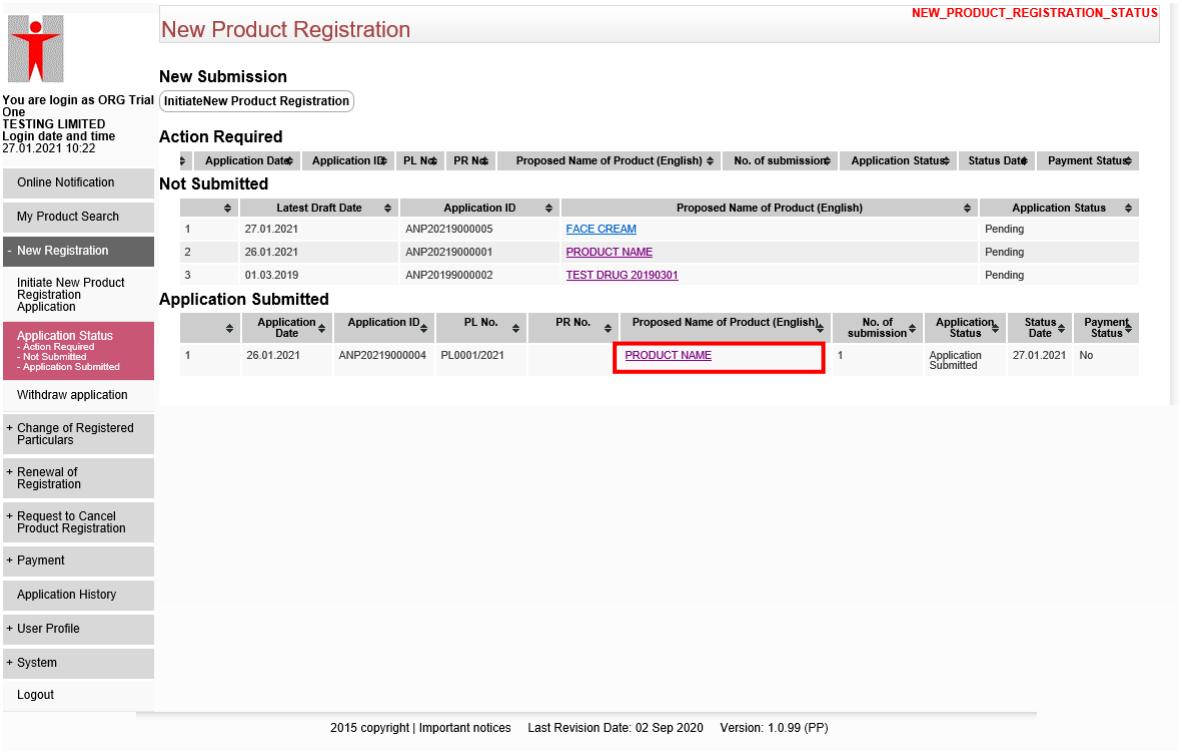


New list added for new version:

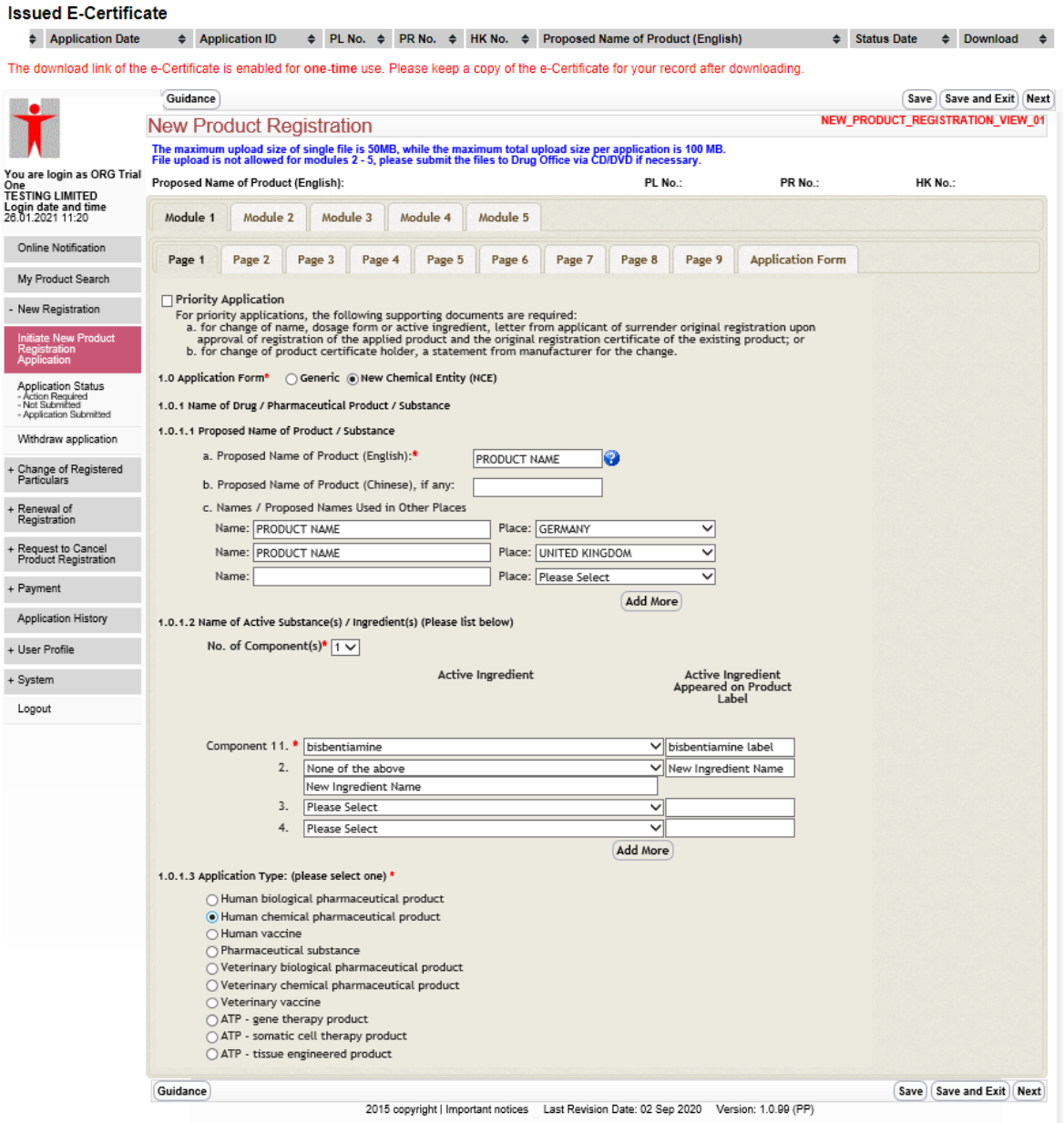


2.5.2.2 Application Submitted:

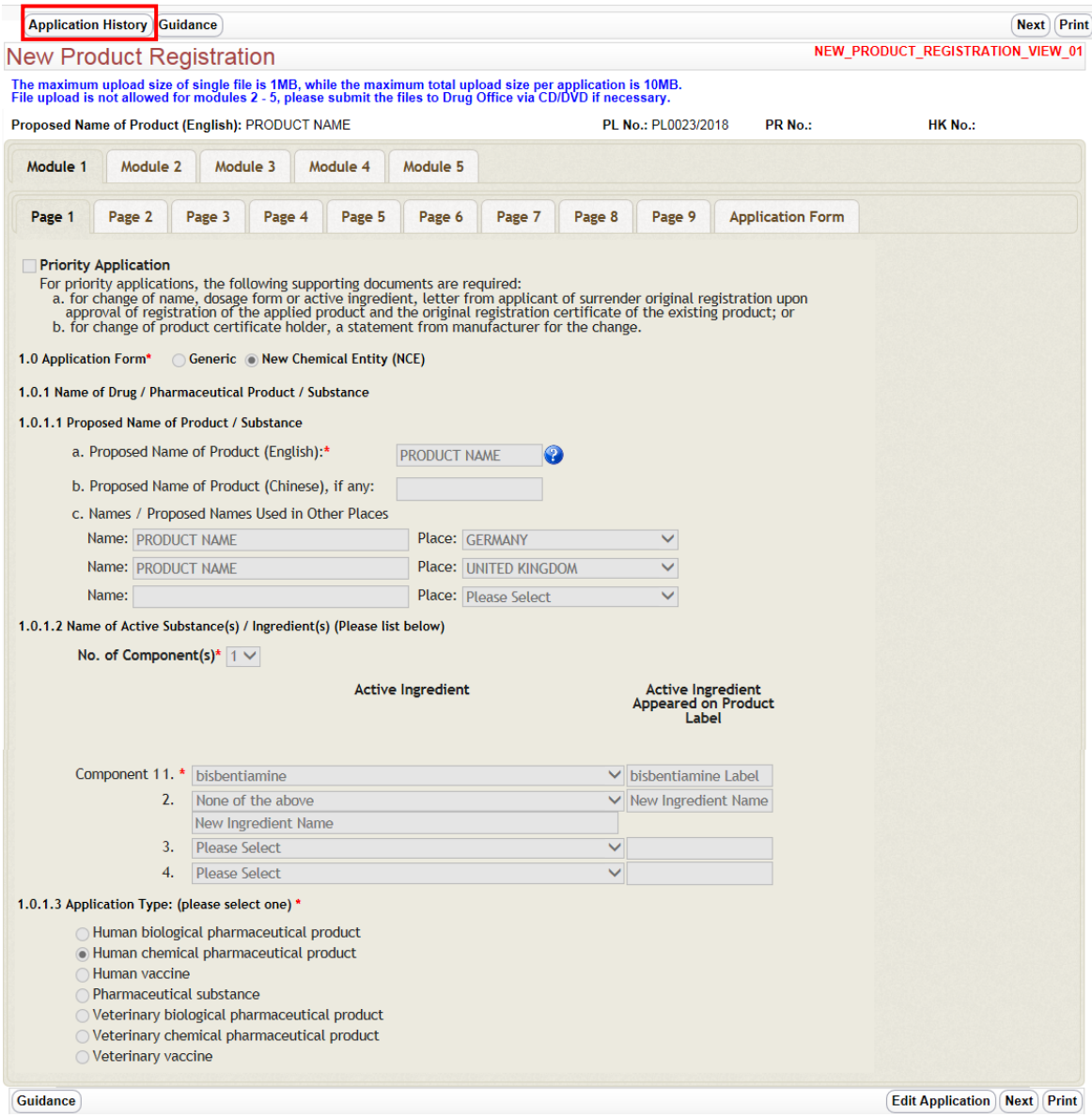
Step 1: Click the application under “Application Submitted” section. Then the page will be redirected to view CTD information page.

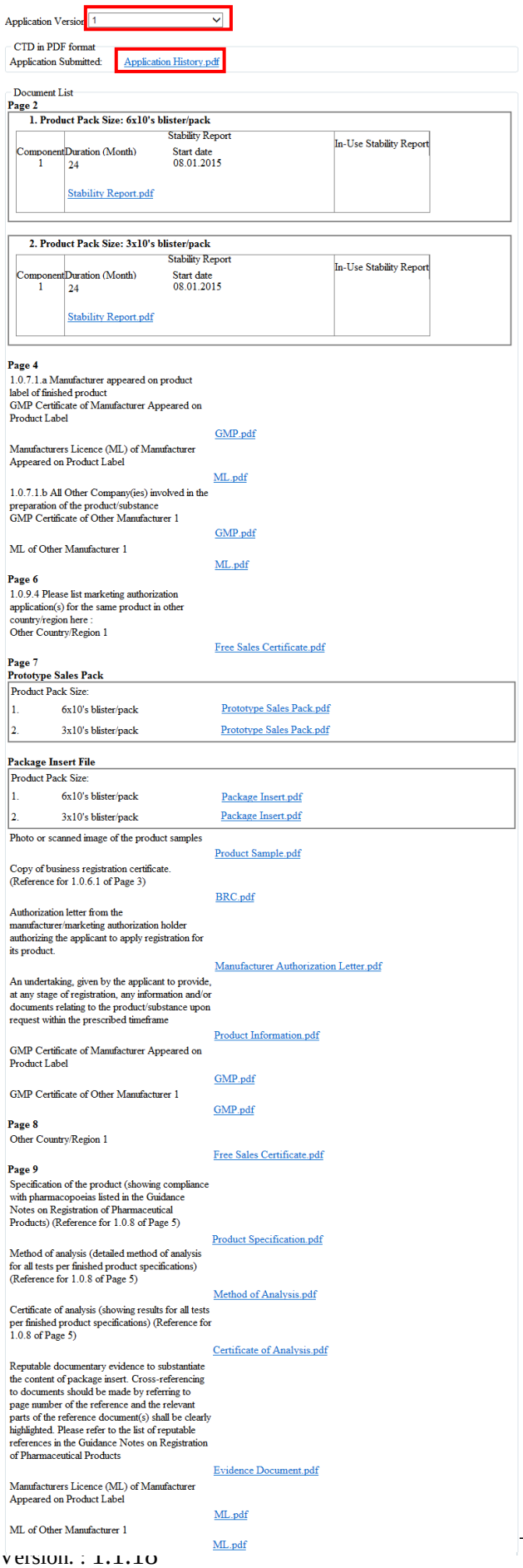


New list added for new version:



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 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):*
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
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



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	Stability Report: 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	Stability Report: 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

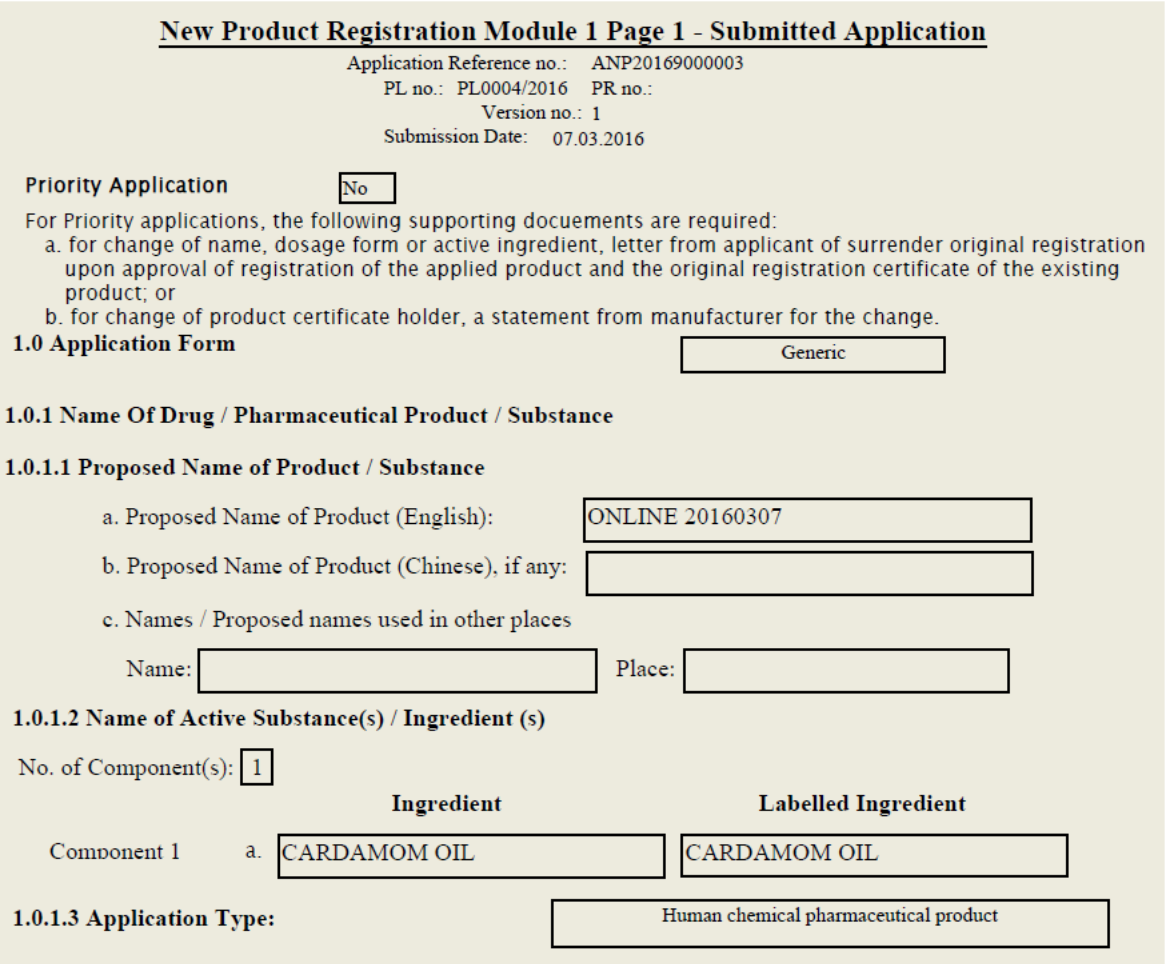
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label

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: No

For Priority applications, the following supporting docuements are required:
a. for change of name, dosage form or active ingredient, letter from applicant of surrender original registration upon approval of registration of the applied product and the original registration certificate of the existing product; or
b. for change of product certificate holder, a statement from manufacturer for the change.

1.0 Application Form: Generic

1.0.1 Name Of Drug / Pharmaceutical Product / Substance

1.0.1.1 Proposed Name of Product / Substance

a. Proposed Name of Product (English): ONLINE 20160307

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

c. Names / Proposed names used in other places

Name: Place:

1.0.1.2 Name of Active Substance(s) / Ingredient (s)

No. of Component(s): 1

		Ingredient	Labelled Ingredient
Component 1	a.	CARDAMOM OIL	CARDAMOM OIL

1.0.1.3 Application Type: Human chemical pharmaceutical product

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

Application Version 1

CTD in PDF format

Application Submitted: Application History.pdf

Document List

Page 2

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

Component	Stability Report 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	Stability Report 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

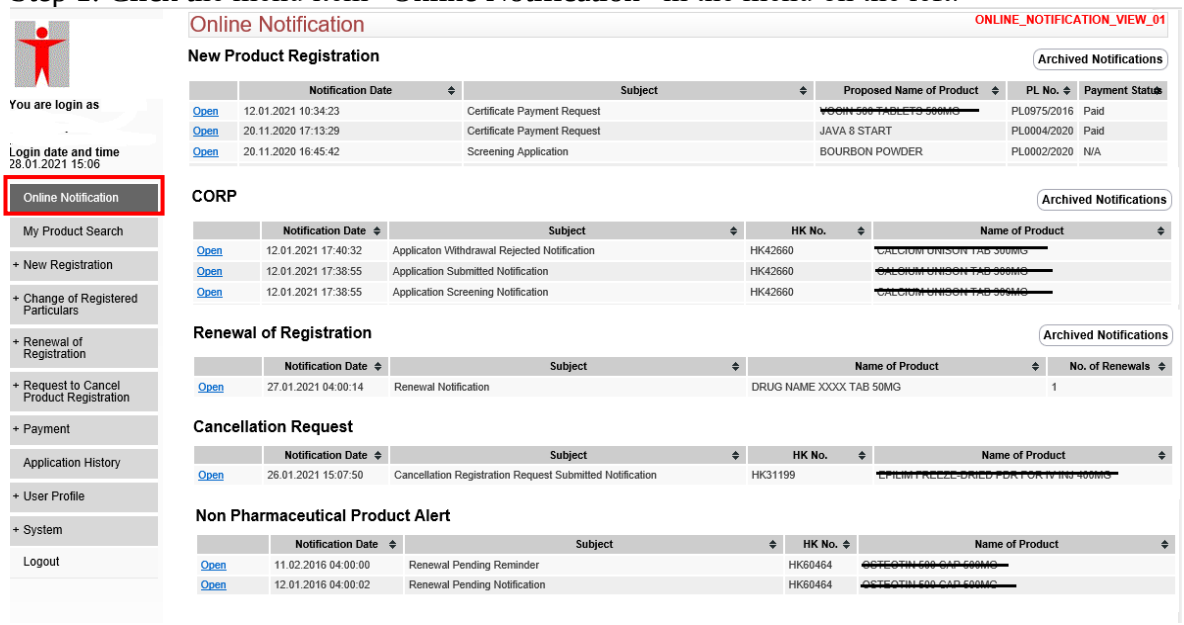
Manufacturers Licence (ML) of Manufacturer Appeared on Product Label — ML.pdf

ML of Other Manufacturer 1 — ML.pdf

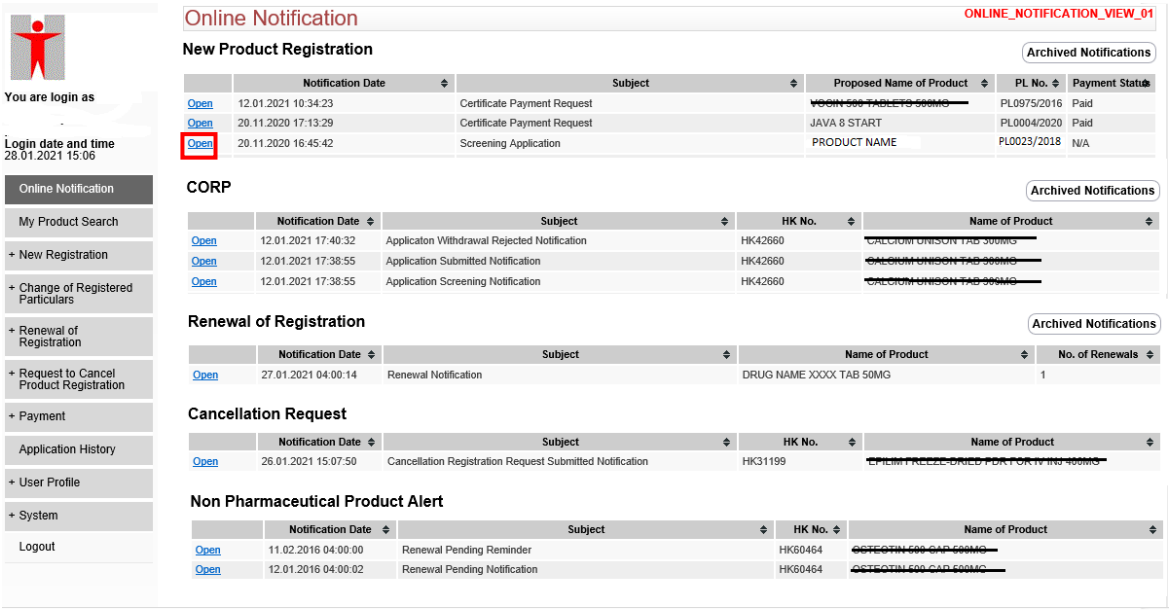
2.5.2.3 Action Required (If the application requires outstanding information requested by pharmacist, the application will be under the "Action Required" section).

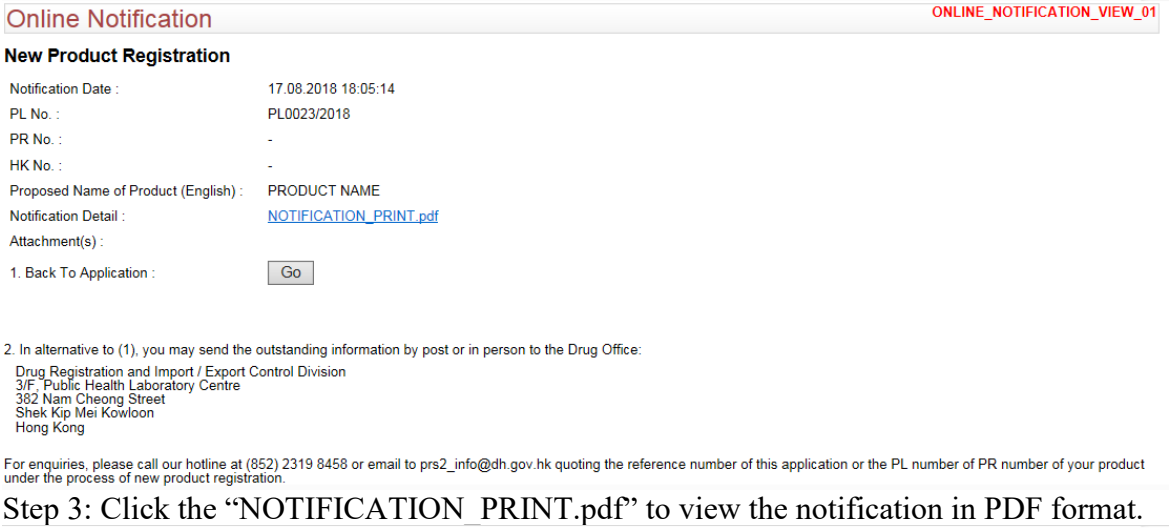
- For application which is "Action Required", applicant will also receive a notification about the required information or comments for the application.
- Applicant needs to update his/her application information and resubmit through online system by the link in the notification or new application pool.

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

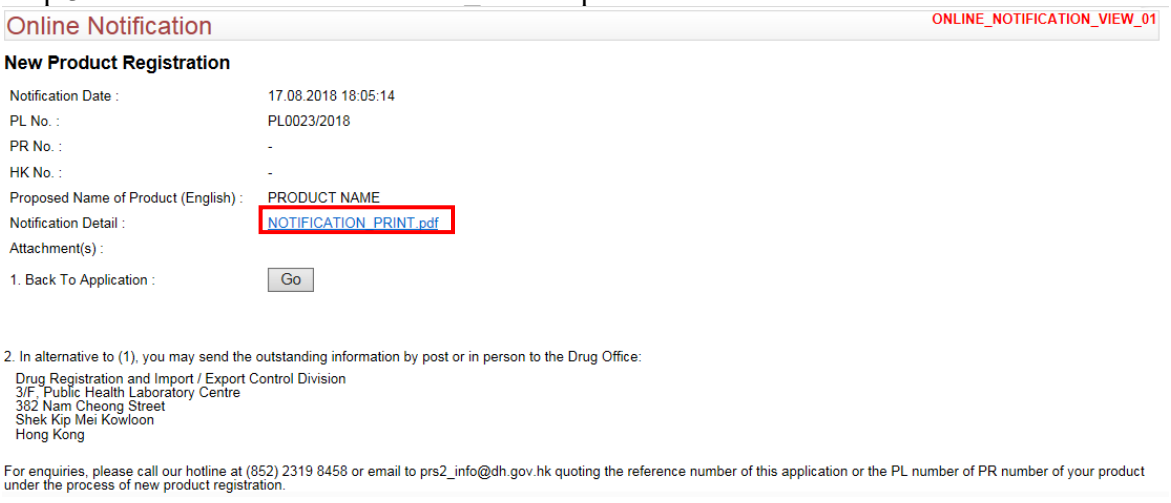


Step 2: Click a notification which subject is "Screening Application" or "Evaluation Application".





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



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

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

Application for Registration of Pharmaceutical Products/Substances

Date: 2018-08-17

PL Number: PL0023/2018

Product Name: PRODUCT NAME

Screened by: Screen Officer

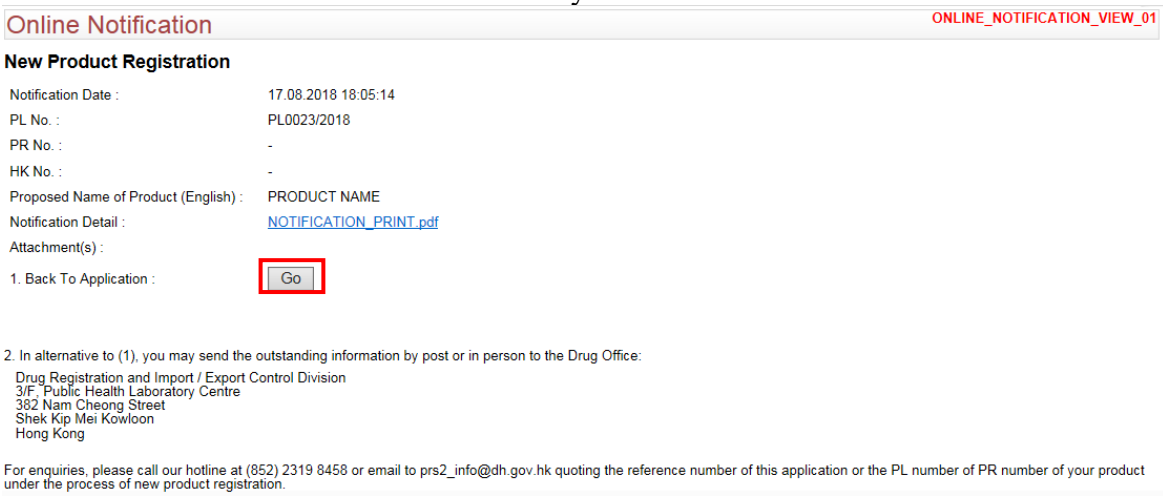
Comments/Outstanding Information:
Section 1.0.1.1: Please update the proposed names used in ohter places

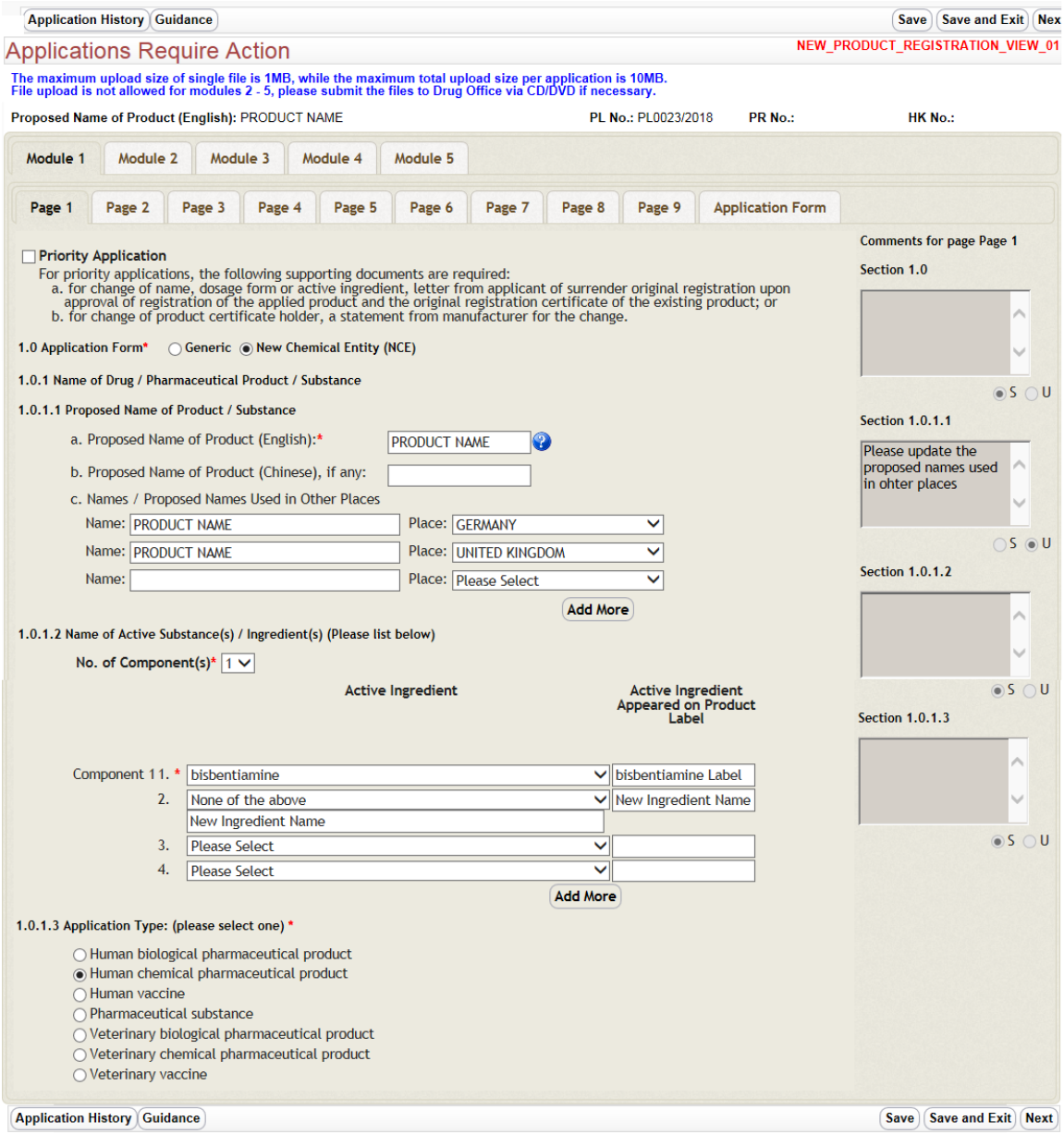
Section 1.0.8.1: Screening Comment

Assessment made By:	Screen Officer
Signature of Assessment Officer:	_____
Name (in BLOCK letters):	Screen Officer
Post Title:	
Date:	2018-08-17

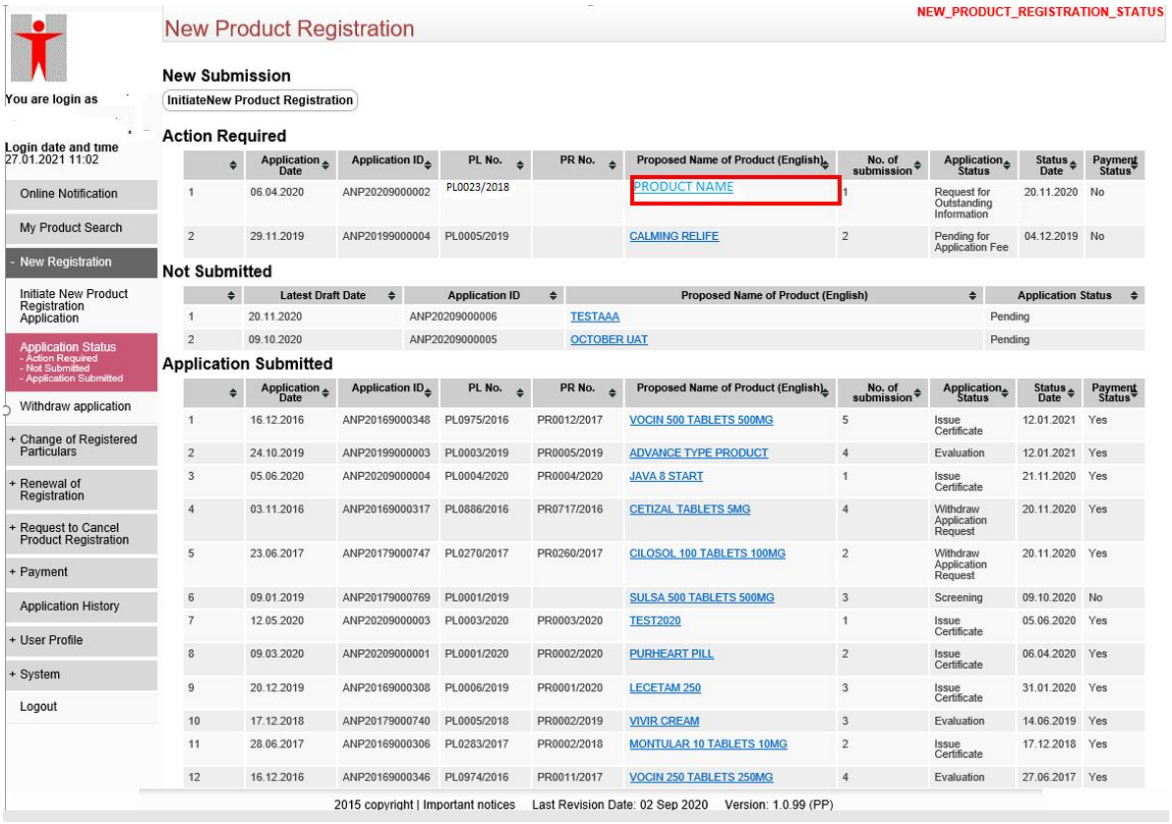
We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority

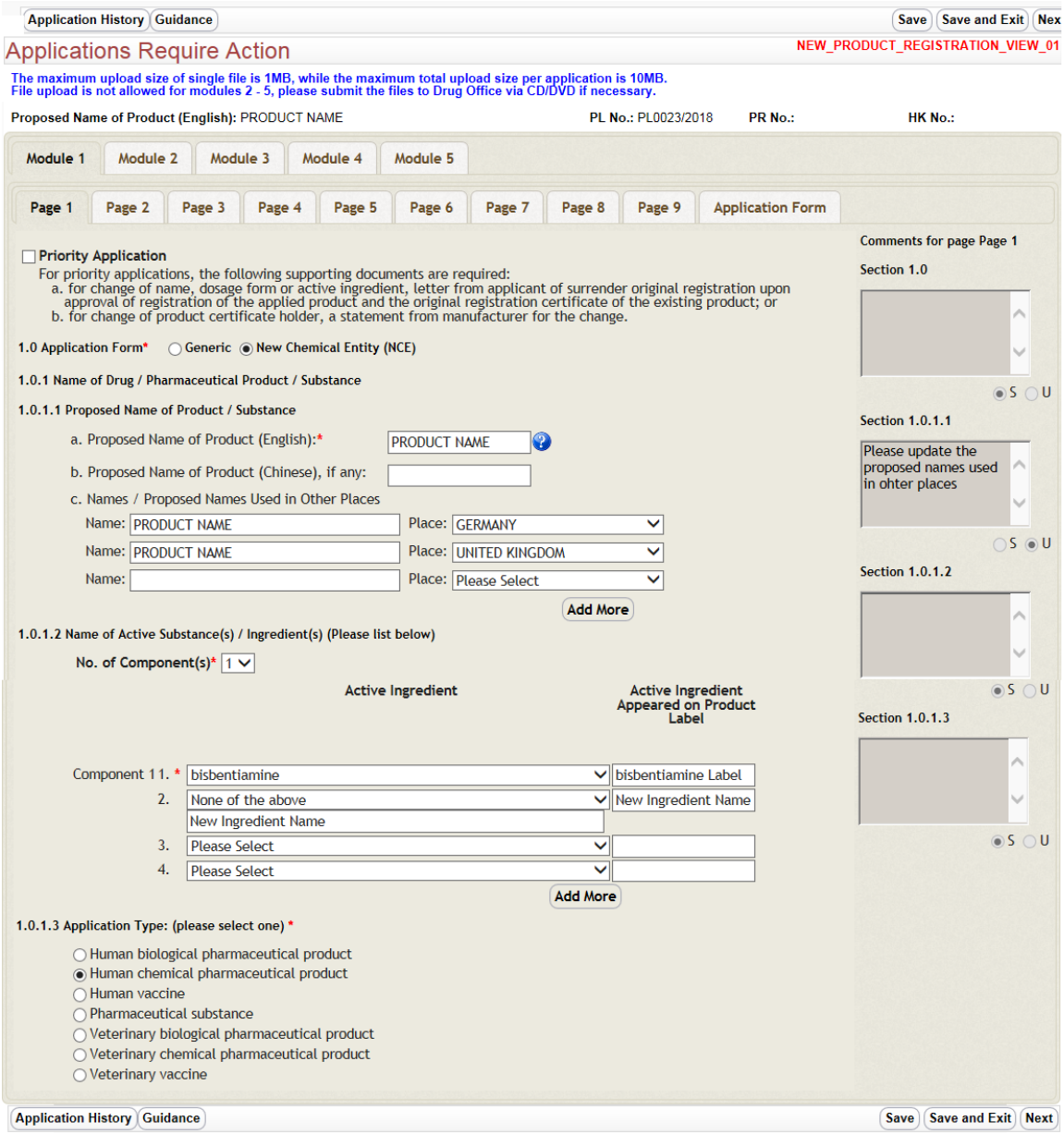
Step 4: Click the “Go” button will redirect the application to the CTD page for outstanding information. Pharmacist’s comment for every section can be viewed at the same time.



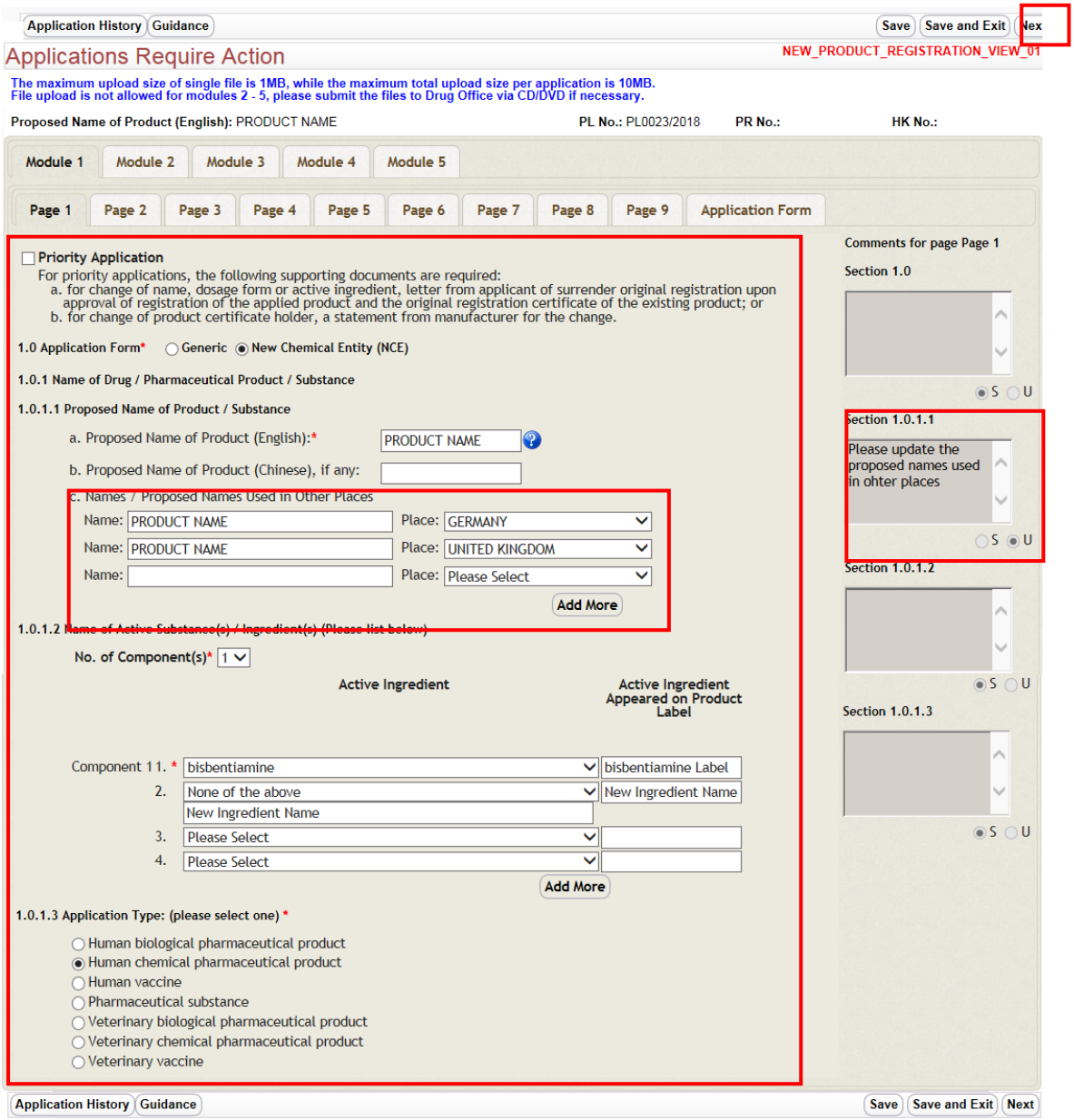


Method 2: ‘Action Required’ under ‘Application status’ of ‘New Registration’ (Resubmit application).
Step 1: Click the application under “Action Required” section will be redirected to view CTD information page with pharmacist comments.


NEW_PRODUCT_REGISTRATION_STATUS
New Product Registration
You are login as
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
Not Submitted
Application Submitted
2015 copyright | Important notices
Last Revision Date: 02 Sep 2020
Version: 1.0.99 (PP)

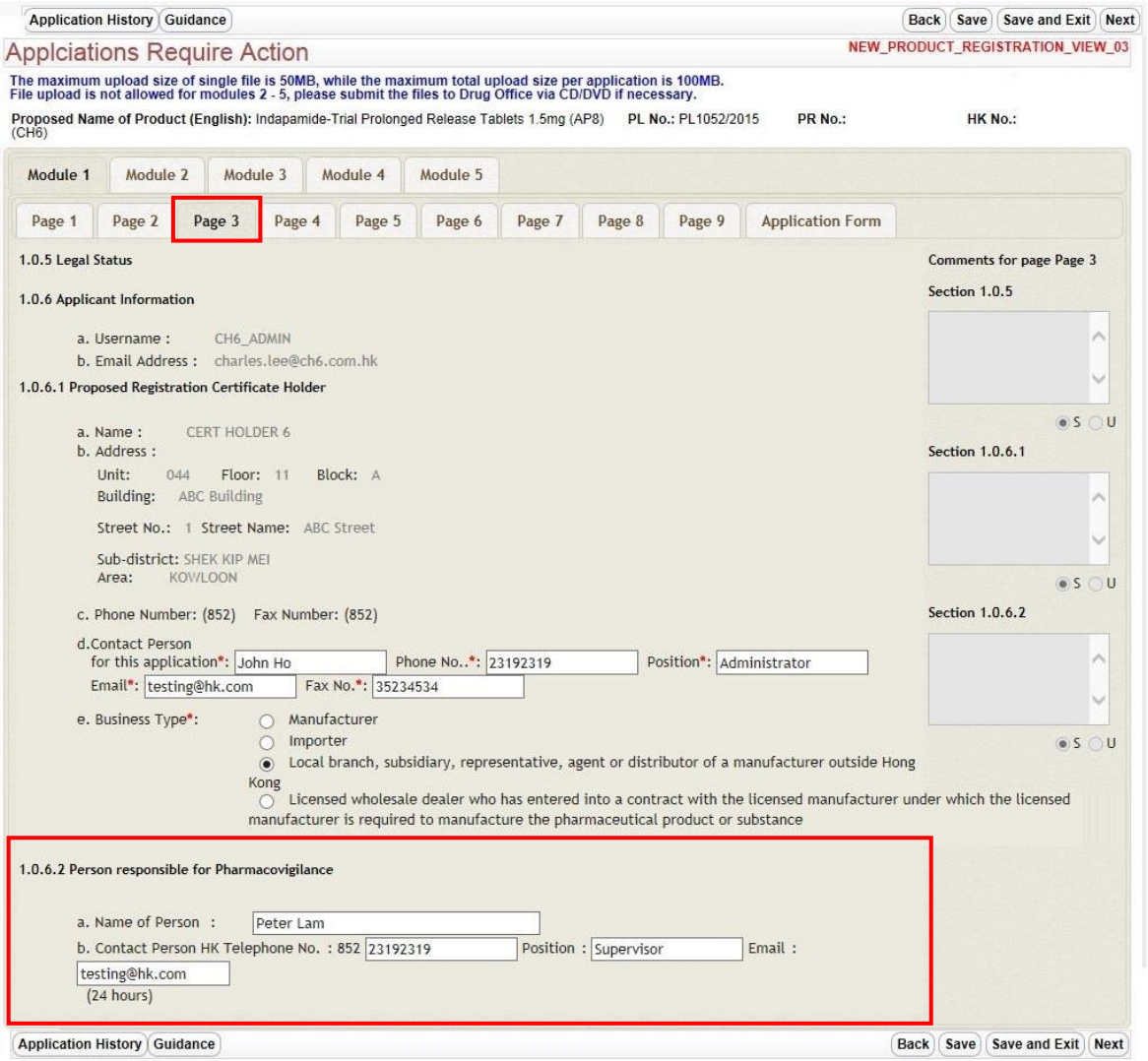


Step2: Update the information according to the comments (if any) given by pharmacist officer or any changes.

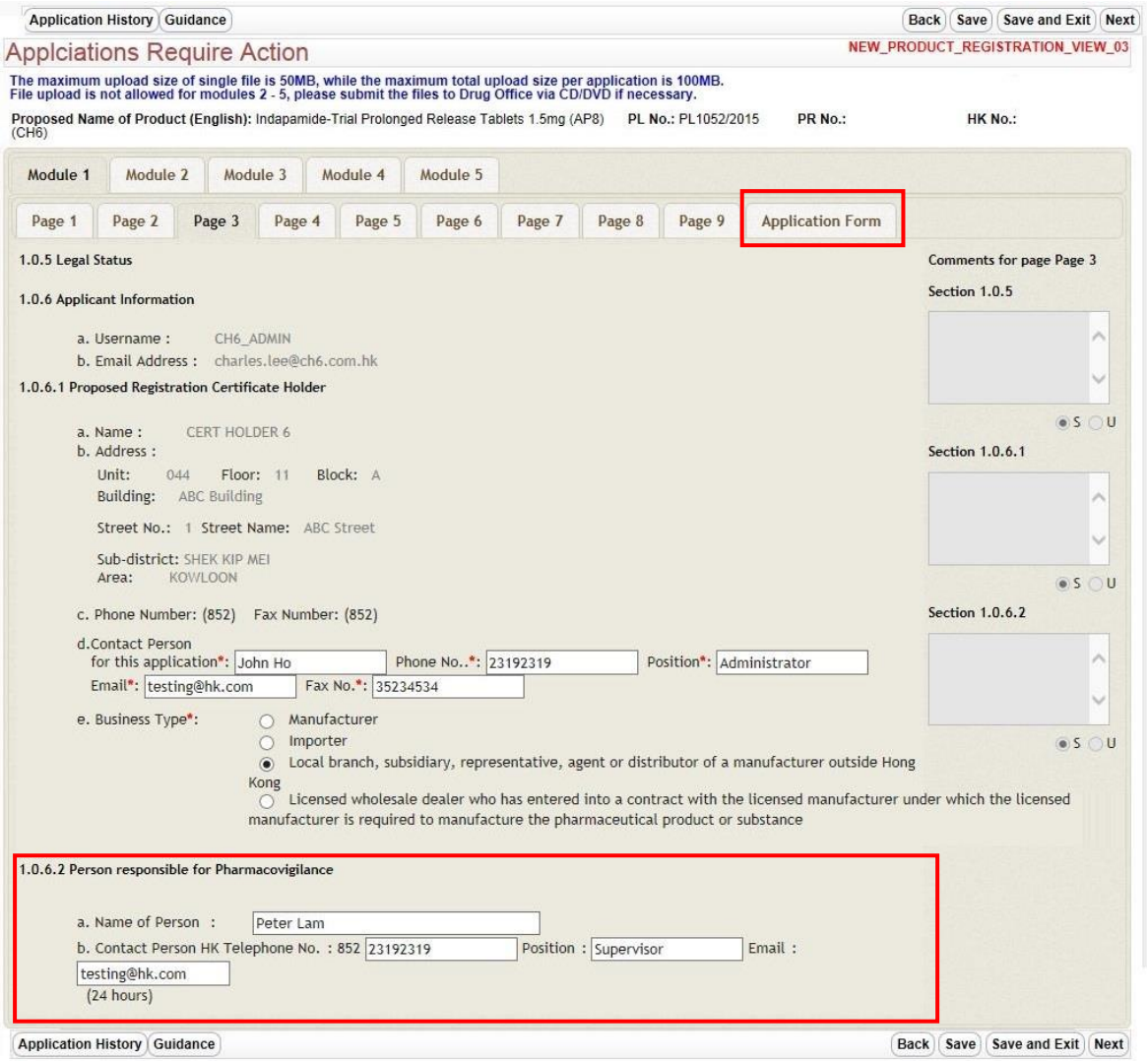


Step3: Click the “Next” button or click the tab to redirect to other page.

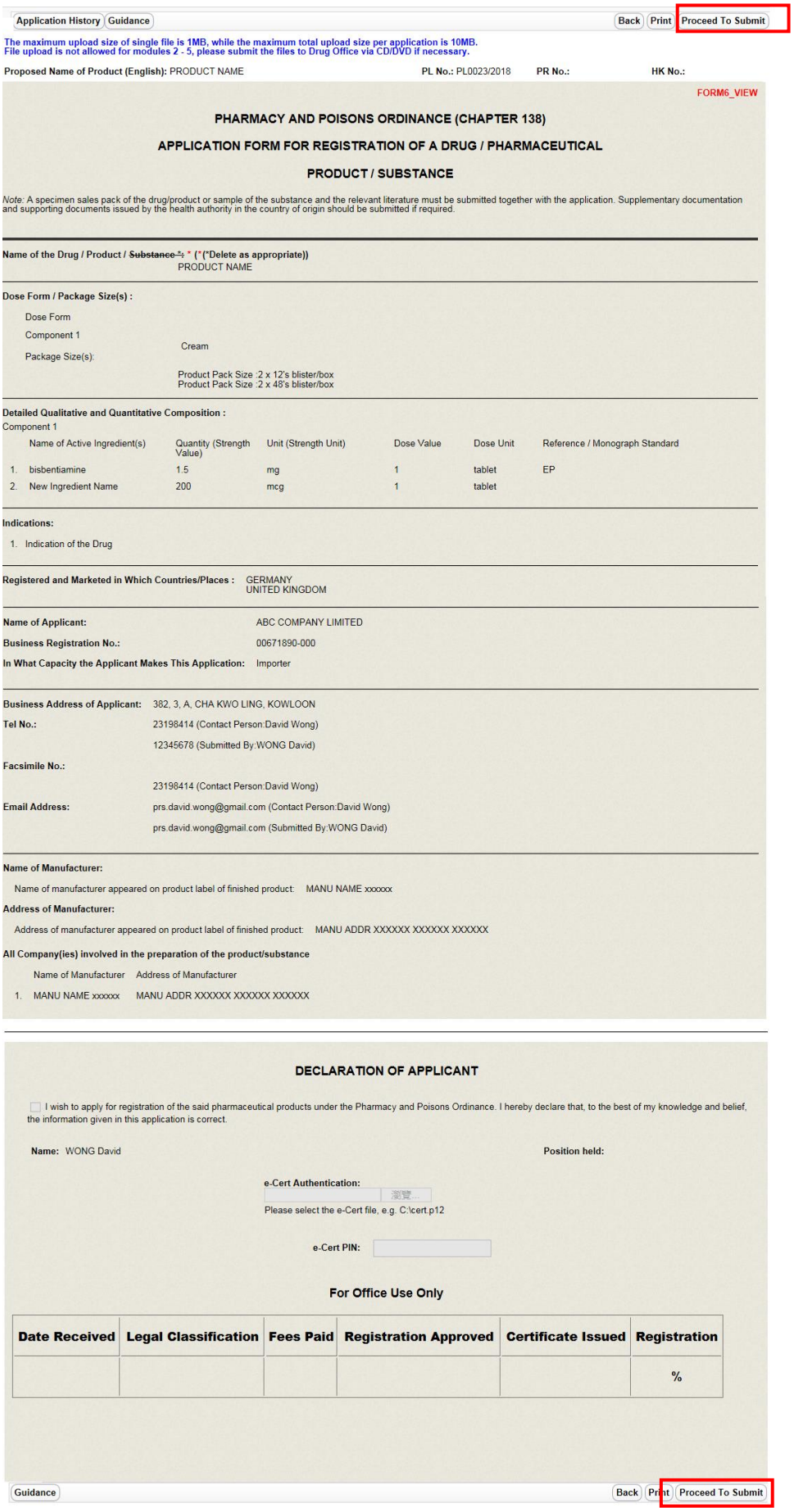
Applicant can also proactively update the information in the CTD. For example, applicant can update the person responsible for Pharmacovigilance information in Page 3.



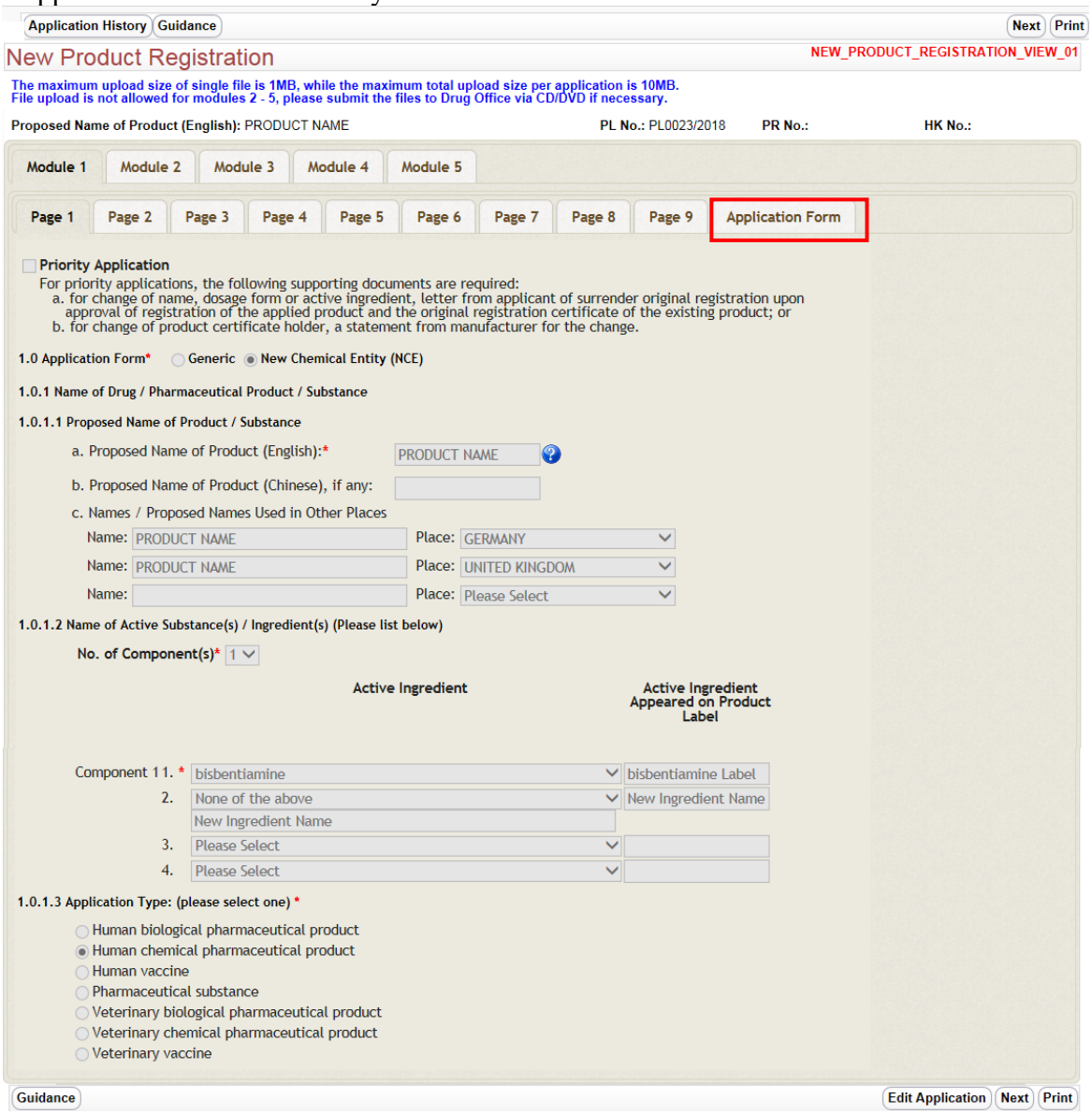
Step 4: After finish updating the application, click the “Application Form” tab.



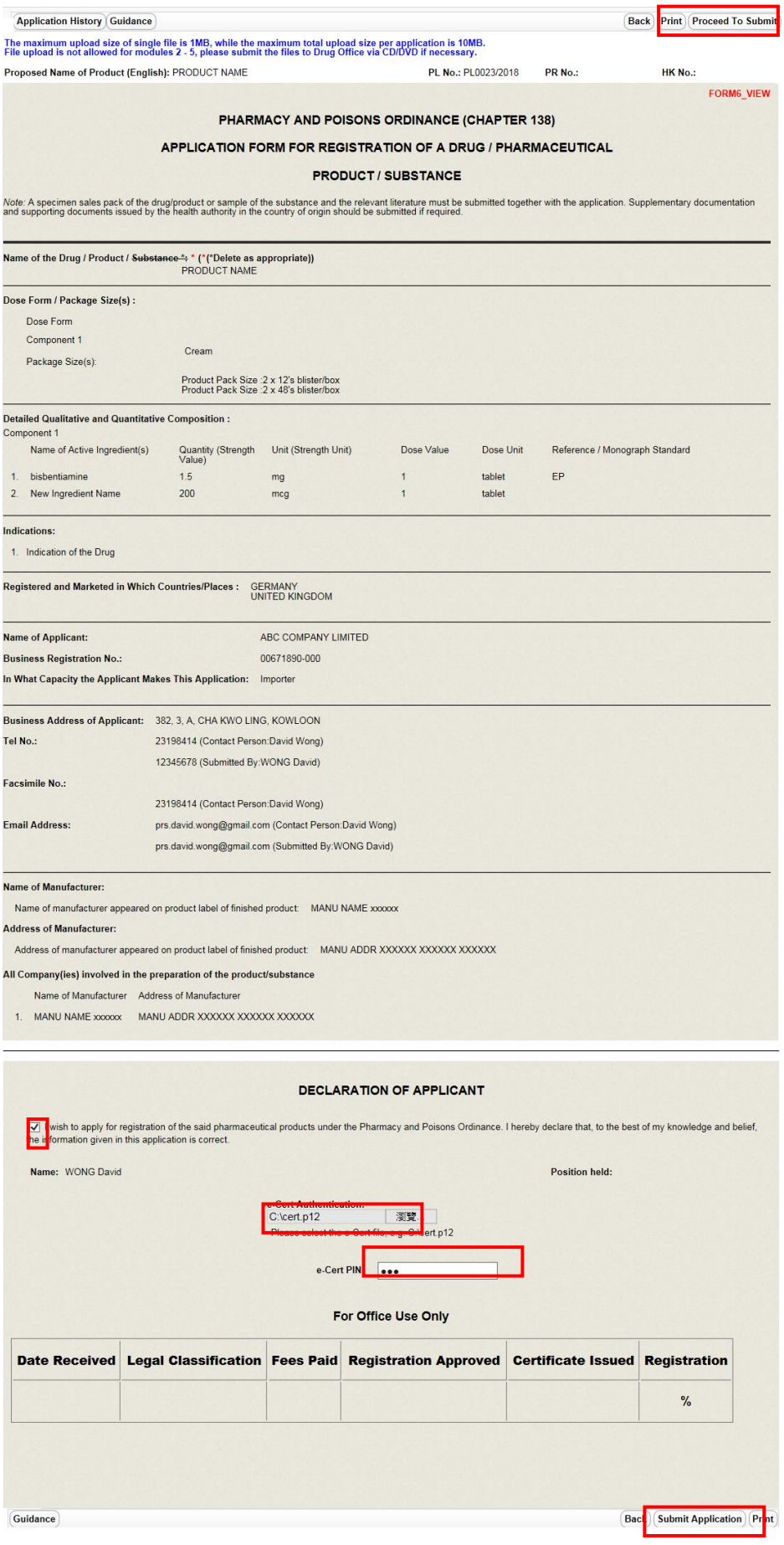
Step 5: Click the “Proceed to Submit” button.


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
Cream
Package Size(s):
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. bisbentiamine | 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

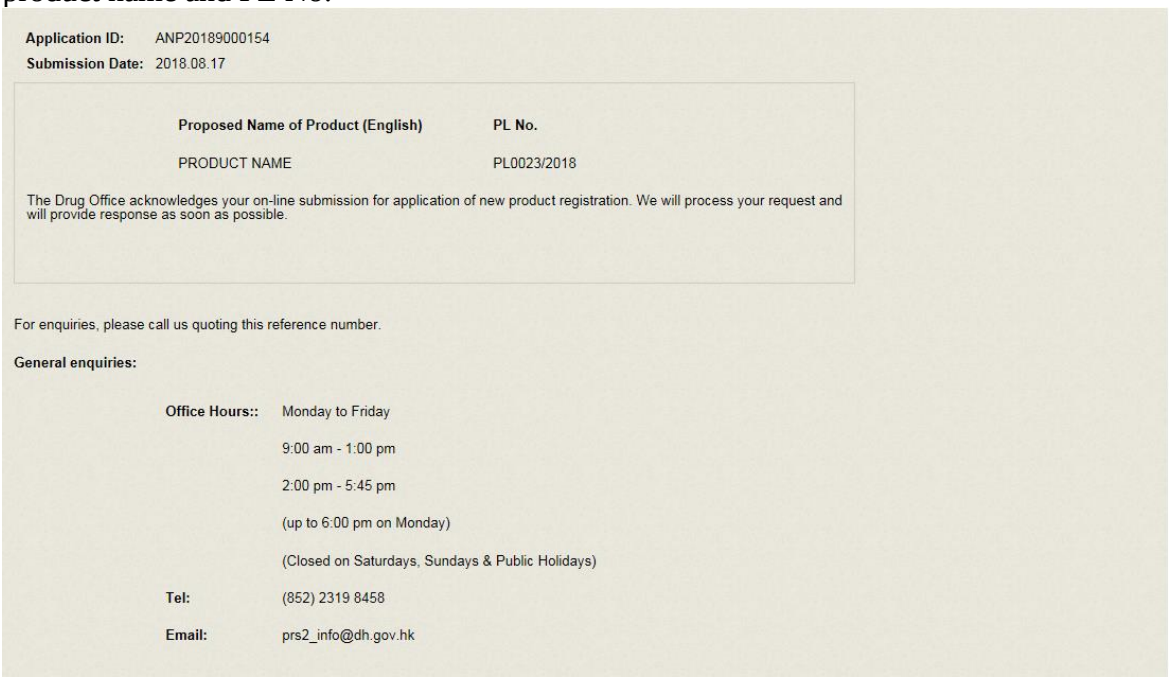
Step 6: Review the page information by clicking the tab if necessary, otherwise click the "Application Form" tab directly.



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.


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
Cream
Package Size(s):
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. bisbentiamine 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 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:

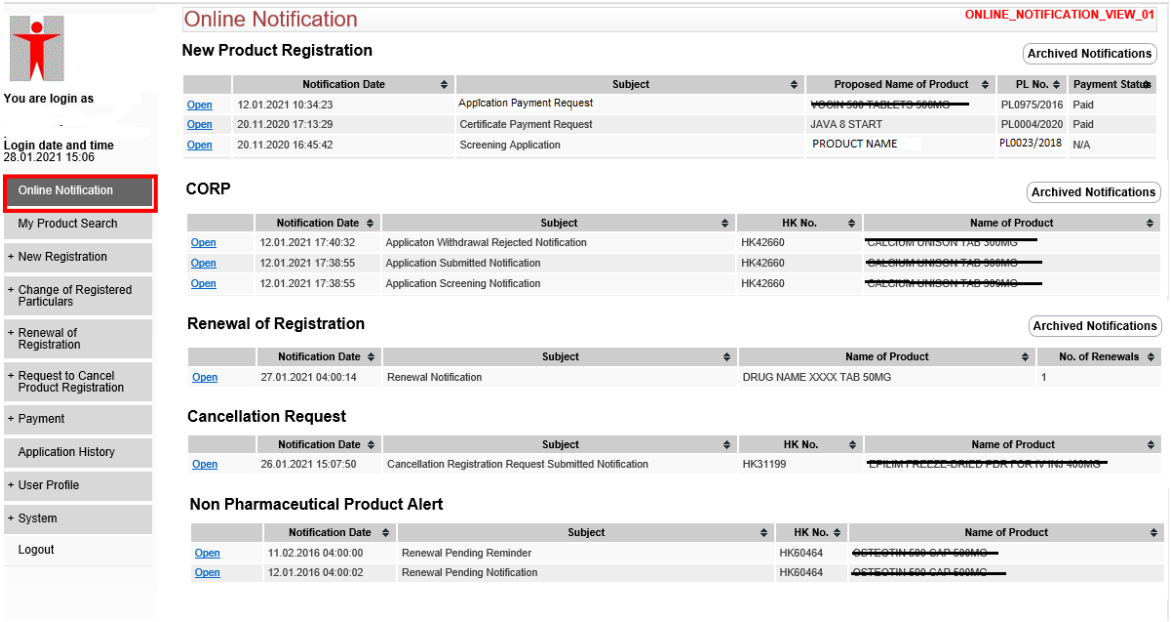
Office Hours:: Monday to Friday
9:00 am - 1:00 pm
2:00 pm - 5:45 pm
(up to 6:00 pm on Monday)
(Closed on Saturdays, Sundays & Public Holidays)

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	~~VOGIN 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	Applicaton 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

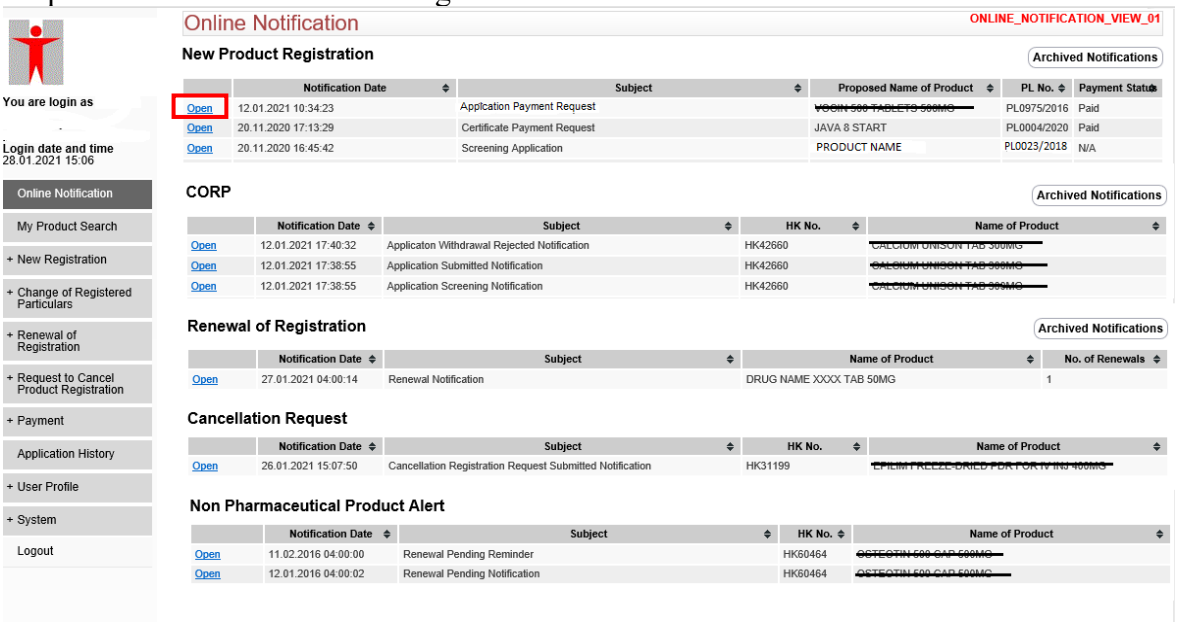
Cancellation Request

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

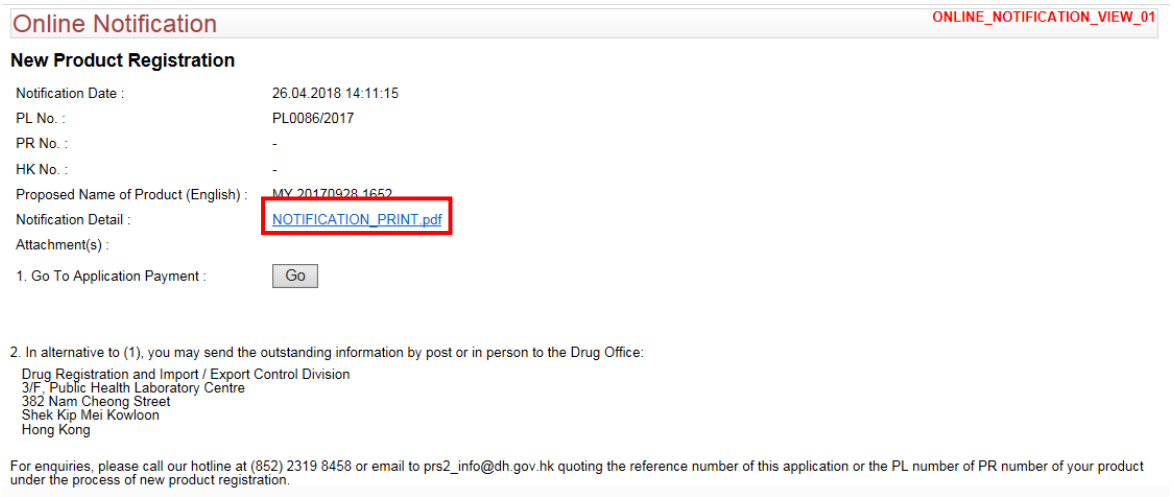
Non Pharmaceutical Product Alert

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

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



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



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
[x] **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

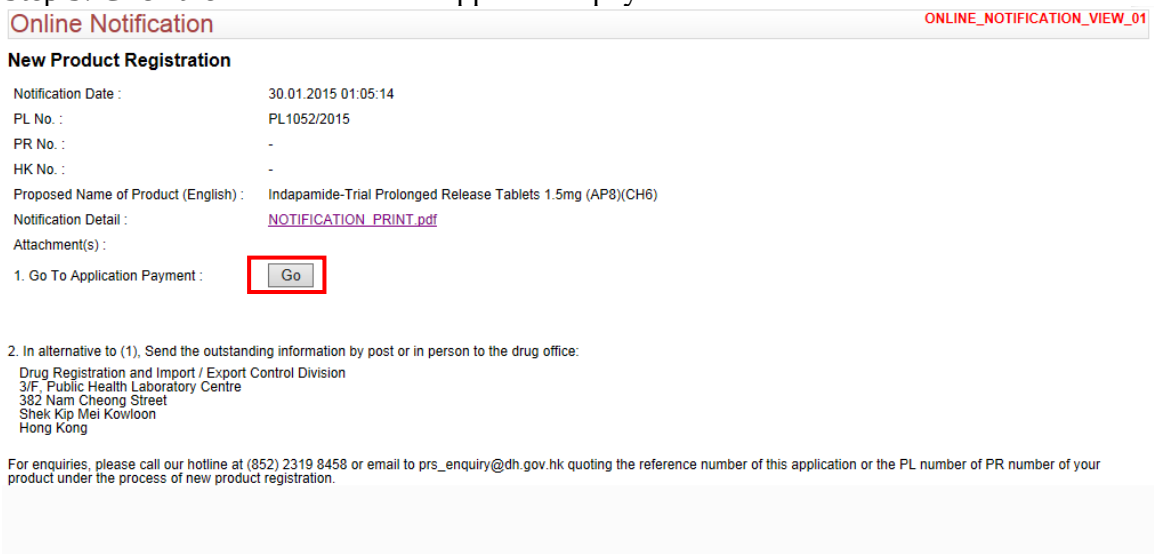
B. Payment Instructions
乙：繳費辦法

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：

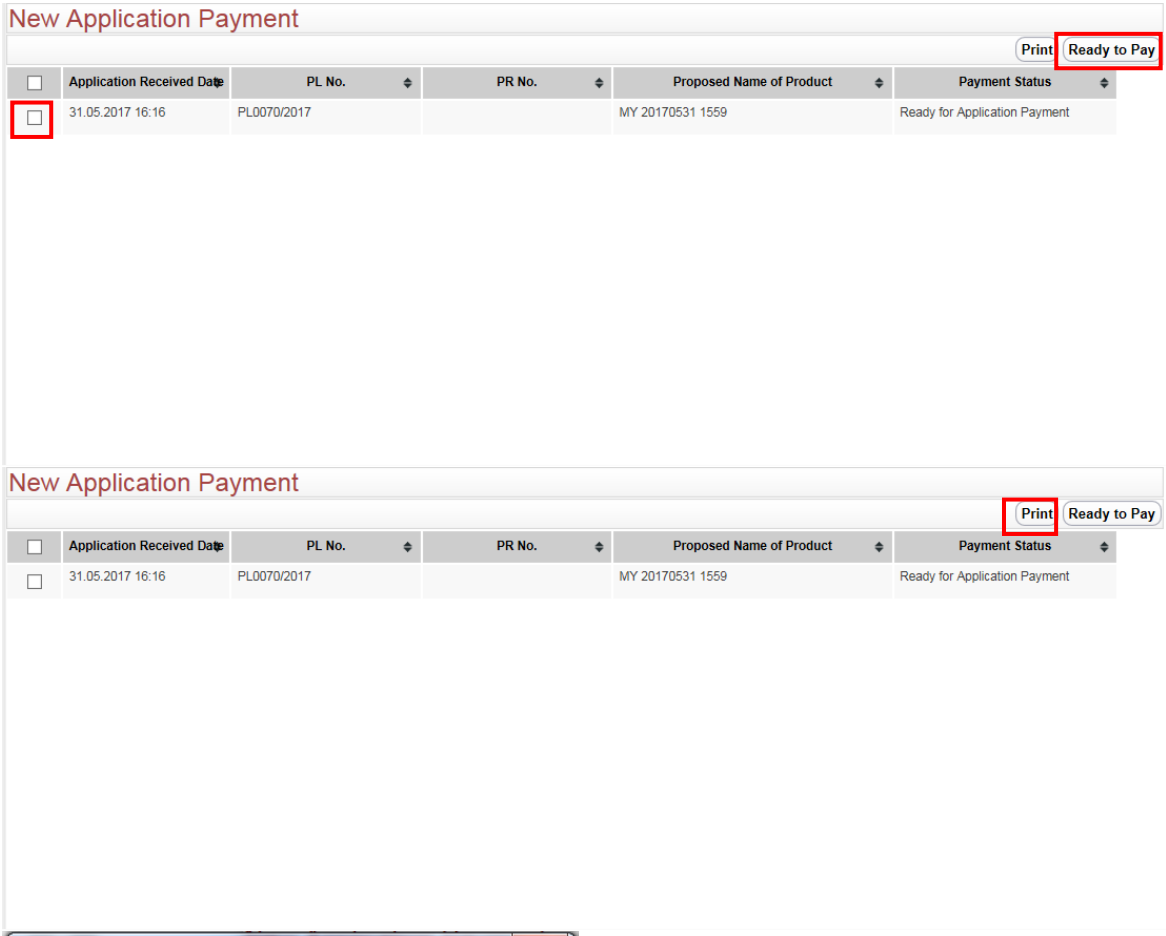
For application(s) made via paper mode, please arrange payment by Method 1 - 2; for application(s) made via electronic mode (i.e., PRS 2.0), please arrangement payment by Method 1 - 4:
如以硬本形式遞交申請,請以方法1 - 2繳費;如以電子形式(即PRS 2.0)遞交申請,請以方法1 - 4繳費:

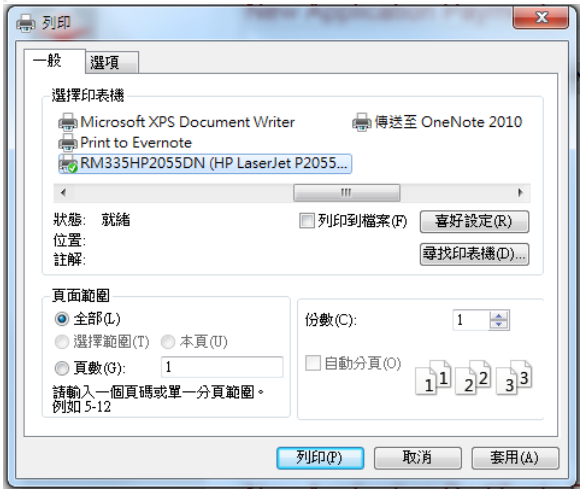
1. By post with payment cheque and this notification letter addressed to "Shroff Office, Drug Office of Department of Health" at Suite 2002-05, 20/F, AIA Kowloon Tower Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong. Please note that crossed cheques should be made payable to "The Government of the Hong Kong Special Administrative Region".
   用支票連同本通知書郵寄衞生署藥物辦公室繳款處收。地址為香港九龍觀塘巧明街100號Landmark East友邦九龍大棲20樓2002-05室。劃線支票抬頭寫上「香港特別行政區政府」。
2. In person with payment cheque or cash and this notification letter at the above address. Hours of operation:
   Monday to Friday: 9:00 a.m. to 1:00 p.m.
   2:00 p.m. to 5:30 p.m.
   (up to 5:45 p.m. on Monday)
   攜同本通知書到上述辦事處以支票或現金繳交。辦事處收款時間:
   星期一至星期五: 上午九時至下午一時
   下午二時至下午五時三十分
   (星期一至下午五時四十五分)
   (Note: CASH should NOT be sent through post
   注意: 請勿郵寄現金)
3. By online credit card (Visa/MasterCard) payment via EGIS in PRS 2.0
   透過PRS2.0的電子政府基建服務以信用卡繳費
   (Link / 網址: <https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp>)
4. By online PPS payment via EGIS in PRS 2.0
   透過PRS2.0的電子政府基建服務以繳費靈繳費
   (Link / 網址: <https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp>)

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

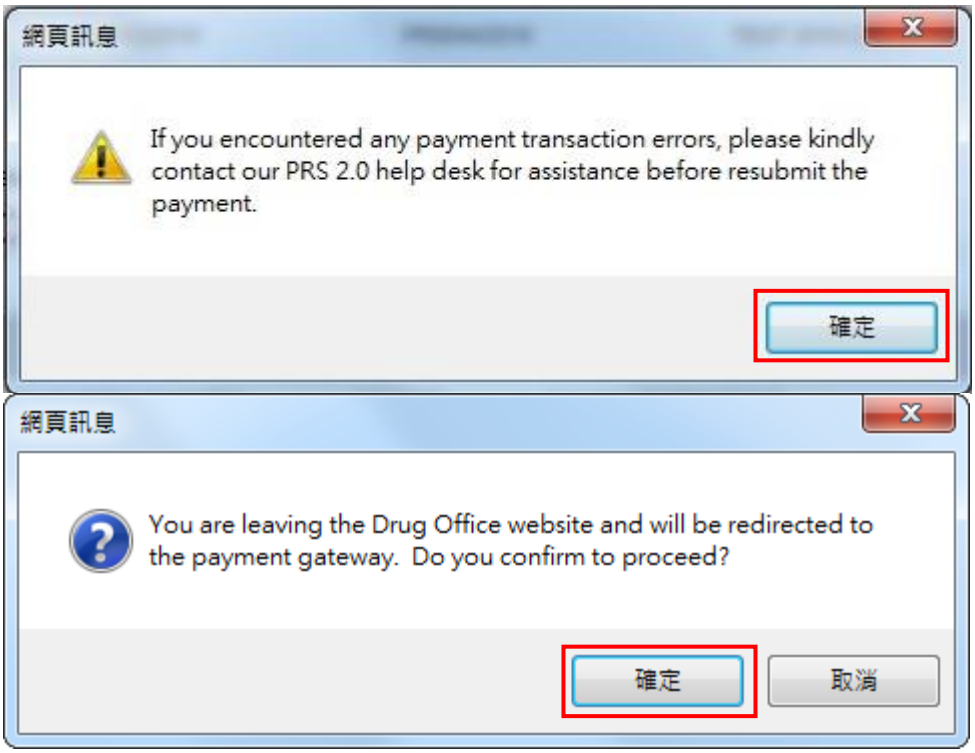


Step 4: Select a single/multiple applications and click "Ready to Pay" button. Select an application and click 'print' if you want to print the payment details.

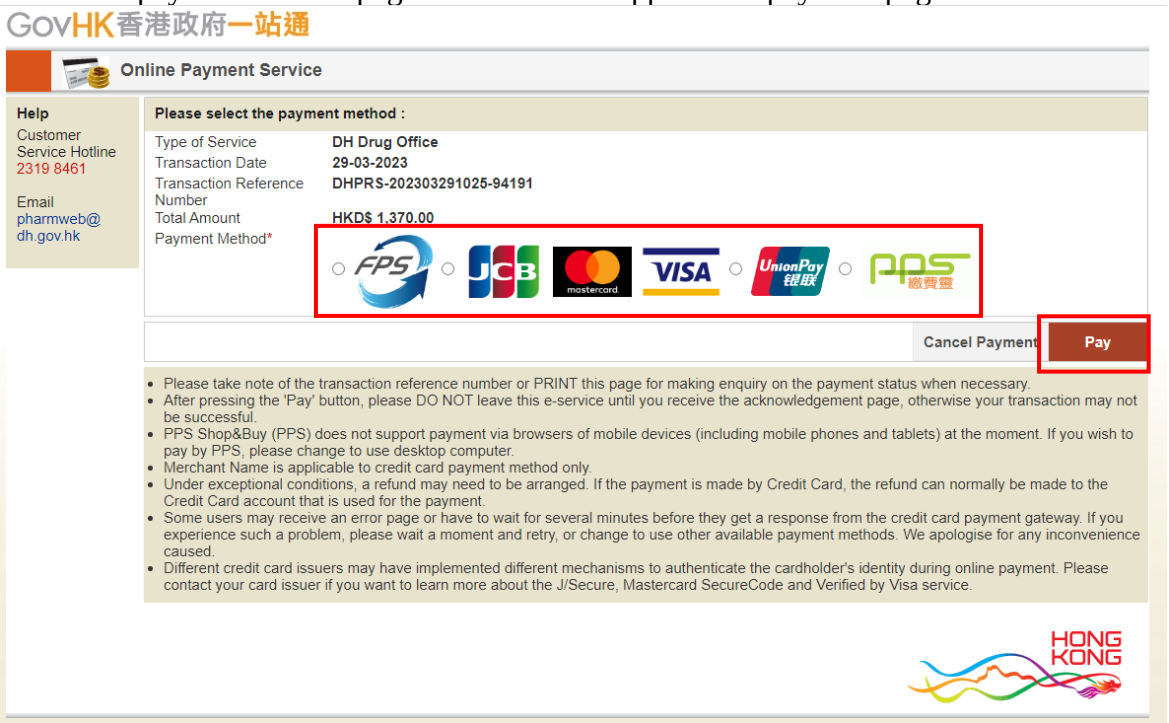




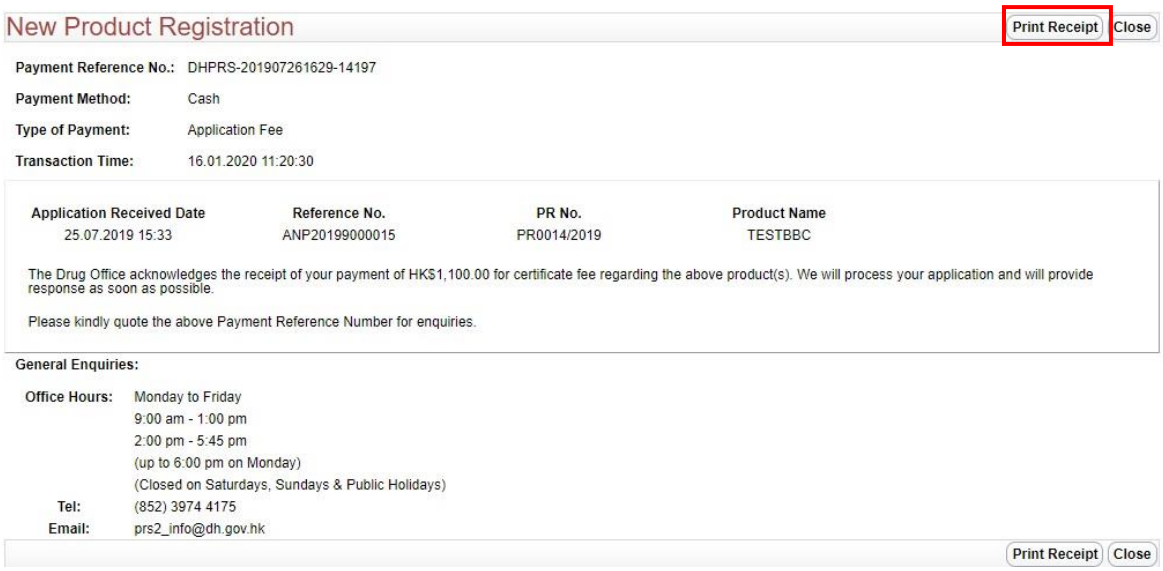
Step 5: Click “Yes” and the page will be redirected to the payment gateway.



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.



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
25.07.2019 15:33
Reference No.
ANP20199000015
PR No.
PR0014/2019
Product Name
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	**Payment Date** 繳費日期
CERT HOLDER 6	30.1.2015

Payment Reference No: 付款編號:	DHPRS-201501300213-90574
EGIS Reference No: EGIS編號:	A201501300000043
Payment Method: 付款方法:	PPS
Payment Amount: 付款金額:	HK$1,100.00

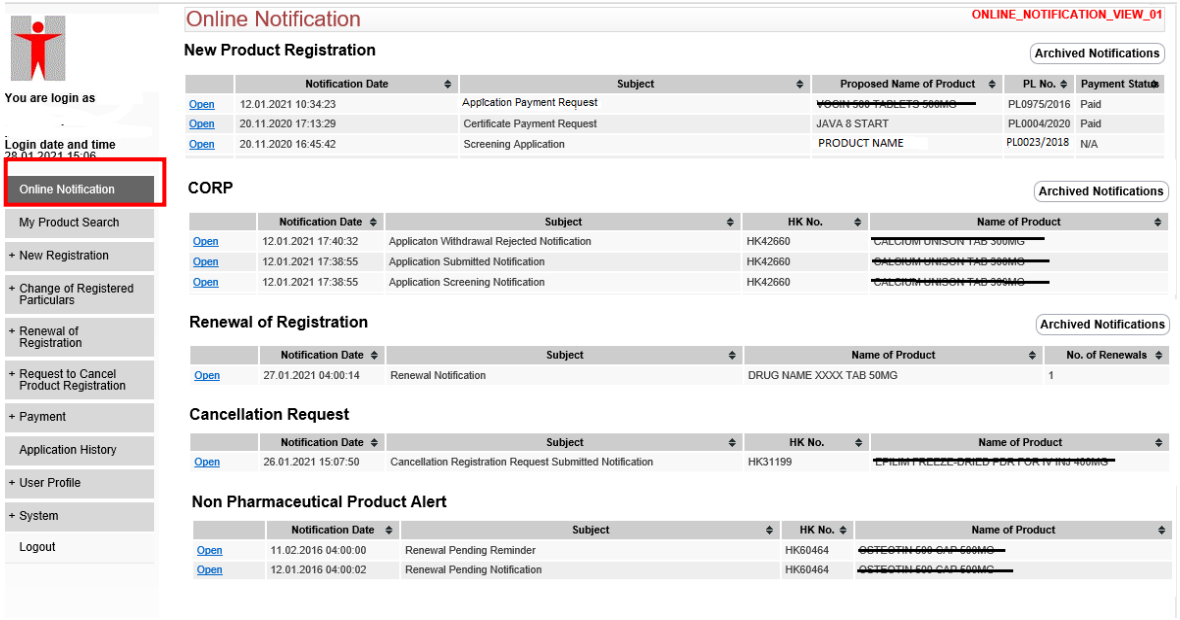
Payment Reference No: DHPRS-201501300213-90574
付款編號:

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

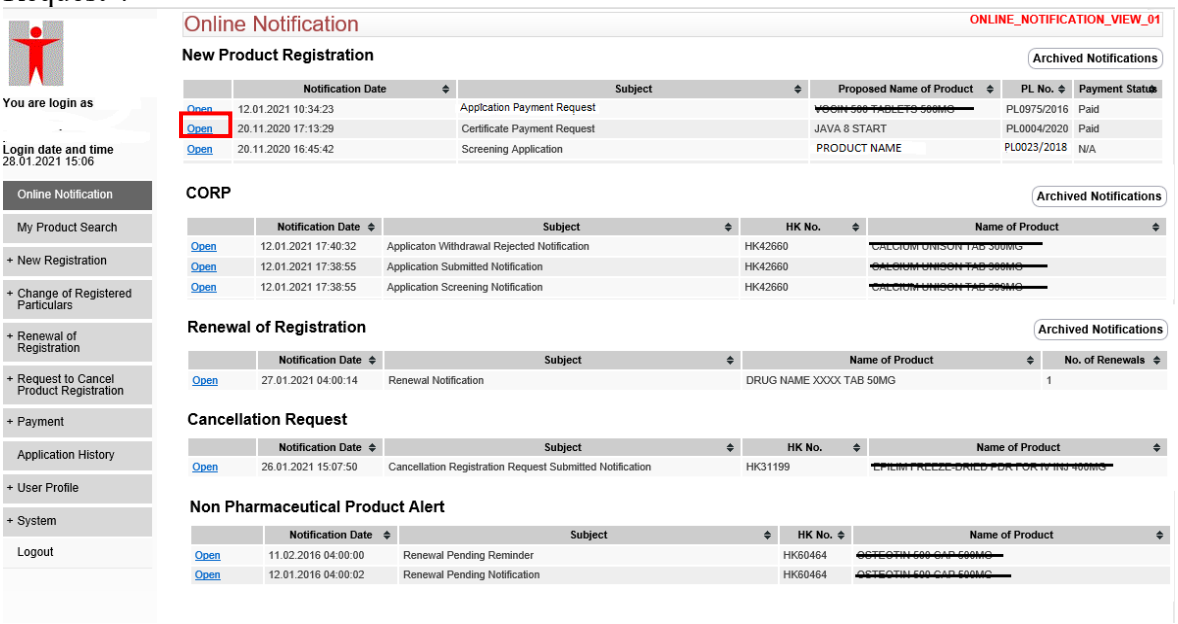
第 2 頁 (共 2 頁)

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

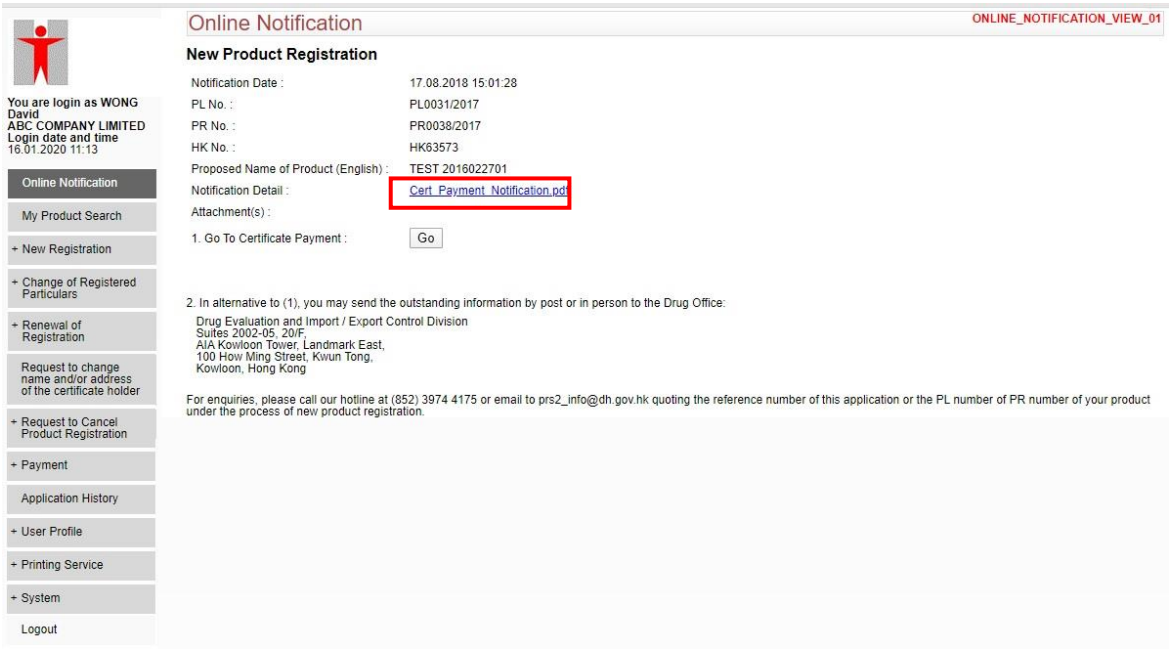
Step 1: Click the menu item “Online Notification” under “New Product Registration” in the menu on the left.



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



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 : 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,
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
[X] **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衞生署藥物辦公室繳款處收。地址為香港九龍南昌街382號公共衞生檢測中心3樓。劃線支票抬頭寫上「香港特別行政區政府」。
2. In person with payment cheque or cash and this notification letter at the above address. Hours of operation:
   Monday to Friday: 9:00 a.m. to 1:00 p.m.
   2:00 p.m. to 5:30 p.m.
   (up to 5:45 p.m. on Monday)
   攜同本通知書到上述辦事處以支票或現金繳交。辦事處收款時間：
   星期一至星期五: 上午九時至下午一時
   下午二時至下午五時三十分
   (星期一至下午五時四十五分)
   (Note: CASH should NOT be sent through post
   注意: 請勿郵寄現金)
3. By online credit card (Visa/MasterCard) payment via EGIS in PRS 2.0
   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「藥劑製品註冊證明書」、「證明書的複本」、「更改註冊詳情」、「臨床試驗 / 藥物測試證明書」及「影印服務」，請填妥丙部 •

C. Certificate(s) Collection Method
丙：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

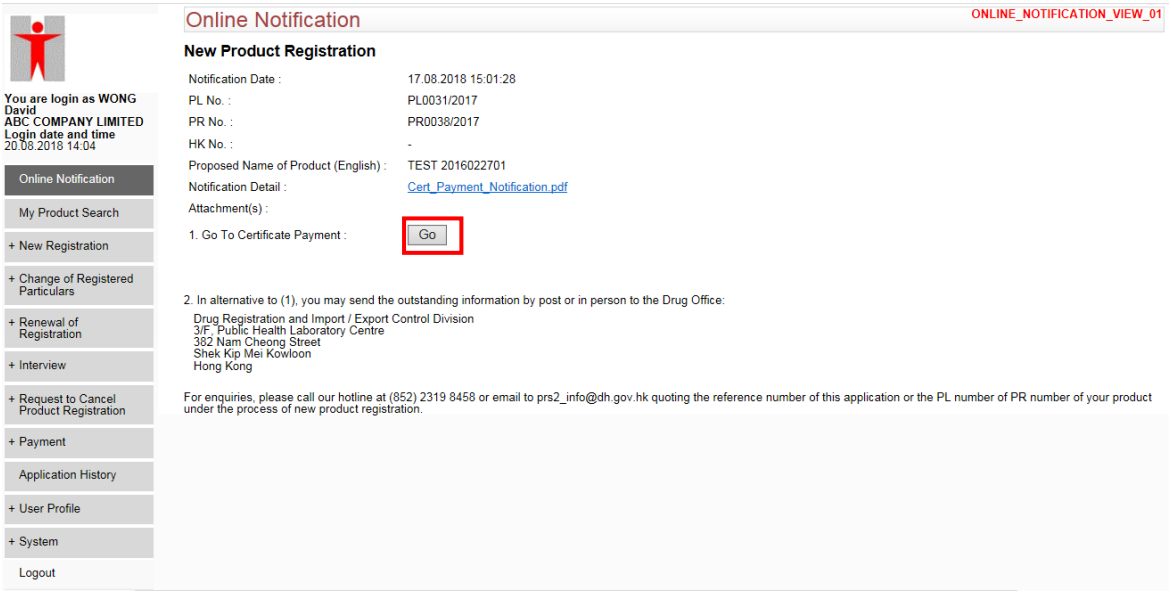
Or或

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

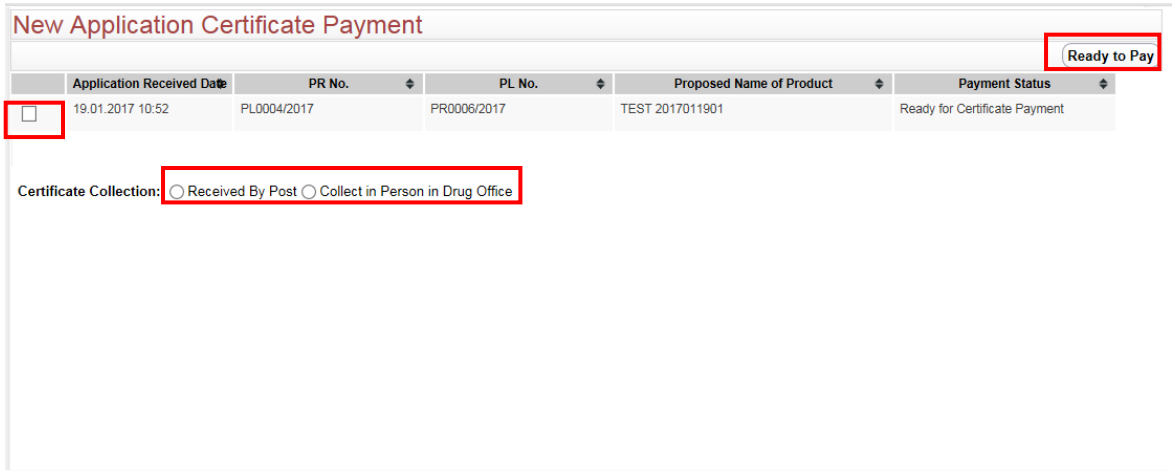
Company Stamp:
公司印鑑：_____

第 3 頁 (共 3 頁)

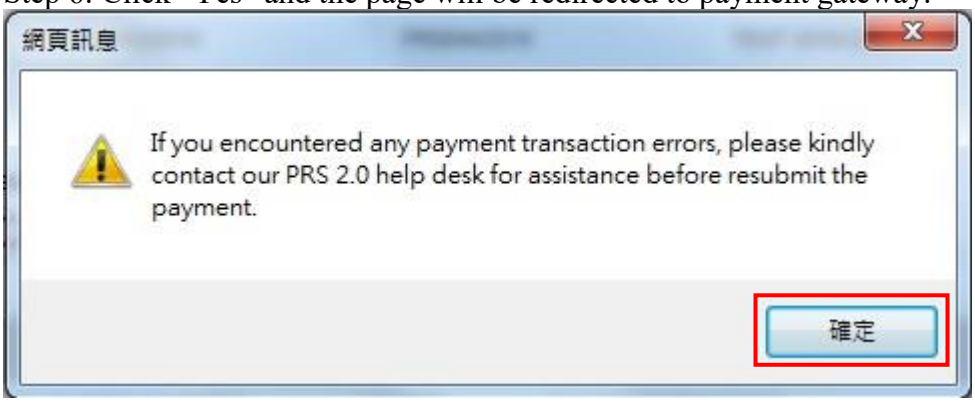
Step 4: Click the "Go" button to the payment page if the fee is paid online.

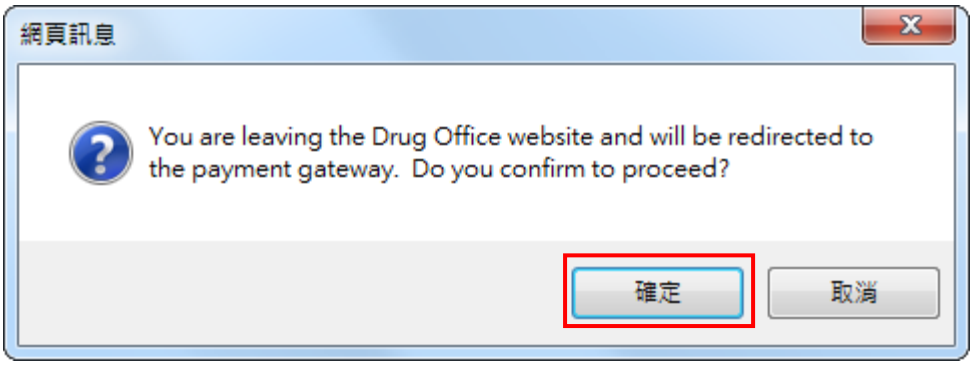


Step 5: Select single/multiple application, then choose the certificate collection method (received by post or collect in person in Drug Office), and then click the “Ready to Pay” button.

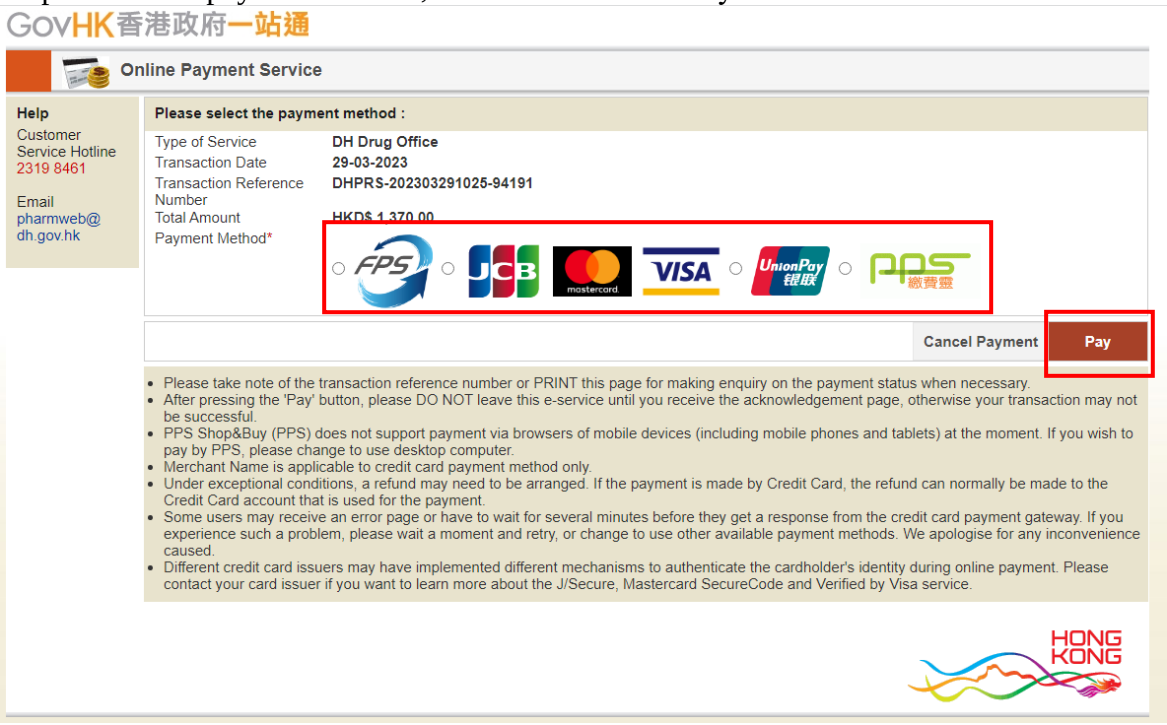


Step 6: Click “Yes” and the page will be redirected to payment gateway.

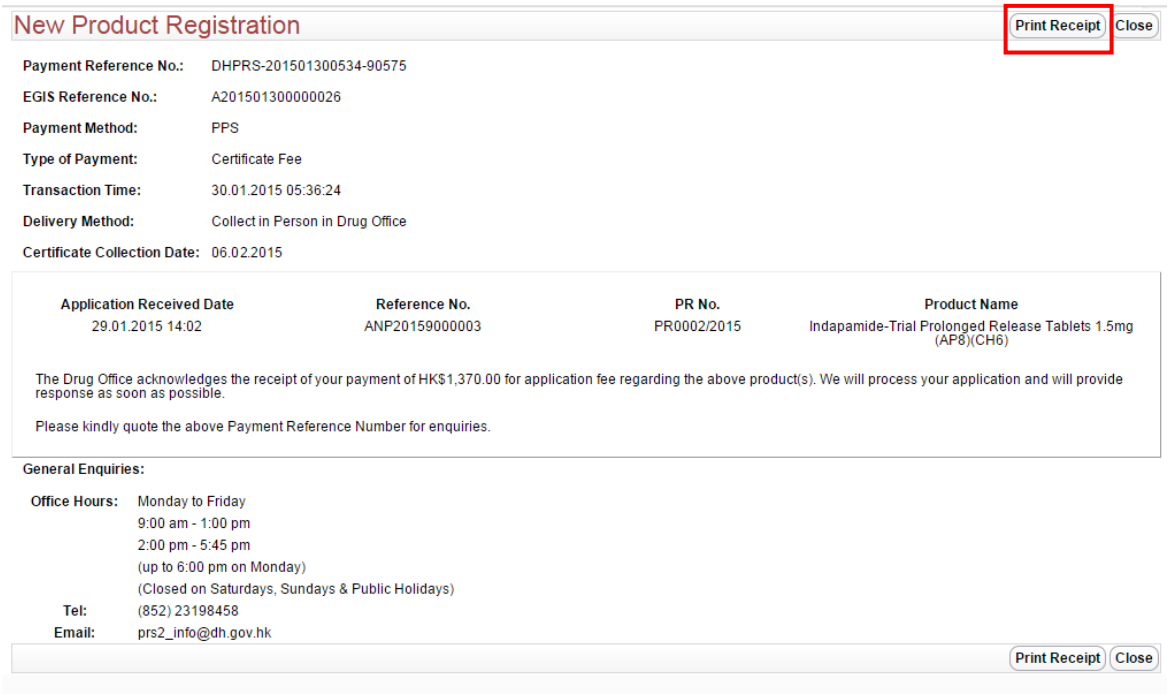




Step 7: Select a payment method, and then click the “Pay” button.



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	**Payment Date** 繳費日期
CERT HOLDER 6	30.1.2015

Payment Reference No: 付款編號:	DHPRS-201501300534-90575
EGIS Reference No: EGIS編號:	A201501300000026
Payment Method: 付款方法:	PPS
Payment Amount: 付款金額:	HK$1,370.00

For Office use

____ certificate(s) collected on _____

Company Stamp:
公司印鑑: _____

Certificate(s) Collection Method
領取證明書方法

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

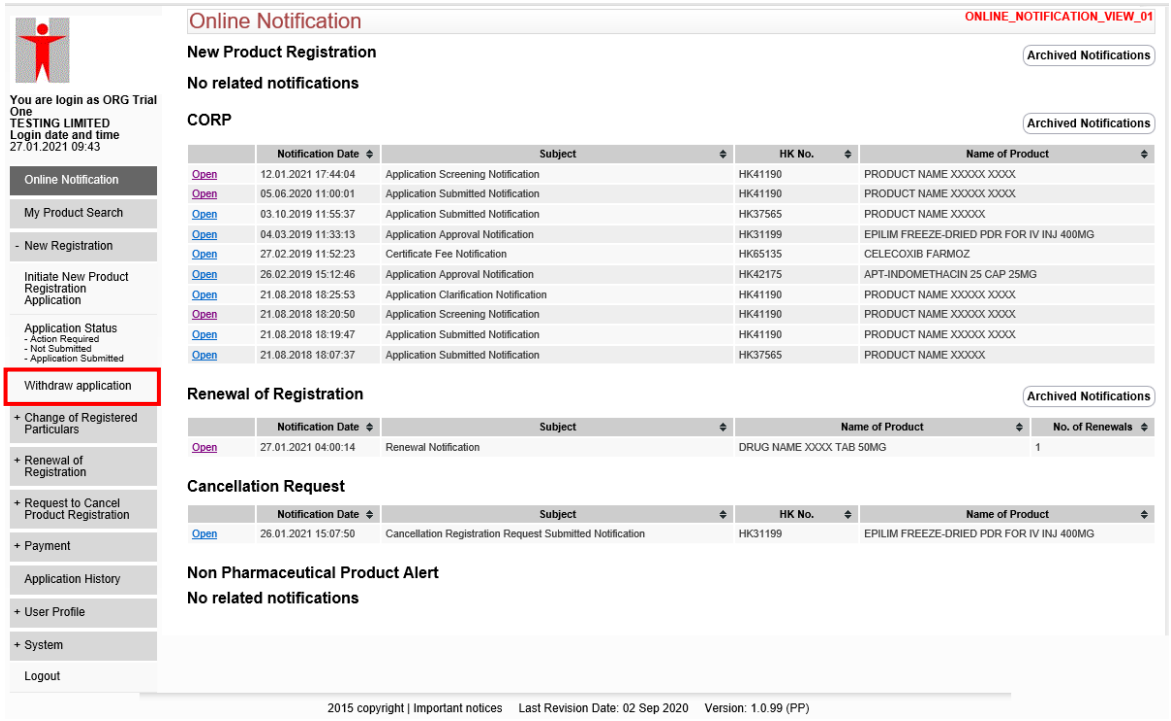
☐ I/we would like to collect the Certificate(s) **by post** ;
我/我等欲以郵遞方式領取證明書

Or或

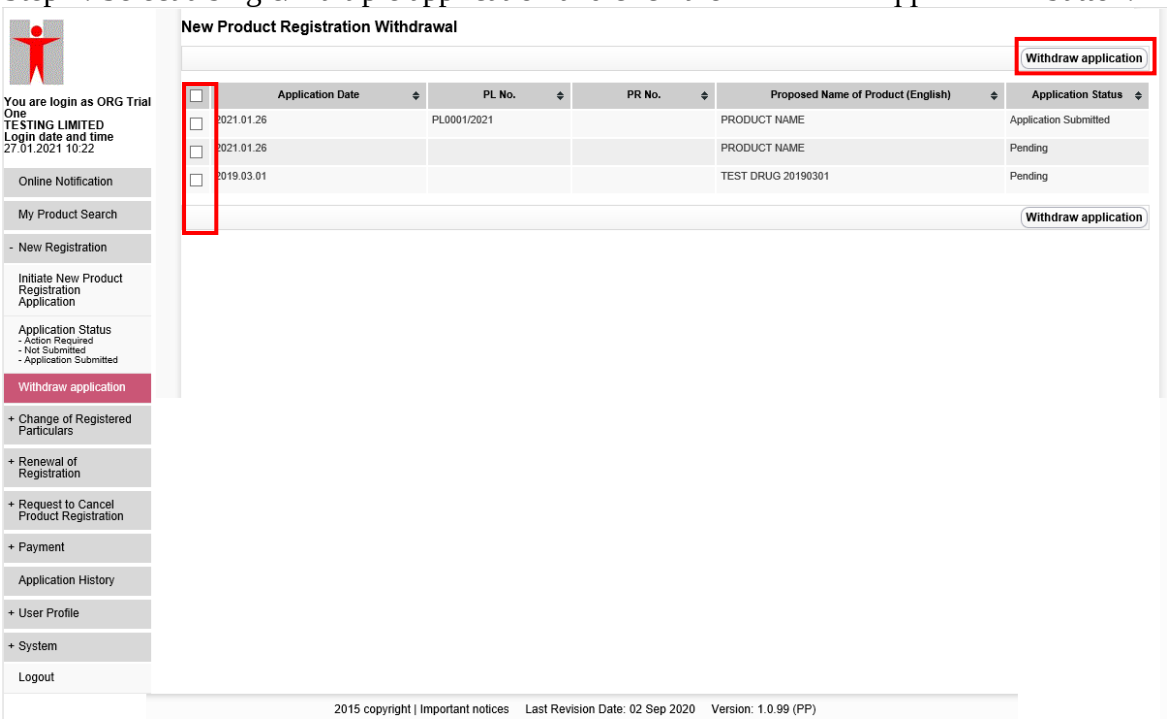
☒ I/we would like to collect the Certificate(s) of Product Registration **in person** at the above address from at least 5 working days from the date of payment made or effective date, whichever is later
我/我等欲在繳交費用或生效日期(以較遲者為準)後最少5個工作天起親自前往上述地址領取證明書

2.5.2.6 Withdraw application

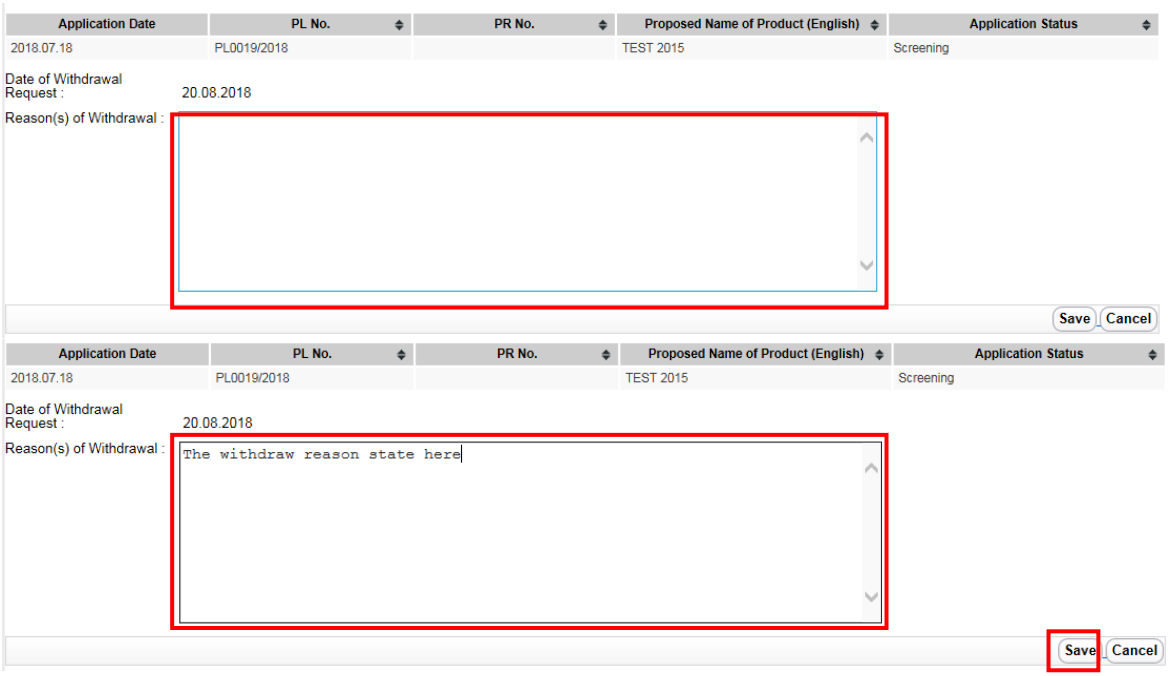
Step 1: Click the menu item “Withdraw application” under “New Product Registration” in the menu on the left.



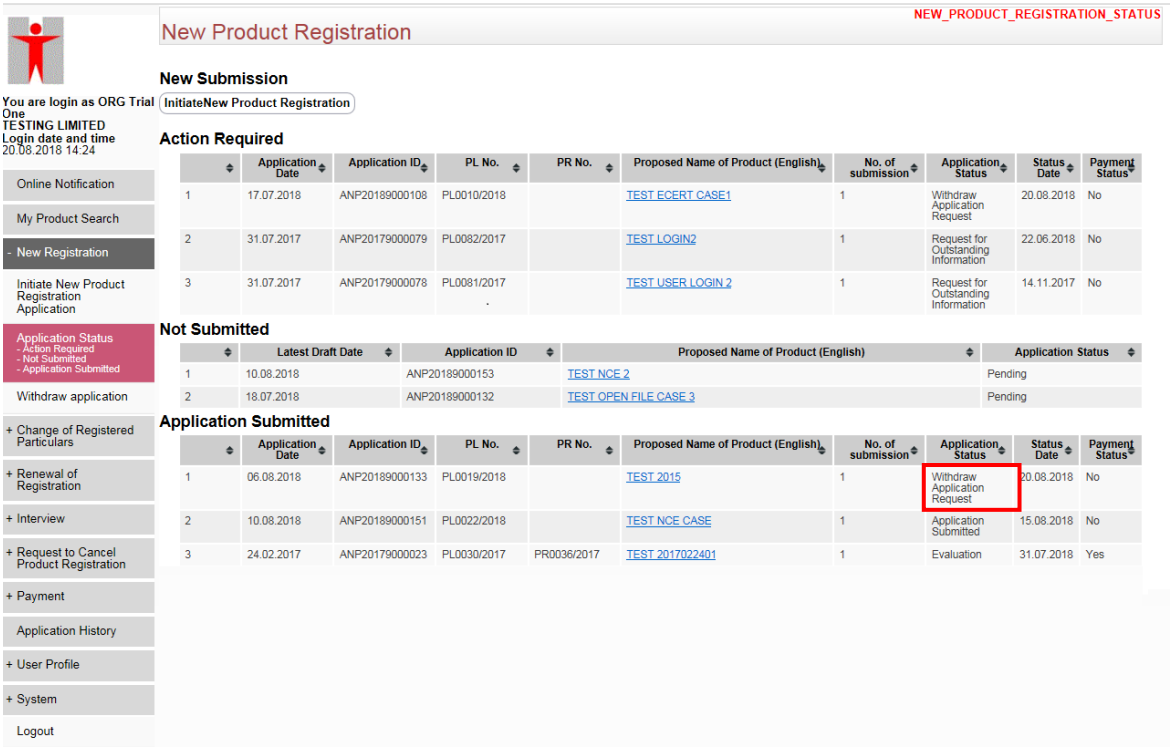
Step 2: Select a single/multiple application and click the “Withdraw application” button.



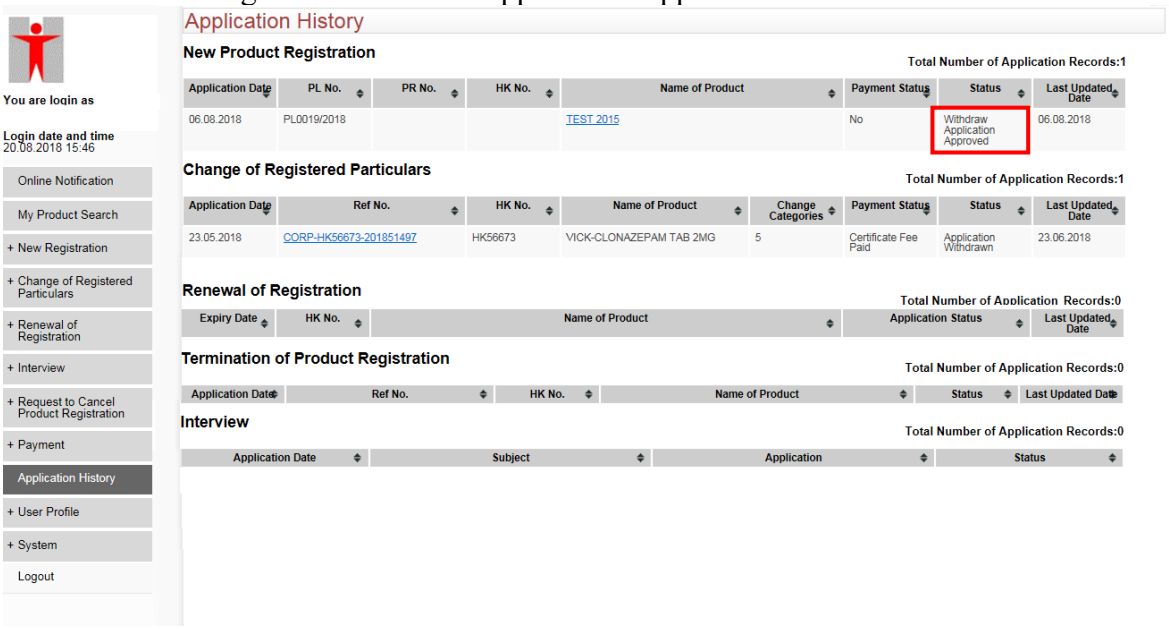
Step 3: Input the reason (s) of withdrawal and click “Save” button to proceed the withdrawal request. Click ‘Cancel’ to cancel the withdrawal request.



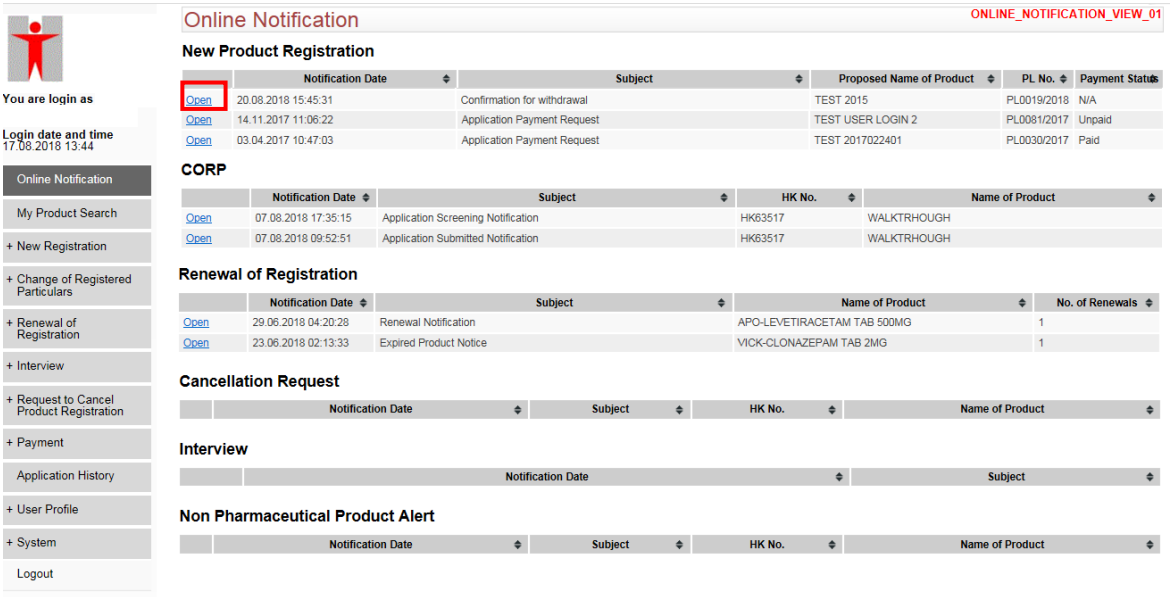
Step 4: Click the menu item “Application Status” under “New Application” in the menu on the left, the application status is changed to “Withdraw Application Request” under “Application Submitted”.

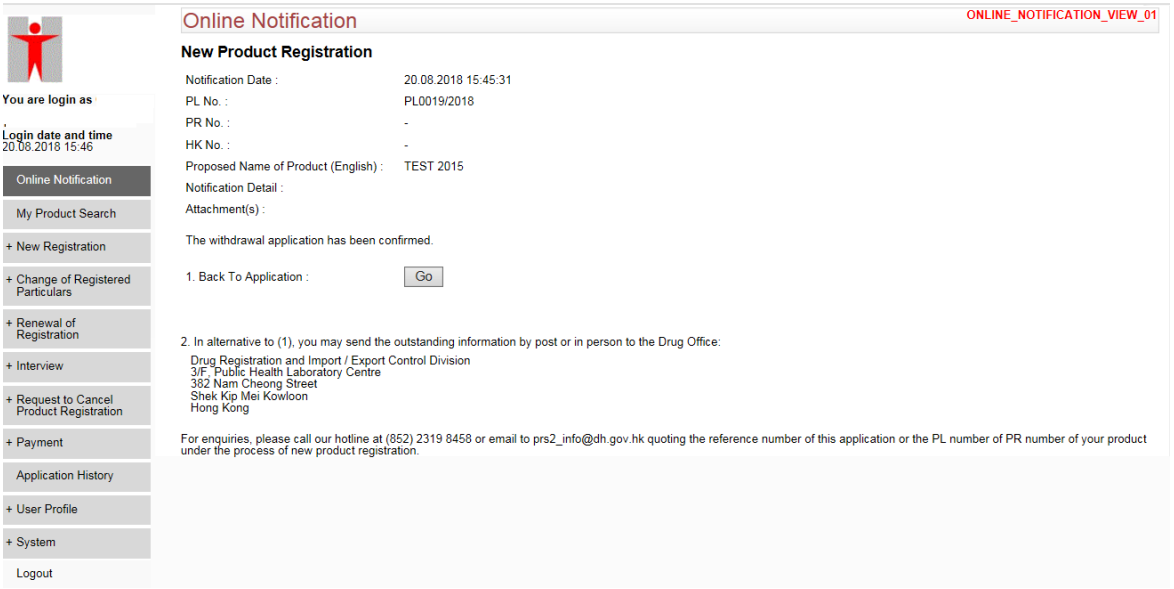


After Drug Office Pharmacist reviewed and confirmed the application, the application status will be changed to “Withdraw Application Approved”.



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





Applicant will receive the confirmation of withdrawal letter by post.

衞生署藥物辦公室
藥物註冊及進出口管制部
香港九龍南昌街 382 號公共衞生檢測中心三樓

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
(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

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

Dear Sirs,

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

Mfd By: My Manufacturer

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

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

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

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

Yours faithfully,

(H.K. CHAN)
for Chief Pharmacist

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

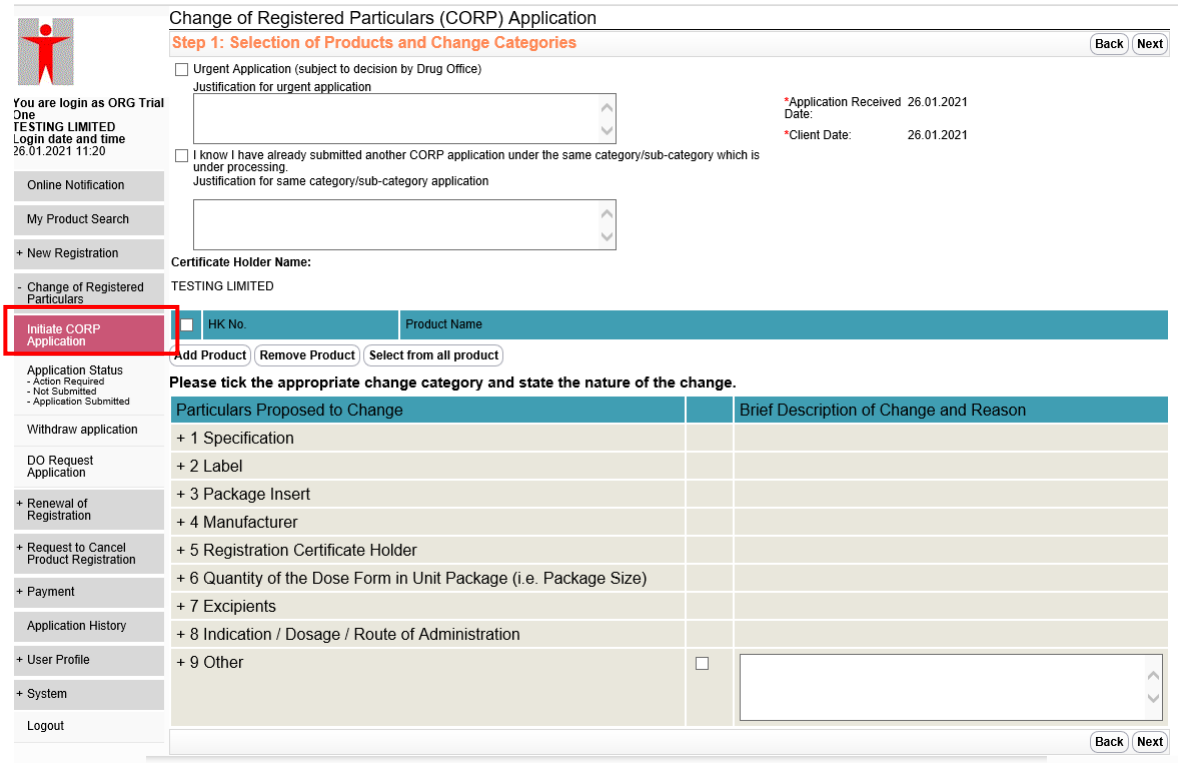
We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority

2.6 CHANGE OF REGISTERED PARTICULARS

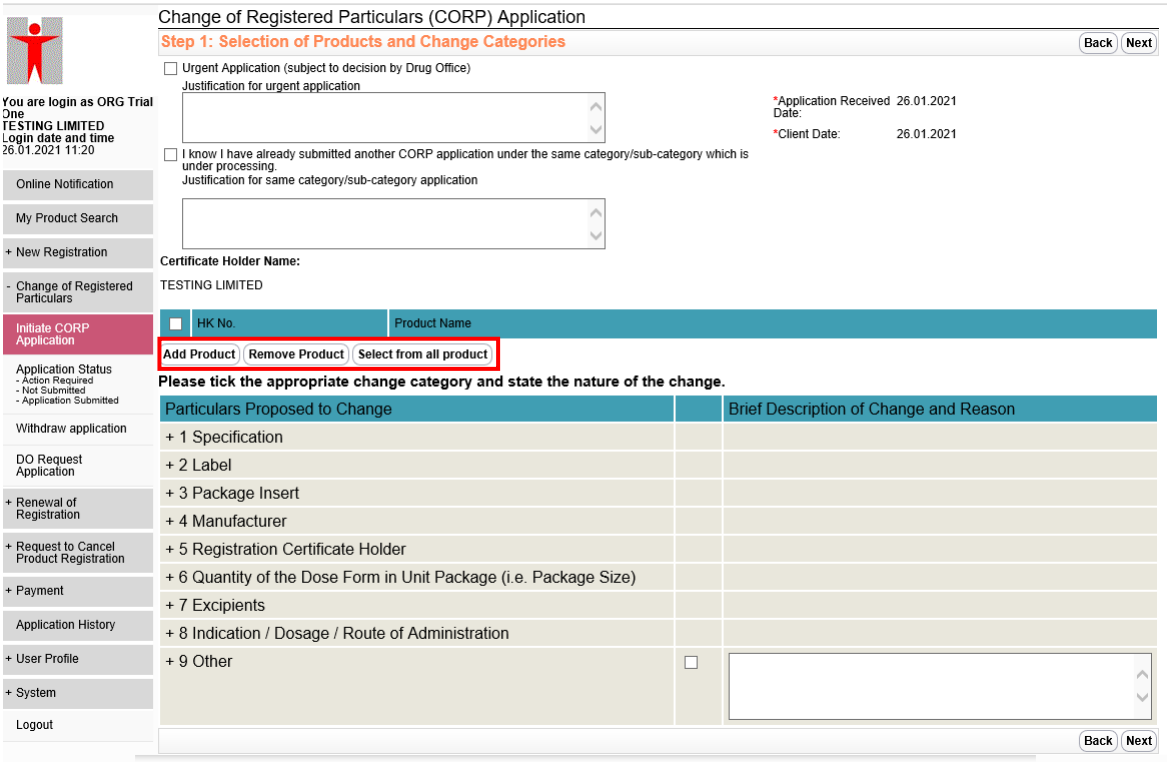
2.6.1 Initiate CORP Application

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

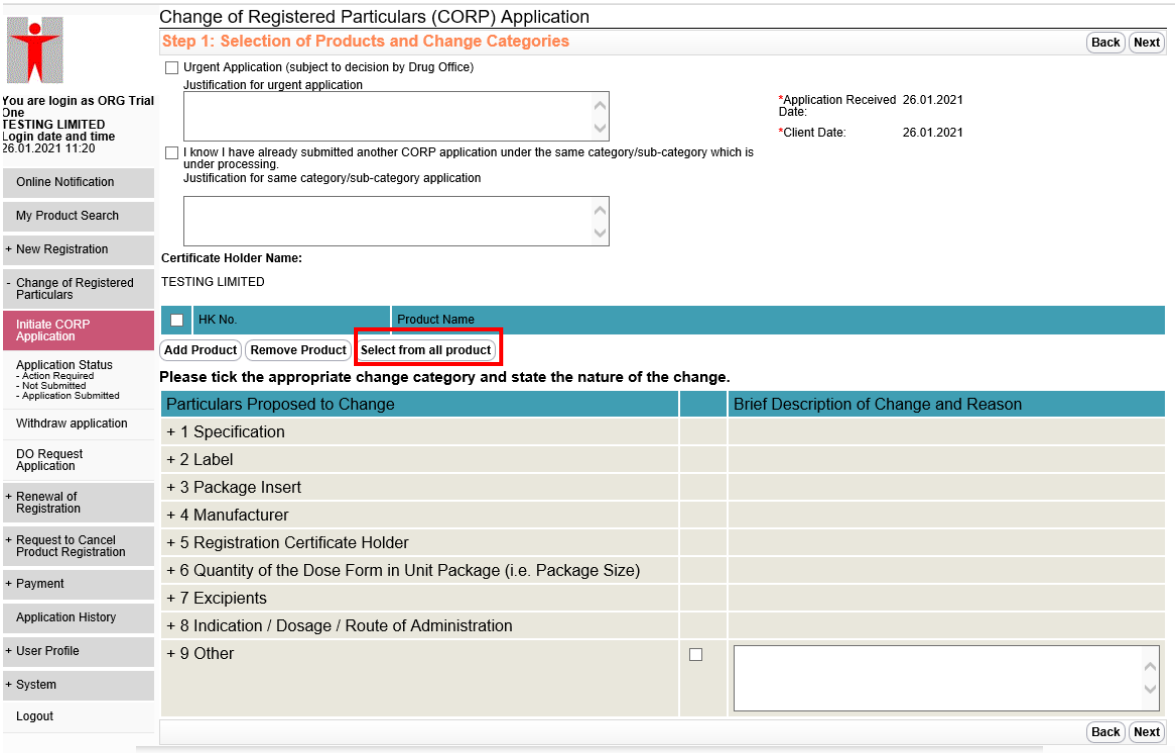
The step 1 page of Change of Registered Particulars (CORP) Application will be displayed for input.



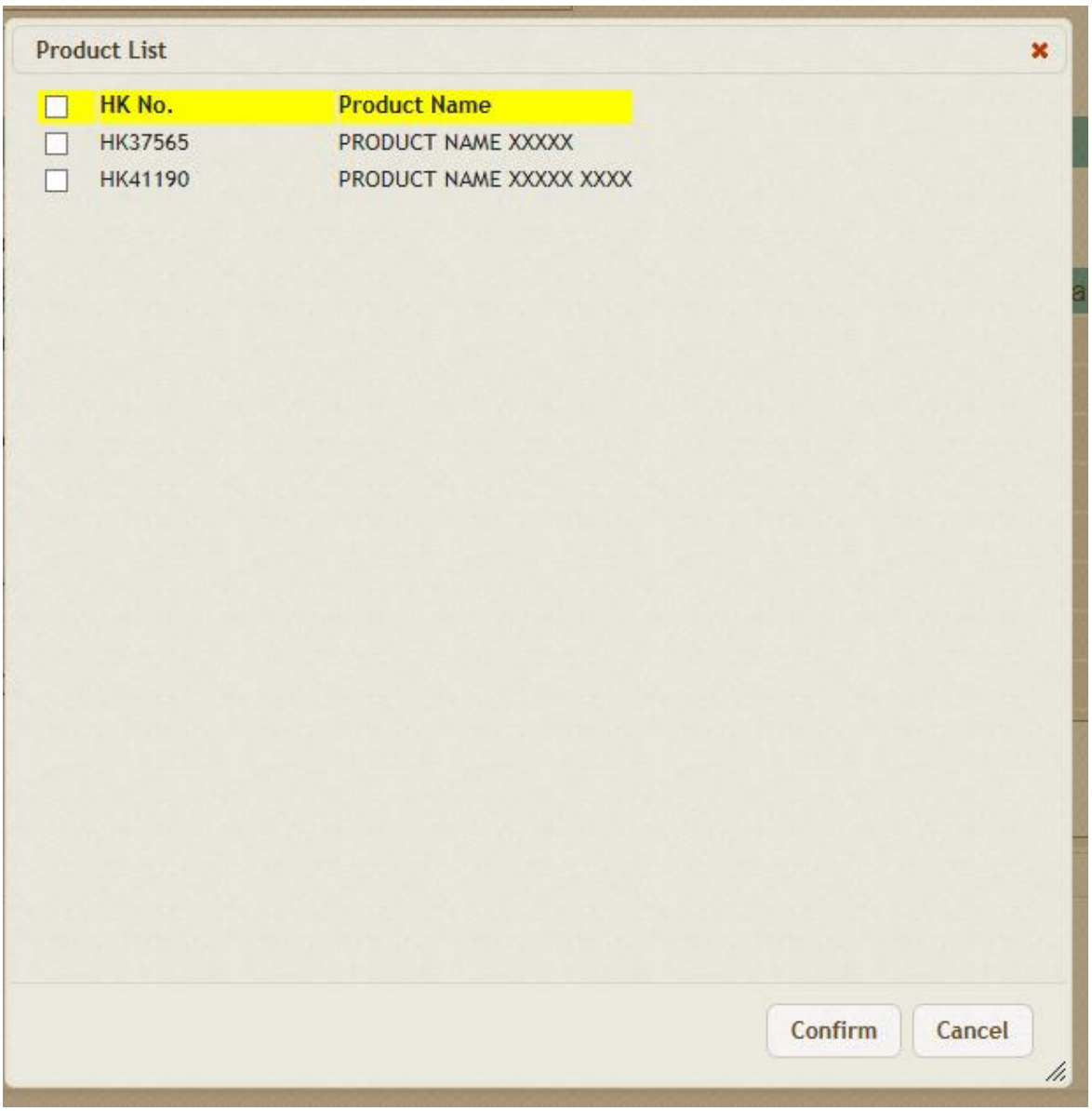
User can click “Add Product” button to add new row and input the product HK registration number directly. Selected product(s) can be removed by using “Remove Product” button.



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



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

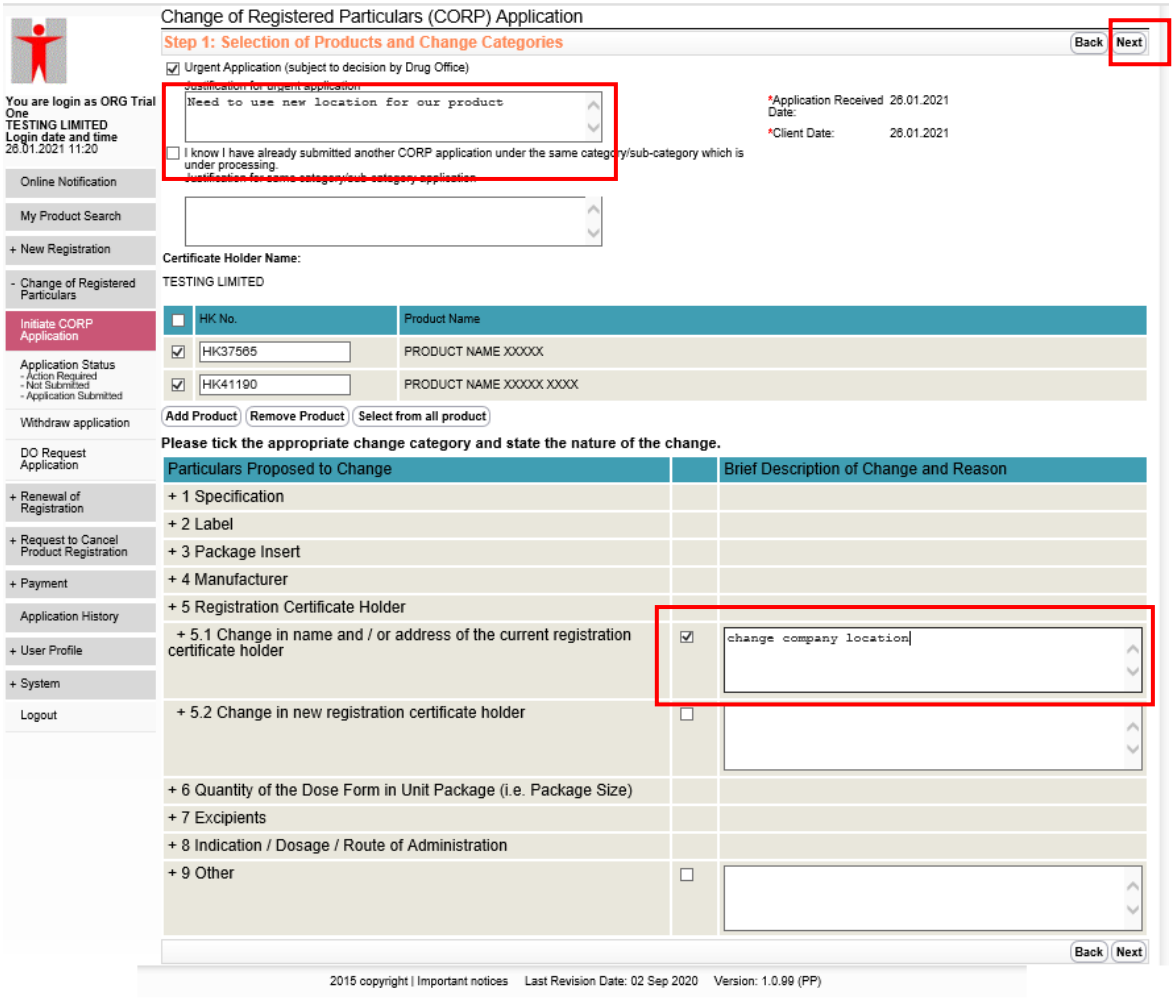


After user selects the product(s) and clicks the “Confirm” button, the selected product(s) will be shown in application step 1 page.

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.



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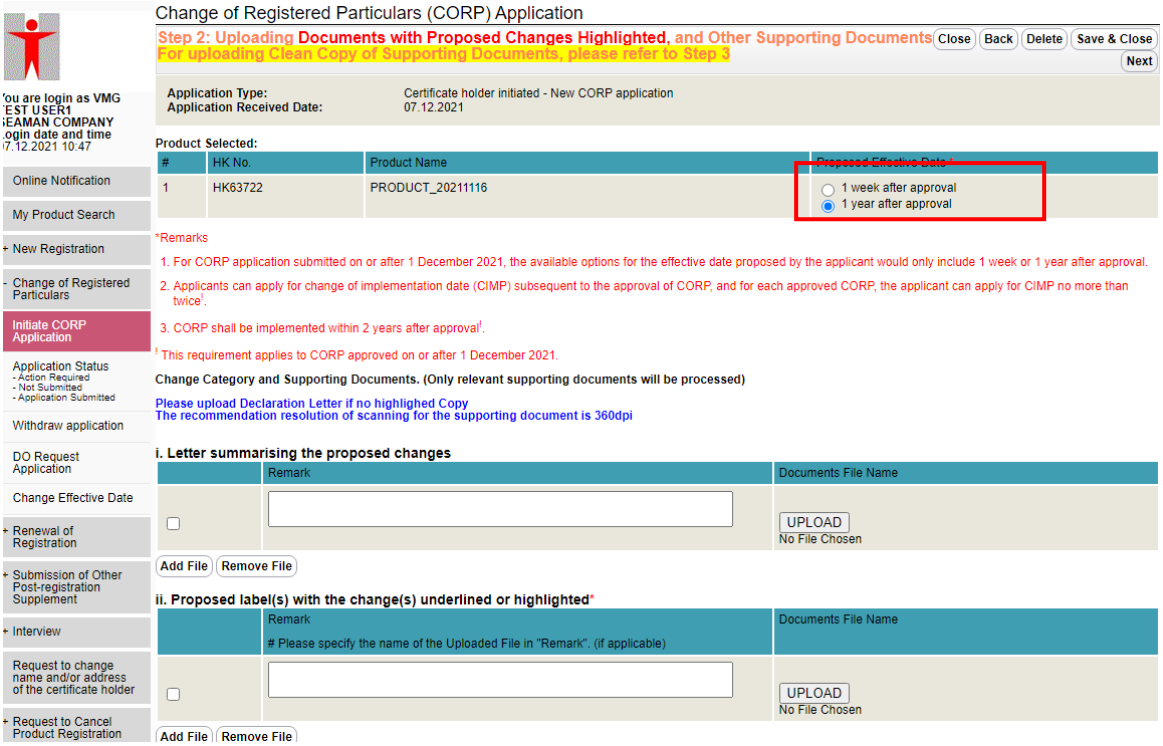
Note:

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.

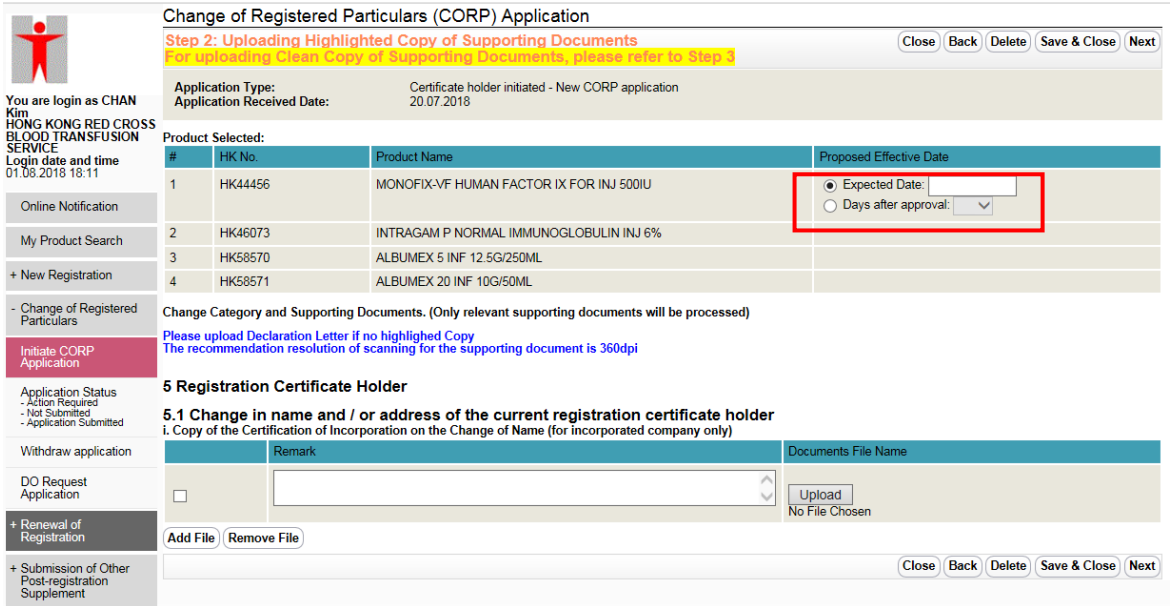
The step 2 page of Change of Registered Particulars (CORP) Application will be displayed for input.

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

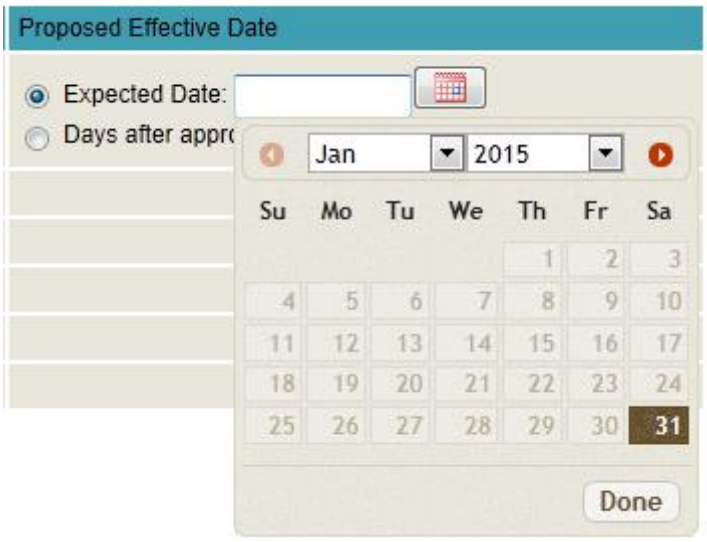


Application should submitted proposed effective date either 1 week after approval or 1 year after approval. By default, 1 year after approval is selected. (except for change in category 5 -Registration Certificate Holder).

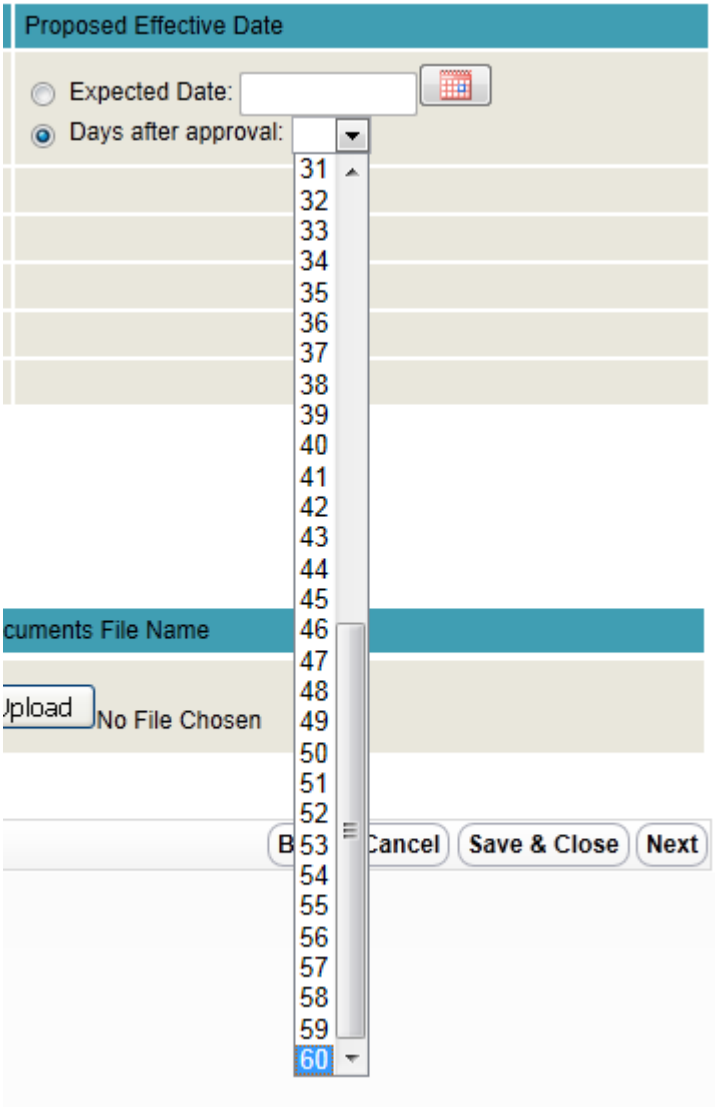
For change in registration certificate holder, proposed effective date can be chosen from two options.



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

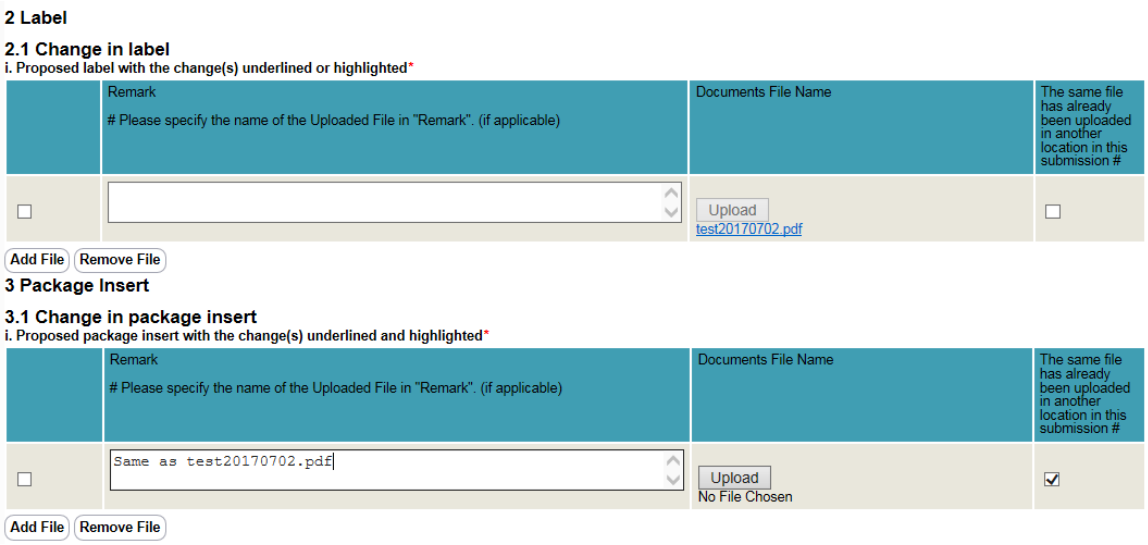


Another one is in the form of “X days after approval”, X can be 1 to 60. It can be selected from the dropdown list as shown below.

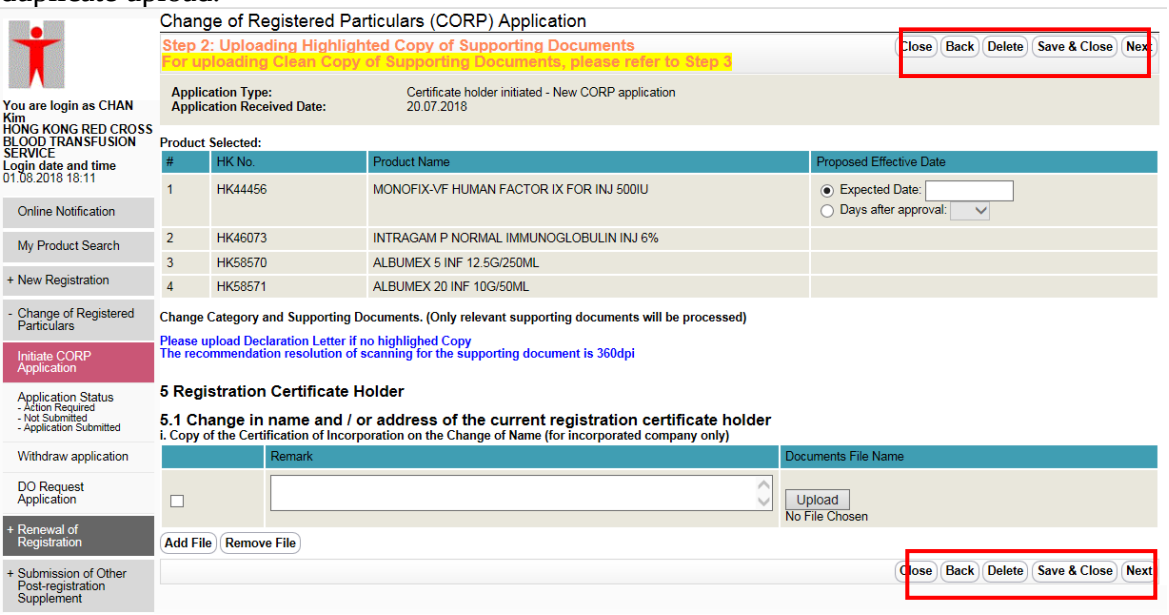


Application can be submitted without any proposed effective date. In such case, the effective date by default is 30 days after approval.

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.



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.



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.

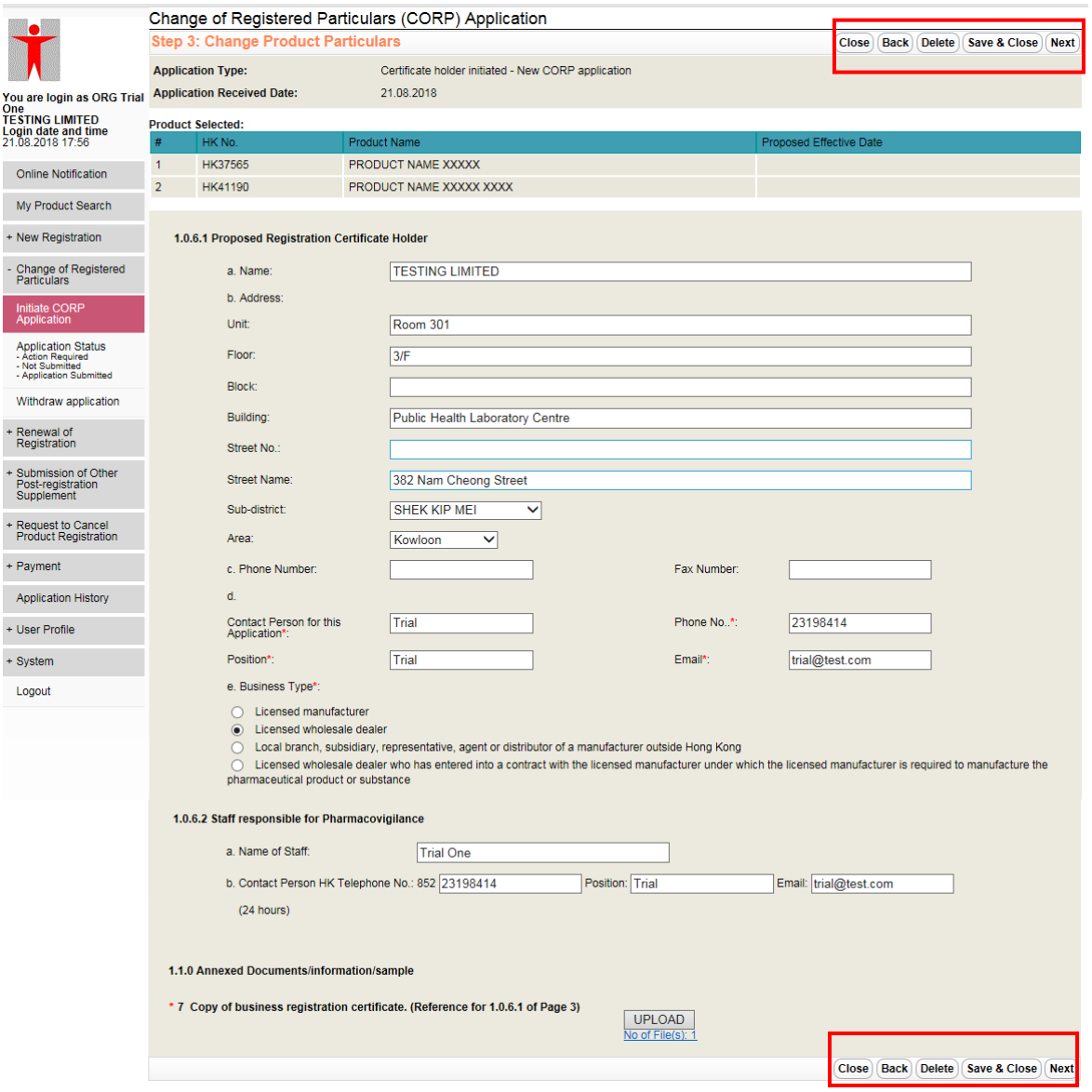
User can click "Back" button without saving and go back to step 1 page to select another product and/ or category for this application.

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.



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.

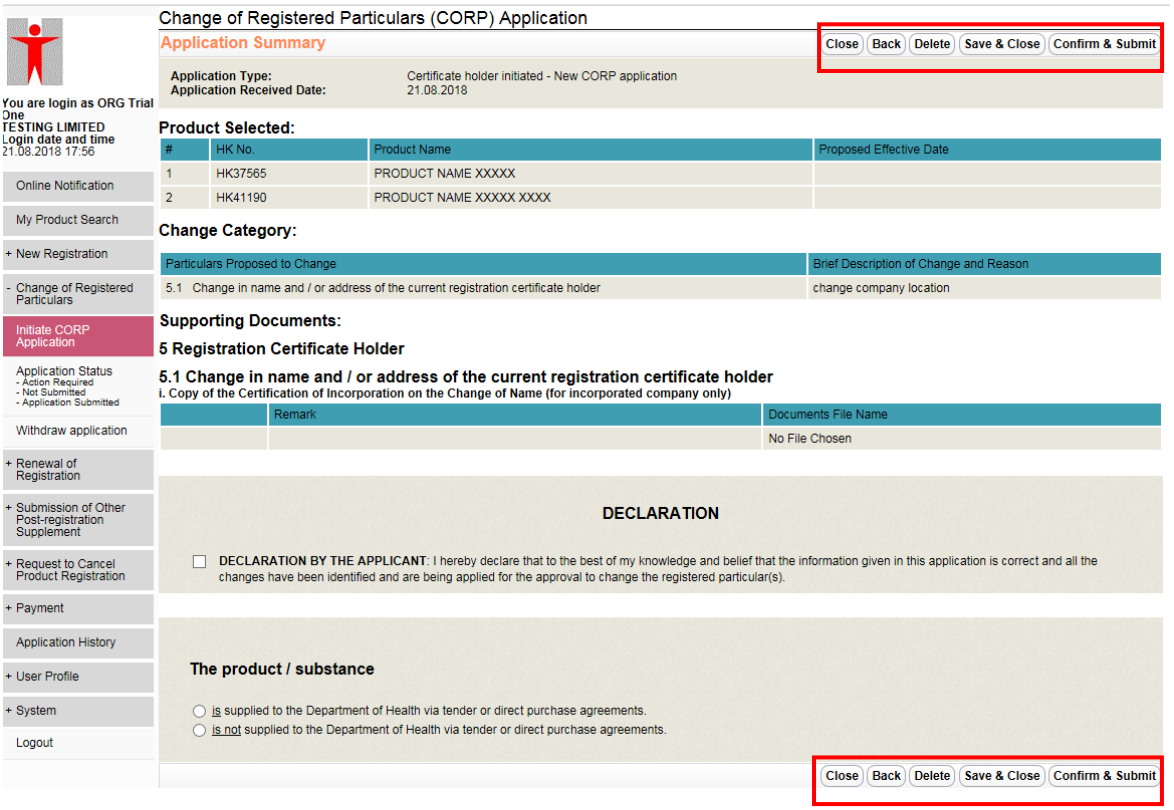
User can click “Back” button without saving and go back to step 2 page to select another proposed effective date or provide other supporting documents for this application.

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.



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.

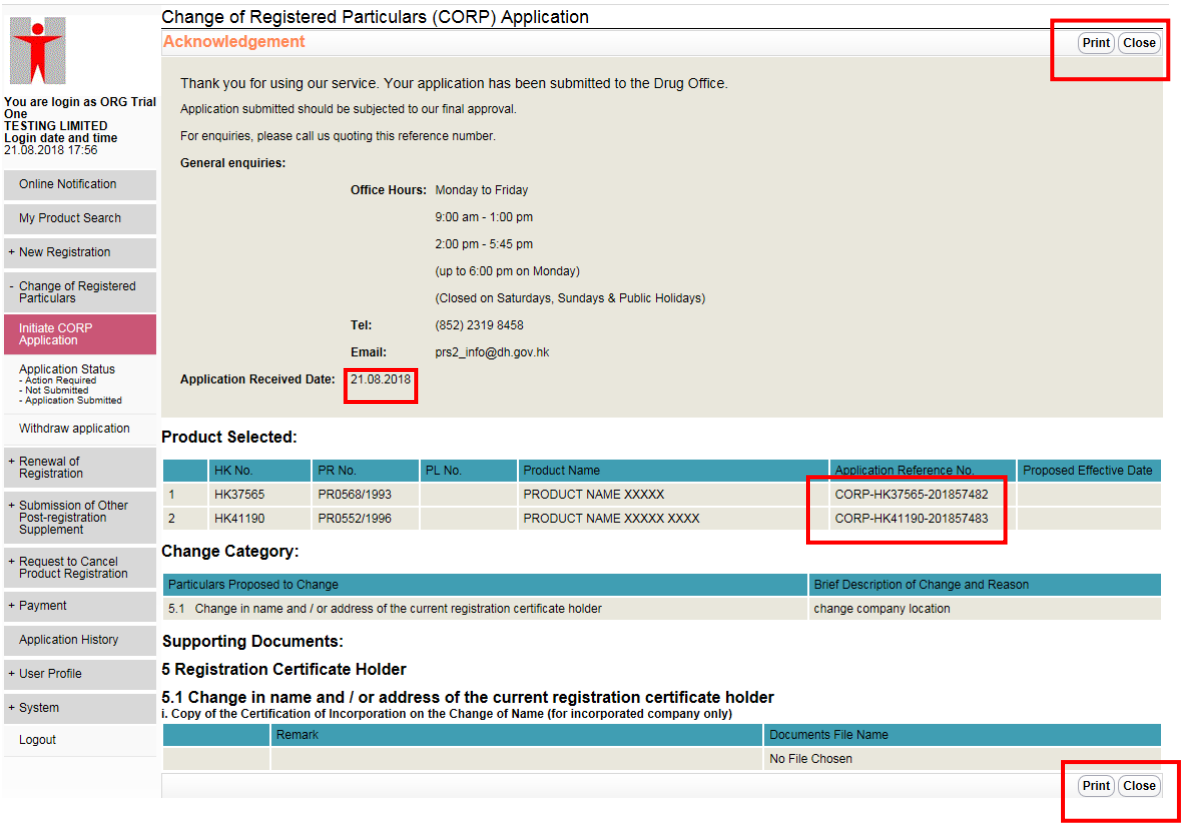
User can click “Back” button without saving and go back to step 3 page for update of product particulars for this application.

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.



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.

衞生署藥物辦公室
藥物註冊及進出口管制部
香港九龍南昌街 382 號公共衞生檢測中心三樓

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
傳真號碼 Faxline No: (852) 2803 4962

21 August 2018

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

Dear Sirs/Madams,

Change of Registered Particulars Acknowledgment

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

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

For enquiries, please call us quoting this reference number.

General Enquiries:

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

Email: pharmgeneral@dh.gov.hk

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

HK No.	PR No.	PL No.	Product Name	Application Reference No.
HK-37565	PR0568/1993		PRODUCT NAME XXXXX	CORP-HK37565-201857482
HK-41190	PR0552/1996		PRODUCT NAME XXXXX XXXX	CORP-HK41190-201857483

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

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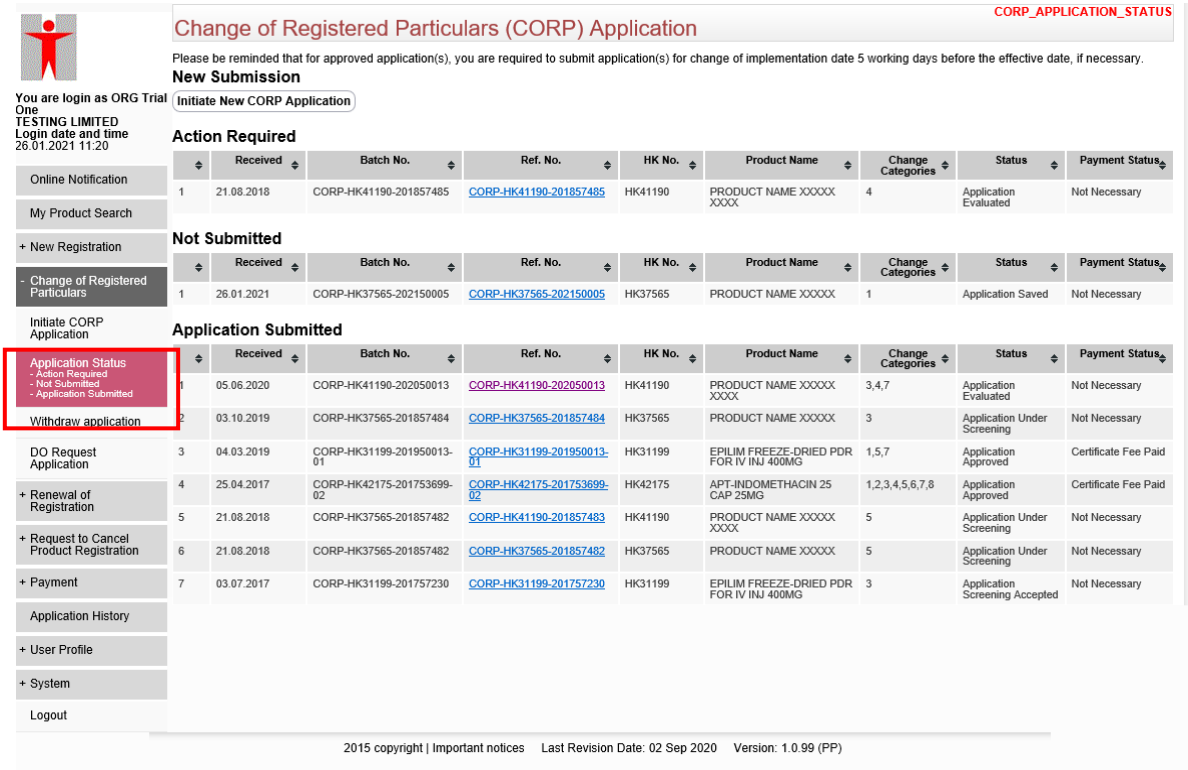
aspire to be an internationally renowned public health authority

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.

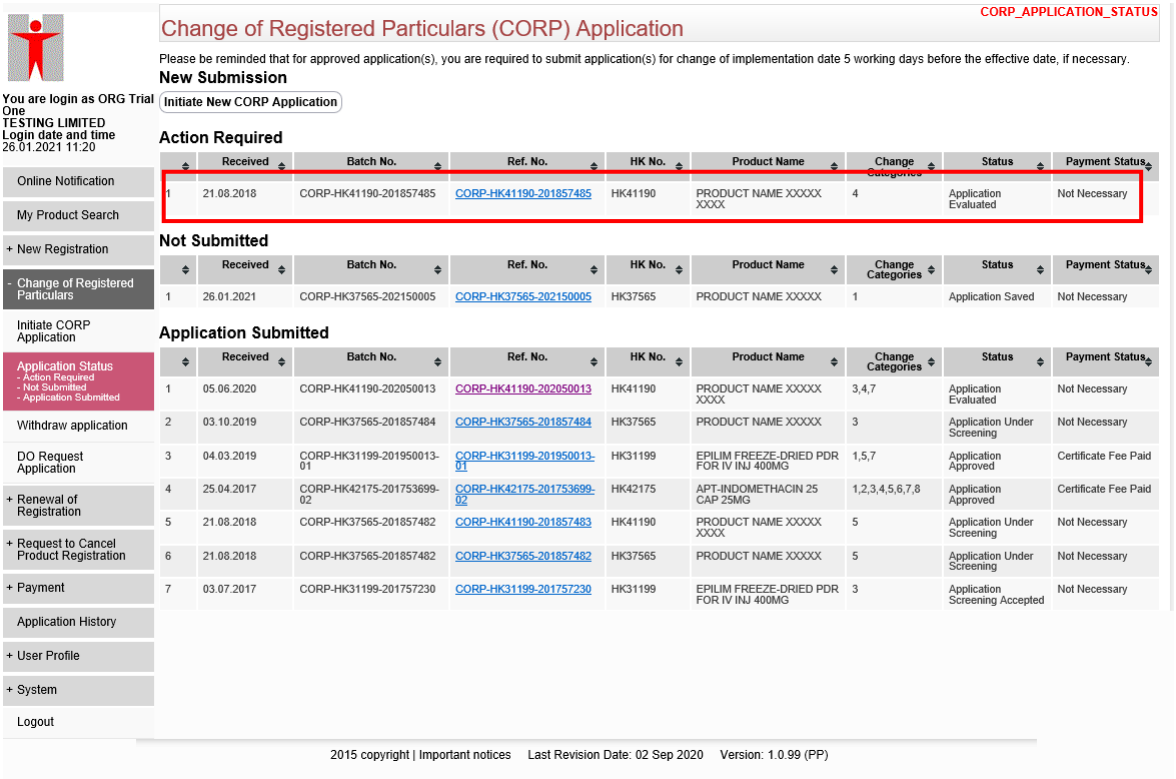
The application status page will be displayed for review.



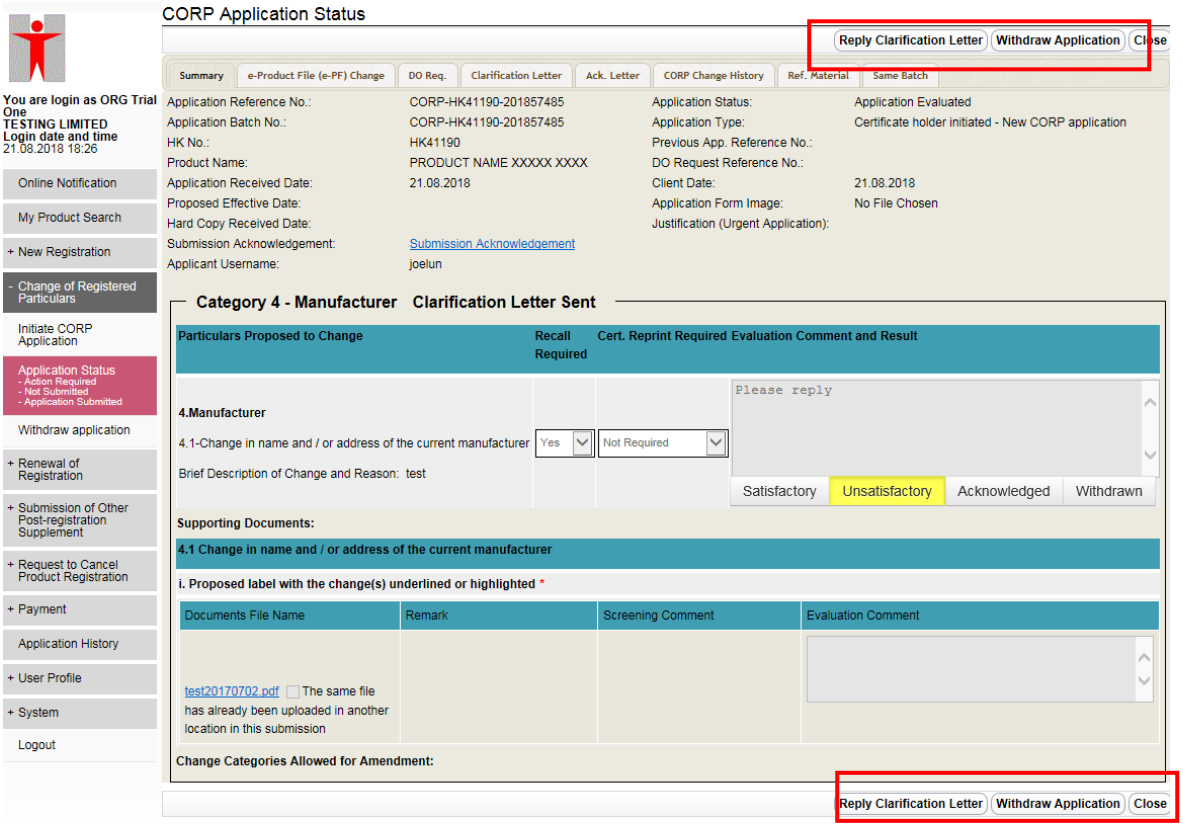
New List added

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



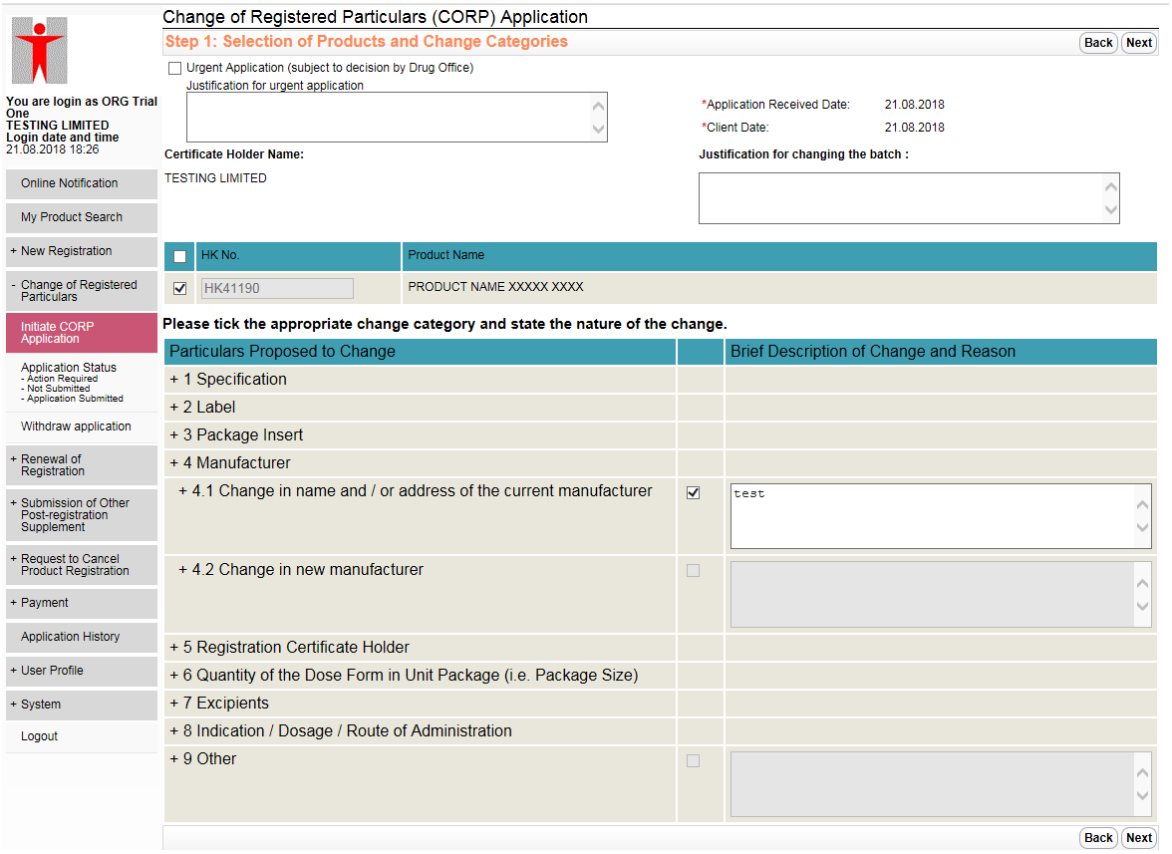
User needs to take necessary action to follow up the applications listed in this section. For example, user needs to reply deficiency / clarification letter or pay signature fee. By clicking the application reference number, related details will be shown as below:



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

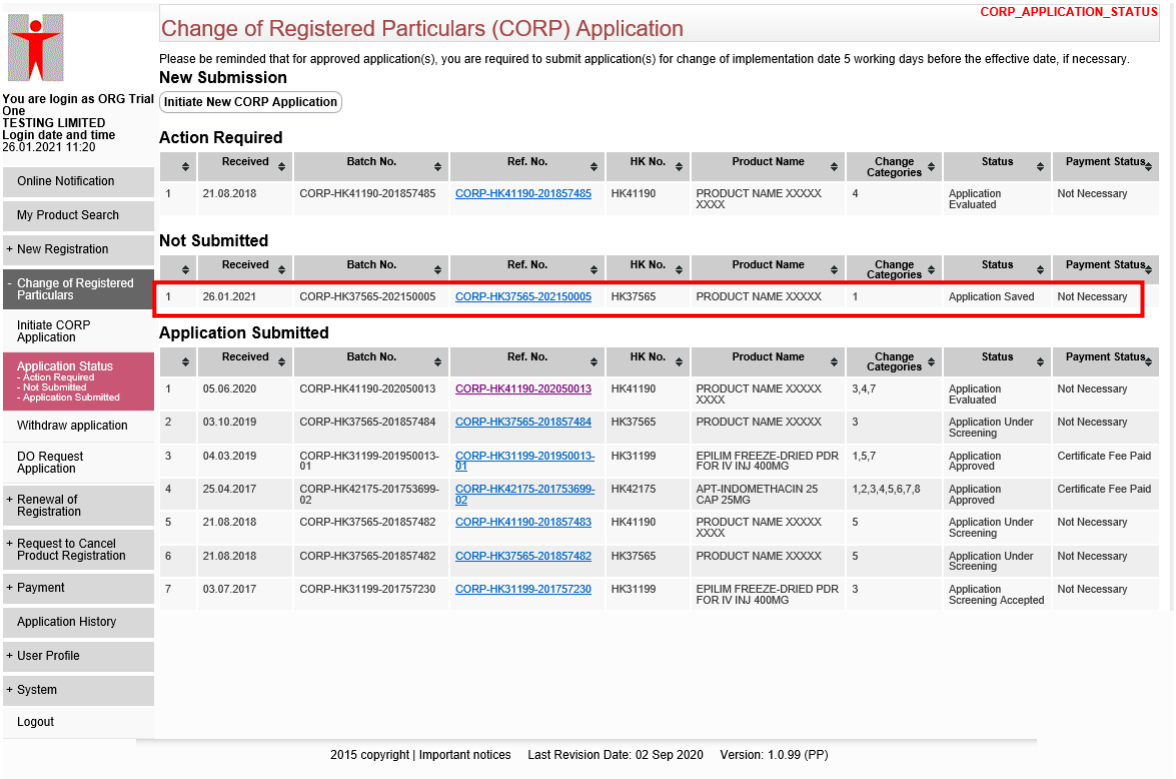
User may click “Reply Deficiency/ Clarification Letter” to reply screening/ evaluation officer with the requested information:

User can click “Submission Acknowledgement” to view the acknowledgement letter

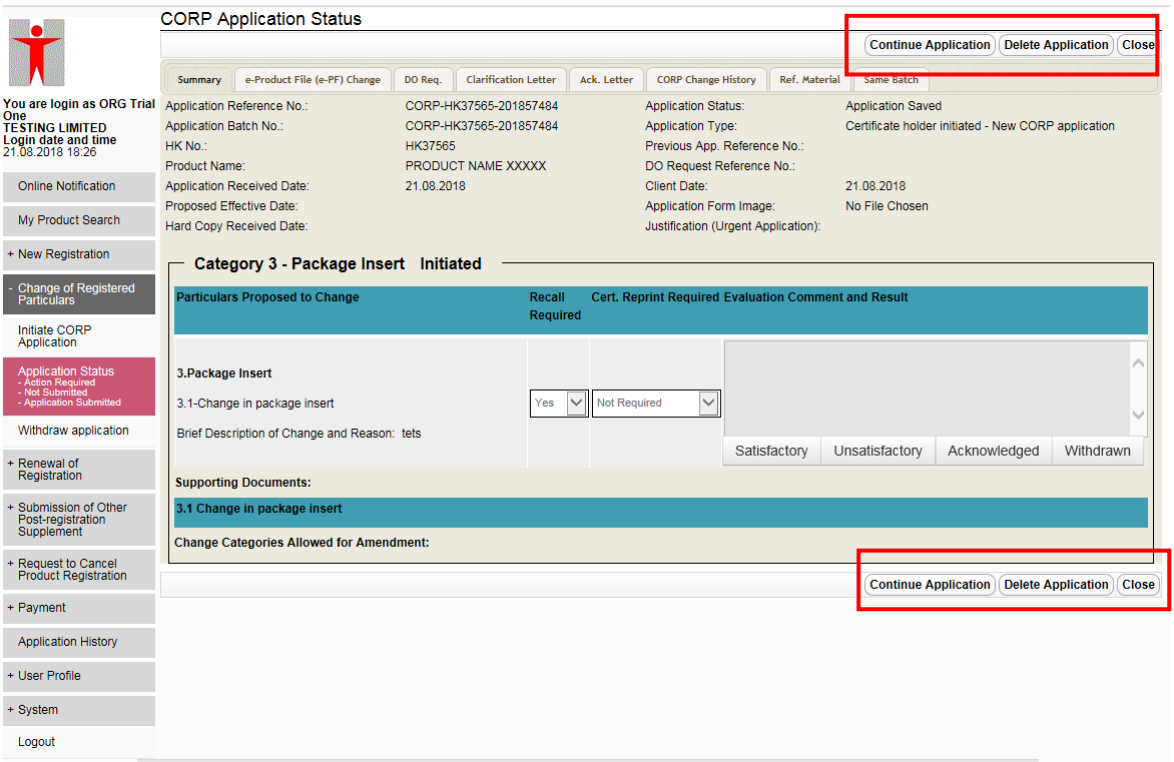


In replied application, selected product(s) can be “deselected”; no new product can be added. If any product from the batch is “deselected”, justification should be provided in the field “Justification for changing the batch”. Unless under the direction of evaluation officer, other category cannot be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

2) Not Submitted

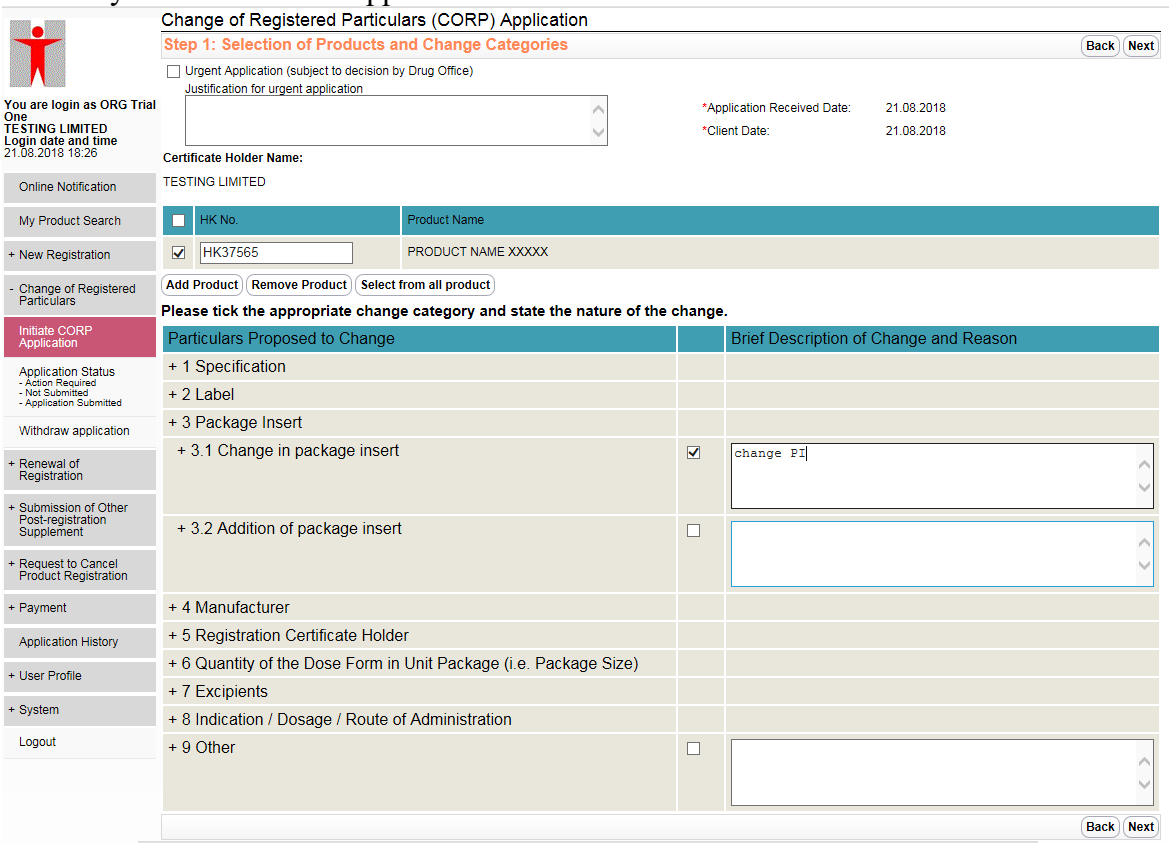


The applications listed in this section has been saved but not yet submitted to Drug Office. User may click the application reference number to continue submission as shown below:

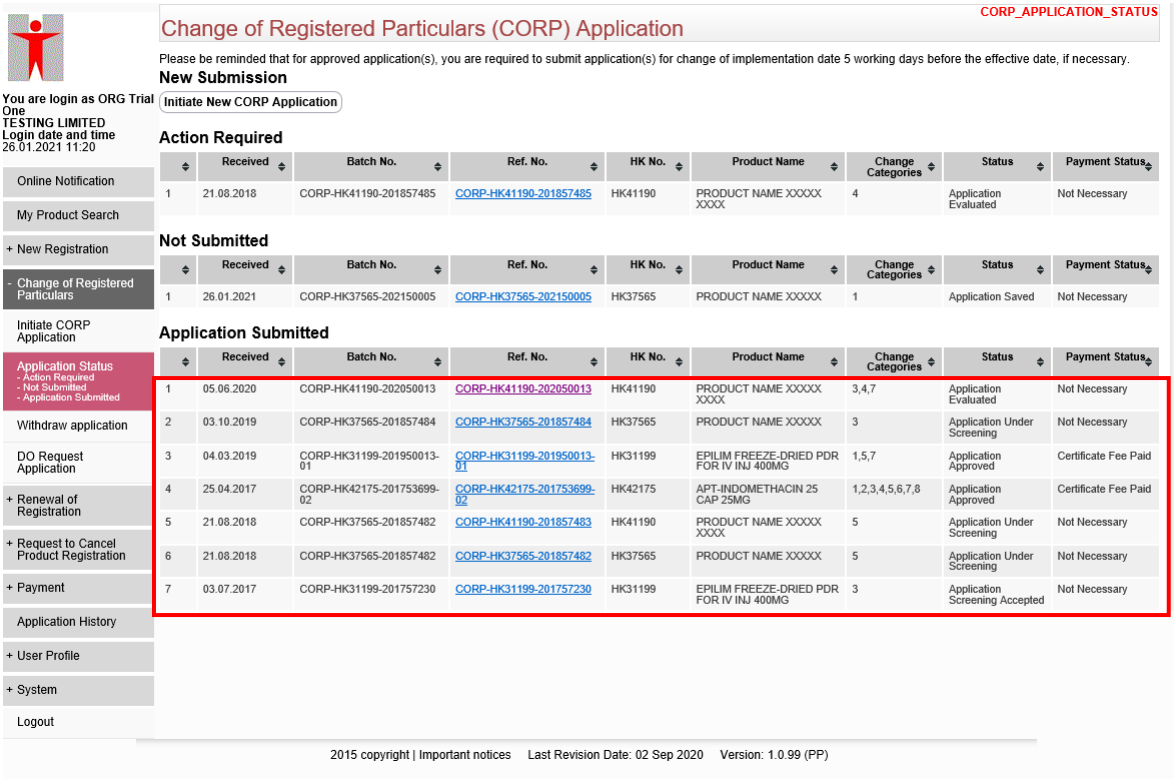


User can click “Delete Application” to delete the application as the application is not yet submitted to Drug Office.

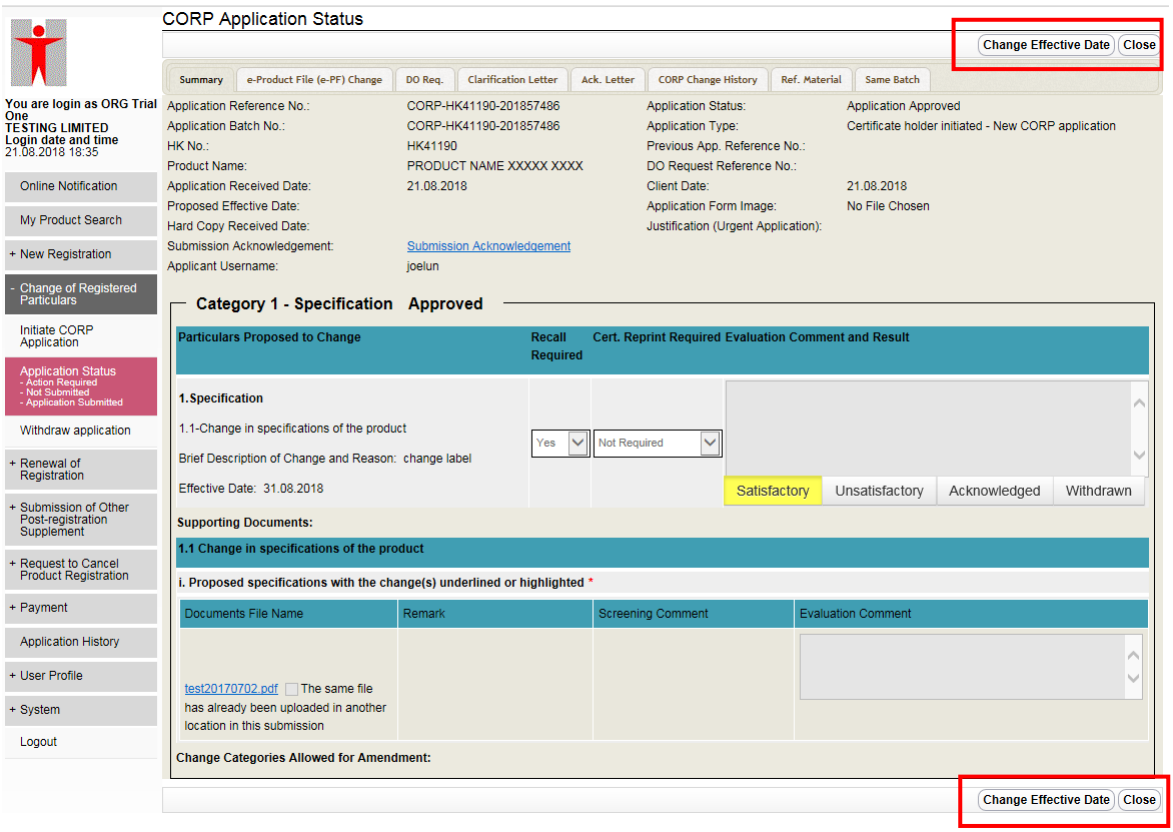
User may click “Continue Application” to continue the submission as shown below:



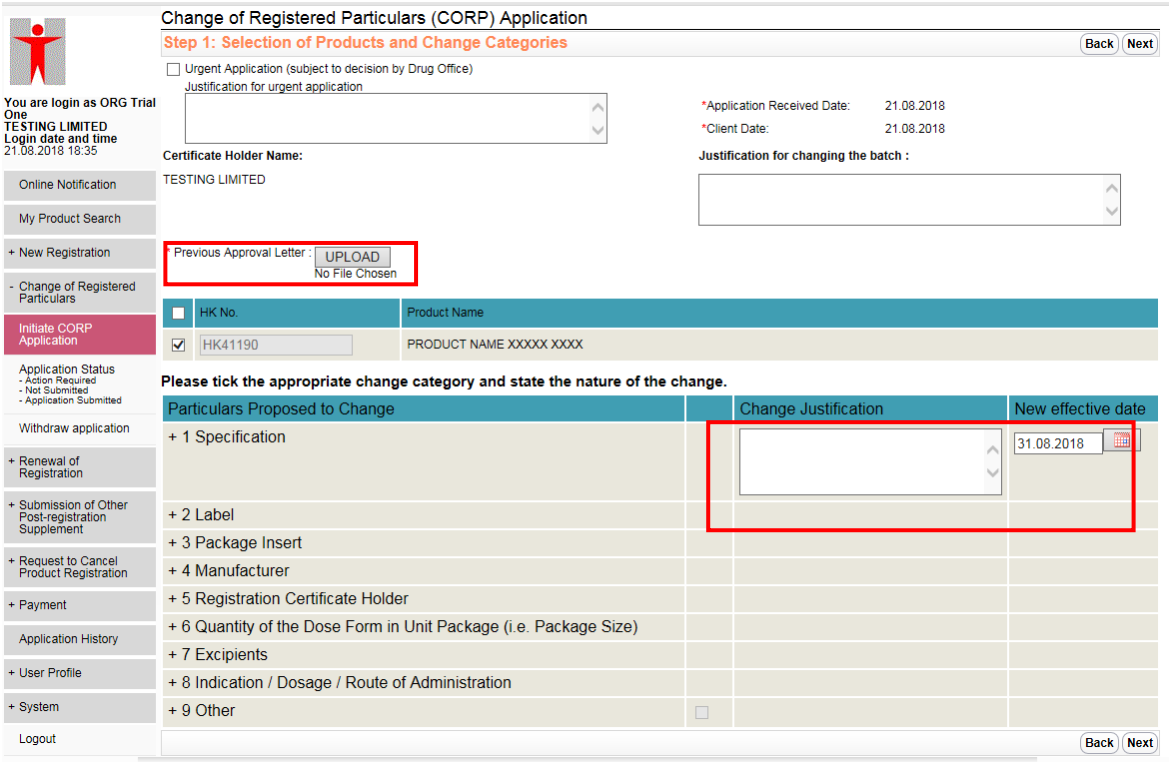
3) Application Submitted



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:



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:



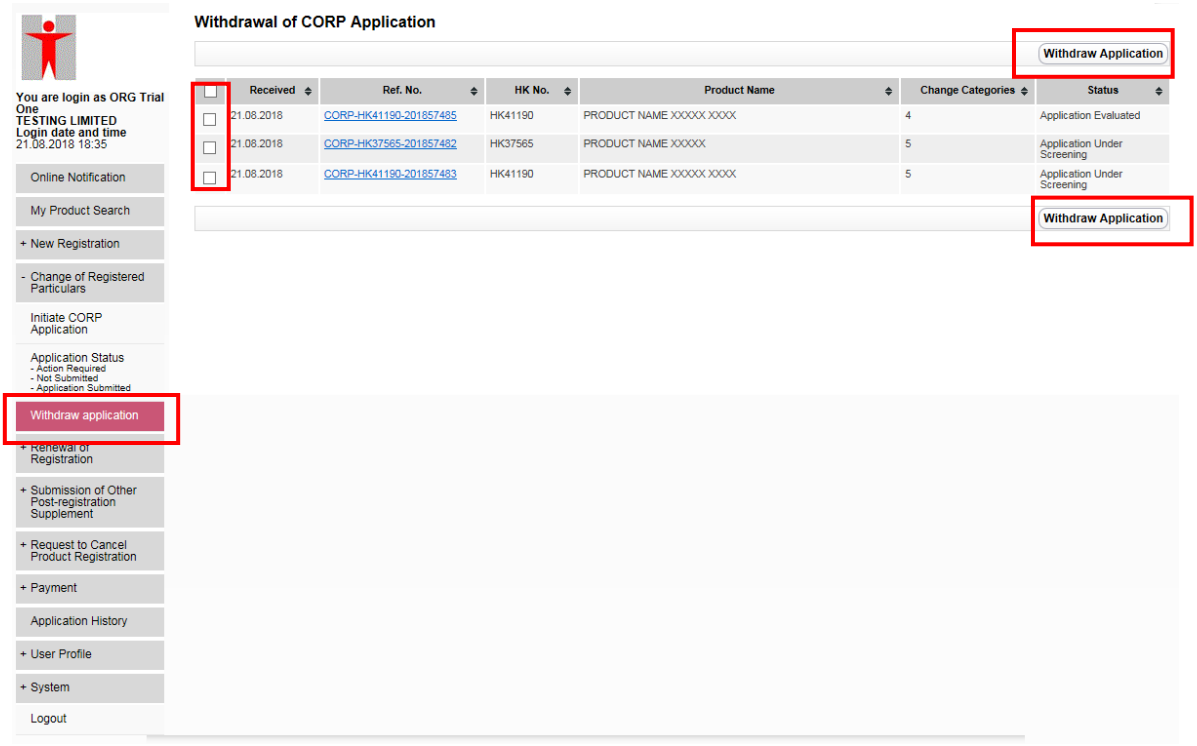
Other than effective date, all information of product particulars is not allowed to change in the application of change in effective date.

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.

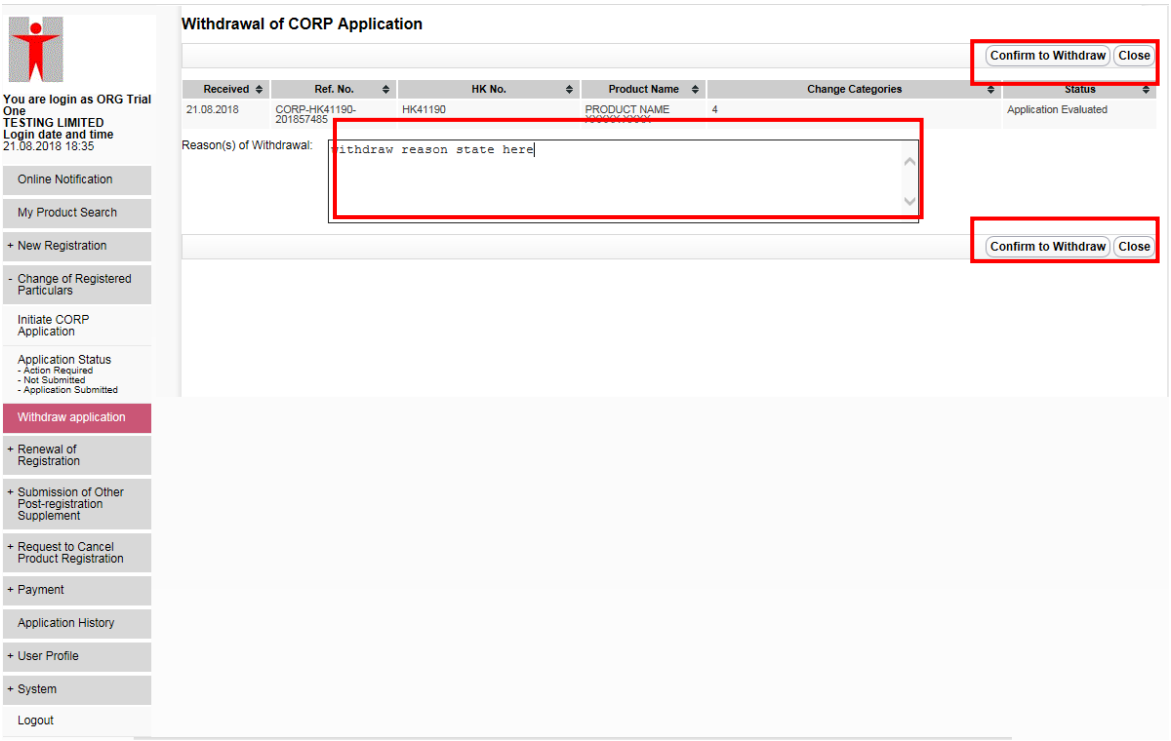
2.6.2 Withdraw application

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

The applications eligible to withdrawal will be shown.



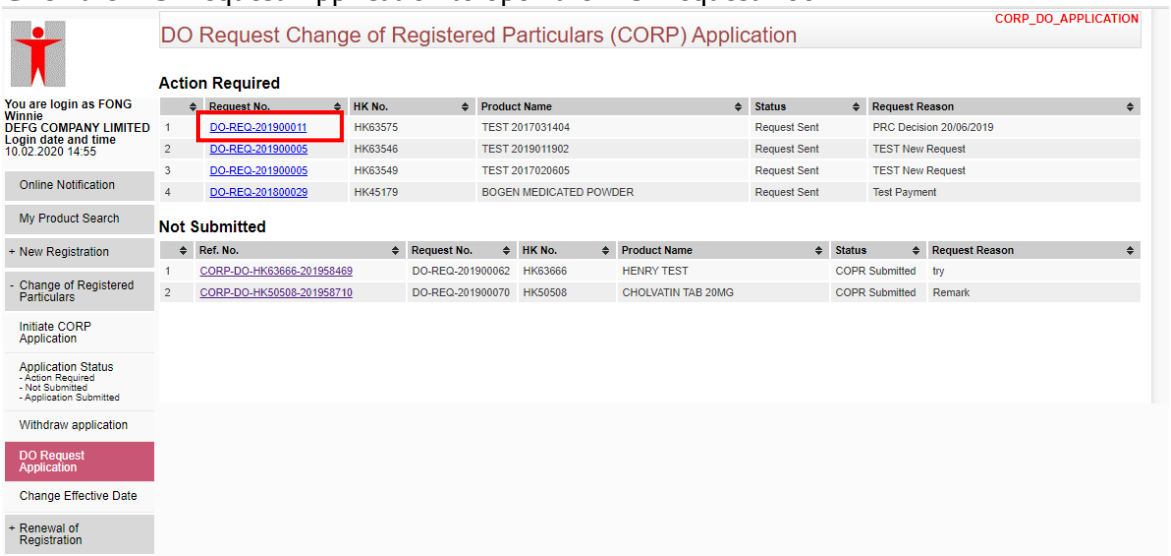
User may select one or more applications and send the request of withdrawal to Drug Office:



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



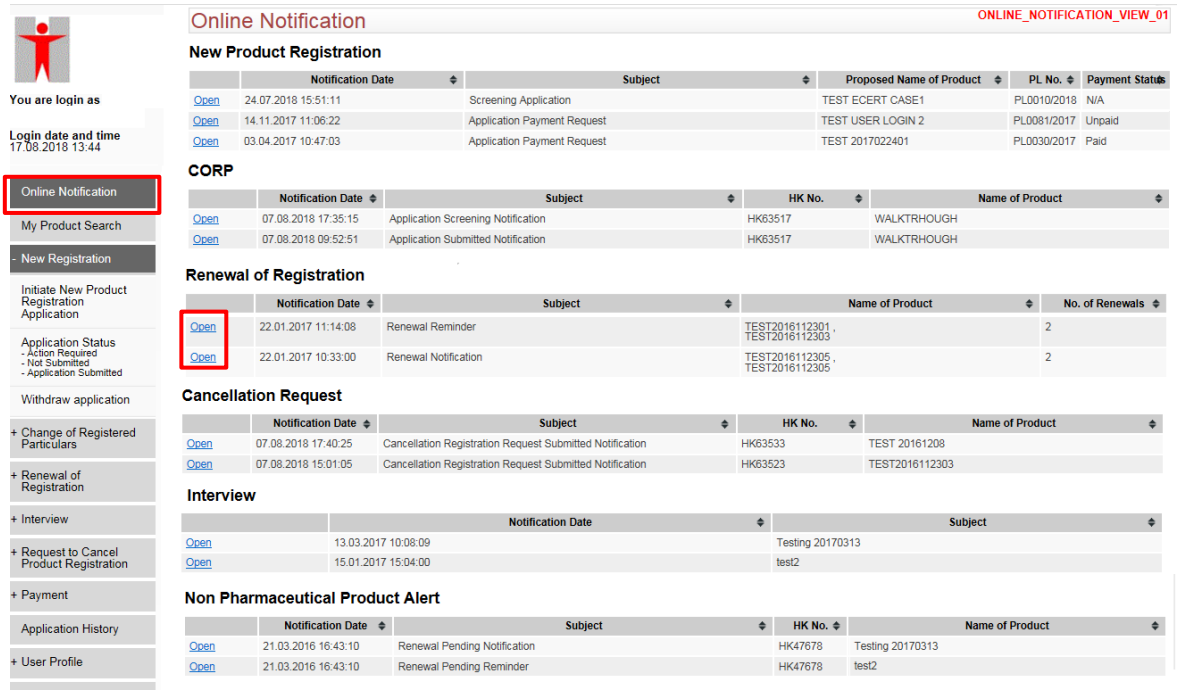
Click the Request No from the Action Required to initiate a CORP to reply this request or Continue the application

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

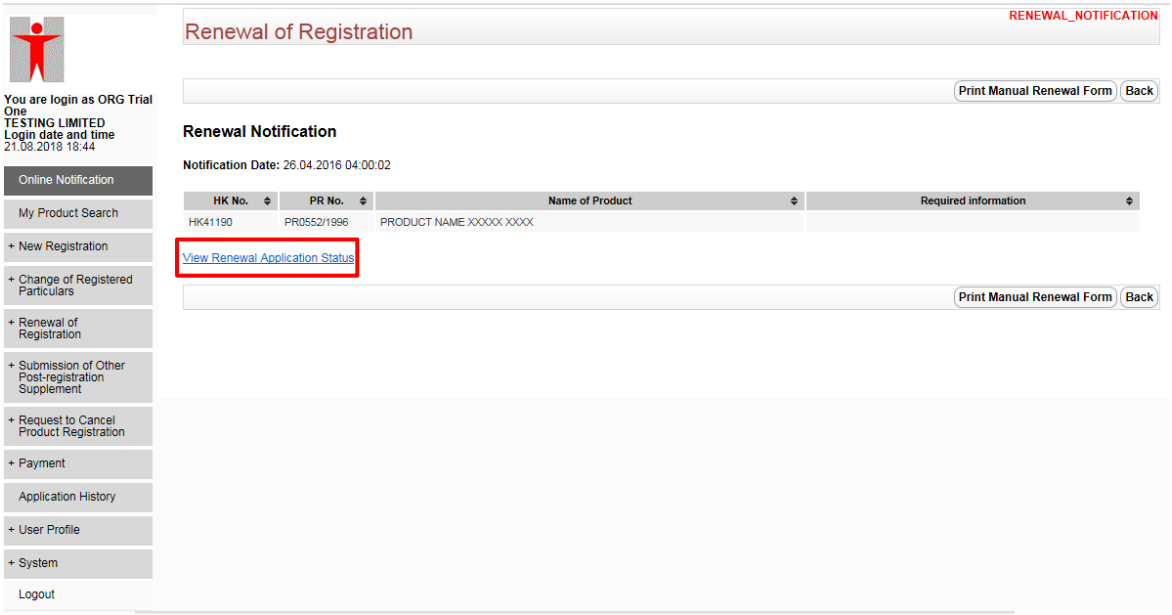
Step 1: Click the menu item “Online Notification” in the menu on the left.



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.



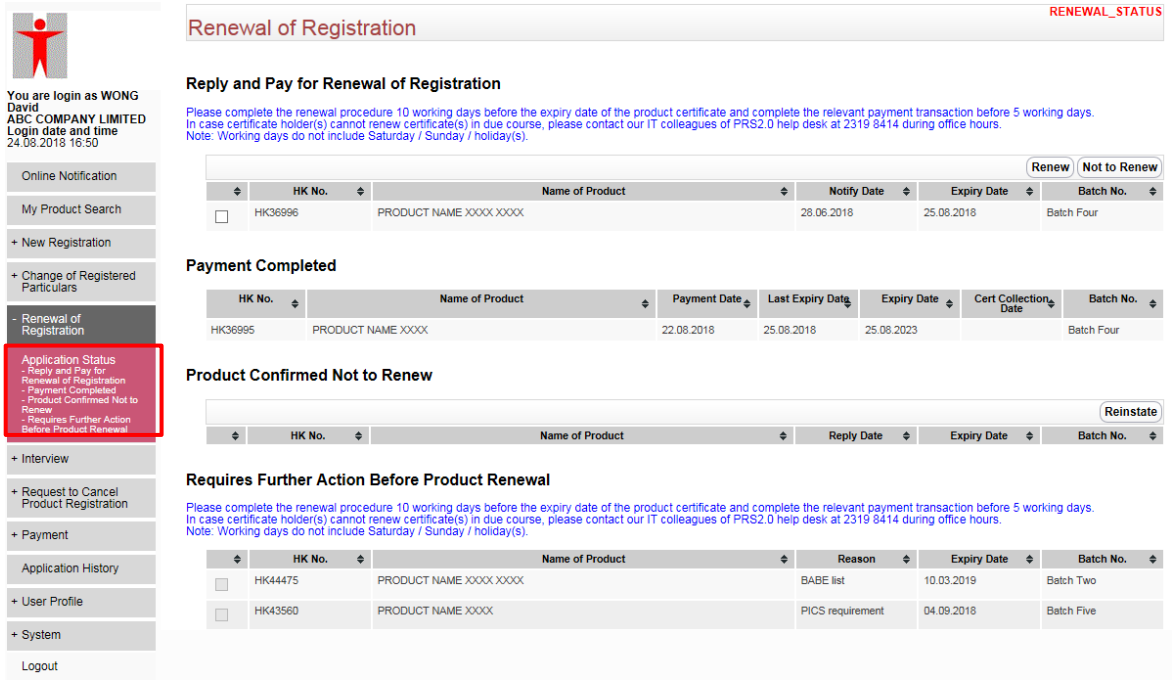
Products that the login user has access rights to will be shown in the list.

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.



New list added for new version:

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:

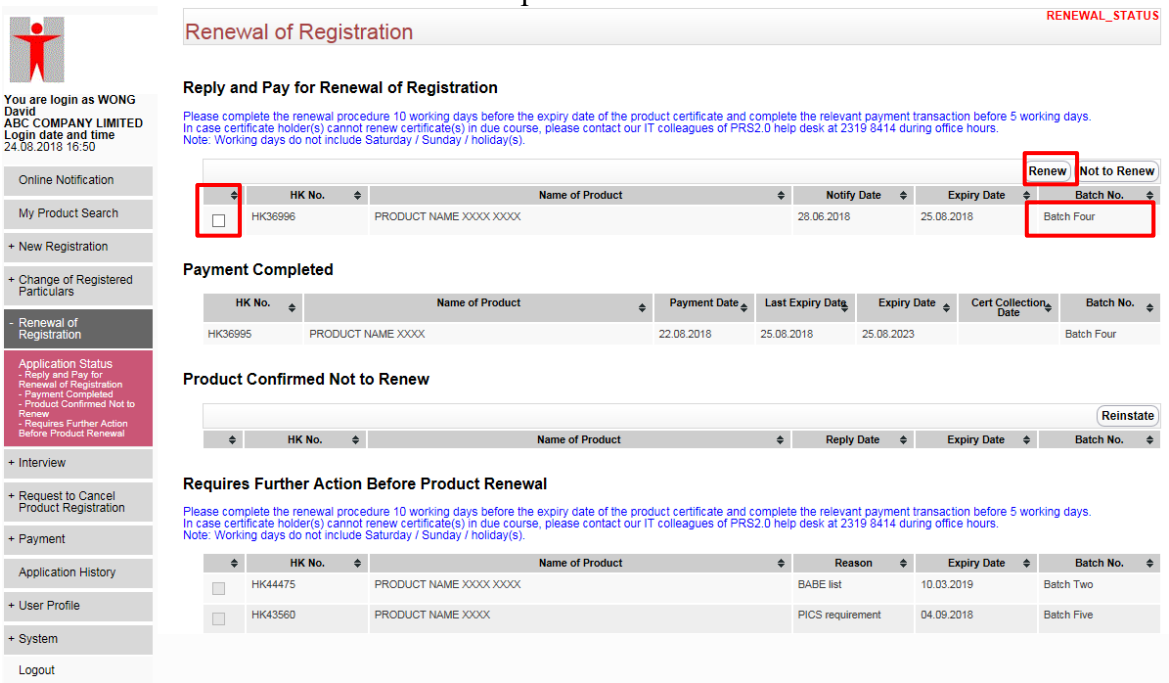
- Submission of BABE report: labeled as “BABE List” under the “Reason” column.
- Submission of Real-time stability report: labeled as “RSTR List” under the “Reason” column.
- Non-pharmaceutical product: labeled as “Non-Pharmaceutical Product” under the “Reason” column.
- Other required information

2.7.2.1 Renewal of Registration by Online Payment or in Person

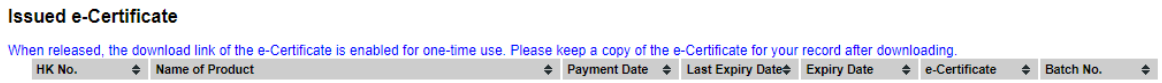
Applicants can select to process the renewal by (i) online payment (Section **Error! Reference source not found.**); or (ii) in person (Section **Error! Reference source not found.**).

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.

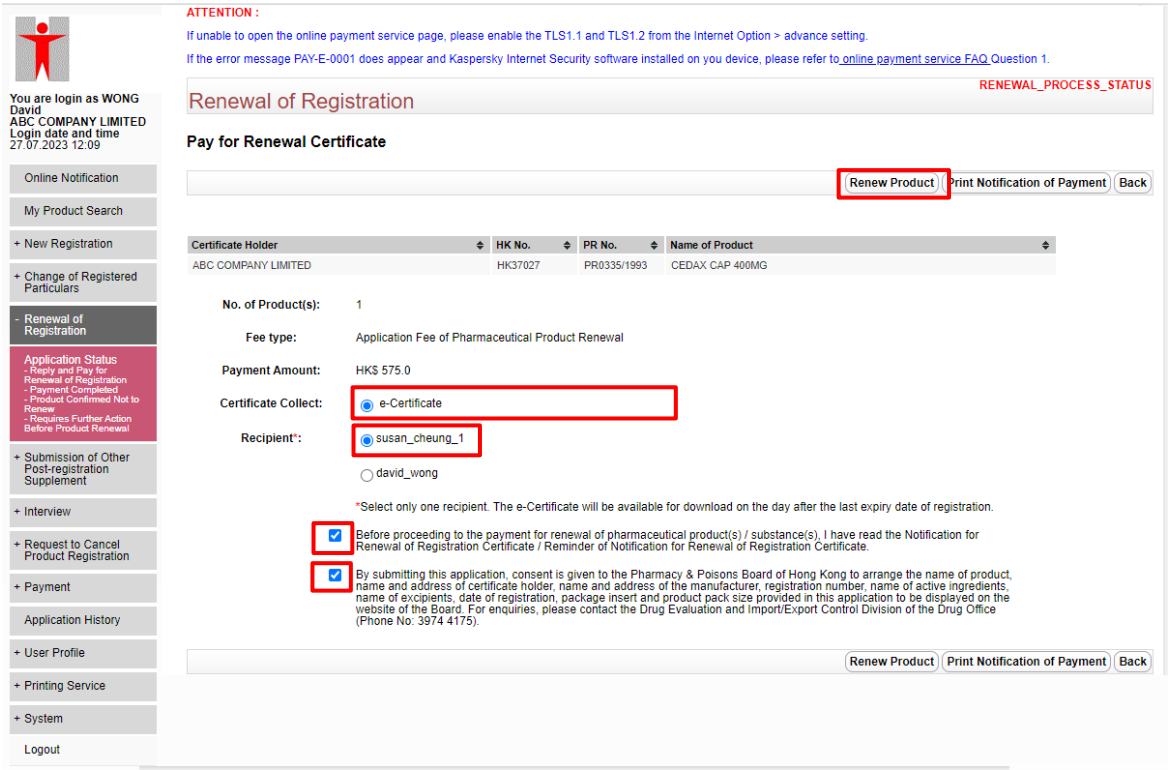


New list added for new version:

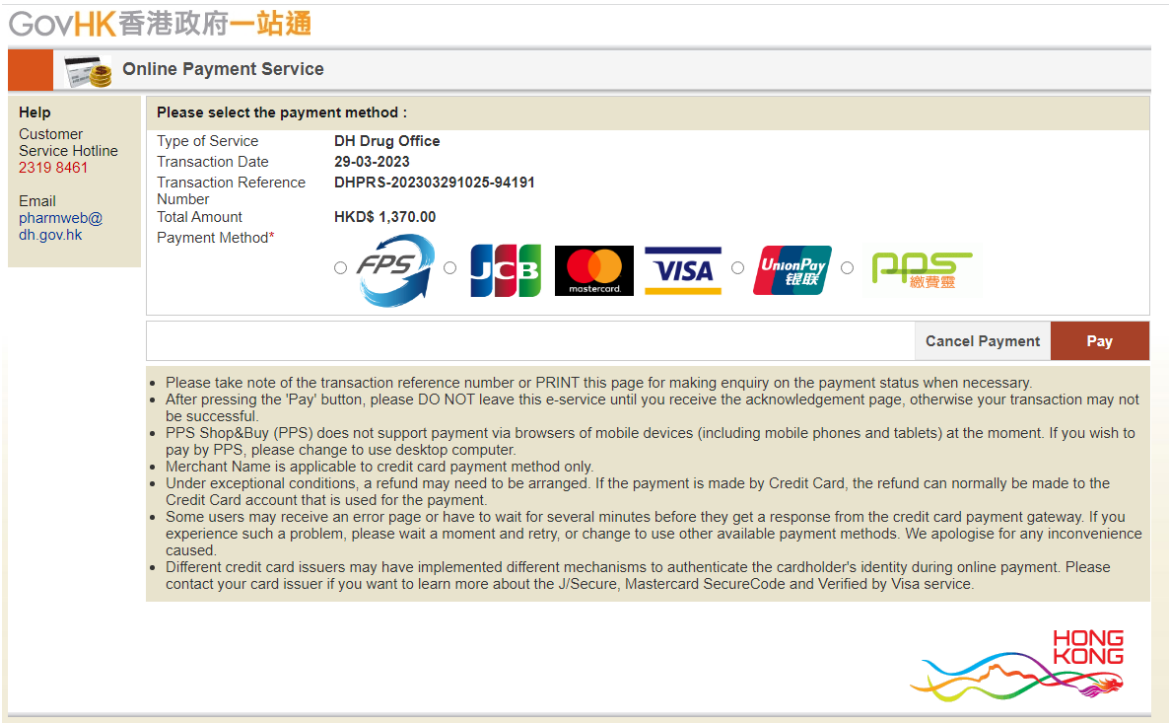


Step 2:

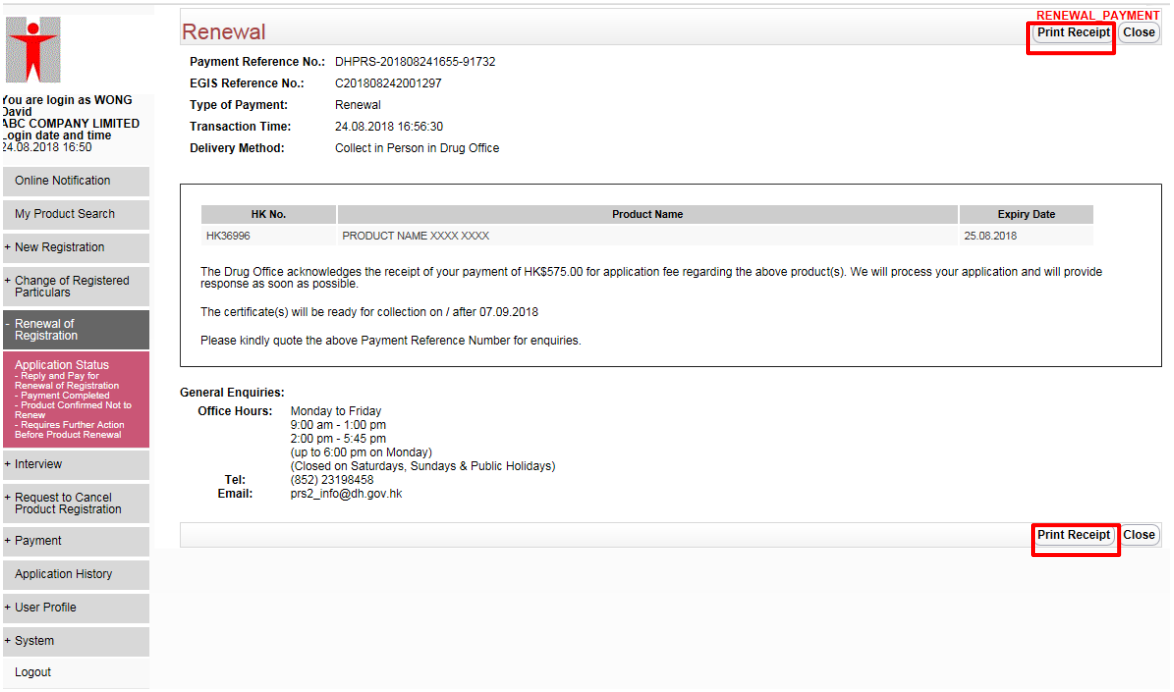
- Select the one Recipient.
- Check the two checkbox “Before proceeding to the online payment for renewal of pharmaceutical product(s) / substance(s), I have read the Notification for Renewal of Registration Certificate / Reminder of Notification for Renewal of Registration Certificate.”
- Click the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



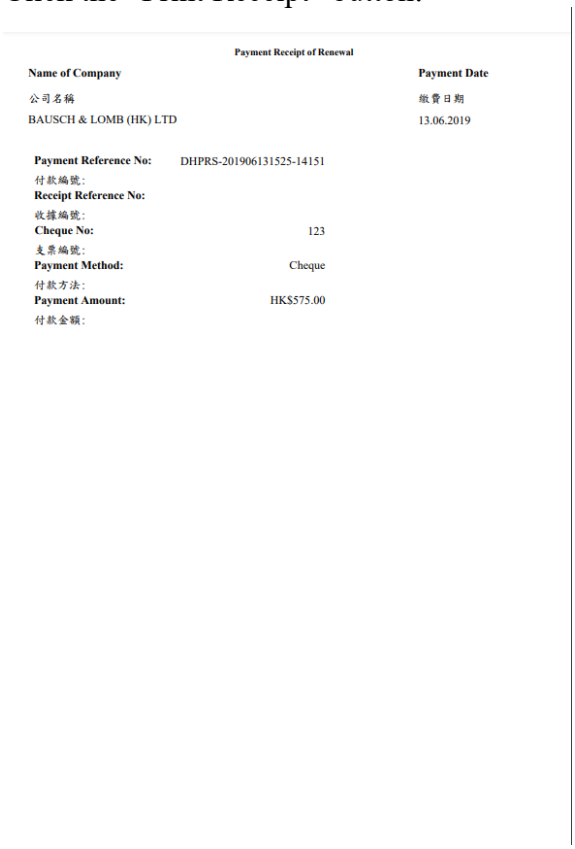
Step 3: Proceed to payment at the external EGIS payment system.



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.



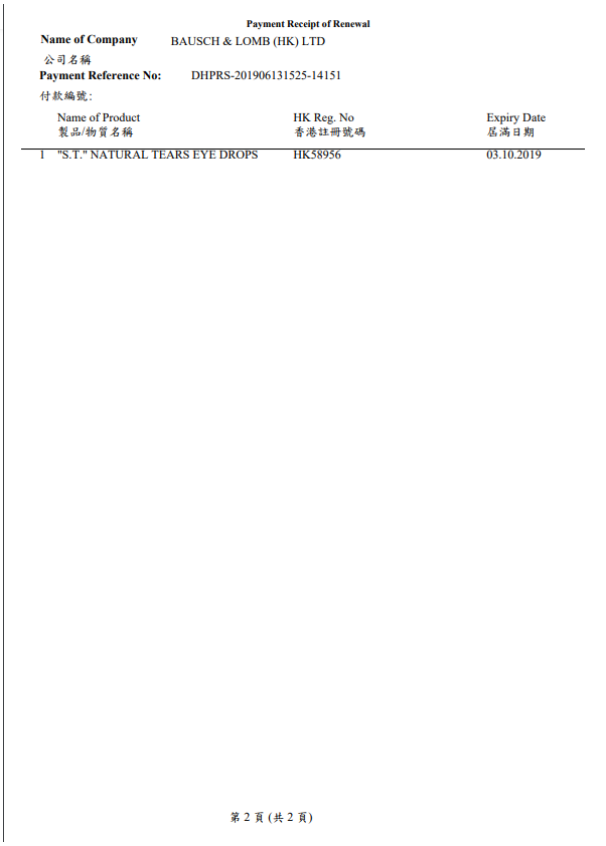
Click the “Print Receipt” button:



Payment Receipt of Renewal

Name of Company 公司名稱	Payment Date 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:



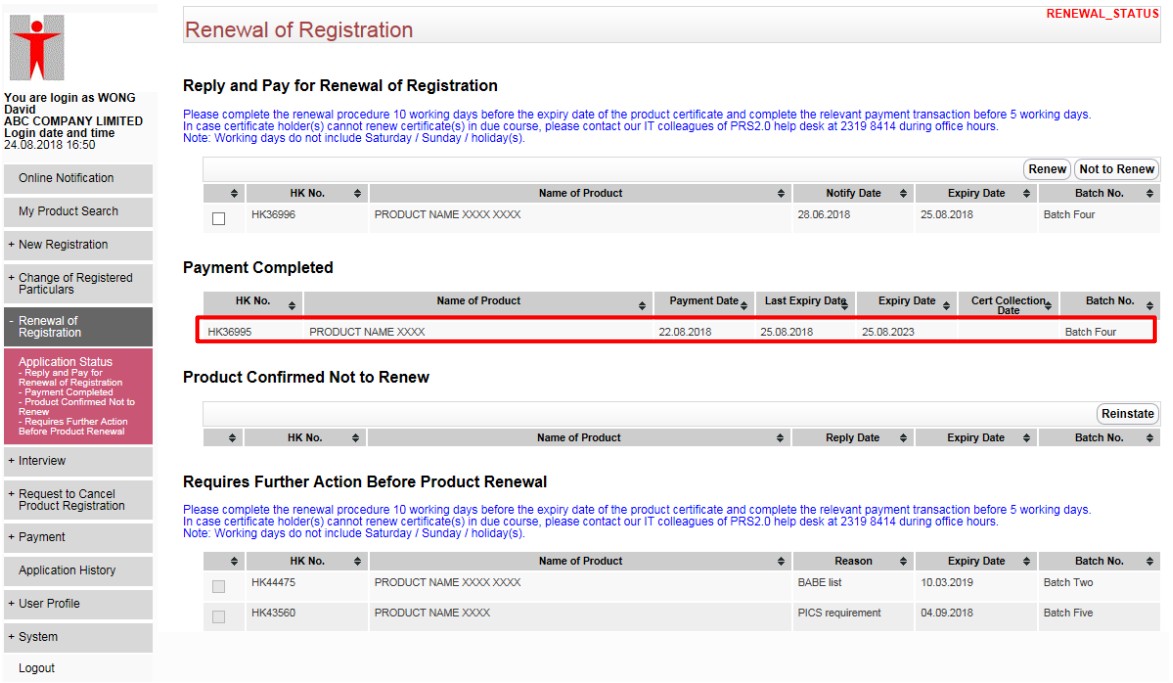
Payment Receipt of Renewal

Name of Company 公司名稱 BAUSCH & LOMB (HK) LTD
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

第 2 頁 (共 2 頁)

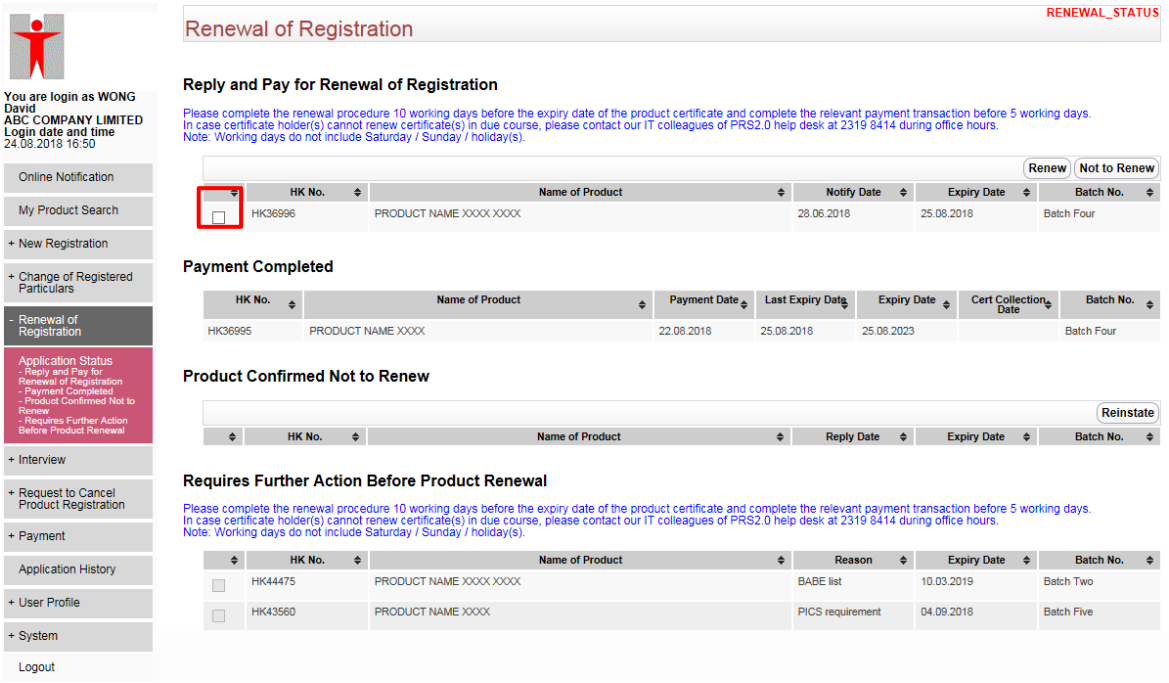
The payment of renewal of registration is completed.



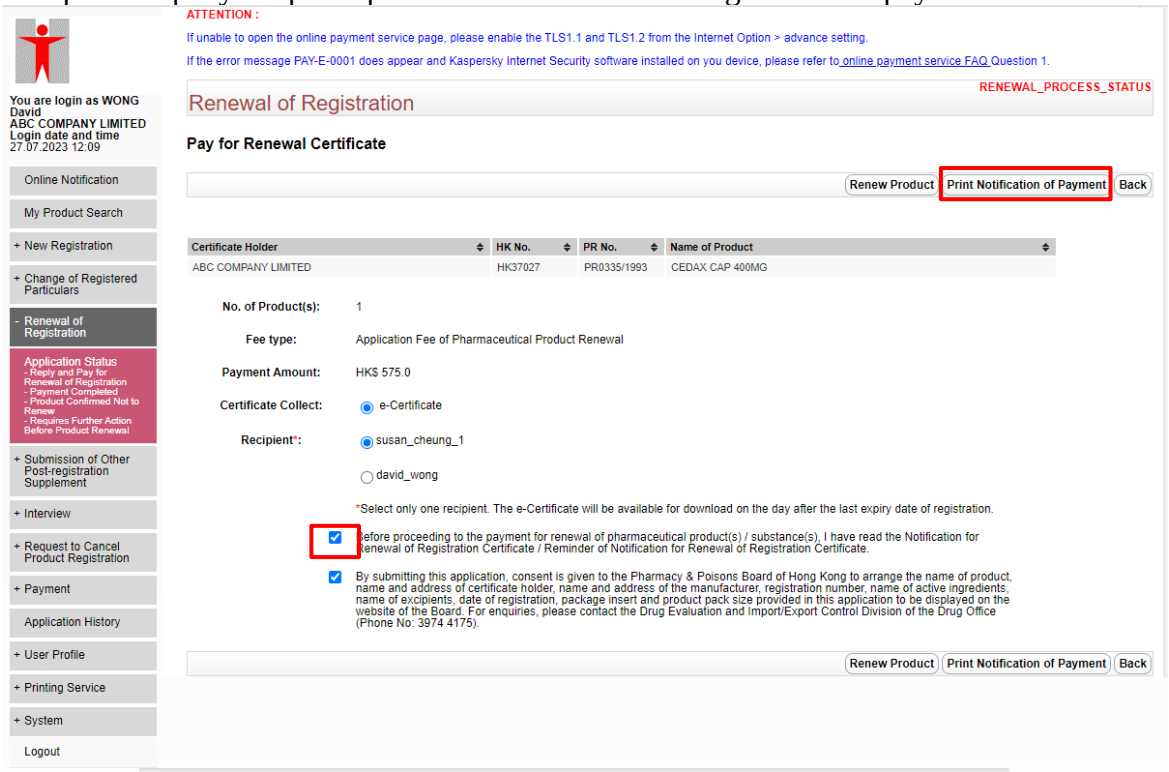
New list added for new version

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.

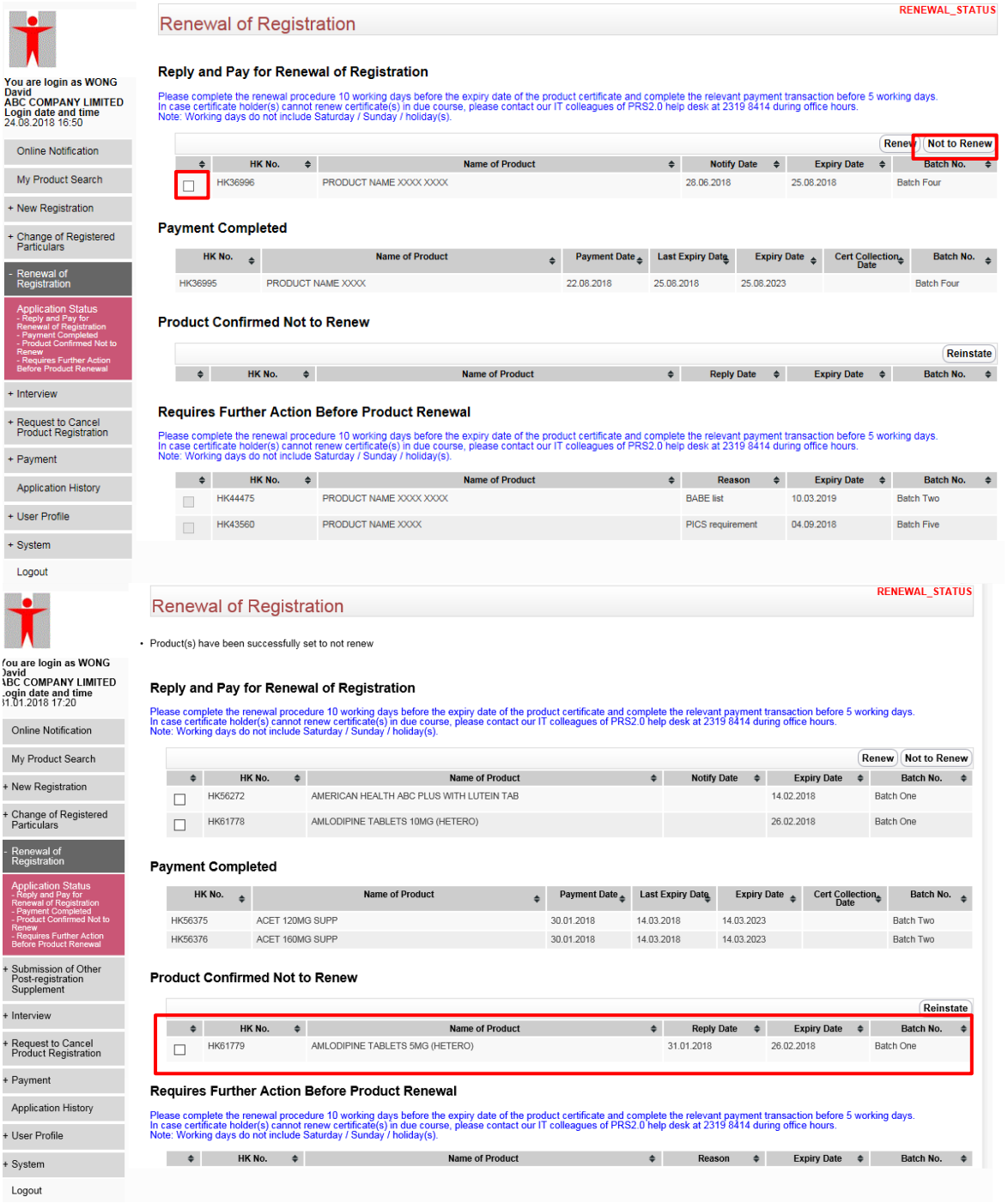


Step 2:
Click the “Print Manual Renewal Form” button. Please print the renewal form with the stamped company chop and proceed to the shroff of Drug Office for payment.



2.7.2.1.3 Not to Renew Product Registration

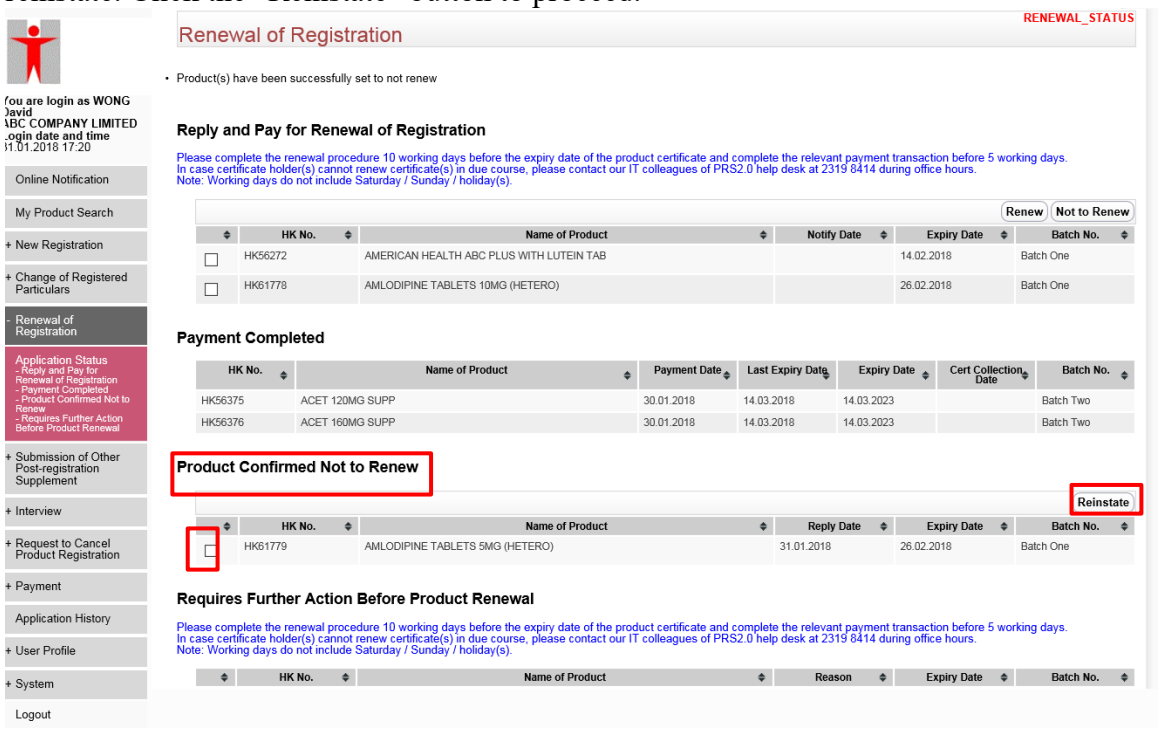
Step 1:
Under the section “Reply and Pay for Renewal of Registration”, select the checkbox(es) for the renewal application(s) decided not to renew the product registration. Click the “Not to Renew” button to proceed.



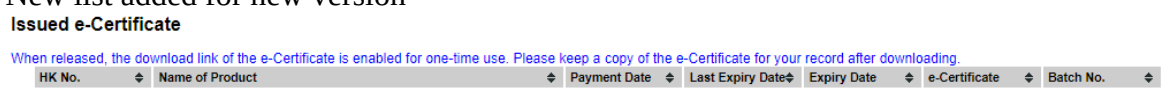
New list added for new version

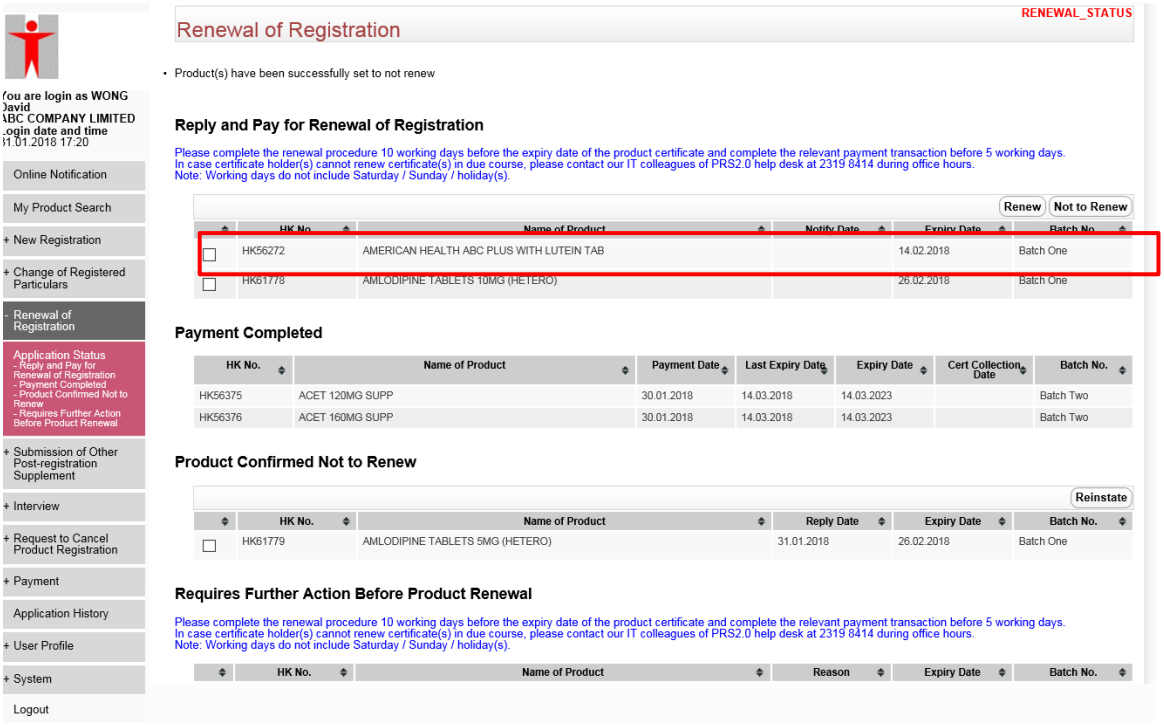
2.7.2.1.4 Reinstate Product Specified as Not Renew

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.

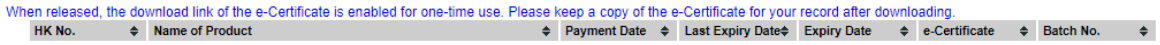


New list added for new version





New list added for new version



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.

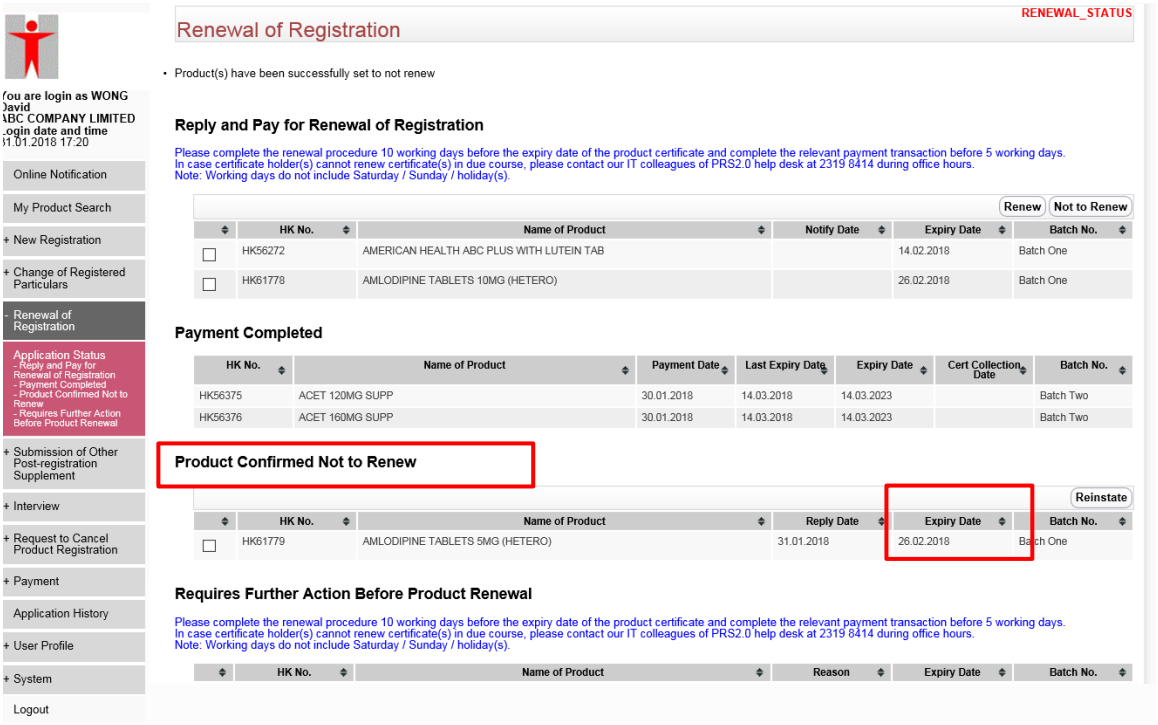
- For product(s) has "BABE List" under the "Reason" column.
  Certificate holder has to submit the Bioavailability and Bioequivalence (BABE) report to the Drug Office through the function "Submission of BABE" under "Submission of Other Post-registration Supplement" (Section **Error! Reference source 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.**)

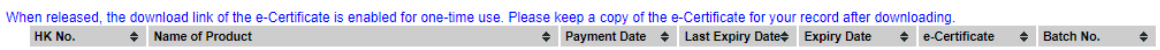
- For product(s) has "Non-Pharmaceutical Product" under the "Reason" column.
  Certificate holder has to provide supporting documents to support the product(s) is pharmaceutical product.

- For product(s) has other required information under the "Reason" column.

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

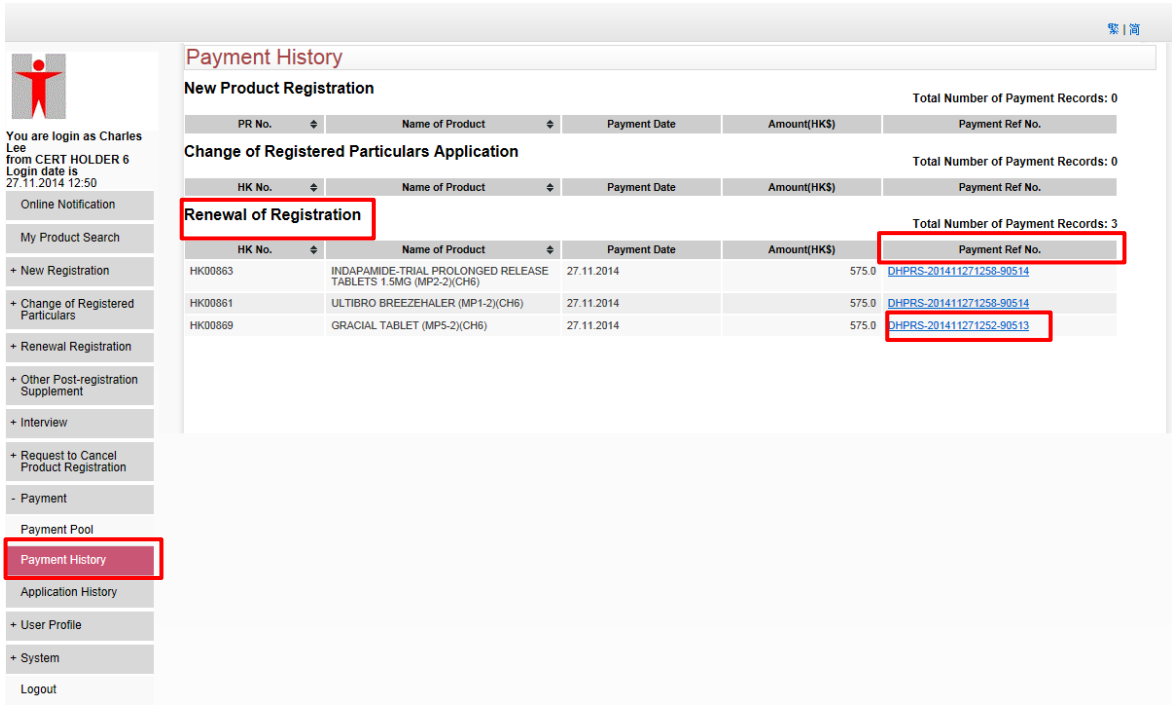


New list added for new version

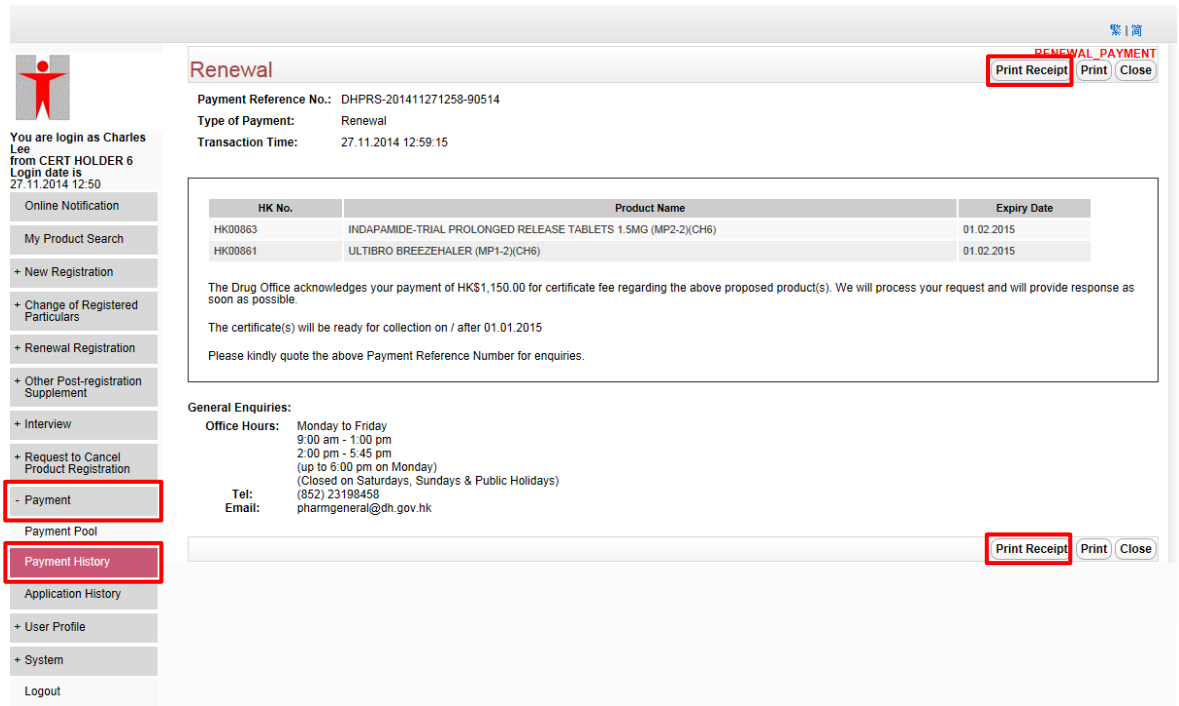


2.7.2.2 Payment History (Renewal)

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”.

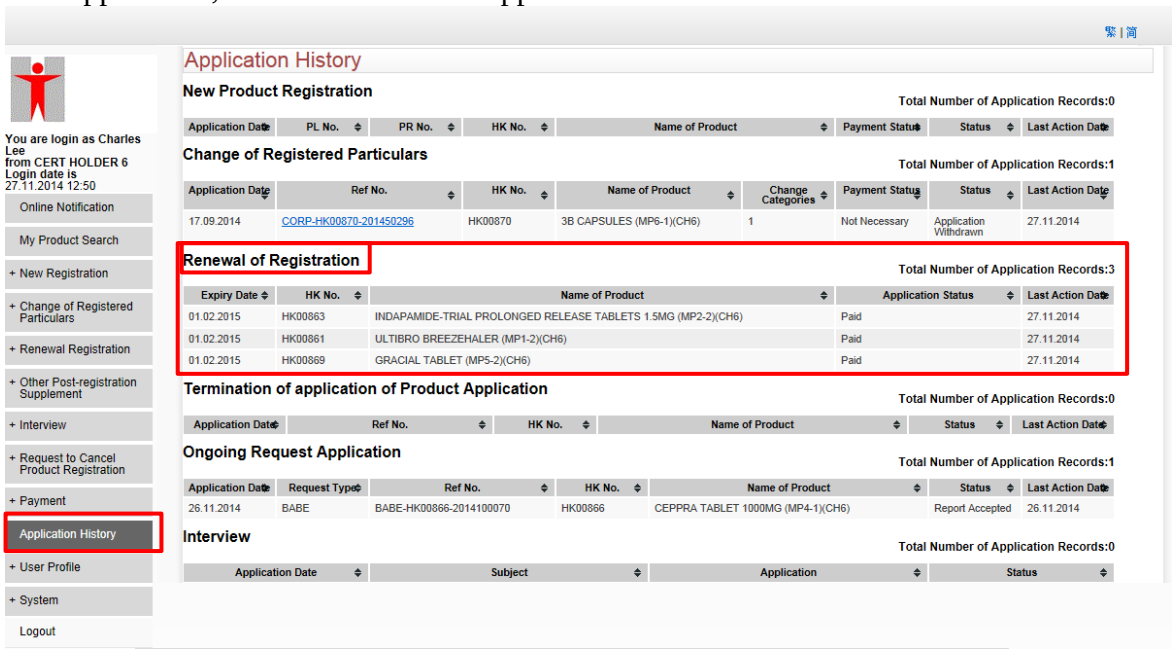


Step 2: The receipt can be reprinted by clicking the “Print Receipt” button.



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.



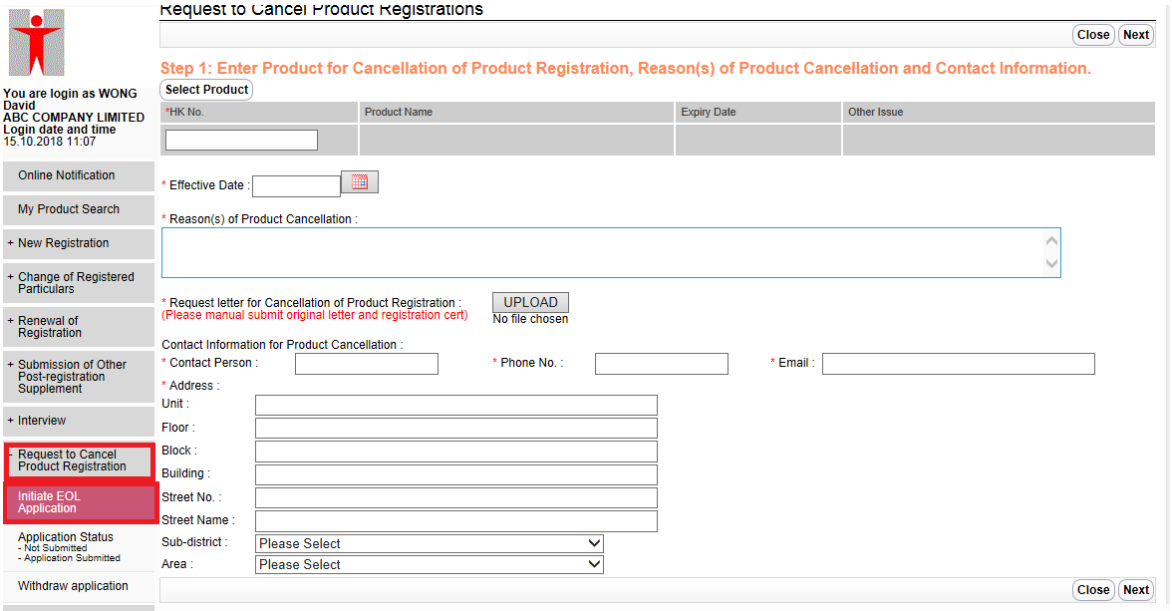
2.8 REQUEST TO CANCEL PRODUCT REGISTRATION

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

2.8.1 Initiate EOL Application

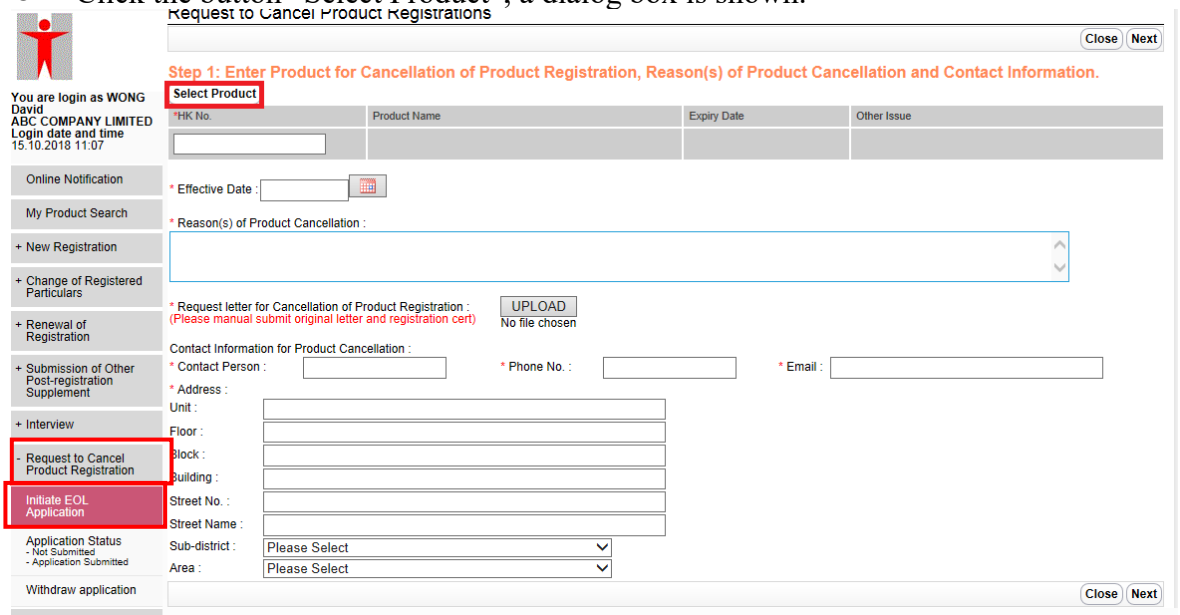
Step 1:

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



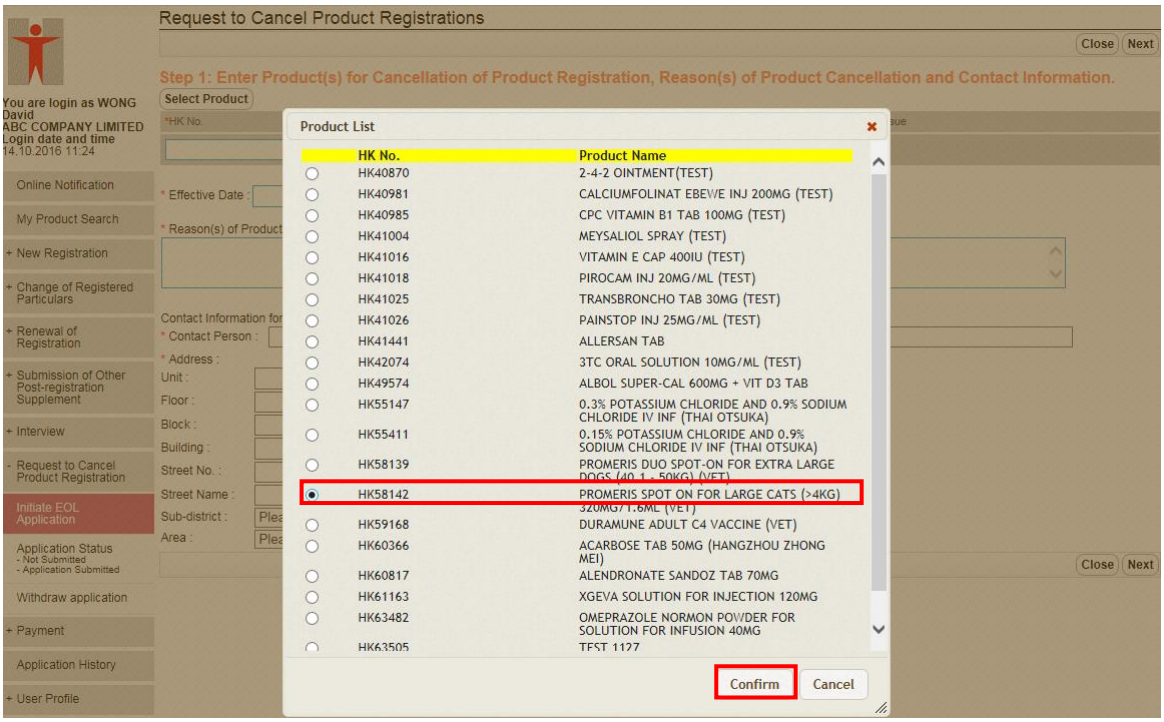
Step 2:

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



Step 3:

- Select a product and then click the button “Confirm”.

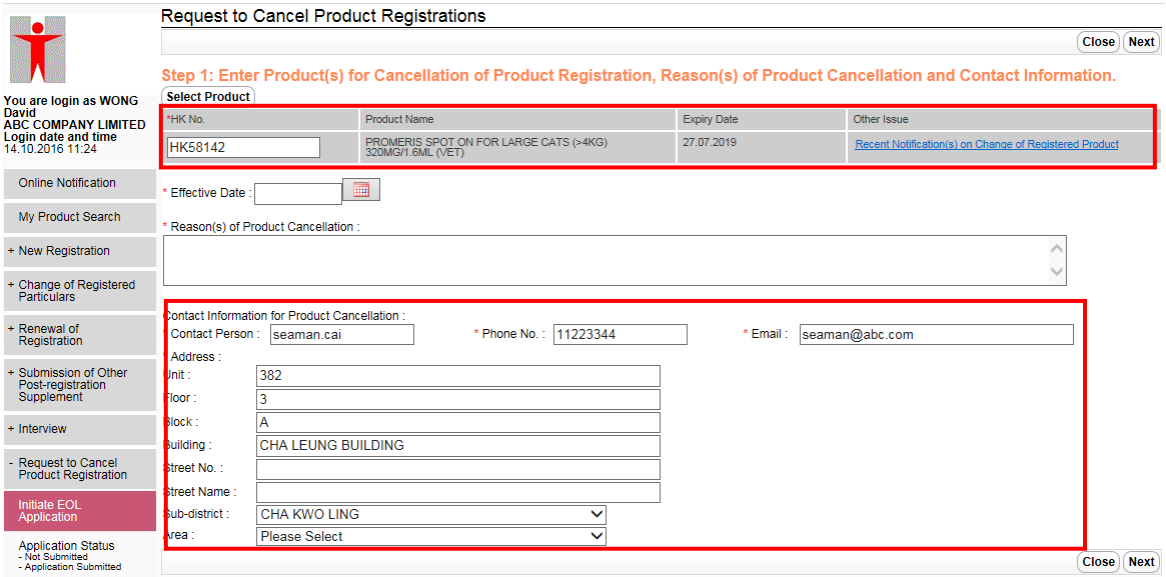


Step 4:

- The product information is filled in automatically.

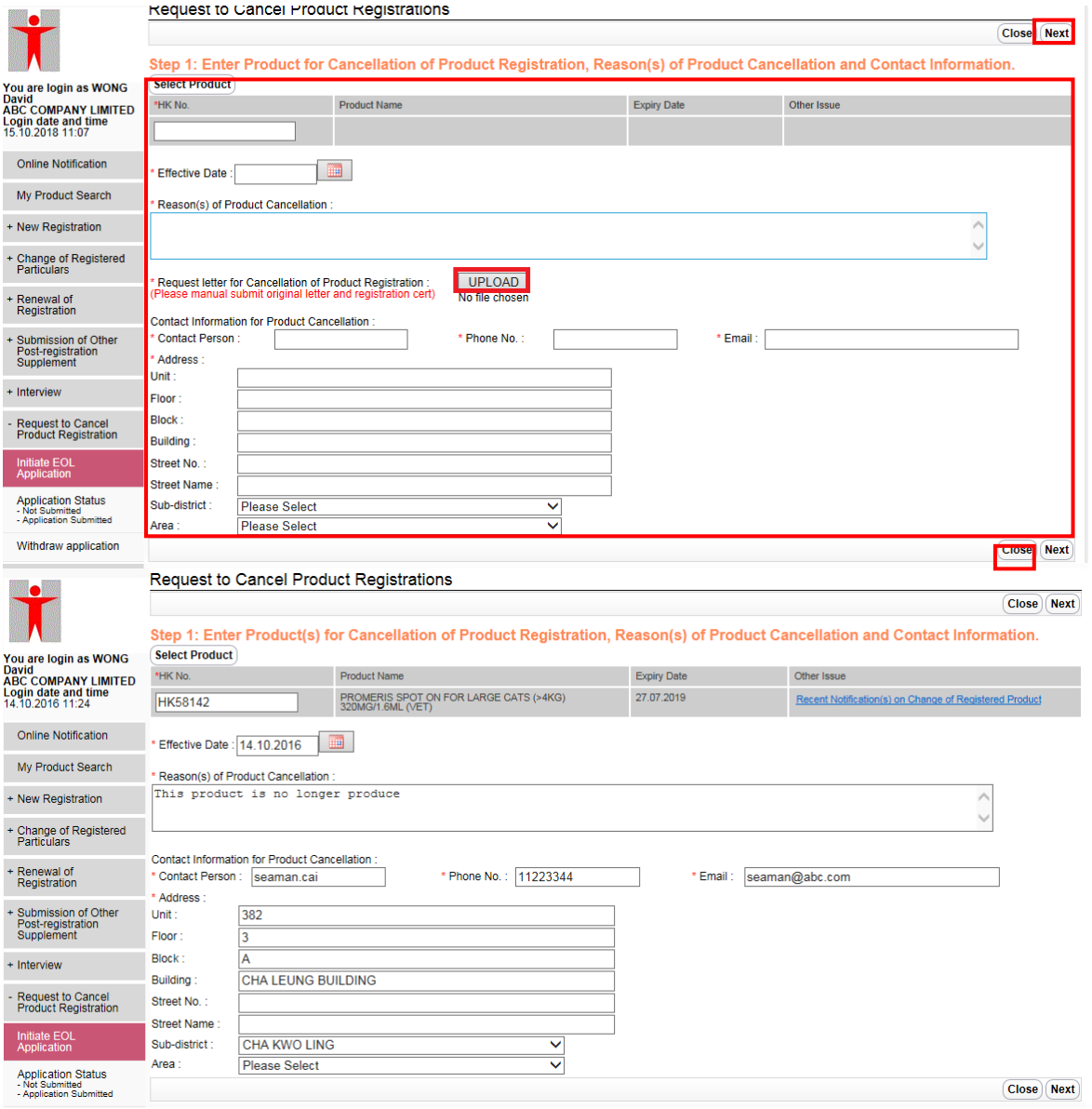
- The “Other Issue” shows the recent communication about the product between certificate holder and Drug Officer.

- Fill the Contact Information.



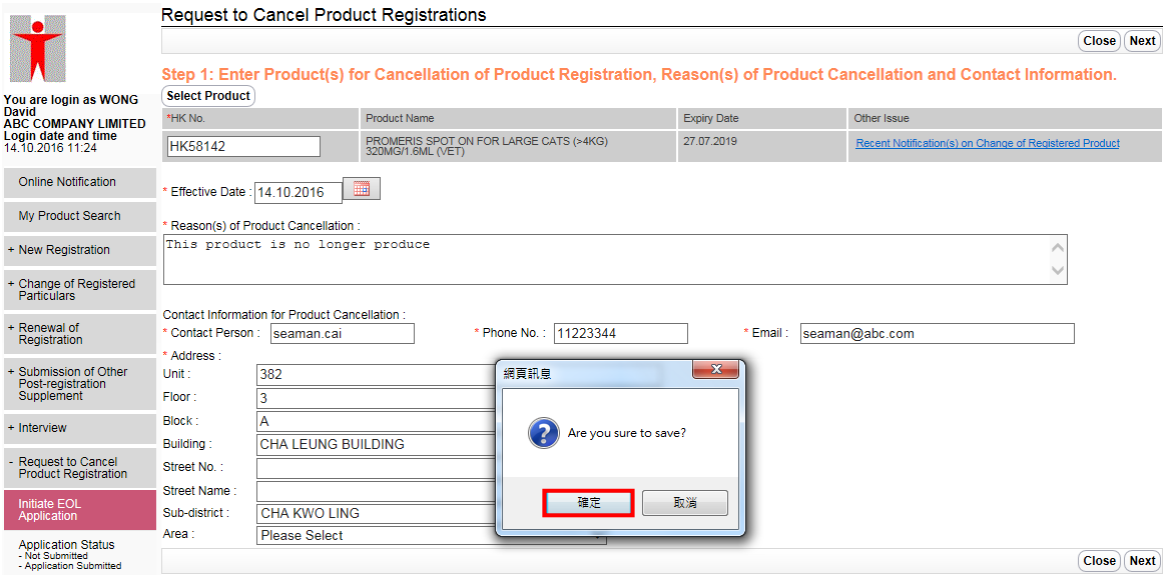
Step 5:

- 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.



Step 6:

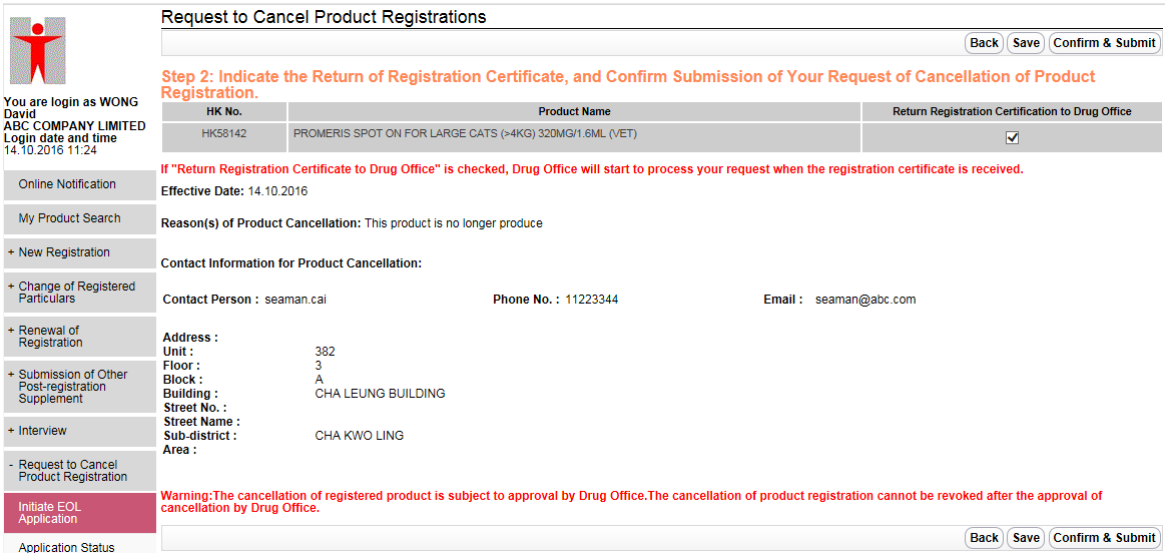
- Click “Next” to save the information.


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
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
* 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:

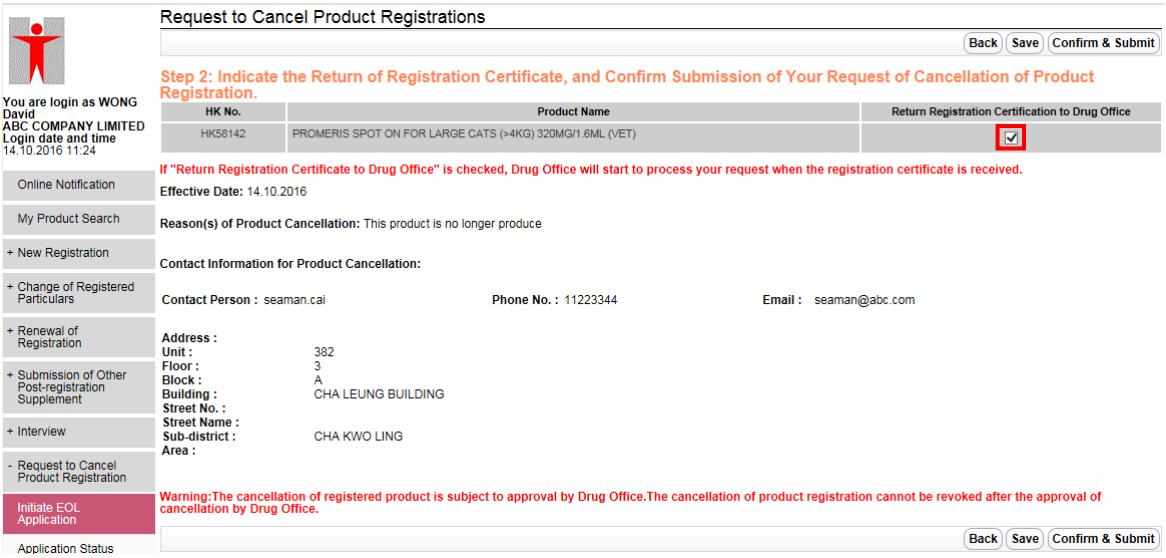
- Verify the information inputted in page1.

- Indicate return product registration certificate to Drug Office.



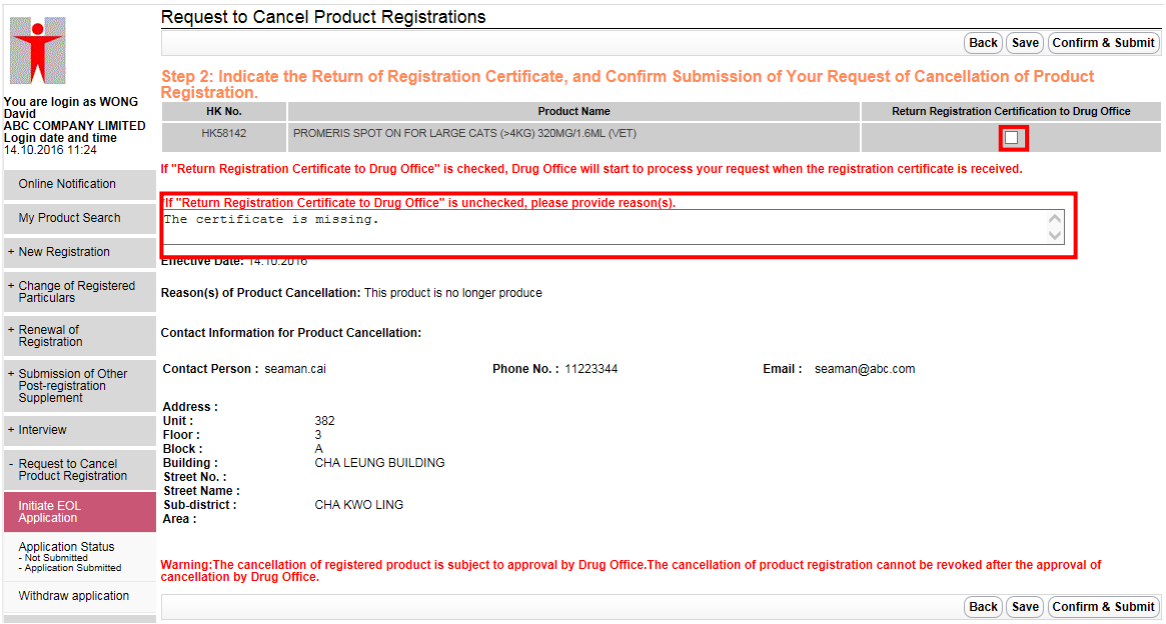
Scenario 1: Return registration certificate to Drug Office.

- Check the checkbox.



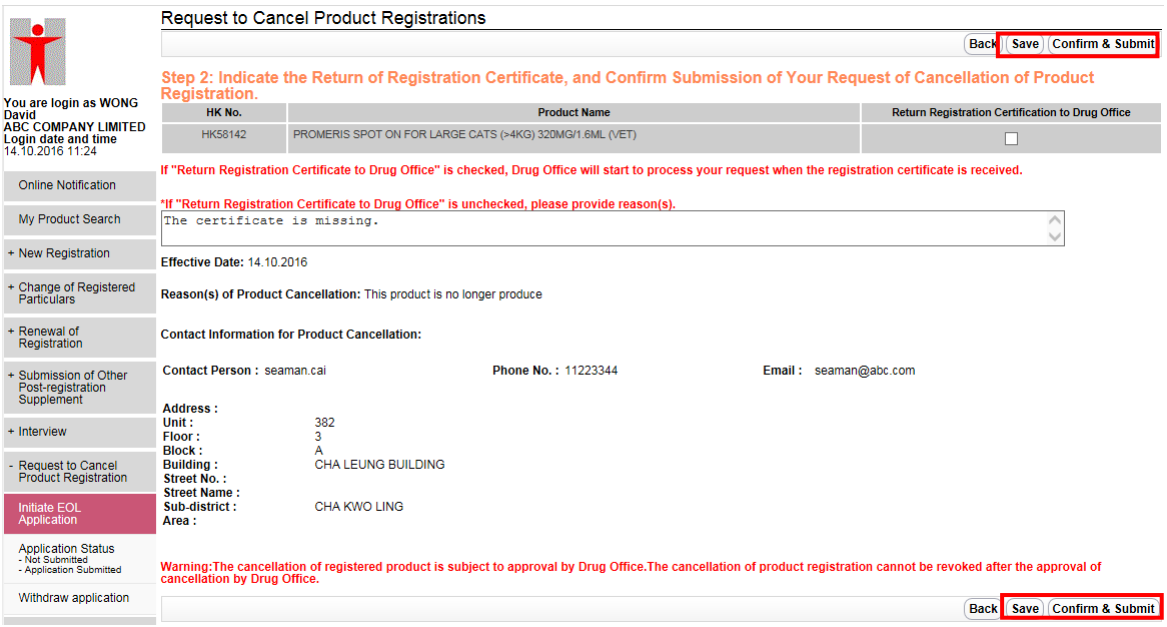
Scenario 2: Not return registration certificate to Drug Office.

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



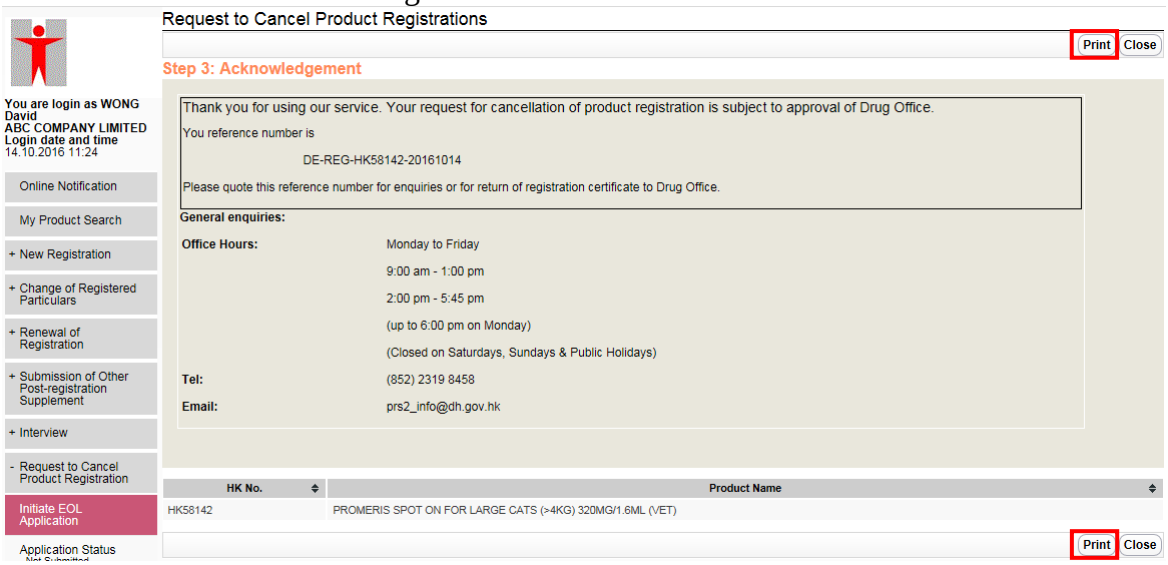
Step 8:

- Click “Save” to save the application as draft or click “Confirm & Submit” to submit the application to Drug Office for evaluation.



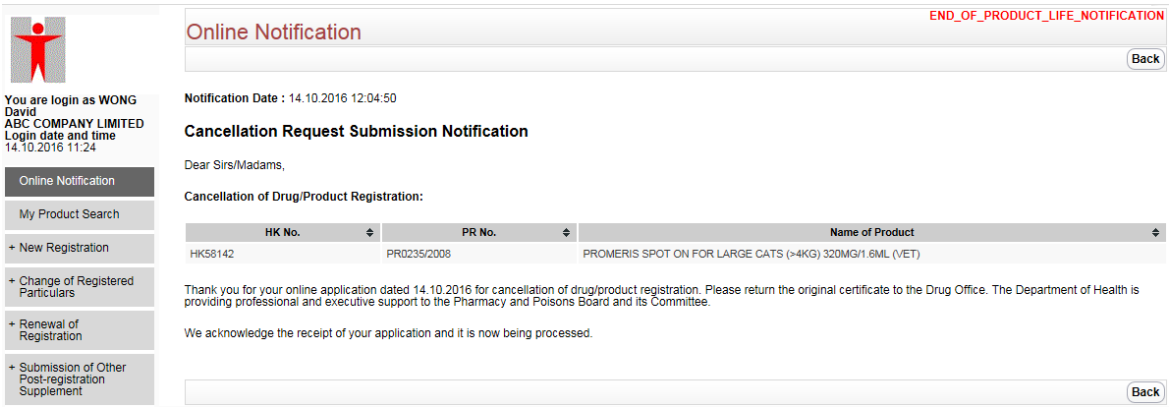
Step 9:

- The system then redirects to an acknowledgement page. User can click “Print” to print the submission acknowledgement.



Step 10:

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



2.8.1.1 Application Enquiry

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

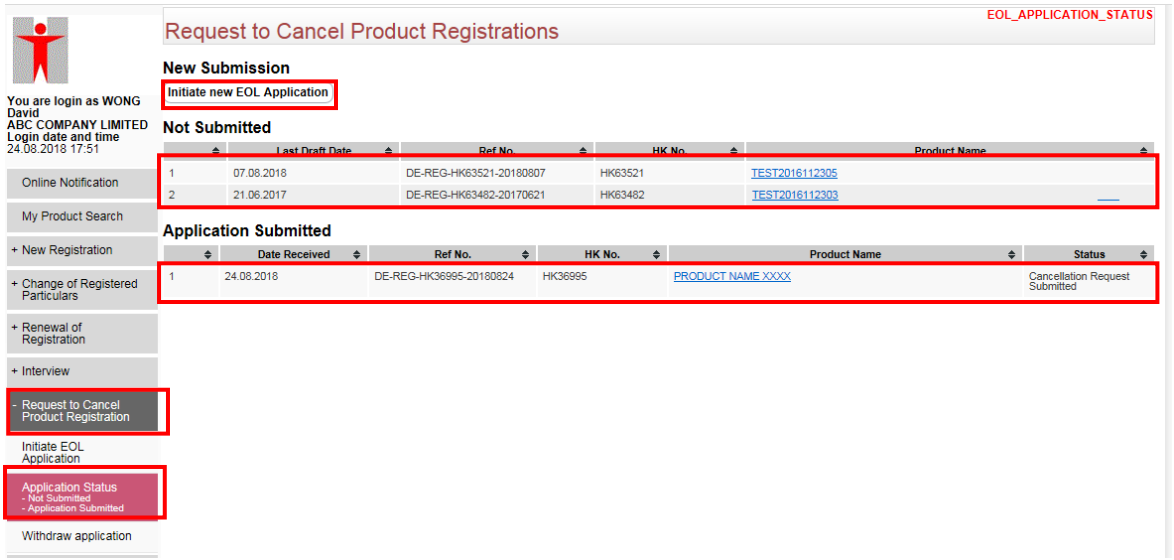
Step 1:

- Click the menu item “Application Status - Not Submitted - Application submitted” under “Request to Cancel Product Registration” in the menu on the left.

- The “Initiate new EOL Application” button redirects the use to “Initiate EOL Application” function (Refer to 4.2.9.1).

- The not submitted pool contains all drafted request to cancel product registration application. User can click the hyperlink on the product name to edit the application.

- The application submitted pool contains all processing applications. User can view the processing status of the application. User can click the hyperlink on the product name to view the application detail.

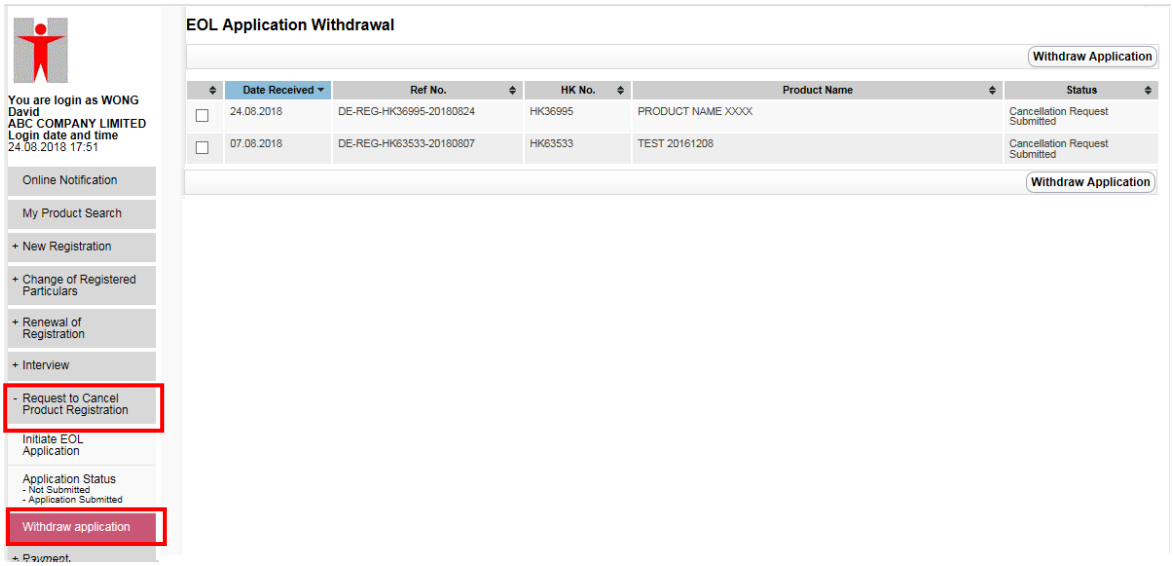


2.8.1.2 Withdraw application

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

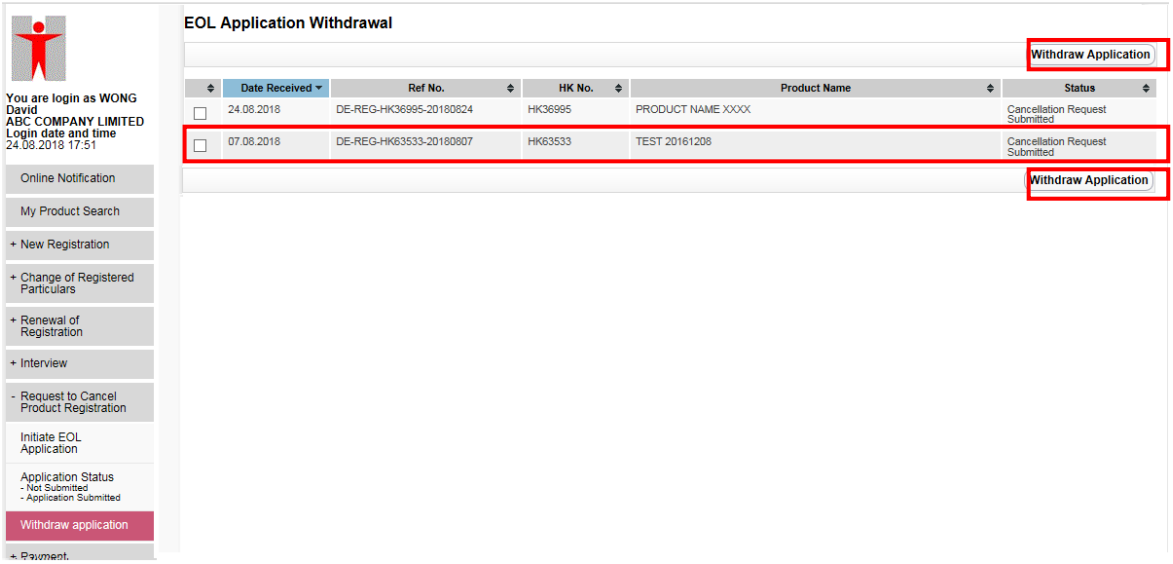
Step 1:

- Click the menu item “Withdraw application” under “Request to Cancel Product Registration” in the menu on the left.



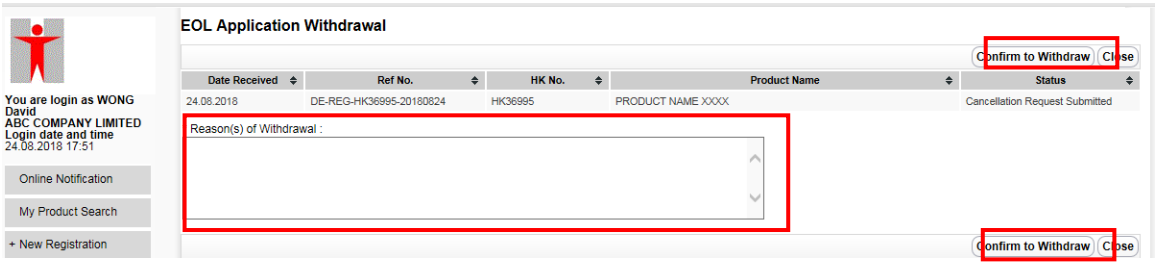
Step 2:

- Select the application(s) for withdrawal and click the button “Withdraw Application”.



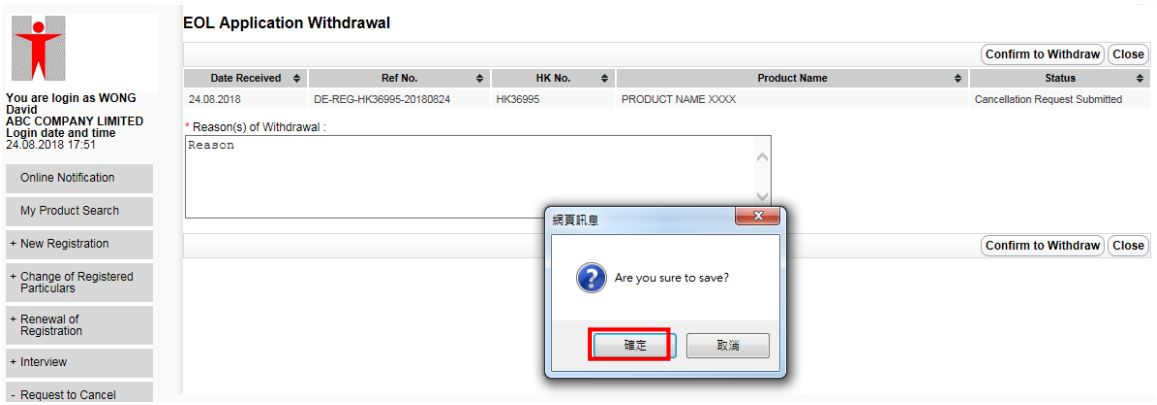
Step 3:

- Input the reason(s) of withdrawal and click the button “Confirm to Withdraw”.



Step 4:

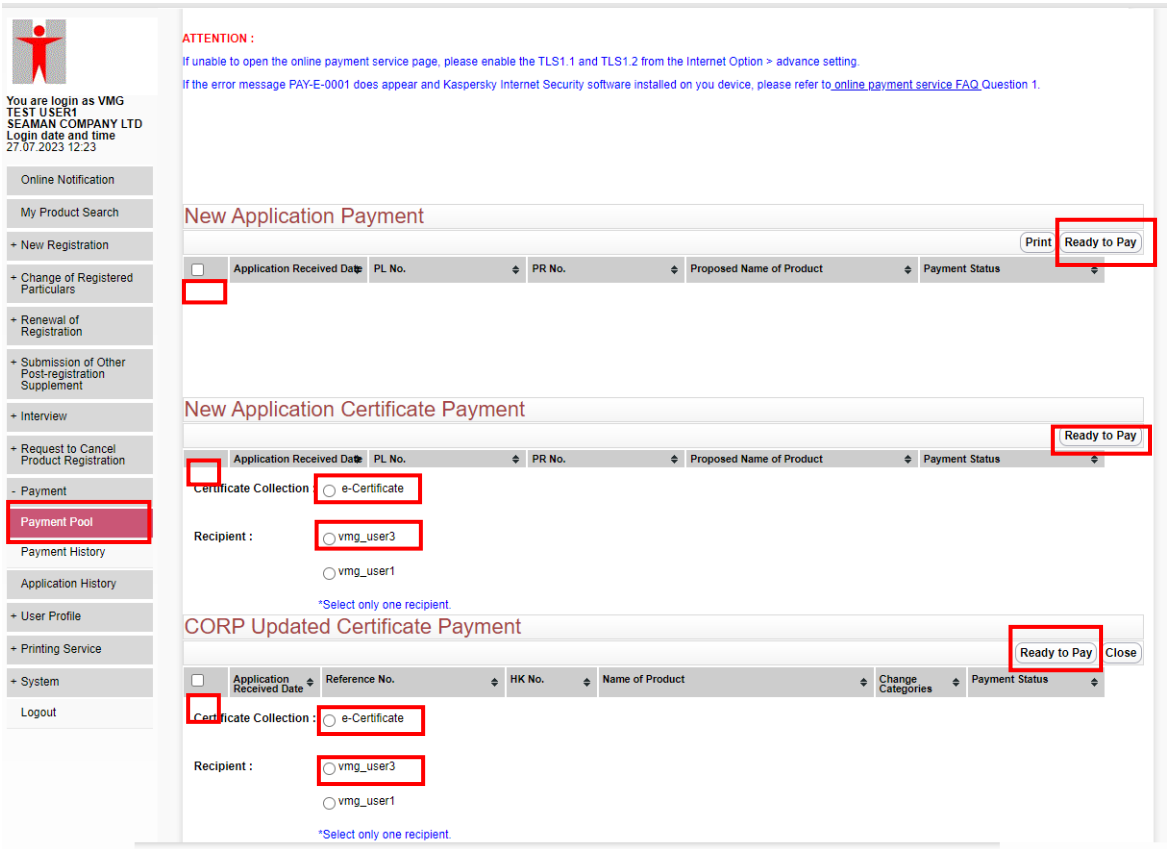
- Click the button “OK” to confirm withdrawal.



2.9 PAYMENT

2.9.1 Payment Pool

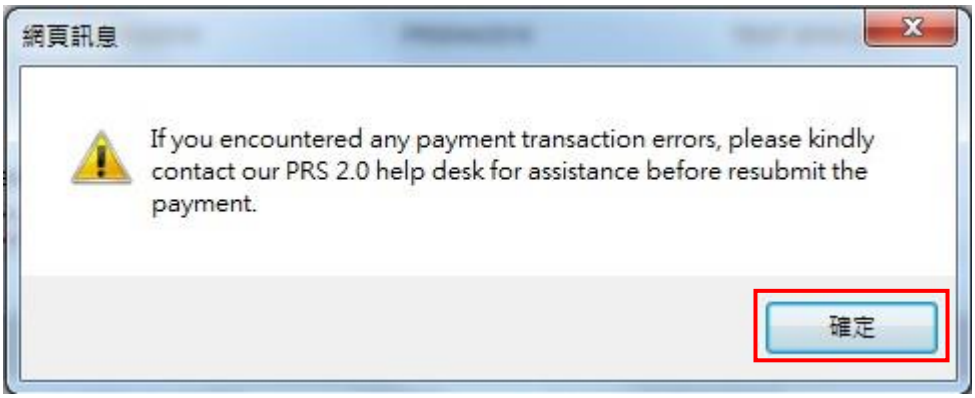
Step 1: Click the menu item “Payment Pool” under the section “Payment” in the menu on the left.

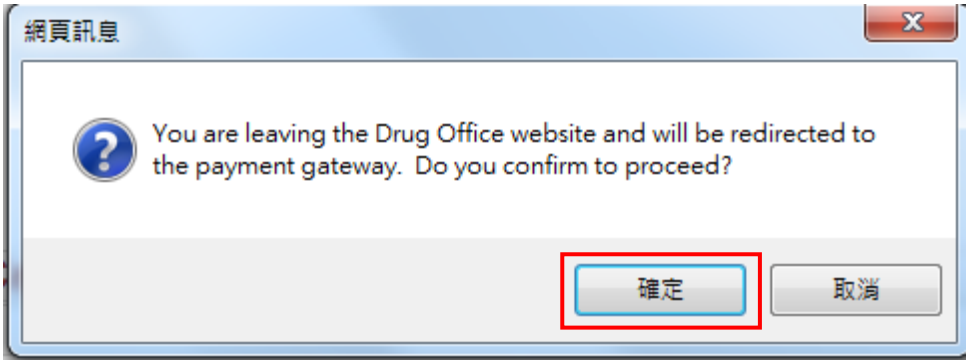


List of applications that require payments will be shown for new product registration and change of registered particulars application. To pay for applications, multi select the applications by selecting the checkbox and click the “Ready to Pay” button to enter the payment flow.

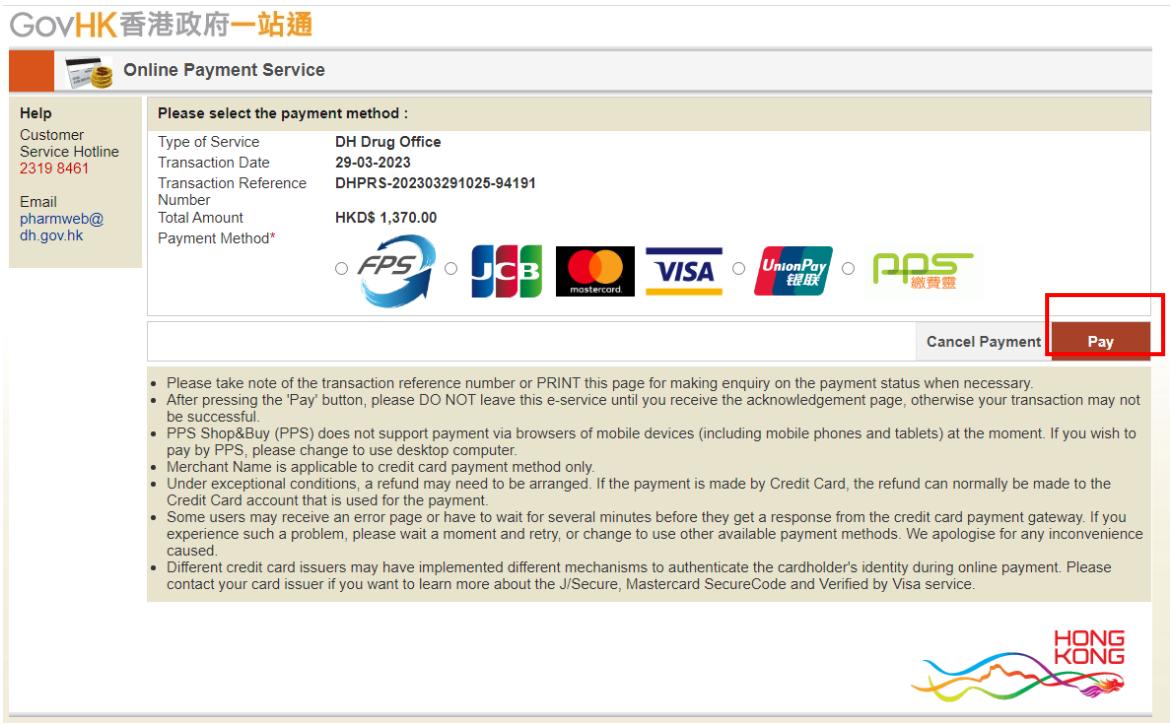
You can select the collection method either by ‘Received by post’ or ‘Collect in person in Drug Office’

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

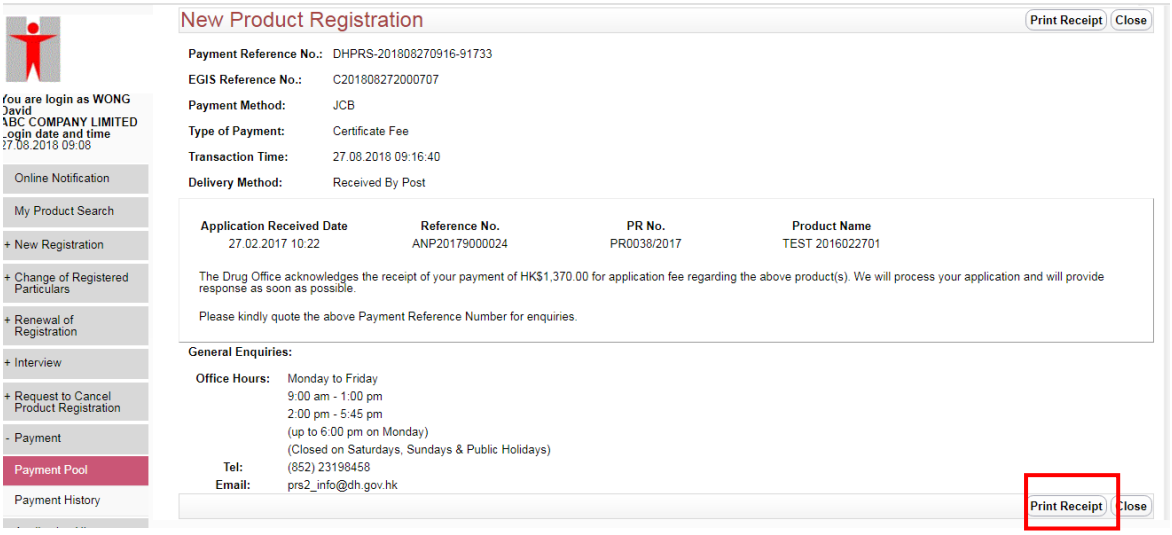




Select the payment method (Visa, Master, JBC, UnionPay, FPS or PPS) and press ‘Pay’ to proceed. Press ‘Cancel payment’ if you want to cancel the payment and back to payment pool.



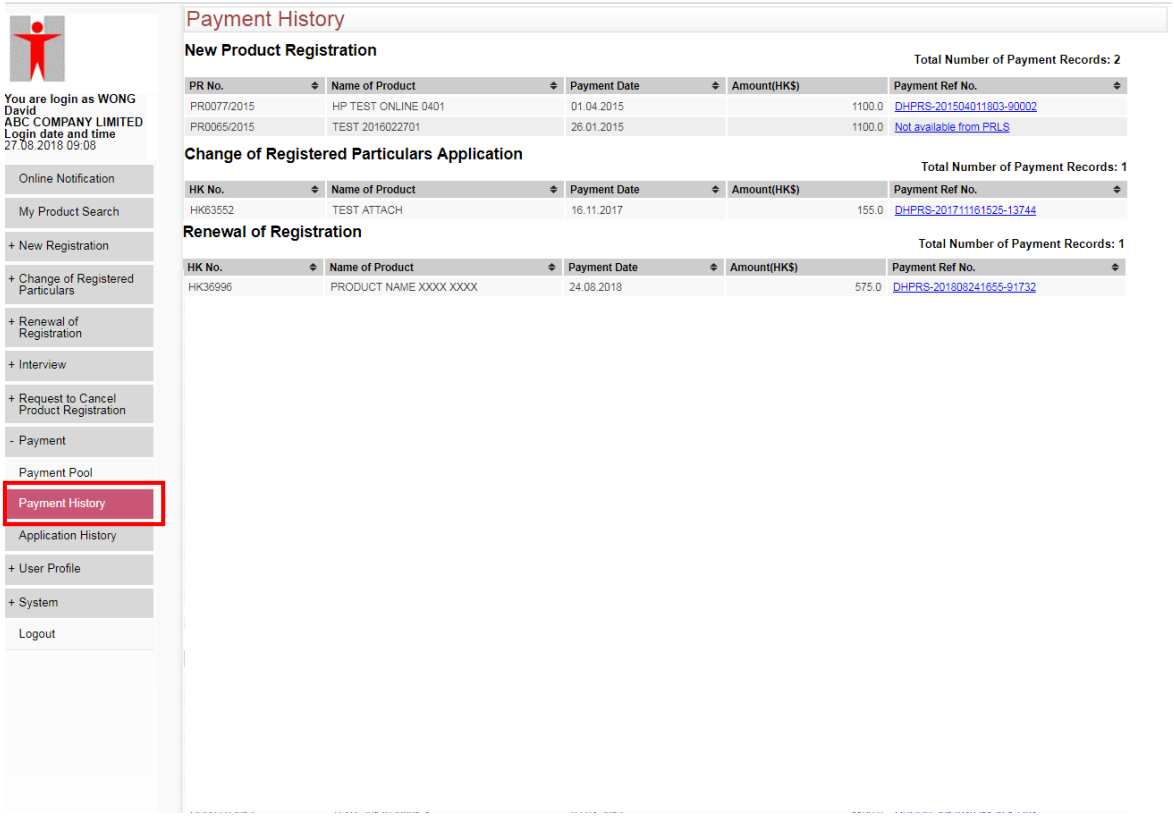
After completion the online payment, system will redirect back to Drug Office PRS2.0 website with payment summary and allow user to print the payment receipt as following:



The print out payment receipt is follow:

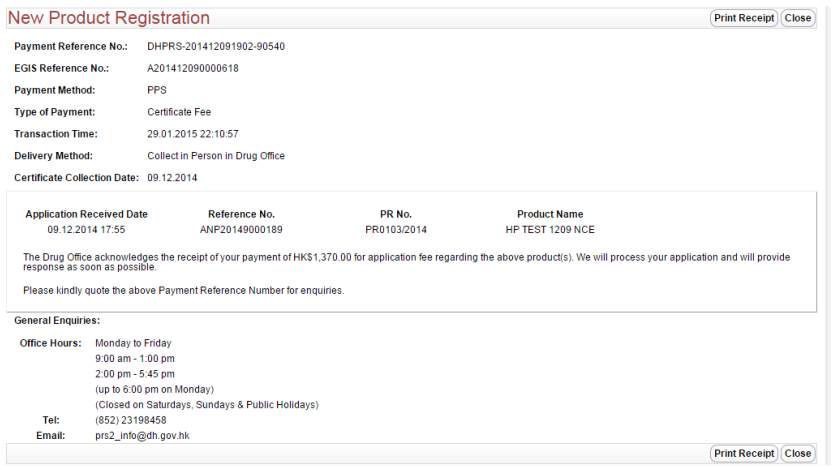
2.9.2 Payment History

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

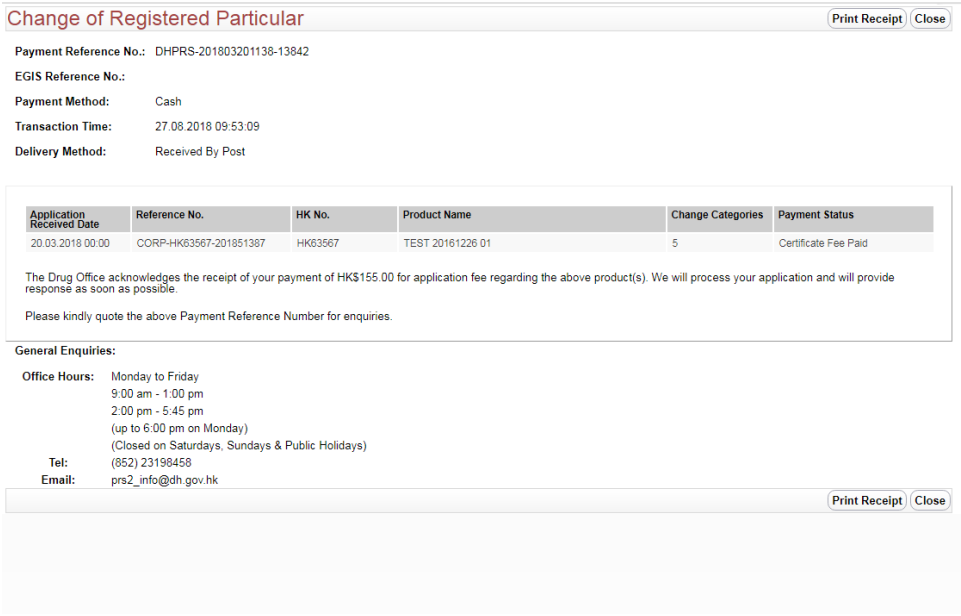


List of historical payments will be shown for new product registration, change of registered particulars and renewal application. To show the detailed information regarding each payment, click the payment reference number.

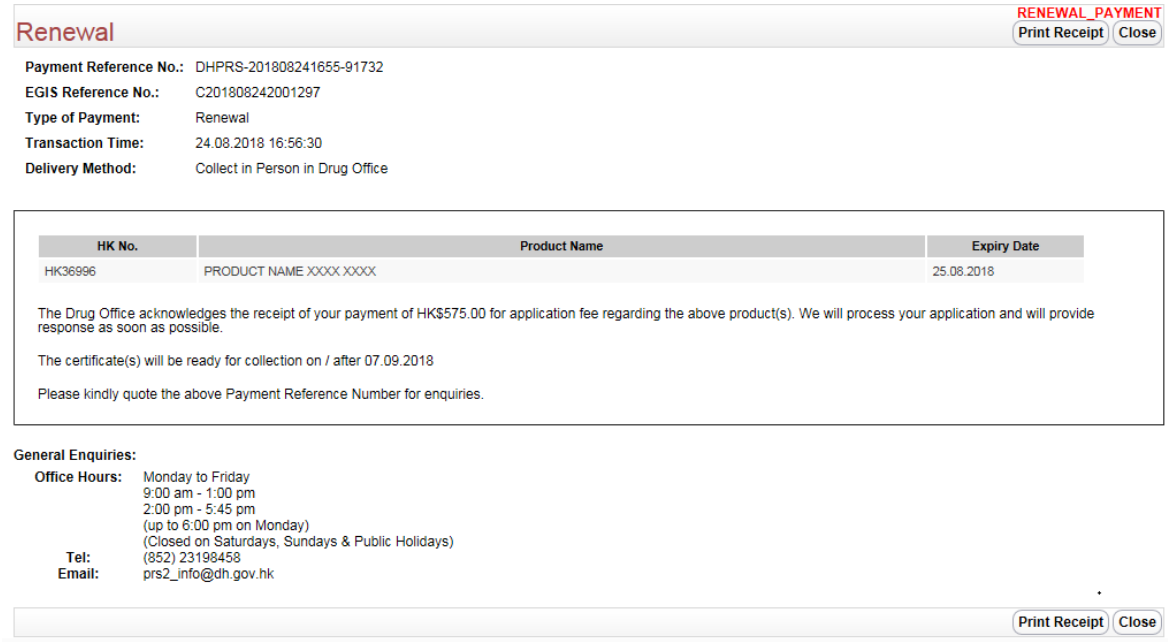
New Product Registration:



Change of Registered Particular:

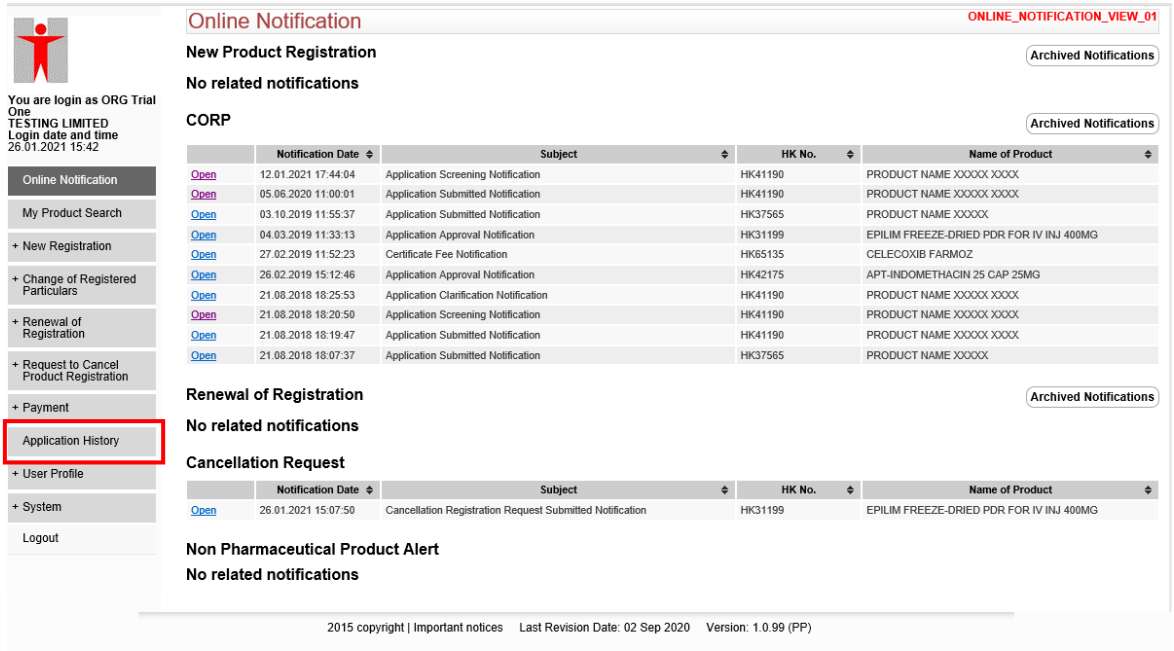


Renewal:



2.10 APPLICATION HISTORY

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



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 ****