Launch of Pharmaceuticals Registration System 2.0 (PRS 2.0)

Briefing Session

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Objectives of Briefing Session

- To promote on-line application submission using PRS 2.0
- To provide basic understanding of using PRS 2.0

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Briefing Agenda

- Introduction to PRS 2.0
- Benefit of Using PRS 2.0
- Registration for On-line User Accounts & System Login
- User Profiles Maintenance
- On-line Registration Application for New Product
- On-line Application for Change of Registered Particulars
- On-line Application for Registered Product Renewal
- On-line Application for Registered Product Cancellation
- Miscellaneous Functions
- Roadmap for Termination of Manual Application Submission Mode
- PRS 2.0 Information on Drug Office Website
- Q&A

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Introduction to PRS 2.0

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Introduction to PRS 2.0

System Requirements

- Web browser: Google Chrome
- Web browser settings: Accept cookies and enable JavaScript

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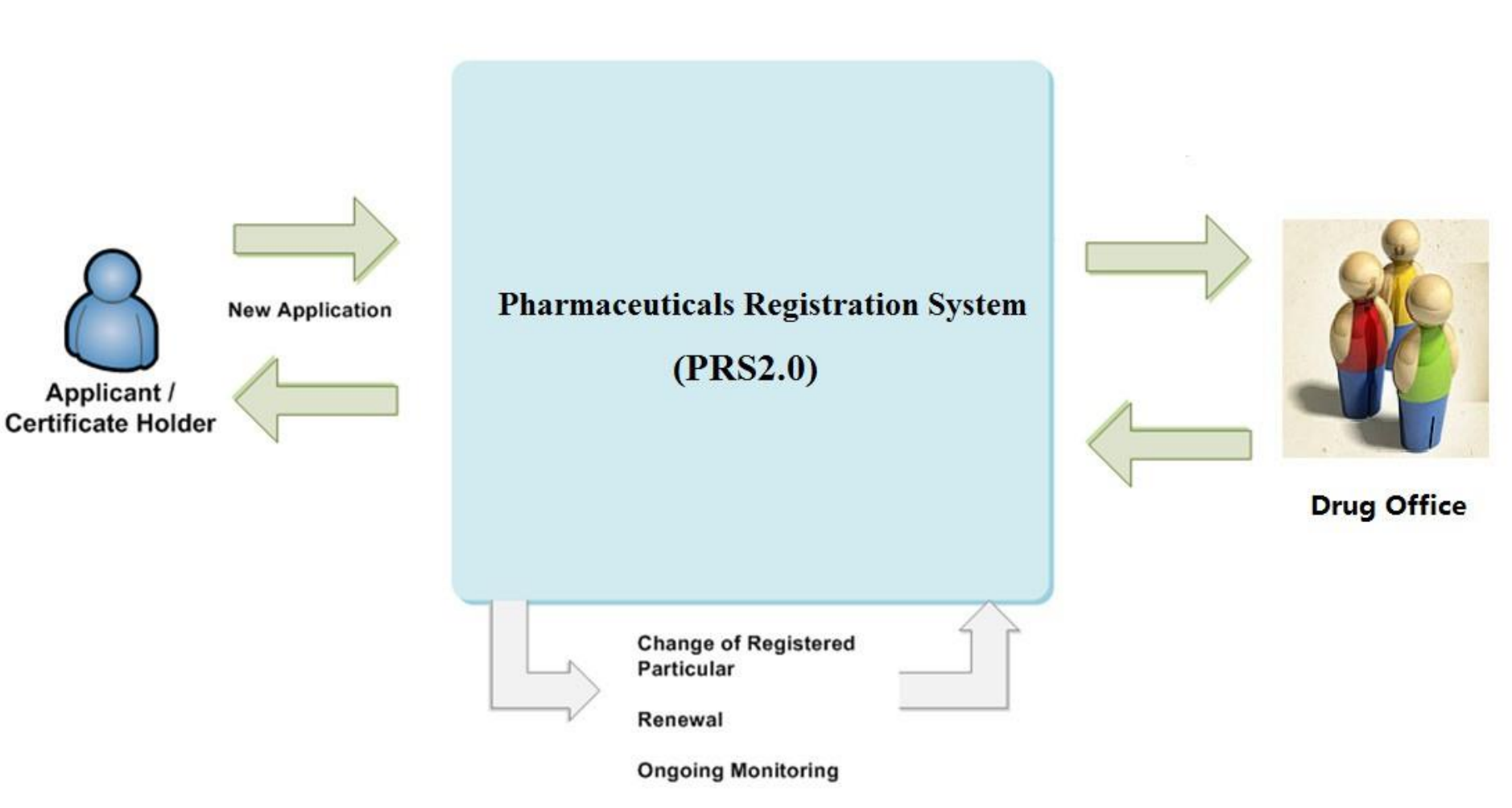
Introduction to PRS 2.0



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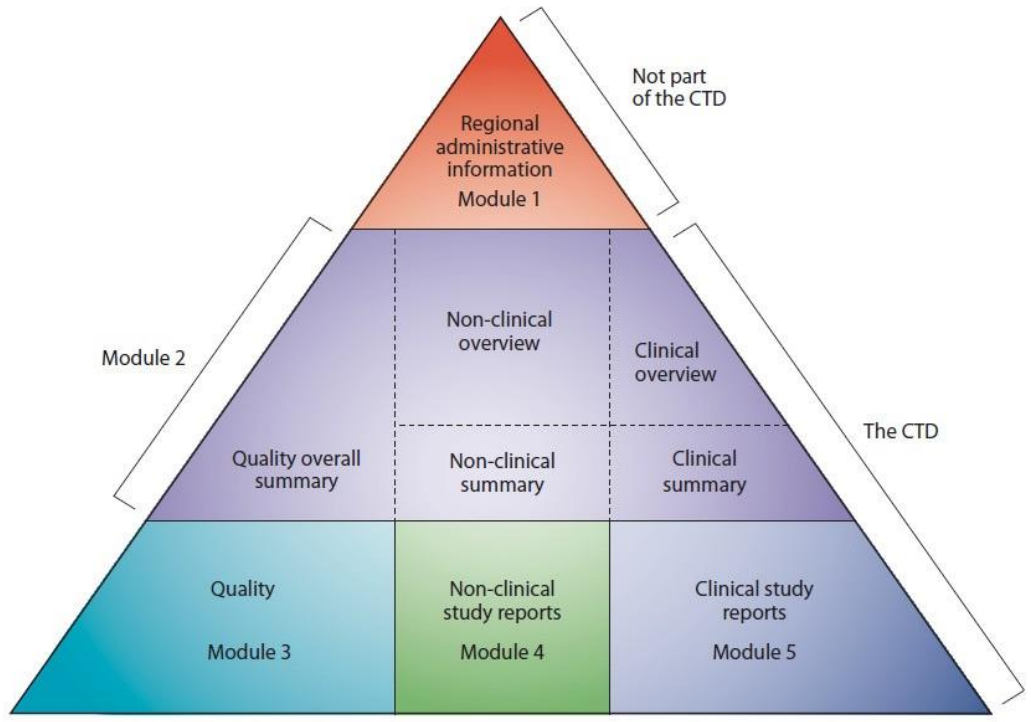
Introduction to PRS 2.0

PRS2.0 Product Data Design

Based on: ***International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Common Technical Document (CTD)*** format



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

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Introduction to PRS 2.0

- A web based Pharmaceuticals Registration System
- Provides user-friendly functions for easy access product information & product life cycle management
- Provides on-line application submission, clarification and on-line payment
- Provides status monitoring for applicants to keep track the application status
- Provides product access control for various users
- Provides on-line notification & email reminder for efficient communication between applicants and officers
- Supports English, Traditional Chinese & Simplified Chinese

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Benefits of Using PRS 2.0

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Benefits of Using PRS 2.0

- Web based on-line system to save time & paper
- Certificate holder information being isolated
- Account access control for applications & products
- On-line user registration & login with e-Cert for better security
- On-line application submission & monitoring
- On-line notification for following up the application
- On-line payment via PPS or Credit Card
- Save time and cost via on-line payment and collect certificate by post
- Daily reminder/notification email delivery
- On-line product information search
- Application & payment history enquiry

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Benefits of Using PRS 2.0

- Web based online system to save time & paper

Welcome to Pharmaceuticals Registration System (PRS2.0)

Username: *

Organizational e-Cert File Location:* Choose File No file chosen

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

e-Cert PIN:*

System Password:*

Login Reset Request for New Account

* mandatory field Reset Password

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

Points to note:

1. Install and configure the required software:
   a. Web browser: [redacted] Chrome
   b. Web browser settings: Accept cookies and enable JavaScript
   c. Ensure [redacted] TLS1.2 are enabled
2. The private key and the PIN of your e-Cert will not be transmitted during the transaction.
3. You should be alert to your surroundings before entering any personal information. Make sure that no one can see your personal particulars and e-Cert password.
4. You should disable options on your browser to avoid storing or retaining your e-Cert password on the personal computer.
5. For organizational e-Cert file location, it is case-insensitive in Windows platform.

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Benefits of Using PRS 2.0

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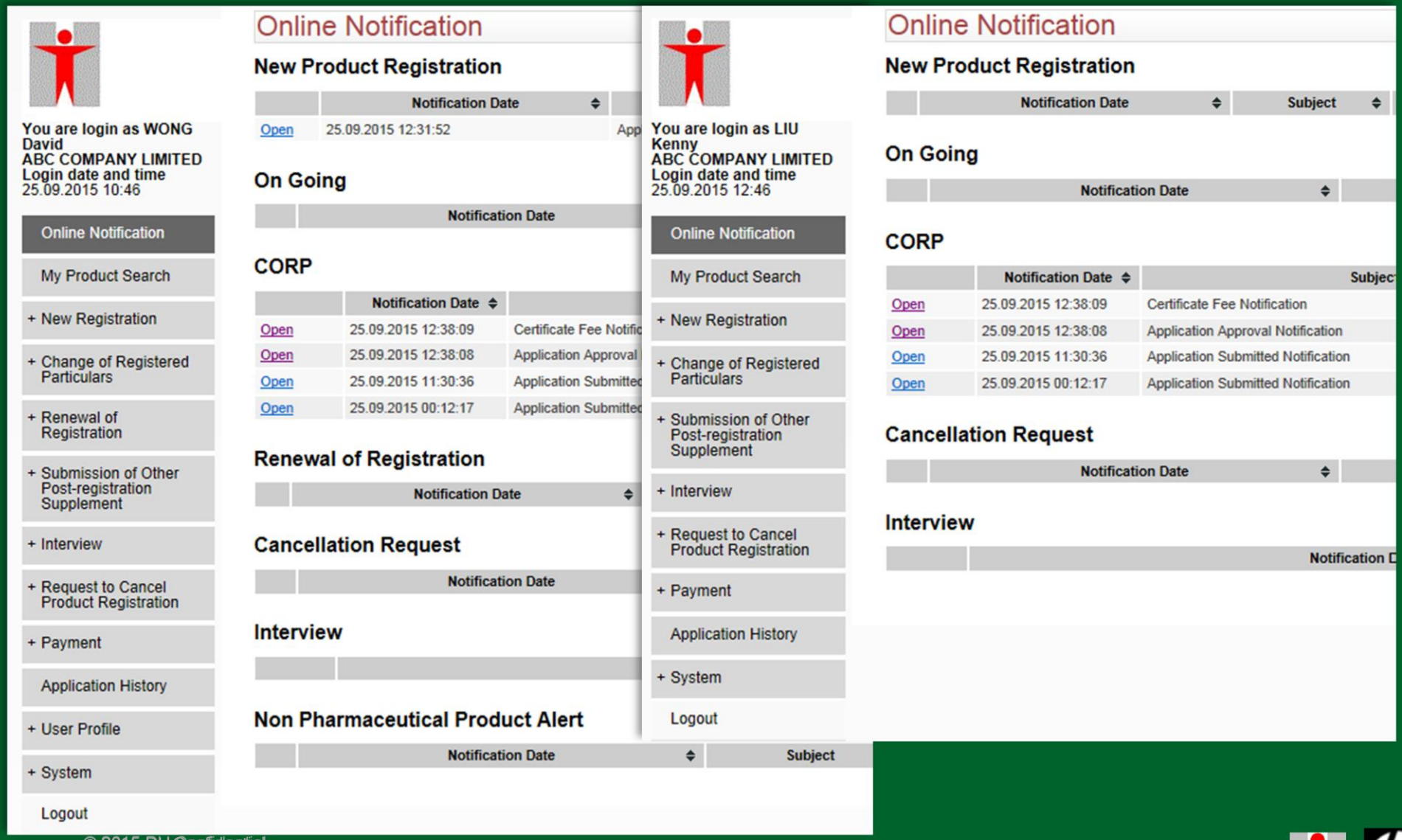
- Account access control for applications & products



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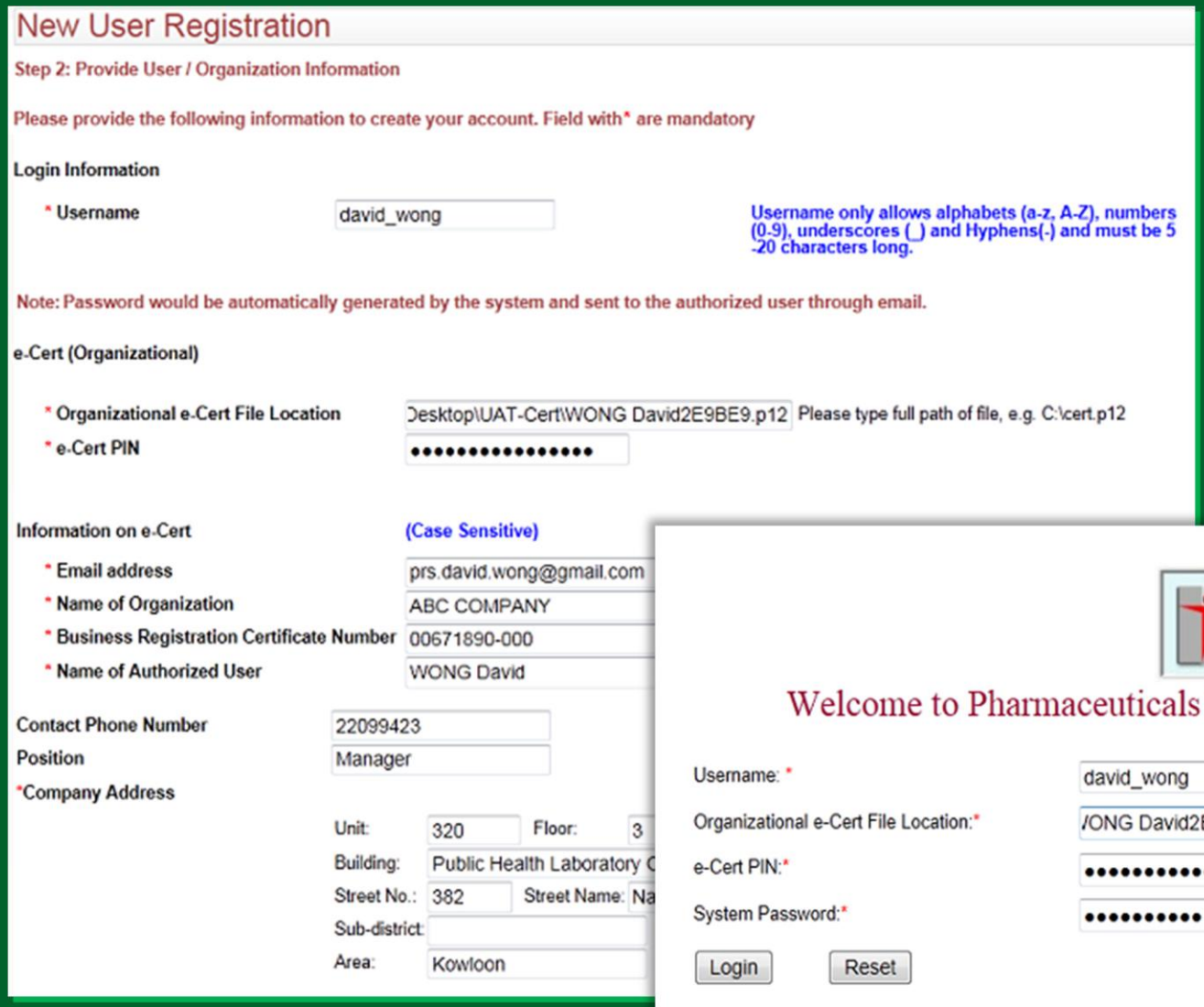
Benefits of Using PRS 2.0

- On-line user registration & login with e-Cert for better security



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Benefits of Using PRS 2.0

- On-line application submission & monitoring

Guidance | Save | Save and Exit | Next

New Product Registration — NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 300MB.
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): VITAMIN E TABLET | PL No.: | PR No.: | HK No.:

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
23.09.2015 23:04

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System

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):* VITAMIN E TABLET

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

c. Names / Proposed Names Used in Other Places

Name:	Place:
VITAMIN E	U.S.A.
VITAMIN GOLD	CANADA
	Please Select

Add More

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

No. of Component(s)* 1

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1 1. *	vitamin E	vitamin E
2.	Please Select	

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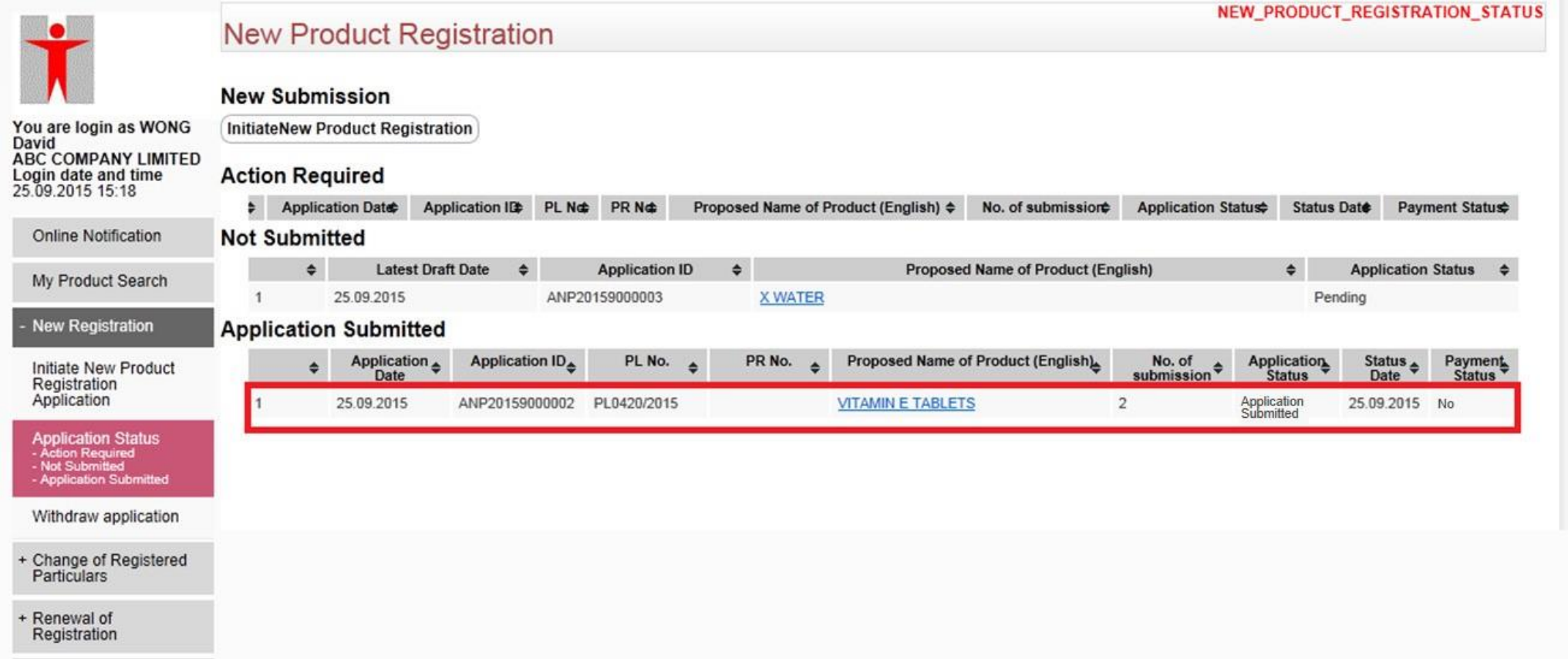
Benefits of Using PRS 2.0

- On-line application submission & monitoring



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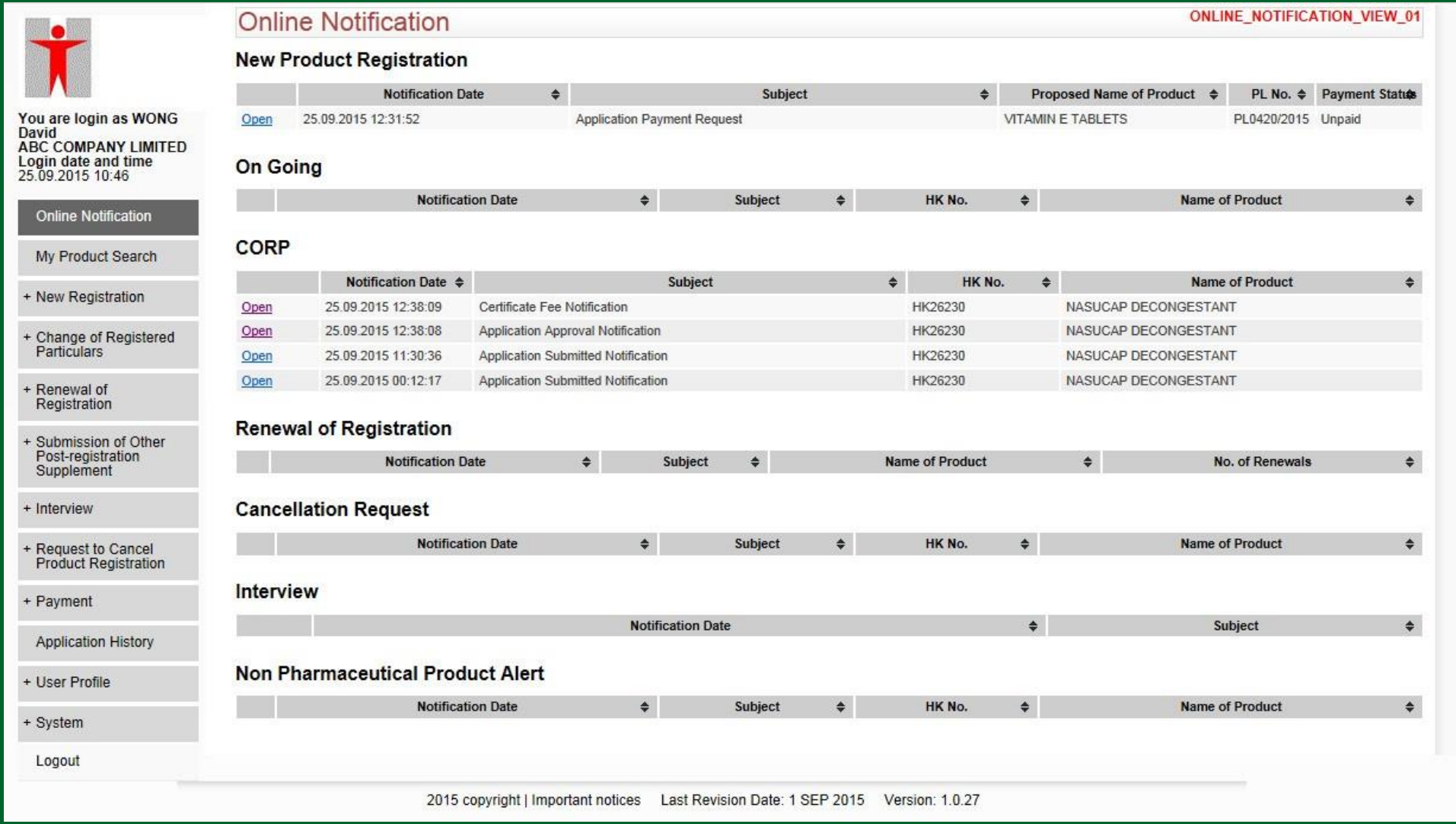
Benefits of Using PRS 2.0

- On-line notification for following up the application



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

Online Notification ONLINE_NOTIFICATION_VIEW_01

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	25.09.2015 12:31:52	Application Payment Request	VITAMIN E TABLETS	PL0420/2015	Unpaid

On Going

	Notification Date	Subject	HK No.	Name of Product

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	25.09.2015 12:38:09	Certificate Fee Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 12:38:08	Application Approval Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 11:30:36	Application Submitted Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 00:12:17	Application Submitted Notification	HK26230	NASUCAP DECONGESTANT

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product

Interview

	Notification Date	Subject

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product

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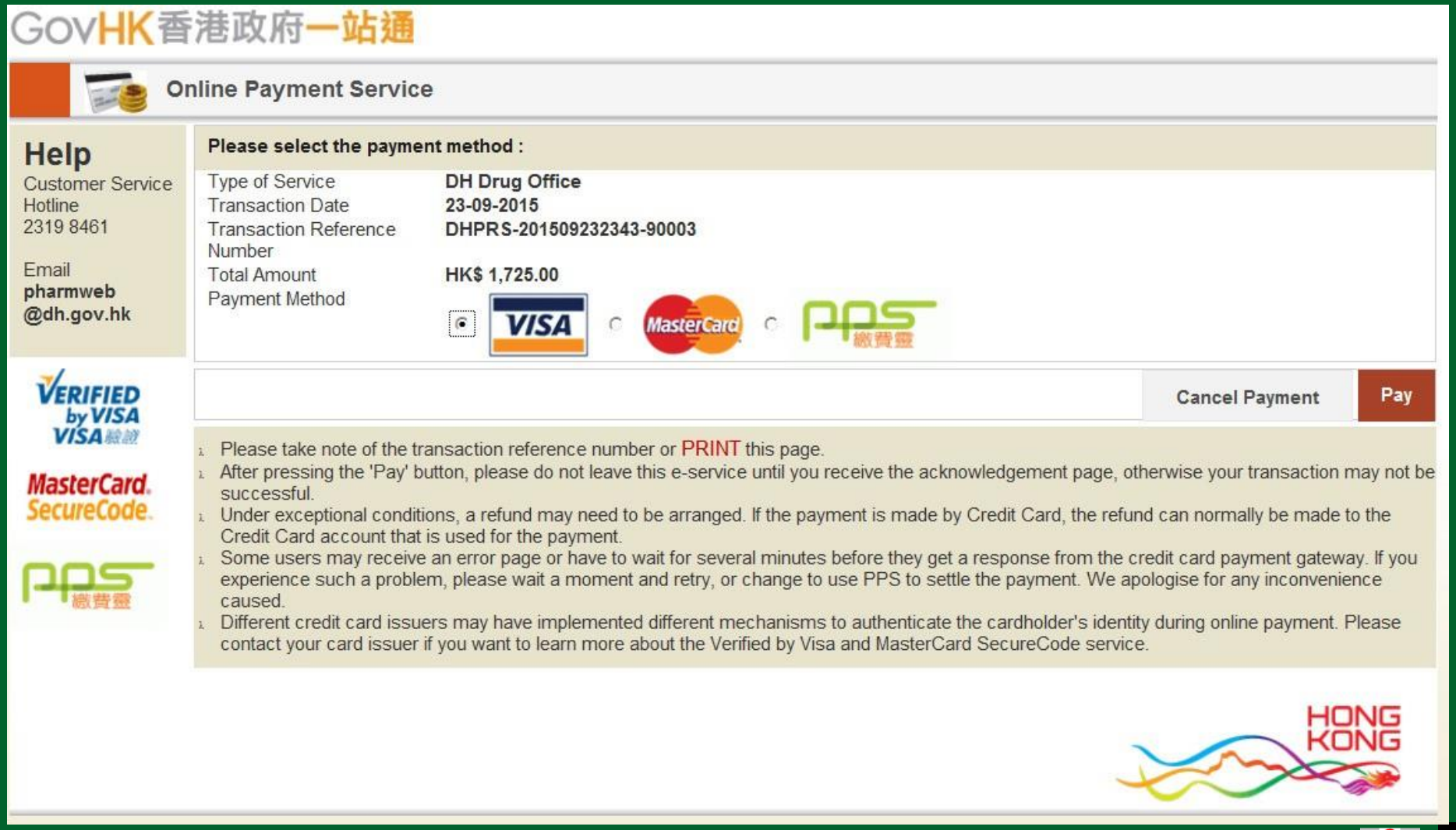
Benefits of Using PRS 2.0

- On-line payment via PPS or Credit Card
- Save time and cost via on-line payment and collect certificate by post



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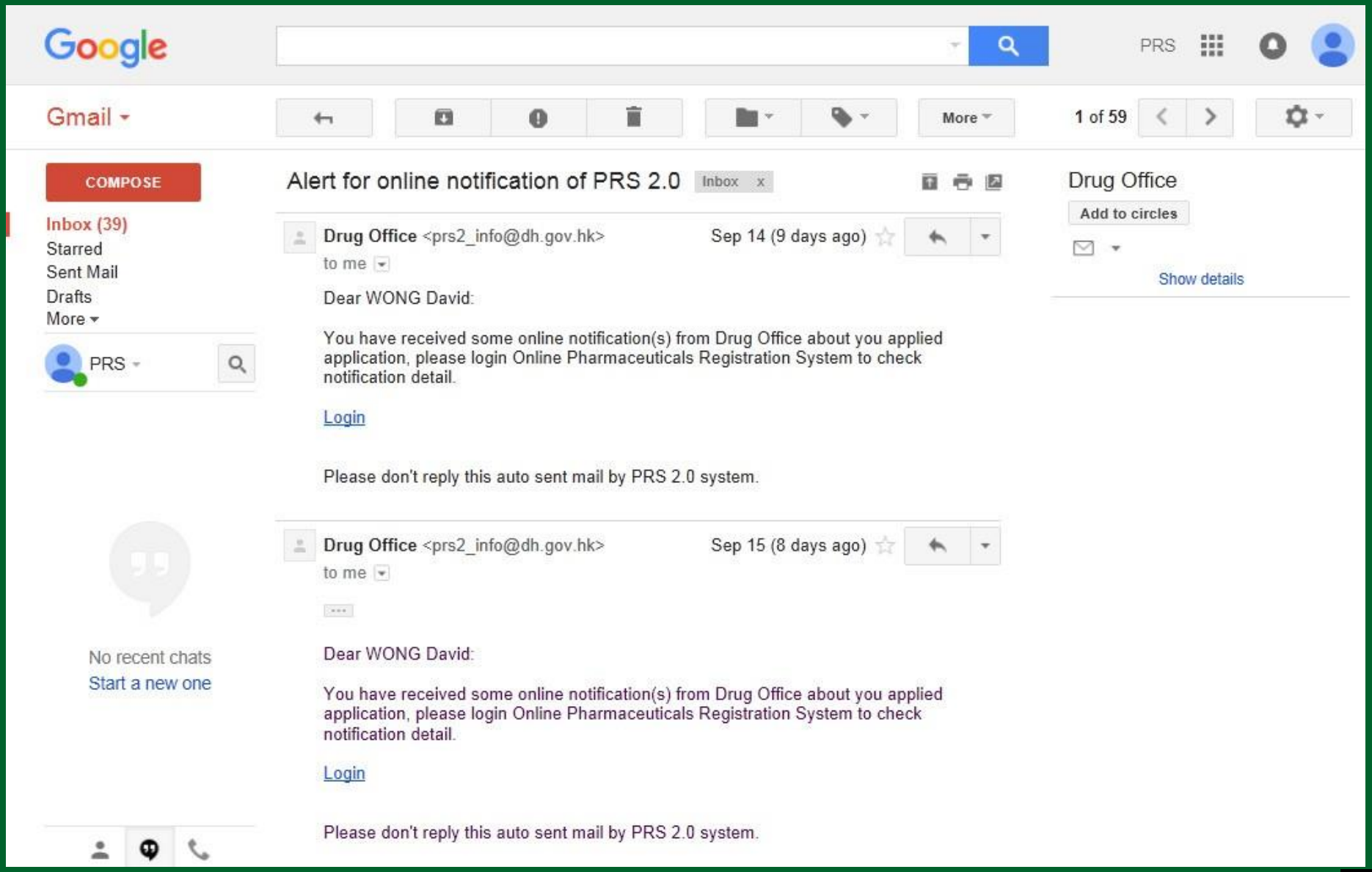
Benefits of Using PRS 2.0

- Reminder/notification email delivery



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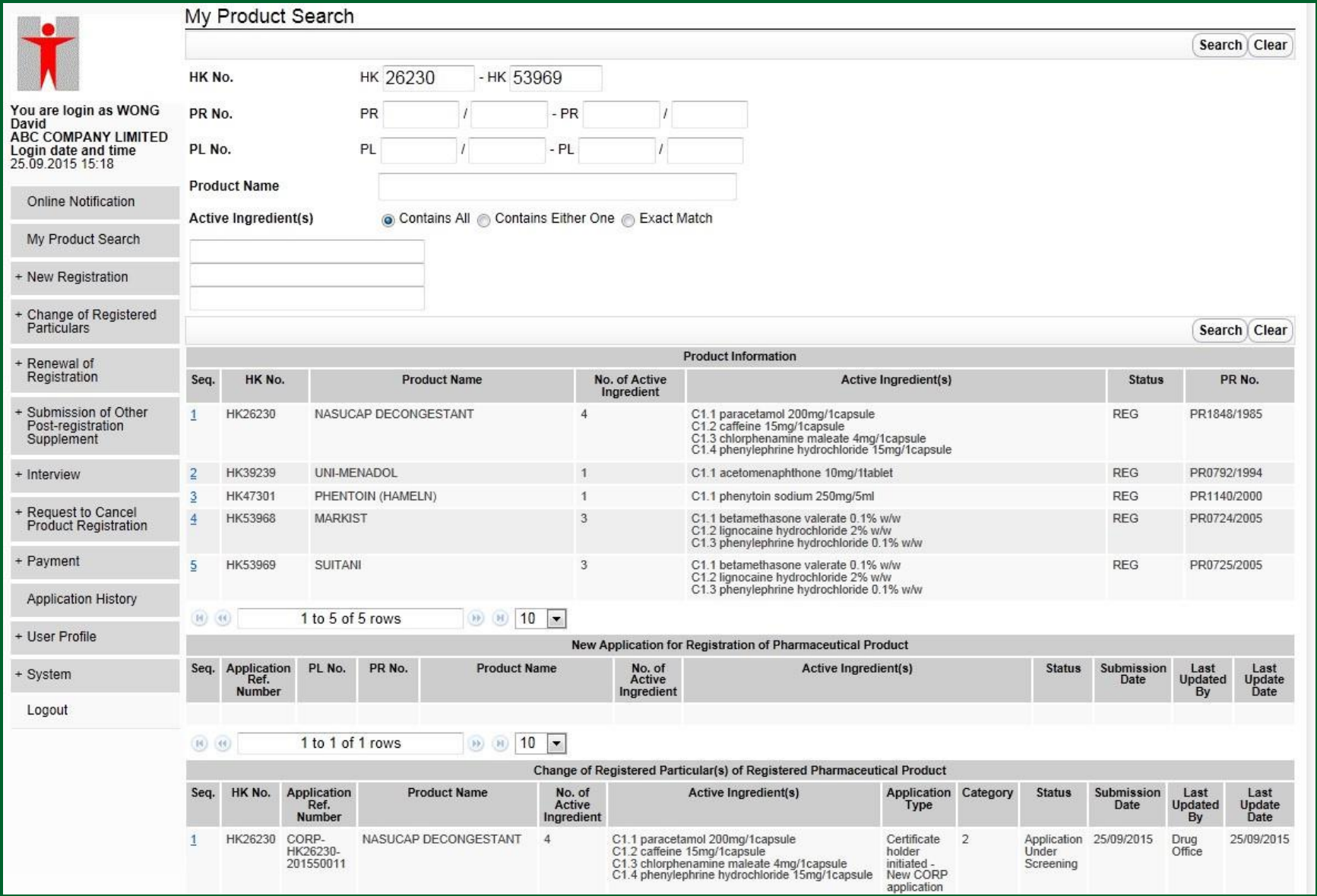
Benefits of Using PRS 2.0

- On-line product/application information search



You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

My Product Search

Search Clear

HK No. HK 26230 - HK 53969

PR No. PR / - PR /

PL No. PL / - PL /

Product Name

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

Search Clear

Product Information

Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	PR No.
1	HK26230	NASUCAP DECONGESTANT	4	C1.1 paracetamol 200mg/1capsule C1.2 caffeine 15mg/1capsule C1.3 chlorphenamine maleate 4mg/1capsule C1.4 phenylephrine hydrochloride 15mg/1capsule	REG	PR1848/1985
2	HK39239	UNI-MENADOL	1	C1.1 acetomenaphthone 10mg/1tablet	REG	PR0792/1994
3	HK47301	PHENTOIN (HAMELN)	1	C1.1 phenytoin sodium 250mg/5ml	REG	PR1140/2000
4	HK53968	MARKIST	3	C1.1 betamethasone valerate 0.1% w/w C1.2 lignocaine hydrochloride 2% w/w C1.3 phenylephrine hydrochloride 0.1% w/w	REG	PR0724/2005
5	HK53969	SUITANI	3	C1.1 betamethasone valerate 0.1% w/w C1.2 lignocaine hydrochloride 2% w/w C1.3 phenylephrine hydrochloride 0.1% w/w	REG	PR0725/2005

1 to 5 of 5 rows 10

New Application for Registration of Pharmaceutical Product

Seq.	Application Ref. Number	PL No.	PR No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Submission Date	Last Updated By	Last Update Date

1 to 1 of 1 rows 10

Change of Registered Particular(s) of Registered Pharmaceutical Product

Seq.	HK No.	Application Ref. Number	Product Name	No. of Active Ingredient	Active Ingredient(s)	Application Type	Category	Status	Submission Date	Last Updated By	Last Update Date
1	HK26230	CORP-HK26230-201550011	NASUCAP DECONGESTANT	4	C1.1 paracetamol 200mg/1capsule C1.2 caffeine 15mg/1capsule C1.3 chlorphenamine maleate 4mg/1capsule C1.4 phenylephrine hydrochloride 15mg/1capsule	Certificate holder initiated - New CORP application	2	Application Under Screening	25/09/2015	Drug Office	25/09/2015

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Benefits of Using PRS 2.0

- Application & payment history enquiry

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
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- + Payment
- Application History
- + User Profile
- + System
- Logout

Application History

New Product Registration

Total Number of Application Records:0

Application Date	PL No.	PR No.	HK No.	Name of Product	Payment Status	Status	Last Updated Date

Change of Registered Particulars

Total Number of Application Records:0

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

Renewal of Registration

Total Number of Application Records:13

Expiry Date	HK No.	Name of Product	Application Status	Last Updated Date
13.01.2016	HK53969	SUITANI OINTMENT	Paid	25.09.2015
13.01.2016	HK53970	RAMATIN OINTMENT	Paid	25.09.2015
24.11.2015	HK60187	LEVOXA TAB 250MG	Paid	03.09.2015
17.09.2015	HK39239	UNI-MENADOL TAB 10MG	Paid	03.09.2015
02.02.2011	HK26230	NASUCAP DECONGESTANT CAP	Issue Certificate	11.02.2015
28.01.2011	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	Issue Certificate	11.02.2015
13.01.2011	HK53968	MARKIST OINTMENT	Issue Certificate	11.02.2015
13.01.2011	HK53970	RAMATIN OINTMENT	Issue Certificate	11.02.2015
13.01.2011	HK53969	SUITANI OINTMENT	Issue Certificate	11.02.2015
17.09.2010	HK39239	UNI-MENADOL TAB 10MG	Issue Certificate	11.02.2015
02.02.2006	HK26230	NASUCAP DECONGESTANT CAP	Issue Certificate	11.02.2015
28.01.2006	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	Issue Certificate	11.02.2015
17.09.2005	HK39239	UNI-MENADOL TAB 10MG	Issue Certificate	11.02.2015

Termination of Product Registration

Total Number of Application Records:0

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

Ongoing Request Application

Total Number of Application Records:0

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

Interview

Total Number of Application Records:1

Application Date	Subject	Application	Status
25.09.2015	Interview for CORP application (HK26230)	- CORP-HK26230-201550011	Declined

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Benefits of Using PRS 2.0

- Application & payment history enquiry

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25.09.2015 15:18

- Online Notification
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- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
  - Payment Pool
  - Payment History
  - Application History
- + User Profile
- + System
- Logout

Payment History

New Product Registration

Total Number of Payment Records: 1

PR No.	Name of Product	Payment Date	Amount(HK$)	Payment Ref No.
PR0386/2015	VITAMIN E TABLETS	25.09.2015	1100.0	DHPRS-201509251504-90006

Change of Registered Particulars Application

Total Number of Payment Records: 11

HK No.	Name of Product	Payment Date	Amount(HK$)	Payment Ref No.
HK39239	UNI-MENADOL	25.09.2015	155.0	DHPRS-201509251525-90007
HK47301	PHENTOIN (HAMELN)	25.09.2015	155.0	DHPRS-201509251525-90007
HK26230	NASUCAP DECONGESTANT	25.09.2015	155.0	DHPRS-201509251525-90007
HK53968	MARKIST	25.09.2015	155.0	DHPRS-201509251525-90007
HK53970	RAMATIN	25.09.2015	155.0	DHPRS-201509251525-90007
HK60186	LEVOXA	25.09.2015	155.0	DHPRS-201509251525-90007
HK60175	PRILIGY	25.09.2015	155.0	DHPRS-201509251525-90007
HK53969	SUITANI	25.09.2015	155.0	DHPRS-201509251525-90007
HK60174	PRILIGY	25.09.2015	155.0	DHPRS-201509251525-90007
HK60187	LEVOXA	25.09.2015	155.0	DHPRS-201509251525-90007
HK60507	PROACTIV	25.09.2015	155.0	DHPRS-201509251525-90007

Renewal of Registration

Total Number of Payment Records: 13

HK No.	Name of Product	Payment Date	Amount(HK$)	Payment Ref No.
HK53969	SUITANI	25.09.2015	575.0	DHPRS-201509250021-90004
HK53970	RAMATIN	25.09.2015	575.0	DHPRS-201509250021-90004
HK60187	LEVOXA	02.09.2015	575.0	DHPRS-201509021953-90002
HK39239	UNI-MENADOL	02.09.2015	575.0	DHPRS-201509021232-90001
HK26230	NASUCAP DECONGESTANT	14.02.2011	575.0	MIGRATION_REF_NO
HK53968	MARKIST	18.01.2011	575.0	MIGRATION_REF_NO
HK47301	PHENTOIN (HAMELN)	30.11.2010	575.0	MIGRATION_REF_NO
HK53970	RAMATIN	23.07.2010	575.0	MIGRATION_REF_NO
HK53969	SUITANI	23.07.2010	575.0	MIGRATION_REF_NO
HK39239	UNI-MENADOL	11.06.2010	575.0	MIGRATION_REF_NO
HK26230	NASUCAP DECONGESTANT	09.01.2006	500.0	MIGRATION_REF_NO
HK47301	PHENTOIN (HAMELN)	29.11.2005	500.0	MIGRATION_REF_NO
HK39239	UNI-MENADOL	12.08.2005	500.0	MIGRATION_REF_NO

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Registration for On-line User Accounts & System Login

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Registration Procedure

1. Apply Organizational e-Cert from Hong Kong Post (www.hongkongpost.gov.hk)

2. Register new on-line user account on PRS 2.0 website

3. Manually Submit PRS 2.0 Online User Application Form to Drug Office

4. Email notification for the result and user account information

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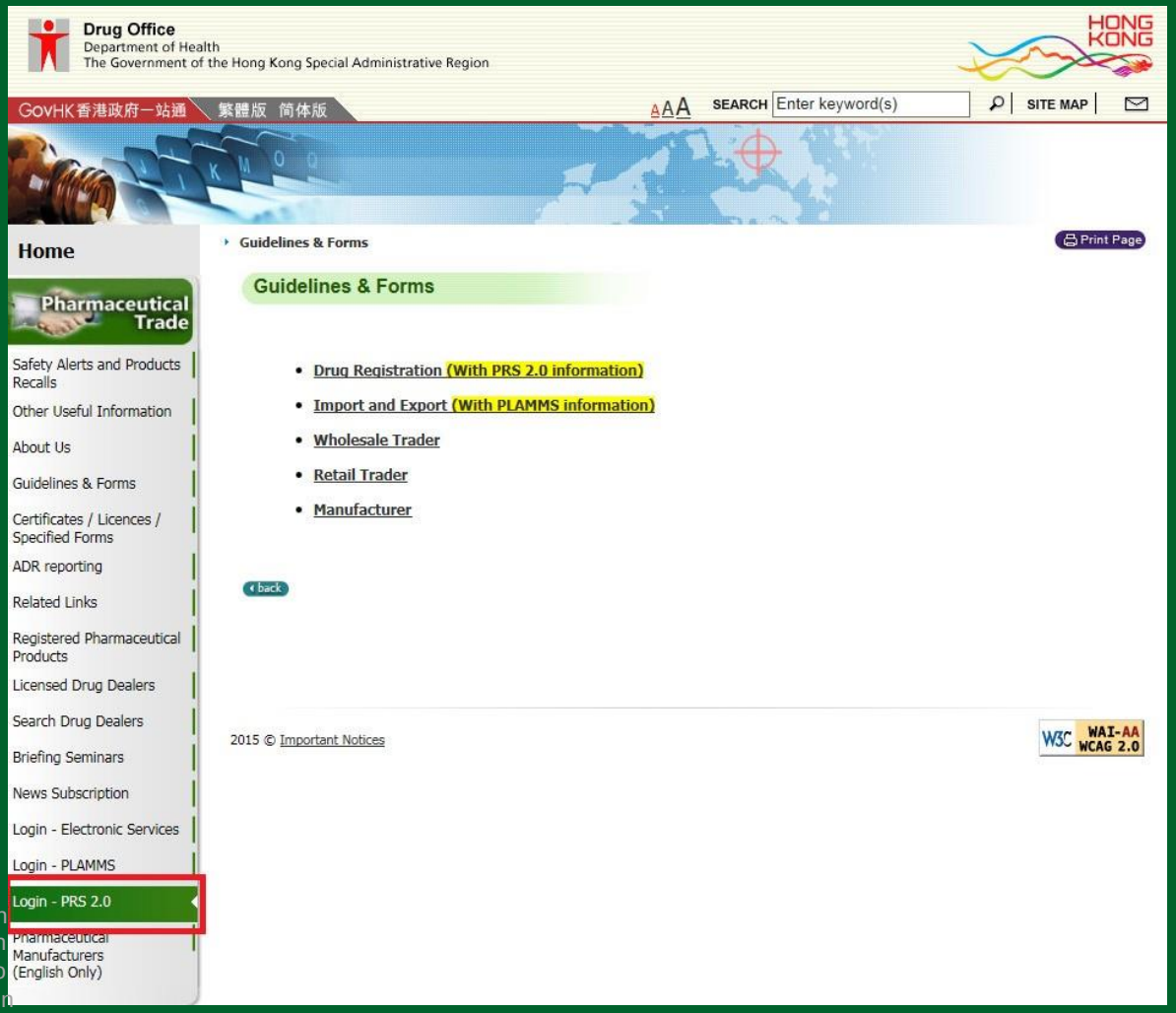
Access to PRS 2.0

- 1. Direct access
  URL: https://www.drugoffice.gov.hk/prs2-ext/login_internet.jsp

- 2. Through shortcut of Drug Office website (www.drugoffice.gov.hk)



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Registration for On-line User Accounts & System Login

- Login of PRS 2.0

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Registration for On-line User Accounts & System Login

- Terms and conditions for the use of PRS2.0

New User Registration

INT-USER_REG_01 USR

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

Terms for the Use of PRS2.0

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

1. Introduction

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

2. Acceptance of Terms of Use

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

You need to read the complete content of the Terms before you are able to click the check box below.

☑ I have read and agree to be legally bound by the above Terms.

Continue Cancel

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Registration for On-line User Accounts & System Login

- User and Organization information

New User Registration

Step 2: Provide User / Organization Information

INT-USER_REG_02 USR

Please provide the following information to create your account. Field with* are mandatory

Login Information

* Username: david_wong

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

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

e-Cert (Organizational)

* Organizational e-Cert File Location: Desktop\UAT-Cert\WONG David2E9BE9.p12 Please type full path of file, e.g. C:\cert.p12

* e-Cert PIN: ••••••••••••••••

Information on e-Cert (Case Sensitive)

* Email address: prs.david.wong@gmail.com

* Name of Organization: ABC COMPANY

* Business Registration Certificate Number: 00671890-000 (e.g. 12345678-123)

* Name of Authorized User: WONG David

Contact Phone Number: 22099423

Position: Manager

*Company Address

Unit: 320 Floor: 3 Block: A

Building: Public Health Laboratory Centre

Street No.: 382 Street Name: Nam Cheong Street

Sub-district:

Area: Kowloon

Back | Continue | Cancel

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Registration for On-line User Accounts & System Login

- Review and confirm account details

New User Registration

INT-USER_REG_03 USR

Step 3: Review and confirm the account details

Please check your account details before submission.

* Username	david_wong
* Email address	prs.david.wong@gmail.com
* Name of Organization	ABC COMPANY
* Business Registration Certificate Number	00671890-000
* Name of Authorized User	WONG David
Contact Phone Number	22099423
Position	Manager
*Company Address	**Unit** : 320 **Floor** : 3 **Block** : A **Building** : Public Health Laboratory Centre **Street No.** : 382 **Street Name** : Nam Cheong Street **Sub-district** : **Area** : Kowloon

Print Edit Submit Cancel

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Registration for On-line User Accounts & System Login

- Acknowledgement for registration of account

New User Registration

INT-USER_REG_04 USR

Thank you for your registration

Your registration request has been submitted to Drug Office successfully.

Your Reference Number is: **DO201509-004**

For enquiries, please call our office at (852) 2319 8414 or email to prs2_info@dh.gov.hk :

Monday to Friday:

9:00 am - 1:00 pm

2:00 pm - 5:45 pm

(up to 6:00 pm on Monday)

(Closed on Saturdays, Sundays & Public Holidays)

Print Close

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Registration for On-line User Accounts & System Login

- Registration Acknowledgement

PRS 2.0 New On-line Account Registration - Acknowledgement of Receipt Inbox x

Drug Office <prs2_info@dh.gov.hk> 12:27 PM (2 hours ago)

to me

Dear Sir / Madam,

Please be informed that your registration request for new on-line account for PRS 2.0 has been submitted to Drug Office successfully.

Your Reference Number is **DO201509-004**

Your faithfully,

Drug Office,
Department of Health,
HKSAR

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Registration for On-line User Accounts & System Login

- Application Form for New On-line User Account Registration

For Drug Office Use Only	
Date Received	_____
Officer Name	_____
Successful Application	☐ Yes ☐ No

Application Form for New On-line User Account Registration for Pharmaceuticals Registration System 2.0 (PRS2.0)

Please complete **ALL** items. Incomplete information may lead to unsuccessful application.

For enquiries relating to PRS2.0 or any changes in personnel information, please call our help desk at 2319 8414 during office hour (Monday-Friday: 09:00-13:00 and 14:00-17:45) or email us at prs2_info@dh.gov.hk.

Please read the "Terms and Conditions for the Use of Pharmaceuticals Registration System 2.0 (PRS2.0) v1.0".

Please send the completed application form to:

Project Manager – PRS2.0
Drug Registration Unit,
Drug Office,
Department of Health,
3/F, Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon.

A. Company Information (Please refer to the current Business Registration Certificate (BRC))

Company Name _____

Company Address _____

BRC Number (First 11 digits) ☐☐☐☐☐☐☐☐ - ☐☐☐

BRC Expiry Date (dd/mm/yyyy) _____

B. e-Certificate (Organizational) Information

1. Please refer to the current e-Certificate(s) of EACH authorized user(s) within the company.
2. Please fill in the particulars of individual user(s) in SEPARATE table.
3. Please copy the table in case of insufficient space.

Particulars	Authorized User
Name of Authorized User	
Position	
Email Address#	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username (1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role*?	Yes / No (Delete as appropriate)

1 v1.3 July 2015

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Registration for On-line User Accounts & System Login

- Application Form for New On-line User Account Registration

Particulars	Authorized User
Name of Authorized User	
Position	
Email Address#	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username (1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role*?	Yes / No (Delete as appropriate)

#The same email address must be included in the e-Certificate during e-Certificate application. Upon successful PRS 2.0 account application, the login password will be sent to the individual applicant through a confirmation email.

*User Administrator Role: Each company must assign at least one or more administrator(s) in the PRS2.0 system. Administrator(s) has the right to grant privileges to other colleagues or subordinates under his/her organization for rights to access various system functions, such as application for new product registration or submission of CORP application or confirming renewal of registered products.

C. Confirmation by Applicant on behalf of the Company

Please tick the checkboxes and confirm the following:

☐ Please provide a copy of the valid BRC.

☐ The staff listed in section B of this application form is authorized to apply for new on-line user account(s) for PRS2.0 on behalf of the company.

Authorized Signature: _____

(Stamped with "for and on behalf of" company chop and signed by a director or a person with equivalent rank)

Name of Signatory: _____ Position: _____

Email Address: _____ Contact Telephone No.: _____

Facsimile Number: (if any) _____ Date: _____

3 v1.3 July 2015

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Registration for On-line User Accounts & System Login

- Approval Notification

PRS 2.0 New On-line Account Registration - Approved Inbox x

Drug Office <prs2_info@dh.gov.hk> 12:38 PM (1 hour ago)

to me

Dear Sir / Madam,

Please be informed that your registration request for new on-line account for PRS 2.0 has been approved by Drug Office.

Username: david_wong
Password: VtTVdzJv

Your faithfully,

Drug Office,
Department of Health,
HKSAR

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Registration for On-line User Accounts & System Login

- Login PRS2.0 with new registered account

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Registration for On-line User Accounts & System Login

- Change password when first login

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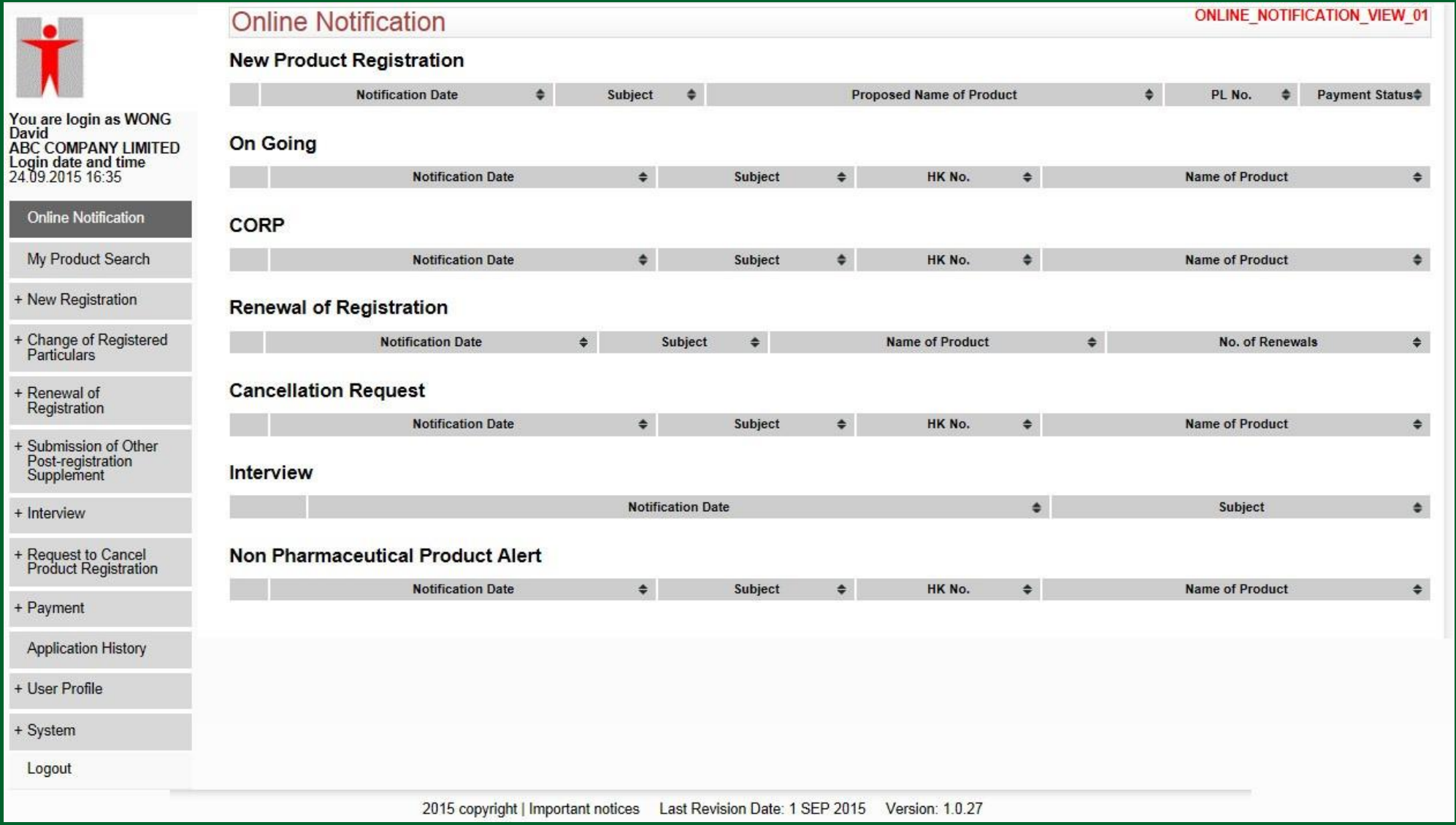
Registration for On-line User Accounts & System Login

- Home page – online notification



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Points to Note for On-line User Account Registration

- Support Organizational e-Cert only (recommend: USB media)
- Each on-line user account requires one e-Cert
- For users under subsidiary/distributor, they should apply e-Cert on behalf of the certificate holder
- The company BRC No. (First 8 digits) on e-Cert must be the same as the BRC No. (First 8 digits) of certificate holder
- Apply e-Cert which has email address
- The information on e-Cert is case-sensitive. e.g. Name of Organization, Name of Authorized User etc

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User Profiles Maintenance

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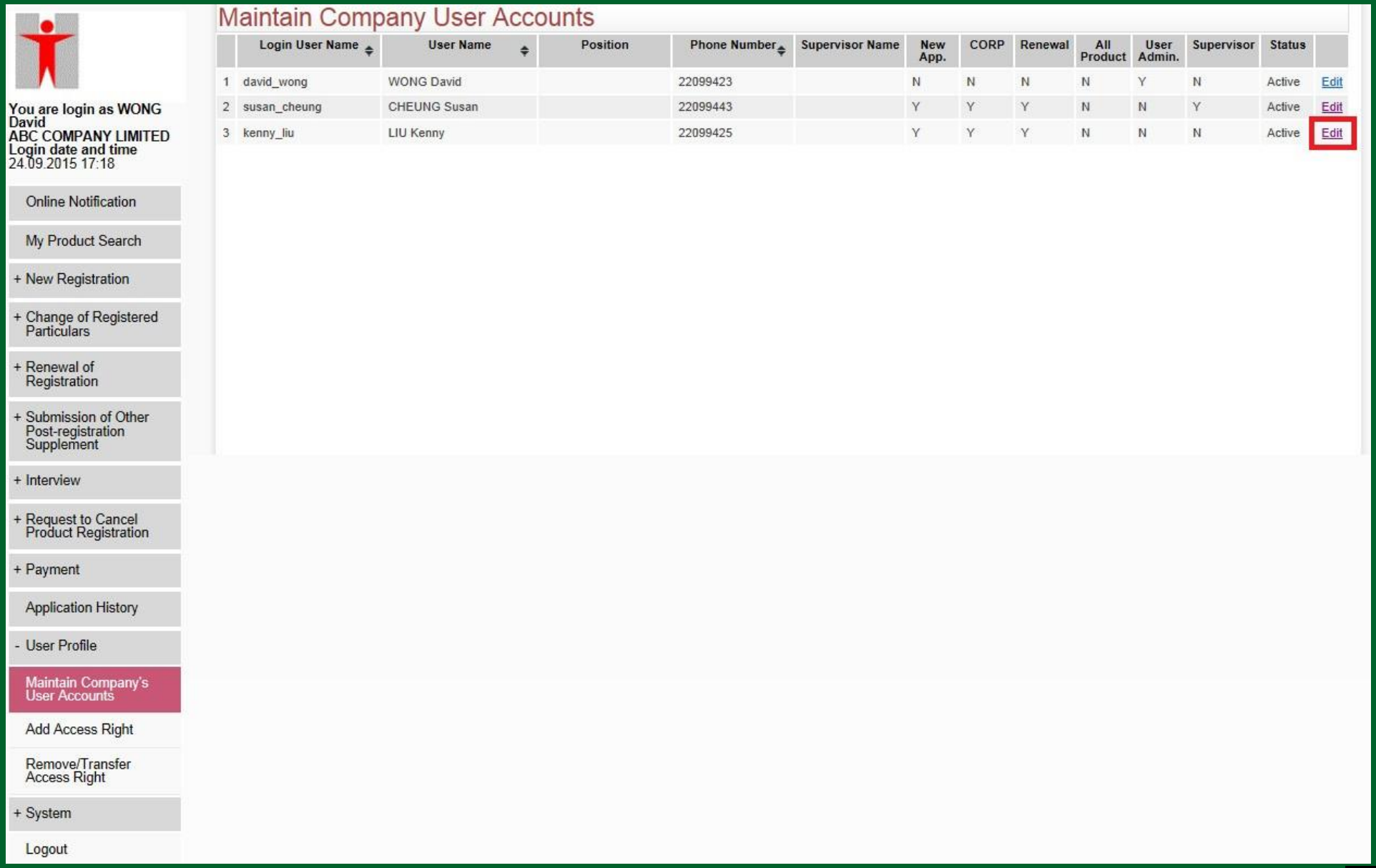
User Profiles Maintenance

- User profiles



	Login User Name	User Name	Position	Phone Number	Supervisor Name	New App.	CORP	Renewal	All Product	User Admin.	Supervisor	Status	
1	david_wong	WONG David		22099423		N	N	N	N	Y	N	Active	Edit
2	susan_cheung	CHEUNG Susan		22099443		Y	Y	Y	N	N	Y	Active	Edit
3	kenny_liu	LIU Kenny		22099425		Y	Y	Y	N	N	N	Active	Edit

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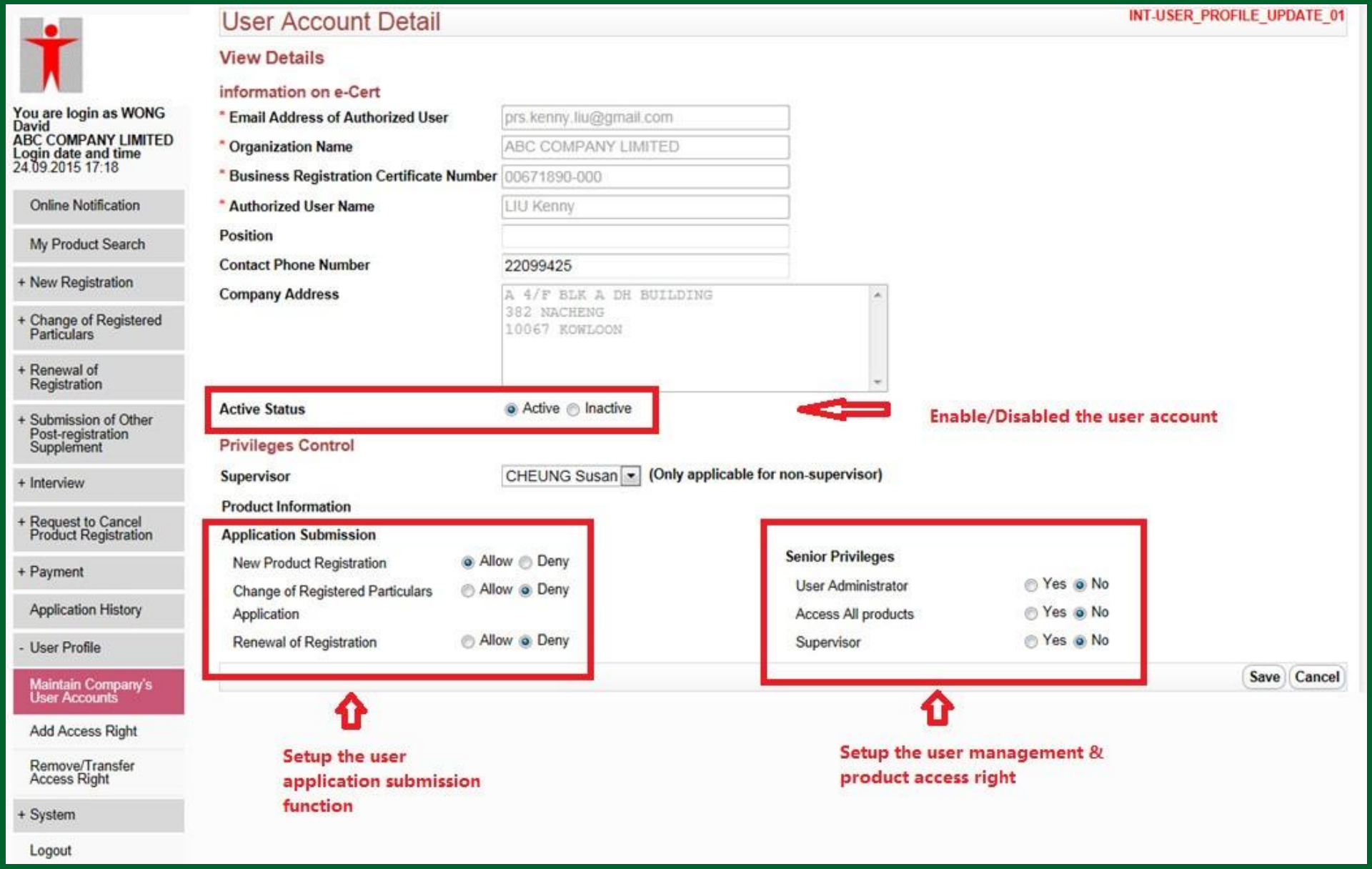
User Profiles Maintenance

- User profile details



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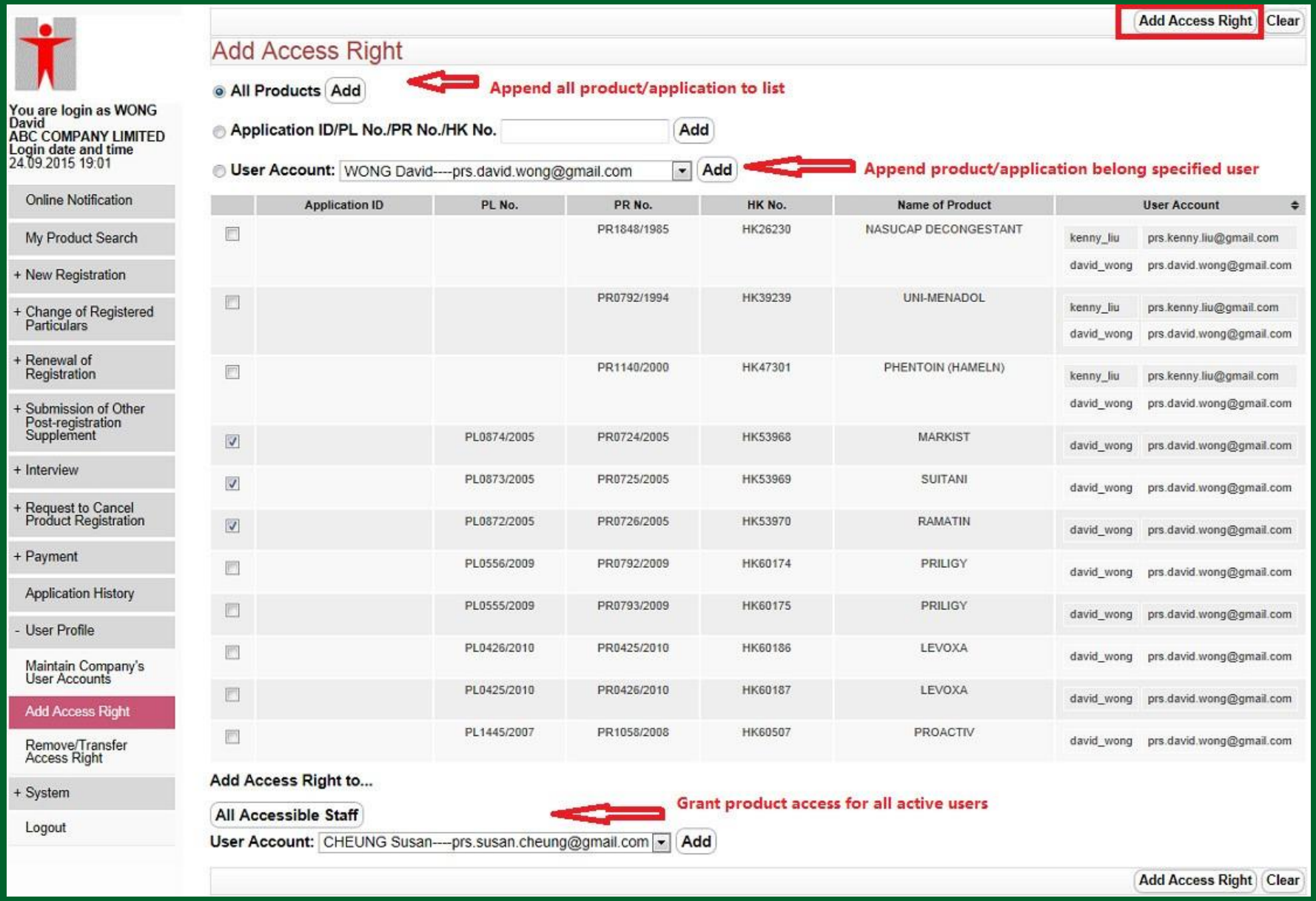
User Profiles Maintenance

- Grant product access right



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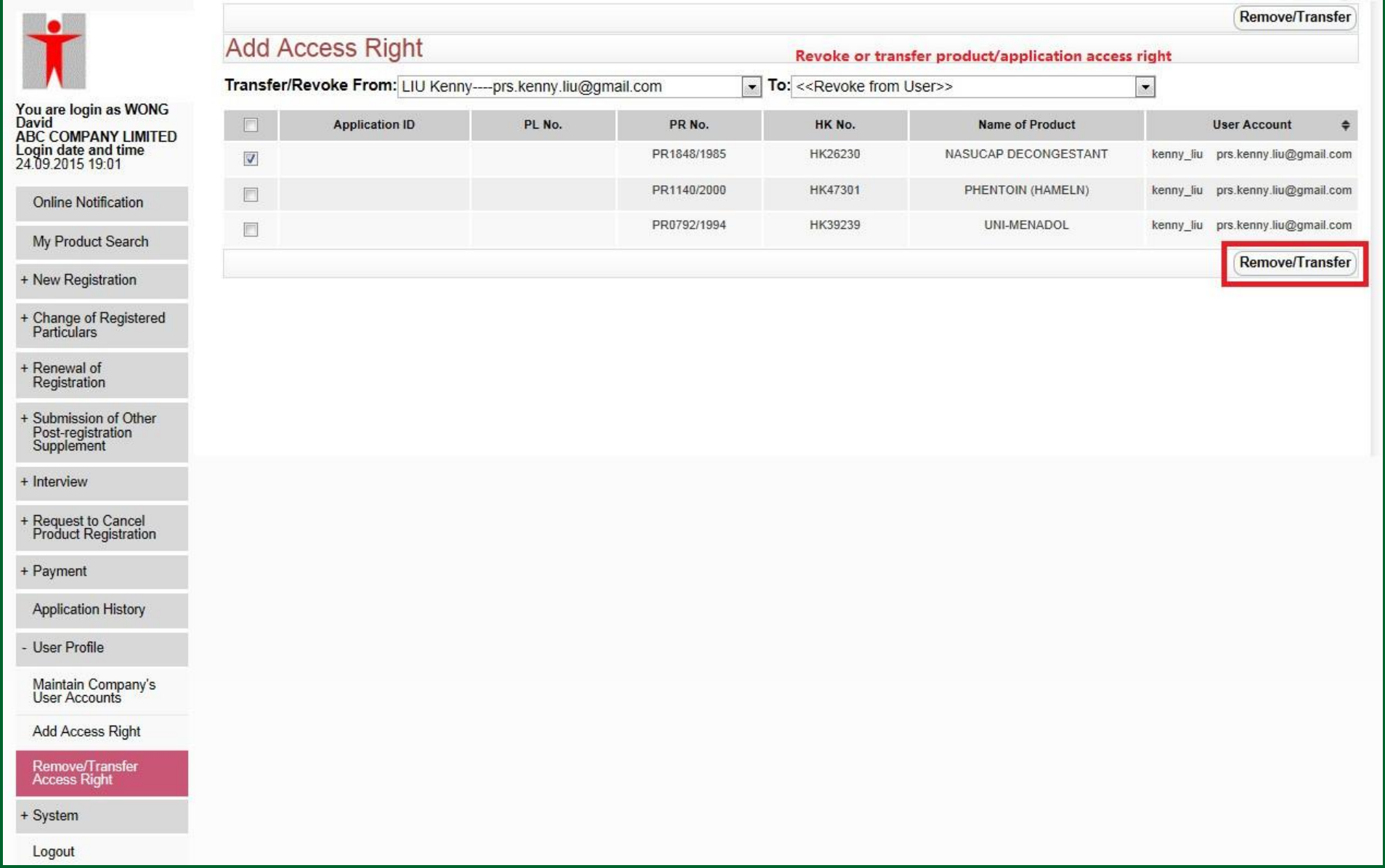
User Profiles Maintenance

- Revoke/transfer product access right



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User Roles

Role	(A) Maintain User Profiles	(B) Maintain Access of Functions	(C) Maintain Access of Products	(D) Accessible Functions	(E) Accessible Products
User Admin	All users	All users	All users	All functions	All products
Supervisor (User)	No	No	Staff in his team	Function granted by Admin	Products granted by Admin
Staff (User)	No	No	No	Function granted by Admin	Products granted by Admin/ supervisor

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On-line Registration Application for New Product

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File Upload Size Limitation

Application	Application Type	Scope	Single File Max. Size	Total File Size Max. Size
New Registration Application	Generic	Module 1	50MB	100MB
		Module 2~5	Submit by CD/DVD	
	NCE	Module 1	50MB	300MB
		Module 2~5	Submit by CD/DVD	
Change of Registered Particulars Application	All Case	All scope	5MB	20MB
Product Renewal Application	All Case	All scope	No File Upload	
Registered Product Cancellation Application	All Case	All scope	No File Upload	

* PRS 2.0 system just supports to upload documents in **PDF format** only.

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Initiate New Product Registration Application

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Submission

InitiateNew Product Registration

Action Required

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

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status

Application Submitted

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

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New Application Page 1 – Product Basic Information

Guidance | Save | Save and Exit | Next

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_01

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 300MB.
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): VITAMIN E TABLET | PL No.: | PR No.: | HK No.:

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 22:32

- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

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):* VITAMIN E TABLETS

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

c. Names / Proposed Names Used in Other Places

Name:	VITAMIN E	Place:	U.S.A.
Name:	GOLD VITAMIN	Place:	CANADA
Name:		Place:	Please Select

Add More

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

No. of Component(s)* 1

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1 1. *	vitamin E	vitamin E
2.	Please Select	
3.	Please Select	
4.	Please Select	

Add More

1.0.1.3 Application Type: (please select one) *

○ Human biological pharmaceutical product
◉ Human chemical pharmaceutical product
○ Human vaccine

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New Application Page 2 – Dose Form, Indication & Pack Size

Guidance | Back | Save | Save and Exit | Next

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 22:32

- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_02

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 300MB.
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): VITAMIN E TABLETS | PL No.: | PR No.: | HK No.:

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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

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

Component	Dose Form of product:*	
1	Tablet	Add

1.0.3 Indication, Route(s) of Administration and Dosage

	Indication:*	Dosage:*	
1	Please refer to pack insert	Please refer to pack insert	Add

Component	Route of administration*		Apply for Data Exclusivity/Description
1	Oral	Add	☐

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

No. of Product Pack Size(s):* 1

1. Product Pack Size* 3 X 12 tablets

Component	Primary Container (container that is in direct contact with the product)		Proposed shelf life (months)*	Proposed storage conditions* (Temperature (°C) and Relative Humidity (RH))	Stability Report*		In-Use Stability Report	
	Packaging Material (e.g. Glass)*	Type of container (e.g. box, bottle)*			Duration (Month)	Start date		
1	Aluminiun	sachet	36	Do not store over 25°C	36	01.04.2010		
					Upload	No of File(s): 1	Upload	No of File(s): 0

Guidance | Back | Save | Save and Exit | Next

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New Application Page 3 – Certificate Holder Information

Guidance | Back | Save | Save and Exit | Next

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_03

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 300MB.
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): VITAMIN E TABLETS **PL No.:** **PR No.:** **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 22:32

- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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

1.0.5 Legal Status

1.0.6 Applicant Information

a. Username : david_wong
b. Email Address : prs.david.wong@gmail.com.ut

1.0.6.1 Proposed Registration Certificate Holder

a. Name : ABC COMPANY LIMITED
b. Address :
Unit: Floor: Block:
Building:
Street No.: Street Name:
Sub-district: CHA KWO LING
Area: KOWLOON

c. BRC Number: 00671890-000 Phone Number: (852) Fax Number: (852)

d.Contact Person for this Application
: Mr. Lee Phone No.: 22099453 Position*: Pharm
Email*: Thomas.lee@abc.com Fax No.*: 22099454

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

1.0.6.2 Staff responsible for Pharmacovigilance

a. Name of Staff : Miss Law
b. Contact Person HK Telephone No.: (852) 22099533 Position: Pharm Email: Mandy.law@abc.com
(24 hours)

Guidance | Back | Save | Save and Exit | Next

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New Application Page 4 – Manufacturer Information

Guidance | Back | Save | Save and Exit | Next

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_04

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

Proposed Name of Product (English): VITAMIN E TABLETS | PL No.: | PR No.: | HK No.:

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 22:32

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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1.0.7 Manufacturers

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

Place/Region* : UNITED KINGDOM

Name of Manufacturer* : FERRING CONTROLLED THERAPEUTICS LTD.

Chinese Name of Manufacturer :

Address* : 1 REDWOOD PLACE PEEL PARK CAMPUS EAST UK

Chinese Address :

GMP Certificate* : Upload No of File(s): 1

GMP Certificate Number* : UK 8065 Insp GMP

GMP Certificate Expiry Date* : 31.12.2016

Manufacturer Licence* : Upload No of File(s): 1

Manufacturer Licence Number* : UK 8065 Insp GMP

Manufacturer Licence Expiry Date* : 31.12.2016

Manufacturing activities/role*

- [x] Batch Release Manufacturer
- [x] Manufacturer of Dosage Form
- [x] Office
- [ ] Other
- [x] Packing Manufacturer
- [x] QC Testing

Add More

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

Yes No

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

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New Application Page 5 – Ingredient Information

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- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_05

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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): VITAMIN E TABLETS | PL No.: | PR No.: | HK No.:

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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1.0.8 Qualitative and Quantitative composition

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

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

Component1

	Name of Active Ingredient(s)*	Quantity (Strength Value)*	Unit (Strength Unit)*	Dose Value*	Dose Unit*
1	vitamin E	200	mg	1	dose

Additional Information

Add

This component does not have any excipient.

Excipient*	Quantity (Strength Value)*	Unit (Strength Unit)*	Dose Value*	Dose Unit*	Function	Refer Mono Stand
water	150	mg	1	dose		Pleas

1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicinal pro manufacturing process of the medicinal product

* No Yes

1.0.8.3 Does the product contain human plasma-derived ingredients?

* No Yes, please fill in the following.

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New Application Page 6 – Other Marketing Information

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- Online Notification
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- New Registration
  - Initiate New Product Registration Application
  - Application Status
    - Action Required
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_06

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Proposed Name of Product (English): VITAMIN E TABLETS | PL No.: | PR No.: | HK No.:

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1.0.9 Other Marketing Authorization Applications

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

* ○ No ◉ Yes

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

* ◉ No ○ Yes

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

* ◉ No ○ Yes

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

Country/Region	Status	Date of Authorization	Product Name	Free Sale Certificate(FSC) attached	Authorization Number	Expire Date of FSC
U.S.A.	Approved	10.02.2015	VITAMIN E	Upload No of File(s): 1	USA 2015-347	Remove
CANADA	Approved	16.06.2014	GOLD VITAMIN	Upload No of File(s): 1	CND 2014-787	Remove

Add More

Guidance | Back | Save | Save and Exit | Next

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New Application Page 7 – Annexed Documents

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- Online Notification
- My Product Search
- New Registration
  - Initiate New Product Registration Application
  - Application Status
    - Action Required
    - Not Submitted
    - Application Submitted
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- Renewal of Registration
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_07

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Proposed Name of Product (English): VITAMIN E TABLETS | **PL No.:** | **PR No.:** | **HK No.:**

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1.1.0 Annexed Documents/information/sample

1.*	Prototype sales pack/outer and inner container labels (Reference for 1.0.4 of Page 2)		Prototype Sale Pack(s) List
2.*	Package insert (Reference for 1.0.3 of Page 2)		Package Insert(s) List
3.	For pharmaceutical substance, please provide a sample for inspection. (Reference for 1.0.1.3 of Page 1)	Upload	No of File(s): 0
4.*	Photo or scanned image of the product samples	Upload	No of File(s): 1
5.	Photo or scanned image of extra component(s) included in the sales pack apart from the drug product and package insert, e.g., measuring cups/spoons, syringe, connectors, alcohol swabs, etc. (if applicable) (Reference for 1.0.4 of Page 2)	Upload	No of File(s): 0
6.	Information on the overseas legal status of the product.	Upload	No of File(s): 0
7.*	Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)	Upload	No of File(s): 1
8.	Authorization letter from the applicant authorizing a person/company to deal with the communication matters related to this application) (if applicable)	Upload	No of File(s): 0
9.*	Authorization letter from the manufacturer/marketing authorization holder authorizing the applicant to apply registration for its product.	Upload	No of File(s): 1
10.*	An undertaking, given by the applicant to provide, at any stage of registration, any information and/or documents relating to the product/substance upon request within the prescribed timeframe	Upload	No of File(s): 1
11.*	Documentary evidence showing the compliance with GMP by the labeled manufacturer and the manufacturer to be shown on the label issued by competent authorities. (Manual submission of certified true copy(ies) is required). (Reference for 1.0.7 of Page 4)		Manufacturer(s) List
12.	An undertaking, given by the manufacturer(s) of the product/substance, to permit the premises where it is to be manufactured, and the operations carried on or to be carried on in the course of manufacturing it, to be inspected by or on behalf of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee.	Upload	No of File(s): 0
13.	A declaration, given by the manufacturer of the product or substance, that, in relation to the manufacture of the product/substance any requirements imposed by or under the law of the country in which it is or is to be manufactured have been or will be complied with.	Upload	No of File(s): 0
14.	Flow chart indicating sequence and activities of the different sites involved in the manufacturing process, including testing site. (Reference for 1.0.7 of Page 4)	Upload	No of File(s): 0

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New Application Page 8 – Annexed Documents

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- Online Notification
- My Product Search
- New Registration
  - Initiate New Product Registration Application
  - Application Status
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    - Application Submitted
  - Withdraw application
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- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_08

The maximum upload size of single file is 50MB, while the maximum total upload size per application is 300MB.
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): VITAMIN E TABLETS | **PL No.:** | **PR No.:** | **HK No.:**

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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1.1.0 Annexed Documents/information/sample

15. Detailed information regarding the manufacturer in respect of its manufacturing and quality control facilities and personnel. (Reference for 1.0.7 of Page 4) — Upload — No of File(s): 0
16.* Master Formula (complete qualitative and quantitative composition of the drug product issued by the manufacturer) (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 1
17. Evidence of the source of animals, the nature of the animal tissues used in manufacturing and production process, showing compliance with one or more of the safety measures taken to minimize the risk of communicable diseases that can be transmitted to human, including but not limited to TSE. (Reference for 1.0.8 of Page 5) — Evidence of the source of animals and/or human origin materials
18. Ph. Eur. Certificate(s) of suitability for TSE (if applicable) or evidence from the manufacturer showing compliance with the US, Australian or European guidelines with respect to minimization of the risk of communicable diseases as stated in Guidance Notes on Registration of Pharmaceutical products. (Reference for 1.0.8 of Page 5)
19. An undertaking from the manufacturer of the product to inform the applicant in case of any change in nature or source of materials (e.g., from chemically synthesized to animal/human origin or vice-versa) of active ingredient (s) or excipient(s)during the application process or after approval of registration has been granted. (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 0
20. An undertaking from the applicant to inform the Drug Office in case of any change in nature or source of materials (e.g., from chemically synthesized to animal/human origin or vice-versa) of active ingredient(s) or excipient(s) during the application process or after approval of registration has been granted. (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 0
21. Information on the sourcing, quality assurance aspects of plasma-derived products, including information such as but not limited to donor selection criteria, viral inactivation procedures with validation, and measures taken to minimize the risk of transmission of CJD by the blood products. (Reference for 1.0.8 of Page 5)
22. Copy of EMA Certificate for a Plasma Master File (PMF) (if applicable) (Reference for 1.0.8 of Page 5)
23.* Free sale certificate of the product issued by the country of origin
(Manual submission of original or certified true copy(ies) is required). (Reference for 1.0.9 of Page 6)
(For NCE)
Official evidence of registration approval of the product (e.g. original or certified true copies of free sale certificates) in two or more of the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA (Reference for 1.0.9.4 of Page 6) — List showing free sale certificate in other market(s)
24.* (For NCE)
Clinical and non-clinical overviews and quality overall summary — Upload — No of File(s): 1
25. Information on clinical trial(s) performed in Hong Kong (Please provide clinical trial certificate no./application reference no.) — Upload — No of File(s): 0

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New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_09

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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): VITAMIN E TABLETS | PL No.: | PR No.: | HK No.:

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- 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
- Submission of Other Post-registration Supplement
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Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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1.1.0 Annexed Documents/information/sample

26.*	(For NCE) Information about the experts who were responsible for writing the non-clinical and clinical overviews and quality overall summary	Upload	No of File(s): 1
27.*	For biological and vaccine products, please provide the protein sequence/schematic diagram of the active substance and details regarding the manufacturing process and process control of the active substance and the product (Reference for 1.0.8 of Page 5)		
28.*	(For NCE) Description of risk-management System (Information on the EU Risk Management Plan (RMP) or US Risk evaluation and mitigation strategies (REMS) imposed on the product and the proposed RMP for Hong Kong. (Reference for 1.0.6 of Page 3)	Upload	No of File(s): 1
29.*	Specification of the product (showing compliance with pharmacopoeias listed in the Guidance Notes on Registration of Pharmaceutical Products) (Reference for 1.0.8 of Page 5)	Upload	No of File(s): 1
30.*	Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)	Upload	No of File(s): 1
31.*	Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)	Upload	No of File(s): 1
32.*	Stability report - real time and accelerated (please refer to testing conditions on Guidance Notes on Registration of Pharmaceutical Products) (Reference for 1.0.4 of Page 2)	Stability Report(s) List	
33.*	Certified true copy of manufacturers licence (Manual submission of certified true copy(ies) is required) (Reference for 1.0.7 of Page 4)	Manufacturer(s) List	
34.	Clinical and scientific documentation substantiating the safety and efficacy of the product (except for generic product applications received on or after 1 OCT 2012 and their originator products have been registered in Hong Kong for over 8 years).	Upload	No of File(s): 0
35.*	Reputable documentary evidence to substantiate the content of package insert. Cross-referencing to documents should be made by referring to page number of the reference and the relevant parts of the reference document (s) shall be clearly highlighted. Please refer to the list of reputable references in the Guidance Notes on Registration of Pharmaceutical Products	Upload	No of File(s): 1
36.	Declaration from manufacturer on whether the different product name(s) listed in the dossier is identical to the product under application in all aspects.	Upload	No of File(s): 0
37.	For capsule dose forms, please provide documentary evidence to substantiate the quality of gelatin / vacant capsule in compliance with pharmacopoeial standard.	Upload	No of File(s): 0
38.	Bioequivalence (BE) data for anti-epileptic drugs.	Upload	No of File(s): 0
39.*	Priority application supporting document(s). (Reference for Page 1)		
40.	Others, please specify	Upload	No of File(s): 0

Additional Information of Product | Add

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New Application Module 2 – Quality Overall Summary

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  - Withdraw application
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New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_MODULE_02

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Proposed Name of Product (English): VITAMIN E TABLETS | **PL No.:** | **PR No.:** | **HK No.:**

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

2.1 Overall CTD Table of Contents of Modules 2-5

Remarks:

2.2 Introduction to Summary

Remarks:

2.3 Quality Overall Summary

Remarks:

2.3.S Drug Substance (name, manufacturer)

Remarks:

2.3.P Drug Product (name, dosage form)

Remarks:

2.3.A Appendices

Remarks:

2.3.R Regional Information

Remarks:

2.4 Nonclinical Overview

Remarks:

2.5 Clinical Overview

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New Application Module 3 – Quality

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New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_MODULE_03

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Proposed Name of Product (English): VITAMIN E TABLETS | **PL No.:** | **PR No.:** | **HK No.:**

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

3.1 Module 3 Table of Contents

Remarks:

3.2.S.1 General Information

Remarks:

3.2.S.1.1 Nomenclature

Remarks:

3.2.S.1.2 Structure

Remarks:

3.2.S.1.3 General Properties

Remarks:

3.2.S.2.1 Manufacturer(s)

Remarks:

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

Remarks:

3.2.S.2.3 Control of Materials

Remarks:

3.2.S.2.4 Controls of Critical Steps and Intermediates

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New Application Module 4 – Non-clinical Study Reports

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New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_MODULE_04

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Proposed Name of Product (English): VITAMIN E TABLETS | PL No.: | PR No.: | HK No.:

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Module 1 | Module 2 | Module 3 | Module 4 | Module 5

4.1 Module 4 Table of Contents

Remarks:

4.2.1.1 Primary Pharmacodynamics

Remarks:

4.2.1.2 Secondary Pharmacodynamics

Remarks:

4.2.1.3 Safety Pharmacology

Remarks:

4.2.1.4 Pharmacodynamic Drug Interactions

Remarks:

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

Remarks:

4.2.2.2 Absorption

Remarks:

4.2.2.3 Distribution

Remarks:

4.2.2.4 Metabolism

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New Application Module 5 – Clinical Study Reports

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  - Initiate New Product Registration Application
  - Application Status
    - Action Required
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    - Application Submitted
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New Product Registration

NEW_PRODUCT_REGISTRATION_VIEW_MODULE_05

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Proposed Name of Product (English): VITAMIN E TABLETS | **PL No.:** | **PR No.:** | **HK No.:**

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

5.1 Module 5 Table of Contents

Remarks:

5.2 Tabular Listing of All Clinical Studies

Remarks:

5.3.1.1 Bioavailiability (BA) Study Reports

Remarks:

5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports

Remarks:

5.3.1.3 In Vitro - In Vivo Correlation Study Reports

Remarks:

5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies

Remarks:

5.3.2.1 Plasma Protein Binding Study Reports and Related Information

Remarks:

5.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies

Remarks:

5.3.2.3 Reports of Studies Using Other Human Biomaterials

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New Application – Application Form

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Guidance | Back | Submit Application

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))
VITAMIN E TABLETS

Dose Form / Package Size(s) :

Dose Form
Component 1 Tablet
Package Size(s): Product Pack Size :3 X 12 tablets

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.	vitamin E	200	mg	1	dose	EP

Indications:

1. Please refer to pack insert

Registered and Marketed in Which Countries/Places : U.S.A.
CANADA

Name of Applicant: ABC COMPANY LIMITED

Business Registration No.: 00671890-000

In What Capacity the Applicant Makes This Application: Manufacturer

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New Application – Application Form

Business Address of Applicant: CHA KWO LING, KOWLOON

Tel No.: 22099453 (Contact Person:Mr. Lee)

Facsimile No.:

22099454 (Contact Person:Mr. Lee)

Email Address: Thomas.lee@abc.com (Contact Person:Mr. Lee)

prs.david.wong@gmail.com.ut (Submitted By:WONG David)

Name of Manufacturer:

Name of manufacturer appeared on product label of finished product: FERRING CONTROLLED THERAPEUTICS LTD.

Address of Manufacturer:

Address of manufacturer appeared on product label of finished product: 1 REDWOOD PLACE PEEL PARK CAMPUS EAST UK

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: VONG David2E9BE9.p12 Please type full path of 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

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Acknowledgement of New Registration Application Submission

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 22:32

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Application ID: ANP20159000235

Submission Date: 2015.09.24

Proposed Name of Product (English)	PL No.
VITAMIN E TABLETS	PL0180/2015

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

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New Registration Application Status Monitoring

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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

New Submission

InitiateNew Product Registration

Action Required

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

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015		VITAMIN E TABLETS	2	Application Submitted	25.09.2015	No

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New Registration Application Fee Payment

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 14:43

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

New Submission

InitiateNew Product Registration

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015		VITAMIN E TABLETS	1	Pending for Application Fee	25.09.2015	No

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

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

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New Registration Application Fee Payment

Online Notification

New Product Registration

Notification Date :	25.09.2015 12:31:52
PL No. :	PL0420/2015
PR No. :	
HK No. :	
Proposed Name of Product (English) :	VITAMIN E TABLETS
Notification Detail :	NOTIFICATION_PRINT.pd
Attachment(s) :	
1. Go To Application Payment :	Go

2. In alternative to (1), you may send the outstanding information by p

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

For enquiries, please call our hotline at (852) 2319 8458 or email to pr
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: 25.09.2015

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:
PL0420/2015

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New Registration Application Fee Payment

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 14:43

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
  - Payment Pool
  - Payment History
- Application History
- + User Profile
- + System
- Logout

New Application Payment

Print | Ready to Pay

	Application Received Date	PL No.	PR No.	Proposed Name of Product	Payment Status
☑	25.09.2015 11:45	PL0420/2015		VITAMIN E TABLETS	Ready for Application Payment

New Application Certificate Payment

Ready to Pay

	Application Received Date	PR No.	PL No.	Proposed Name of Product	Payment Status

Certificate Collection: ○ Received By Post ◉ Collect in Person in Drug Office

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New Registration Application - Payment Gateway

GovHK 香港政府一站通

Online Payment Service

Help

Customer Service Hotline 2319 8461

Email **pharmweb @dh.gov.hk**

Please select the payment method :

Type of Service	**DH Drug Office**
Transaction Date	**25-09-2015**
Transaction Reference Number	**DHPRS-201509251504-90006**
Total Amount	**HK$ 1,100.00**
Payment Method	VISA / MasterCard / PPS 繳費靈

Cancel Payment | Pay

- Please take note of the transaction reference number or PRINT this page.
- After pressing the 'Pay' button, please do not leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful.
- Under exceptional conditions, a refund may need to be arranged. If the payment is made by Credit Card, the refund can normally be made to the Credit Card account that is used for the payment.
- Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use PPS to settle the payment. We apologise for any inconvenience caused.
- Different credit card issuers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please contact your card issuer if you want to learn more about the Verified by Visa and MasterCard SecureCode service.

HONG KONG

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Result of New Registration Application Fee Payment

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 14:43

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
  - Payment Pool
  - Payment History
  - Application History
- + User Profile
- + System
- Logout

New Product Registration

Print Receipt | Close

Payment Reference No.: DHPRS-201509251504-90006

EGIS Reference No.: A201509251170473

Payment Method: MasterCard

Type of Payment: Application Fee

Transaction Time: 25.09.2015 15:07:04

Application Received Date	Reference No.	PR No.	Product Name
25.09.2015 11:45	ANP20159000002	PR0386/2015	VITAMIN E TABLETS

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) 23198458

Email: prs2_info@dh.gov.hk

Print Receipt | Close

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Result of New Registration Application Fee Payment

Name of Company 公司名稱	Payment Date 繳費日期
ABC COMPANY LIMITED	25.9.2015

Payment Reference No: 付款編號:	DHPRS-201509251504-90006
EGIS Reference No: EGIS編號:	A201509251170473
Payment Method: 付款方法:	MasterCard
Payment Amount: 付款金額:	HK$1,100.00

	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
1	VITAMIN E TABLETS	PL0420/2015	PR0386/2015	ANP20159000002

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New Registration Application Fee Paid

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Submission

InitiateNew Product Registration

Action Required

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

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015	PR0386/2015	VITAMIN E TABLETS	1	Evaluation	25.09.2015	Yes

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New Registration Application Reply Clarification

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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

New Submission

InitiateNew Product Registration

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015	PR0386/2015	VITAMIN E TABLETS	1	Request for Outstanding Information	25.09.2015	Yes

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

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

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New Registration Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Notification Date :	25.09.2015 16:22:54
PL No. :	PL0420/2015
PR No. :	PR0386/2015
HK No. :	HK63643
Proposed Name of Product (English) :	VITAMIN E TABLETS
Notification Detail :	NOTIFICATION_PRINT.pdf
Attachment(s) :	
1. Back To Application :	Go

2. In alternative to (1), you may send the outstanding information by post c

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

For enquiries, please call our hotline at (852) 2319 8458 or email to prs2_
under the process of new product registration.

Application for Registration of Pharmaceutical Products/Substances

Date: 2015-09-25

PR Number: PR0386/2015

Product Name: VITAMIN E TABLETS

Evaluated by: Belinda Chan

Comments/Outstanding Information:
Section 1.0.3: Please specified the indication and dosage in this section

Assessment made By:	Belinda Chan
Signature of Assessment Officer:	_____
Name (in BLOCK letters):	BELINDA CHAN
Post Title:	
Date:	2015-09-25

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New Registration Application Reply Clarification

Application History | Guidance | Save | Save and Exit | Next

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_01

Proposed Name of Product (English): VITAMIN E TABLETS PL No.: PL0420/2015 PR No.: PR0386/2015 HK No.:

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

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):* VITAMIN E TABLETS

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

c. Names / Proposed Names Used in Other Places

Name:	VITAMIN E	Place:	U.S.A.
Name:	GLOD VITAMIN	Place:	CANADA
Name:		Place:	Please Select

Add More

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

No. of Component(s)* 1

	Active Ingredient	Active Ingredient Appeared on Product Label
Component 1 1. *	vitamin E	vitamin E
2.	Please Select	
3.	Please Select	
4.	Please Select	

Add More

1.0.1.3 Application Type: (please select one) *

○ Human biological pharmaceutical product
◉ Human chemical pharmaceutical product

Comments for page Page 1

Section 1.0 ◉ S ○ U

Section 1.0.1.1 ◉ S ○ U

Section 1.0.1.2 ◉ S ○ U

Section 1.0.1.3 ◉ S ○ U

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New Registration Application Reply Clarification

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

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_02

Proposed Name of Product (English): VITAMIN E TABLETS | PL No.: PL0420/2015 | PR No.: PR0386/2015 | HK No.:

Module 1 | Module 2 | Module 3 | Module 4 | Module 5

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

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

Component	Dose Form of product:*	
1	Tablet	Add

1.0.3 Indication, Route(s) of Administration and Dosage

	Indication:*	Dosage:*	
1	please refer to package insert on page #3	please refer to package insert on page #3	Add

Component	Route of administration*		Apply for Data Exclusivity/Description
1	Oral	Add	☐

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

No. of Product Pack Size(s):* 1

1. Product Pack Size* 3 X 12 unit

Component	Primary Container (container that is in direct contact with the product)		Proposed shelf life (months)*	Proposed storage conditions* (Temperature (°C) and Relative Humidity (RH))	Stability Report*		In-Use Stability Report	
	Packaging Material (e.g. Glass)*	Type of container (e.g. box, bottle)*			Duration (Month)	Start date		
1	Aluminiun	sachet	36	Do not store over 25°C	36	01.04.2010		
					Upload	No of File(s): 1	Upload	No of File(s): 0

Comments for page Page 2

Section 1.0.2

S U

Section 1.0.3

Please specified the indication and dosage in this section

S U

Section 1.0.4

S U

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New Registration Application Reply Clarification

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

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_03

Proposed Name of Product (English): VITAMIN E TABLETS **PL No.:** PL0420/2015 **PR No.:** PR0386/2015 **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

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1.0.5 Legal Status

1.0.6 Applicant Information

a. Username : david_wong
b. Email Address : prs.david.wong@gmail.com

1.0.6.1 Proposed Registration Certificate Holder

a. Name : ABC COMPANY LIMITED
b. Address :
Unit: A Floor: 4 Block: A
Building: DH BUILDING
Street No.: 382 Street Name: NACHENG
Sub-district: SHEK KIP MEI
Area: KOWLOON

c. BRC Number: 00671890-000 Phone Number: (852) Fax Number: (852)

d.Contact Person for this Application
: Mr. Lee Phone No.: 22099423 Position*: Pharm
Email*: Thomas.lee@abc.com Fax No.*: 22099424

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

1.0.6.2 Staff responsible for Pharmacovigilance

a. Name of Staff : Miss Law
b. Contact Person HK Telephone No.: (852) 22099426 Position: Pharm Email: Mandy.law@abc.com
(24 hours)

Comments for page Page 3

Section 1.0.5
◉ S ○ U

Section 1.0.6.1
◉ S ○ U

Section 1.0.6.2
◉ S ○ U

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

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New Registration Application Reply Clarification

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

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_04

Proposed Name of Product (English): VITAMIN E TABLETS **PL No.:** PL0420/2015 **PR No.:** PR0386/2015 **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History

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1.0.7 Manufacturers

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

Place/Region* : UNITED KINGDOM
Name of Manufacturer* : LIVE SOURCE CO., LTD
Chinese Name of Manufacturer :
Address* : 332 PLACE PARK RD, YUKA CITY, UK
Chinese Address :
GMP Certificate* : Upload No of File(s): 1
GMP Certificate Number* : UK GMP 2015-0368
GMP Certificate Expiry Date* : 31.12.2016
Manufacturer Licence* : Upload No of File(s): 1
Manufacturer Licence Number* : UK GMP 2015-0368
Manufacturer Licence Expiry Date* : 31.12.2016

Manufacturing activities/role*
- [x] Batch Release Manufacturer
- [x] Manufacturer of Dosage Form
- [ ] Office
- [ ] Other
- [ ] Packing Manufacturer
- [ ] QC Testing
- [ ] Stability testing

Add More

1.0.7.1.b All Other Manufacturer(s) involved in the preparation of the product/substance
Yes No

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

Comments for page Page 4

Section 1.0.7.1.a
S U

Section 1.0.7.1.b
S U

Section 1.0.7.1.c
S U

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

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New Registration Application Reply Clarification

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

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_05

Proposed Name of Product (English): VITAMIN E TABLETS PL No.: PL0420/2015 PR No.: PR0386/2015 HK No.:

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System

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1.0.8 Qualitative and Quantitative composition

Due to security reason, your previous inputted sensitive data will not be shown.
You can re-input the sensitive data by untick the "Same as previous" checkbox.

Excipient: Same as previous? ☑

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

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

Component1

	Name of Active Ingredient(s)*	Quantity (Strength Value)*	Unit (Strength Unit)*	Dose Va
1	vitamin E	200	mg	

Additional Information

Add

1.0.8.2 Are there any animal and/or human origin materials (excluding human plasma-derived materials) contained or used in the manufacturing process of the medicinal pr
manufacturing process of the medicinal product

* ◉ No ○ Yes

1.0.8.3 Does the product contain human plasma-derived ingredients?

* ◉ No ○ Yes, please fill in the following.

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New Registration Application Reply Clarification

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

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_06

Proposed Name of Product (English): VITAMIN E TABLETS **PL No.:** PL0420/2015 **PR No.:** PR0386/2015 **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

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1.0.9 Other Marketing Authorization Applications

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

* ○ No ◉ Yes

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

* ◉ No ○ Yes

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

* ◉ No ○ Yes

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

Country/Region	Status	Date of Authorization	Product Name	Free Sale Certificate (FSC) attached	Authorization Number	Expire Date of FSC	
U.S.A.	Approved	20.03.2014	VITAMIN E	Upload No of File (s): 1	USA 2014-038		Remove
CANADA	Approved	01.12.2014	GLOD VITAMIN	Upload No of File (s): 1	CND 2014-684		Remove

Add More

Comments for page Page 6

Section 1.0.9.1 ○ S ○ U

Section 1.0.9.2 ○ S ○ U

Section 1.0.9.3 ○ S ○ U

Section 1.0.9.4 ○ S ○ U

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

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New Registration Application Reply Clarification

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

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_07

Proposed Name of Product (English): VITAMIN E TABLETS **PL No.:** PL0420/2015 **PR No.:** PR0386/2015 **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

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1.1.0 Annexed Documents/information/sample

1.*	Prototype sales pack/outer and inner container labels (Reference for 1.0.4 of Page 2)	Prototype Sale Pack(s) List	
2.*	Package insert (Reference for 1.0.3 of Page 2)	Package Insert(s) List	
3.	For pharmaceutical substance, please provide a sample for inspection. (Reference for 1.0.1.3 of Page 1)	Upload	No of File(s): 0
4.*	Photo or scanned image of the product samples	Upload	No of File(s): 1
5.	Photo or scanned image of extra component(s) included in the sales pack apart from the drug product and package insert, e.g., measuring cups/spoons, syringe, connectors, alcohol swabs, etc. (if applicable) (Reference for 1.0.4 of Page 2)	Upload	No of File(s): 0
6.	Information on the overseas legal status of the product.	Upload	No of File(s): 0
7.*	Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)	Upload	No of File(s): 1
8.	Authorization letter from the applicant authorizing a person/company to deal with the communication matters related to this application) (if applicable)	Upload	No of File(s): 0
9.*	Authorization letter from the manufacturer/marketing authorization holder authorizing the applicant to apply registration for its product.	Upload	No of File(s): 1
10.*	An undertaking, given by the applicant to provide, at any stage of registration, any information and/or documents relating to the product/substance upon request within the prescribed timeframe	Upload	No of File(s): 1
11.*	Documentary evidence showing the compliance with GMP by the labeled manufacturer and the manufacturer to be shown on the label issued by competent authorities. (Manual submission of certified true copy(ies) is required). (Reference for 1.0.7 of Page 4)	Manufacturer(s) List	
12.	An undertaking, given by the manufacturer(s) of the product/substance, to permit the premises where it is to be manufactured, and the operations carried on or to be carried on in the course of manufacturing it, to be inspected by or on behalf of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee.	Upload	No of File(s): 0
13.	A declaration, given by the manufacturer of the product or substance, that, in relation to the manufacture of the product/substance any requirements imposed by or under the law of the country in which it is or is to be manufactured have been or will be complied with.	Upload	No of File(s): 0
14.	Flow chart indicating sequence and activities of the different sites involved in the manufacturing process, including testing site. (Reference for 1.0.7 of Page 4)	Upload	No of File(s): 0

Comments for page Page 7

Section 1.1.0-P1

S U

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

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New Registration Application Reply Clarification

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

Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_08

Proposed Name of Product (English): VITAMIN E TABLETS **PL No.:** PL0420/2015 **PR No.:** PR0386/2015 **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

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1.1.0 Annexed Documents/information/sample

Due to security reason, your previous inputted sensitive data will not be shown.
You can re-input the sensitive data by untick the "Same as previous" checkbox.

15. Detailed information regarding the manufacturer in respect of its manufacturing and quality control facilities and personnel. (Reference for 1.0.7 of Page 4) — Upload — No of File(s): 0
16.* Master Formula (complete qualitative and quantitative composition of the drug product issued by the manufacturer) (Reference for 1.0.8 of Page 5) — Same as previous? ☑
17. Evidence of the source of animals, the nature of the animal tissues used in manufacturing and production process, showing compliance with one or more of the safety measures taken to minimize the risk of communicable diseases that can be transmitted to human, including but not limited to TSE. (Reference for 1.0.8 of Page 5) — Evidence of the source of animals and/or human origin materials
18. Ph. Eur. Certificate(s) of suitability for TSE (if applicable) or evidence from the manufacturer showing compliance with the US, Australian or European guidelines with respect to minimization of the risk of communicable diseases as stated in Guidance Notes on Registration of Pharmaceutical products. (Reference for 1.0.8 of Page 5)
19. An undertaking from the manufacturer of the product to inform the applicant in case of any change in nature or source of materials (e.g., from chemically synthesized to animal/human origin or vice-versa) of active ingredient(s) or excipient(s)during the application process or after approval of registration has been granted. (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 0
20. An undertaking from the applicant to inform the Drug Office in case of any change in nature or source of materials (e.g., from chemically synthesized to animal/human origin or vice-versa) of active ingredient(s) or excipient(s) during the application process or after approval of registration has been granted. (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 0
21. Information on the sourcing, quality assurance aspects of plasma-derived products, including information such as but not limited to donor selection criteria, viral inactivation procedures with validation, and measures taken to minimize the risk of transmission of CJD by the blood products. (Reference for 1.0.8 of Page 5)
22. Copy of EMA Certificate for a Plasma Master File (PMF) (if applicable) (Reference for 1.0.8 of Page 5)
23.* Free sale certificate of the product issued by the country of origin (Manual submission of original or certified true copy(ies) is required). (Reference for 1.0.9 of Page 6)
(For NCE)
Official evidence of registration approval of the product (e.g. original or certified true copies of free sale certificates) in two or more of the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA (Reference for 1.0.9.4 of Page 6) — List showing free sale certificate in other market(s)
24.* (For NCE)
Clinical and non-clinical overviews and quality overall summary — Same as previous? ☑
25. Information on clinical trial(s) performed in Hong Kong (Please provide clinical trial certificate no./application reference no.) — Upload — No of File(s): 0

Comments for page Page 8

Section 1.1.0-P2

◉ S ○ U

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New Registration Application Reply Clarification

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Applciations Require Action

NEW_PRODUCT_REGISTRATION_VIEW_09

Proposed Name of Product (English): VITAMIN E TABLETS **PL No.:** PL0420/2015 **PR No.:** PR0386/2015 **HK No.:**

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

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1.1.0 Annexed Documents/information/sample

26.* (For NCE) Information about the experts who were responsible for writing the non-clinical and clinical overviews and quality overall summary — Upload — No of File(s): 1

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

28.* (For NCE) Description of risk-management System (Information on the EU Risk Management Plan (RMP) or US Risk evaluation and mitigation strategies (REMS) imposed on the product and the proposed RMP for Hong Kong. (Reference for 1.0.6 of Page 3) — Upload — No of File(s): 1

29.* Specification of the product (showing compliance with pharmacopoeias listed in the Guidance Notes on Registration of Pharmaceutical Products) (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 1

30.* Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 1

31.* Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5) — Upload — No of File(s): 1

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

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

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

35.* Reputable documentary evidence to substantiate the content of package insert. Cross-referencing to documents should be made by referring to page number of the reference and the relevant parts of the reference document(s) shall be clearly highlighted. Please refer to the list of reputable references in the Guidance Notes on Registration of Pharmaceutical Products — Upload — No of File(s): 1

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

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

38. Bioequivalence (BE) data for anti-epileptic drugs. — Upload — No of File(s): 0

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

40. Others, please specify — Upload — No of File(s): 0

Additional Information of Product — Add

Comments for page Page 9

Section 1.1.0-P3

S U

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

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New Registration Application Reply Clarification

Guidance | Back | Submit Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 22:32

- 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
- Submission of Other Post-registration Supplement
- Interview
- Request to Cancel Product Registration
- Payment
- Application History
- User Profile
- System
- Logout

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))
VITAMIN E TABLETS

Dose Form / Package Size(s) :

Dose Form
Component 1
Tablet
Package Size(s):
Product Pack Size :3 X 12 tablets

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.	vitamin E	200	mg	1	dose	EP

Indications:

1. Please refer to pack insert

Registered and Marketed in Which Countries/Places : U.S.A.
CANADA

Name of Applicant: ABC COMPANY LIMITED

Business Registration No.: 00671890-000

In What Capacity the Applicant Makes This Application: Manufacturer

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New Registration Application Reply Clarification

22099423 (Submitted By:WONG David)

Facsimile No.:

22099424 (Contact Person:Mr. Lee)

Email Address: Thomas.lee@abc.com (Contact Person:Mr. Lee)

prs.david.wong@gmail.com (Submitted By:WONG David)

Name of Manufacturer:

Name of manufacturer appeared on product label of finished product: LIVE SOURCE CO., LTD

Address of Manufacturer:

Address of manufacturer appeared on product label of finished product: 332 PLACE PARK RD, YUKA CITY, UK

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: VONG David2E9BE9.p12 Please type full path of file, e.g. C:\cert.p12

e-Cert PIN: ••••••••••••••••

For Office Use Only

Date Received	Legal Classification	Fees Paid	Registration Approved	Certificate Issued	Registration

Application History | Guidance | Back | Submit Application

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Acknowledgement of New Registration Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration

Print

PR No.: PR0386/2015

Submission Date: 2015.09.25

Proposed Name of Product (English)	PR No.
VITAMIN E TABLETS	PR0386/2015

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

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New Registration Application Status Monitoring

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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

New Submission

InitiateNew Product Registration

Action Required

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

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015	PR0386/2015	VITAMIN E TABLETS	2	Evaluation	25.09.2015	Yes

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New Registration Application Certificate Fee Payment

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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
- + Submission of Other Post-registration Supplement
- + Interview

New Submission

InitiateNew Product Registration

Action Required

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015	PR0386/2015	VITAMIN E TABLETS	2	Pending for Certificate Fee	25.09.2015	Yes

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

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

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New Registration Application Certificate Fee Payment

Online Notification

New Product Registration

Notification Date :	25.09.2015 21:25:26
PL No. :	PL0420/2015
PR No. :	PR0386/2015
HK No. :	
Proposed Name of Product (English) :	VITAMIN E TABLETS
Notification Detail :	
Attachment(s) :	NOTIFICATION_F
1. Go To Certificate Payment :	Go

2. In alternative to (1), you may send the outstanding information by

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

For enquiries, please call our hotline at (852) 2319 8458 or email to
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: 25.09.2015

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:
PR0386/2015

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New Registration Application Certificate Fee Payment

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
  - Payment Pool
  - Payment History
  - Application History
- + User Profile
- + System
- Logout

New Application Payment

Print | Ready to Pay

	Application Received Date	PL No.	PR No.	Proposed Name of Product	Payment Status

New Application Certificate Payment

Ready to Pay

	Application Received Date	PR No.	PL No.	Proposed Name of Product	Payment Status
☑	25.09.2015 11:45	PL0420/2015	PR0386/2015	VITAMIN E TABLETS	Ready for Certificate Payment

Certificate Collection: ◉ Received By Post ○ Collect in Person in Drug Office

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New Registration Application Certificate Fee Payment

GovHK 香港政府一站通

Online Payment Service

Help
Customer Service Hotline 2319 8461

Email **pharmweb @dh.gov.hk**

Please select the payment method :

Type of Service	**DH Drug Office**
Transaction Date	**25-09-2015**
Transaction Reference Number	**DHPRS-201509252137-90008**
Total Amount	**HK$ 1,370.00**
Payment Method	VISA / MasterCard / PPS 繳費靈

Cancel Payment **Pay**

- Please take note of the transaction reference number or PRINT this page.
- After pressing the 'Pay' button, please do not leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful.
- Under exceptional conditions, a refund may need to be arranged. If the payment is made by Credit Card, the refund can normally be made to the Credit Card account that is used for the payment.
- Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use PPS to settle the payment. We apologise for any inconvenience caused.
- Different credit card issuers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please contact your card issuer if you want to learn more about the Verified by Visa and MasterCard SecureCode service.

HONG KONG

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Result of New Registration Application Certificate Fee Payment

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
- Payment Pool
- Payment History

New Product Registration

Print Receipt | Close

Payment Reference No.: DHPRS-201509252137-90008

EGIS Reference No.: A201509251244433

Payment Method: VISA

Type of Payment: Certificate Fee

Transaction Time: 25.09.2015 21:38:53

Delivery Method: Received By Post

Application Received Date	Reference No.	PR No.	Product Name
25.09.2015 11:45	ANP20159000002	PR0386/2015	VITAMIN E TABLETS

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

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Result of New Registration Application Certificate Fee payment

Name of Company 公司名稱	Payment Date 繳費日期
ABC COMPANY LIMITED	25.9.2015

Payment Reference No: 付款編號:	DHPRS-201509252137-90008
EGIS Reference No: EGIS編號:	A201509251244433
Payment Method: 付款方法:	VISA
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:

[X] 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

Name of Company ABC COMPANY LIMITED
公司名稱
Payment Reference No: DHPRS-201509252137-90008
付款編號:

	Name of Product 製品/物質名稱	PL No. PL 號碼	PR No. PR 號碼	HK No. HK 號碼	Reference No. 參考編號
1	VITAMIN E TABLETS	PL0420/2015	PR0386/2015	HK63643	ANP20159000002

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Payment History of New Registration Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
  - Payment Pool
  - Payment History

Payment History

New Product Registration

Total Number of Payment Records: 2

PR No.	Name of Product	Payment Date		Amount(HK$)	Payment Ref No.
PR0386/2015	VITAMIN E TABLETS	25.09.2015	Certificate Fee	1370.0	DHPRS-201509252137-90008
PR0386/2015	VITAMIN E TABLETS	25.09.2015	Application Fee	1100.0	DHPRS-201509251504-90006

Change of Registered Particulars Application

Total Number of Payment Records: 11

HK No.	Name of Product	Payment Date	Amount(HK$)	Payment Ref No.
HK39239	UNI-MENADOL	25.09.2015	155.0	DHPRS-201509251525-90007
HK47301	PHENTOIN (HAMELN)	25.09.2015	155.0	DHPRS-201509251525-90007
HK26230	NASUCAP DECONGESTANT	25.09.2015	155.0	DHPRS-201509251525-90007
HK53968	MARKIST	25.09.2015	155.0	DHPRS-201509251525-90007
HK53970	RAMATIN	25.09.2015	155.0	DHPRS-201509251525-90007
HK60186	LEVOXA	25.09.2015	155.0	DHPRS-201509251525-90007
HK60175	PRILIGY	25.09.2015	155.0	DHPRS-201509251525-90007
HK53969	SUITANI	25.09.2015	155.0	DHPRS-201509251525-90007
HK60174	PRILIGY	25.09.2015	155.0	DHPRS-201509251525-90007
HK60187	LEVOXA	25.09.2015	155.0	DHPRS-201509251525-90007
HK60507	PROACTIV	25.09.2015	155.0	DHPRS-201509251525-90007

Renewal of Registration

Total Number of Payment Records: 14

HK No.	Name of Product	Payment Date	Amount(HK$)	Payment Ref No.
HK53969	SUITANI	25.09.2015	575.0	DHPRS-201509250021-90004
HK53970	RAMATIN	25.09.2015	575.0	DHPRS-201509250021-90004
HK60187	LEVOXA	02.09.2015	575.0	DHPRS-201509021953-90002

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New Registration Application Status Monitoring

NEW_PRODUCT_REGISTRATION_STATUS

New Product Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- 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

New Submission

InitiateNew Product Registration

Action Required

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

Not Submitted

	Latest Draft Date	Application ID	Proposed Name of Product (English)	Application Status
1	25.09.2015	ANP20159000003	X WATER	Pending

Application Submitted

	Application Date	Application ID	PL No.	PR No.	Proposed Name of Product (English)	No. of submission	Application Status	Status Date	Payment Status
1	25.09.2015	ANP20159000002	PL0420/2015	PR0386/2015	VITAMIN E TABLETS	2	Issue Certificate	25.09.2015	Yes

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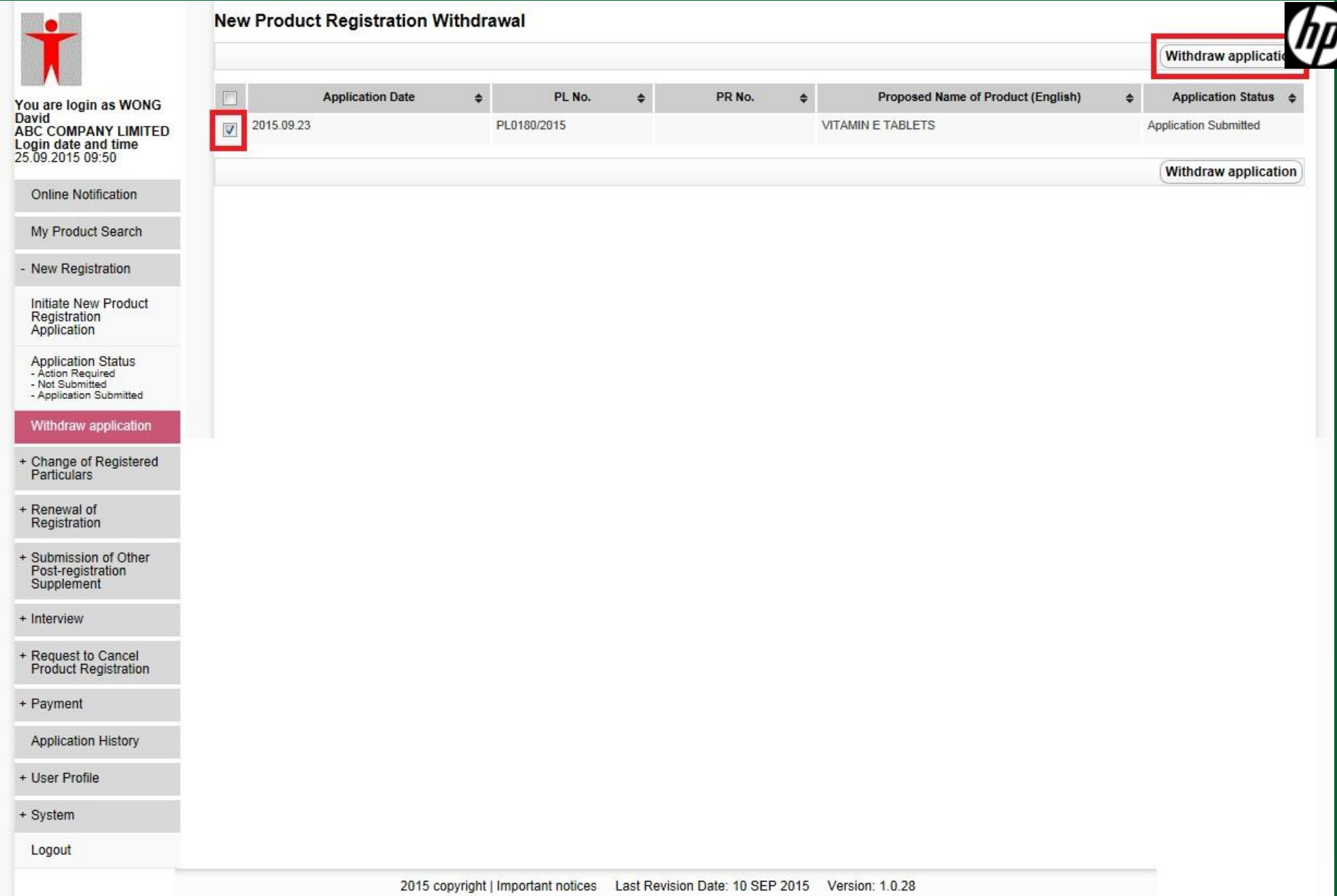
New Registration Application Withdrawal



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New Registration Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 09:50

- 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
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Application Date	PL No.	PR No.	Proposed Name of Product (English)	Application Status
2015.09.23	PL0180/2015		VITAMIN E TABLETS	Application Submitted

Date of Withdrawal Request : 25.09.2015

Reason(s) of Withdrawal : No need to application

Save Cancel

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Points to Note for New Registration Application

- Capital letters should be used for product name
- Select appropriate ingredient from ingredient list (when the ingredient with different synonyms)
- Fill out the Real-time Stability Test Report's start date instead of accelerated Stability Test Report (Module 1 page 2 CTD 1.0.4)
- Submit physical documents (GMP/Manufacturer License, Free Sale Certificate/CPP) after the new application submitted

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On-line Application for Change of Registered Particulars

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Initiate New CORP Application

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

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

Application Submitted

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

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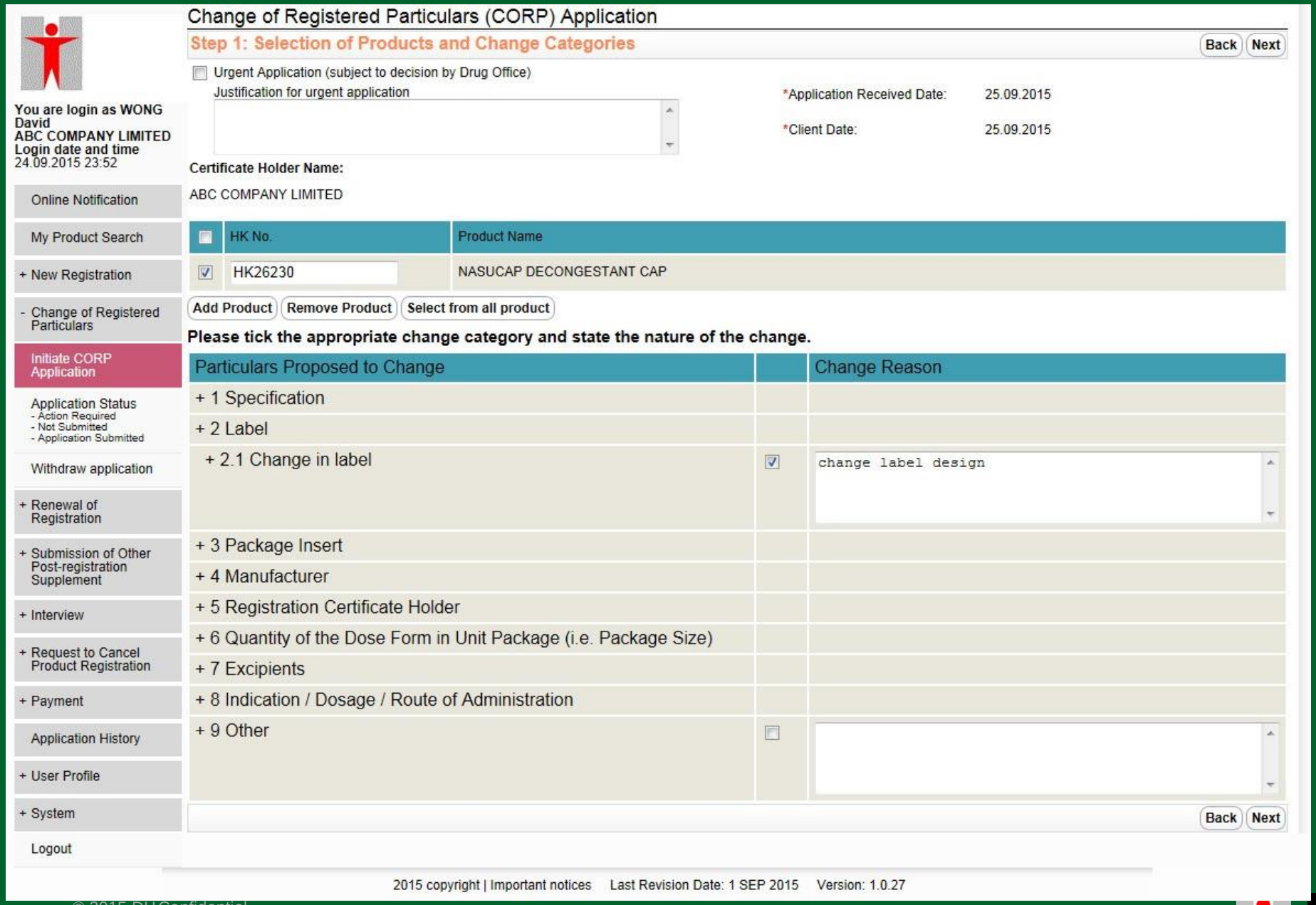
Initiate New CORP Application

- Step 1 – Select products & change categories



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Initiate New CORP Application

- Step 2 – Upload supporting document(s)

Change of Registered Particulars (CORP) Application

Step 2: Uploading Supporting Documents

Back | Cancel | Save & Close | Next

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK26230	NASUCAP DECONGESTANT CAP	Expected Date: 31.01.2016 / Days after approval:

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

2 Label

2.1 Change in label

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

	Remark	Documents File Name
☐	new design with highlight changed	Upload Label_highlighted copy.pdf

Add File | Remove File

Back | Cancel | Save & Close | Next

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Initiate New CORP Application

- Step 3 – Change product particulars

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Change of Registered Particulars (CORP) Application

Step 3: Change Product Particulars

Back | Cancel | Save & Close | Next

Application Type: Certificate holder initiated - New CORP application

Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK26230	NASUCAP DECONGESTANT CAP	31.01.2016

1.0.3 Indication, Route(s) of Administration and Dosage

Indication: Dosage: Add

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

No. of Product Pack Size(s):* 1

1. Product Pack Size 3 X 12 unit

Prototype sales package* Upload No of File(s): 1

☑ Declare to change this pack size

Prototype package insert Upload No of File(s): 1

Component	Primary Container (container that is in direct contact with the product)		Proposed shelf life (months)*	Proposed storage conditions*	Stability Report		In-Use Stability Report
	Packaging Material (e.g. Glass)*	Type of container (e.g. box, bottle)*		(Temperature (°C) and Relative Humidity (RH))	Duration (Month)	Start Date	
1	Glass	bottle	36	Do not store over 15°C	24	10.12.2012	Upload No of File(s): 0
					Upload No of File(s): 1		

1.0.5 Legal Status

Proposed Dispensing Classification
○ Subject to prescription ◉ Not subject to prescription

Back | Cancel | Save & Close | Next

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Initiate New CORP Application

- Review application summary

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Change of Registered Particulars (CORP) Application

Application Summary

Back | Cancel | Save & Close | Confirm & Submit

Application Type: Certificate holder initiated - New CORP application
Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK26230	NASUCAP DECONGESTANT CAP	31.01.2016

Change Category:

Particulars Proposed to Change	Change Reason
2.1 Change in label	change label design

Supporting Documents:

2 Label

2.1 Change in label

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

	Remark	Documents File Name
1	new design with highlight changed	Label_highlighted copy.pdf

Back | Cancel | Save & Close | Confirm & Submit

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Initiate New CORP Application

- Acknowledgement of CORP application submission

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Change of Registered Particulars (CORP) Application

Acknowledgement

Print Close

Thank you for using our service. Your application has been submitted to the Drug Office.

Application submitted should be subjected to our final approval.

For enquiries, please call us quoting this reference number.

General enquiries:

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

Tel: (852) 2319 8458

Email: prs2_info@dh.gov.hk

Application Received Date: 25.09.2015

Product Selected:

	HK No.	PR No.	PL No.	Product Name	Application Reference No.	Proposed Effective Date
1	HK26230	PR1848/1985		NASUCAP DECONGESTANT CAP	CORP-HK26230-201550011	31.01.2016

Change Category:

Particulars Proposed to Change	Change Reason
2.1 Change in label	change label design

Supporting Documents:

2 Label

2.1 Change in label

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

	Remark	Documents File Name
1	new design with highlight changed	Label_highlighted copy.pdf

Print Close

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Initiate New CORP Application

- CORP application status

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
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  - Initiate CORP Application
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    - Action Required
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550011	CORP-HK26230-201550011	HK26230	NASUCAP DECONGESTANT CAP	2	Application Submitted	Not Necessary
2	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
3	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
12	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid

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CORP Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

New Submission

Initiate New CORP Application

Action Required

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550011	CORP-HK26230-201550011	HK26230	NASUCAP DECONGESTANT CAP	2	Application Evaluated	Not Necessary

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
2	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
3	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid

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CORP Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Online Notification

Application Clarification Notification

Notification Date: 25.09.2015 18:47:34
Notification Letter: ClarificationLetter.pdf

Dear Certificate Holder,

We want to info you following application(s) h

Application Ref. No.	HK No.
CORP-HK26230-201550011	HK26230

Dear Sir/Madam,

1. NASUCAP DECONGESTANT CAP (HK-26230)

I refer to your application dated 25 Sep 2015 for change of registered particulars of the above-listed product/substance.

Your application change of registered particulars has been assessed, with results and remarks as indicated.

a. Label Unsatisfactory
- Please provide the updated label
i. Proposed label with the change(s) underlined or highlighted
- Label_highlighted copy.pdf label design out date

Yours faithfully,

(Christy WONG)
Pharmacist

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CORP Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- - Change of Registered Particulars
  - Initiate CORP Application
  - Application Status
    - Action Required
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile

CORP Application Status

Reply Clarification Letter | Close

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

Application Reference No.:	CORP-HK26230-201550011	Application Status:	Application Evaluated
Application Batch No.:	CORP-HK26230-201550011	Application Type:	Certificate holder initiated - New CORP application
HK No.:	HK26230	Previous App. Reference No.:	
Product Name:	NASUCAP DECONGESTANT CAP	DO Request Reference No.:	
Application Received Date:	25.09.2015	Client Date:	25.09.2015
Proposed Effective Date:	31.01.2016	Application Form Image:	No File Chosen
Hard Copy Received Date:		Justification (Urgent Application):	

Category 2 - Label Clarification Letter Sent

Particulars Proposed to Change	Recall Required	Cert. Reprint Required	Evaluation Comment and Result
2.Label 2.1-Change in label Change Reason: change label design	Yes	Not Required	Please provide the updated label Satisfactory / Unsatisfactory / Acknowledged / Withdrawn

Supporting Documents:

2.1 Change in label

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

Documents File Name	Remark	Screening Comment	Evaluation Comment
Label_highlighted copy.pdf	new design with highlight changed		label design out date

Change Categories Allowed for Amendment:

Reply Clarification Letter | Close

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CORP Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Step 1: Selection of Products and Change Categories

Back Next

☐ Urgent Application (subject to decision by Drug Office)

Justification for urgent application

*Application Received Date: 25.09.2015

*Client Date: 25.09.2015

Certificate Holder Name:

ABC COMPANY LIMITED

Justification for changing the batch :

	HK No.	Product Name
☑	HK26230	NASUCAP DECONGESTANT CAP

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

Particulars Proposed to Change		Change Reason
+ 1 Specification		
+ 2 Label		
+ 2.1 Change in label	☑	change label design
+ 3 Package Insert		
+ 4 Manufacturer		
+ 5 Registration Certificate Holder		
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)		
+ 7 Excipients		
+ 8 Indication / Dosage / Route of Administration		
+ 9 Other	☐	

Back Next

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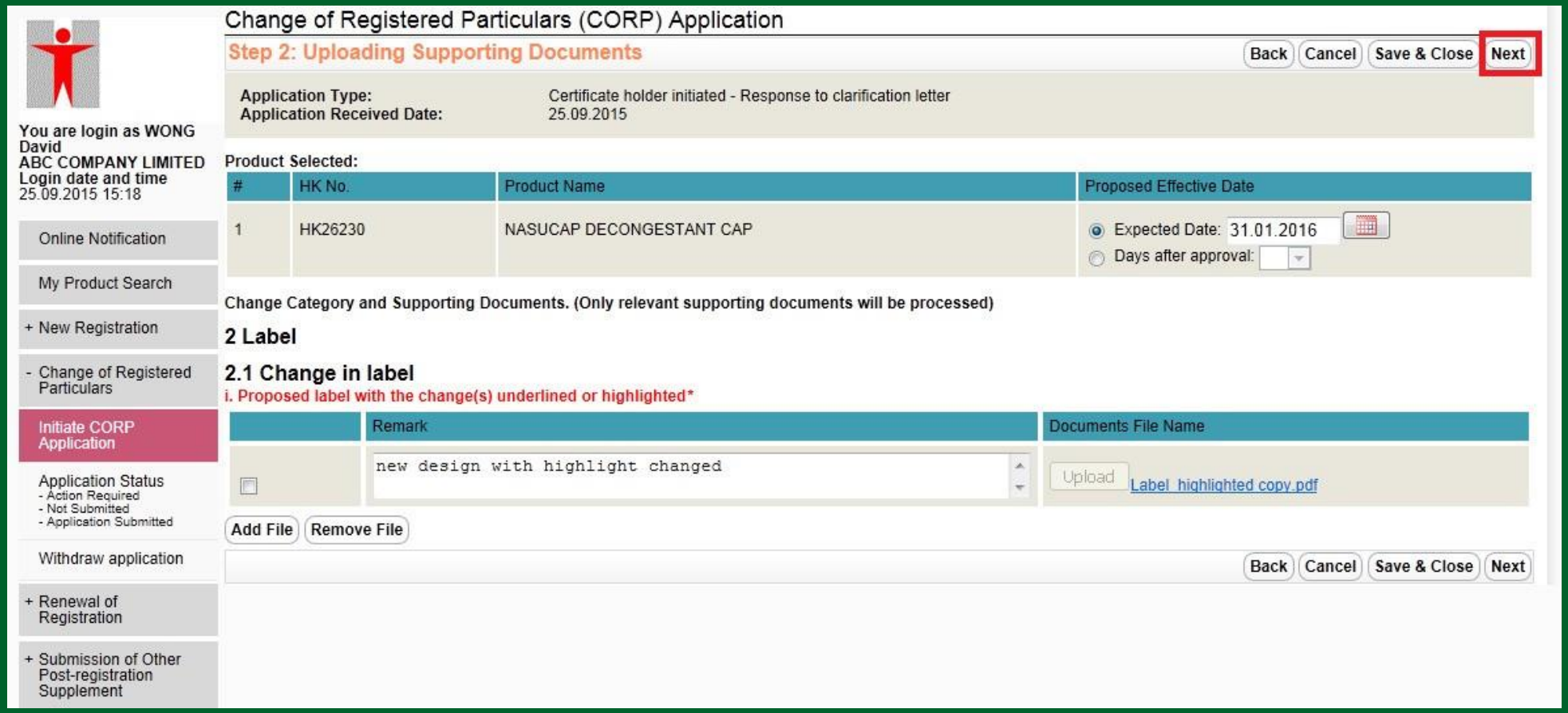
CORP Application Reply Clarification



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CORP Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Step 3: Change Product Particulars

Back | Cancel | Save & Close | Next

Application Type: Certificate holder initiated - Response to clarification letter

Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK26230	NASUCAP DECONGESTANT CAP	31.01.2016

1.0.3 Indication, Route(s) of Administration and Dosage

Indication: Dosage: Add

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

No. of Product Pack Size(s):* 1

1. Product Pack Size 3 X 12 unit

Prototype sales package* Upload No of File(s): 1

☑ Declare to change this pack size

Prototype package insert Upload No of File(s): 1

Component	Primary Container (container that is in direct contact with the product)		Proposed shelf life (months)*	Proposed storage conditions*	Stability Report		In-Use Stability Report
	Packaging Material (e.g. Glass)*	Type of container (e.g. box, bottle)*		(Temperature (°C) and Relative Humidity (RH))	Duration (Month)	Start Date	
1	Glass	bottle	36	Do not store over 15°C	24	10.12.2012	Upload No of File (s): 0
					Upload	No of File(s): 1	

1.0.5 Legal Status

Proposed Dispensing Classification
○ Subject to prescription ◉ Not subject to prescription

Back | Cancel | Save & Close | Next

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CORP Application Reply Clarification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Application Summary

Back | Cancel | Save & Close | Confirm & Submit

Application Type: Certificate holder initiated - Response to clarification letter
Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	Proposed Effective Date
1	HK26230	NASUCAP DECONGESTANT CAP	31.01.2016

Change Category:

Particulars Proposed to Change	Change Reason
2.1 Change in label	change label design

Supporting Documents:

2 Label

2.1 Change in label

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

	Remark	Documents File Name
1	new design with highlight changed	Label_highlighted copy.pdf

Back | Cancel | Save & Close | Confirm & Submit

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CORP Application Reply Clarification

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ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
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- Initiate CORP Application
- Application Status
  - Action Required
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  - Application Submitted
- Withdraw application
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- + Payment
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particulars (CORP) Application

Acknowledgement

Print Close

Thank you for using our service. Your application has been submitted to the Drug Office.

Application submitted should be subjected to our final approval.

For enquiries, please call us quoting this reference number.

General enquiries:

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

Tel: (852) 2319 8458

Email: prs2_info@dh.gov.hk

Application Received Date: 25.09.2015

Product Selected:

	HK No.	PR No.	PL No.	Product Name	Application Reference No.	Proposed Effective Date
1	HK26230	PR1848/1985		NASUCAP DECONGESTANT CAP	CORP-HK26230-201550011-01	31.01.2016

Change Category:

Particulars Proposed to Change	Change Reason
2.1 Change in label	change label design

Supporting Documents:

2 Label

2.1 Change in label

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

	Remark	Documents File Name
1	new design with highlight changed	Label_highlighted copy.pdf

Print Close

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CORP Application Reply Clarification

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550011-01	CORP-HK26230-201550011-01	HK26230	NASUCAP DECONGESTANT CAP	2	Application Submitted	Not Necessary
2	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
3	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
12	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid

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Approved CORP Application: Change Of Implementation Date

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550011-01	CORP-HK26230-201550011-01	HK26230	NASUCAP DECONGESTANT CAP	2	Application Approved	Not Necessary
2	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
3	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
12	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid

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Approved CORP Application: Change Of Implementation Date

Dear Sir/Madam,

1. NASUCAP DECONGESTANT CAP (HK-26230)

Thank you for your application(s) on the change of registered particulars for the above-named product(s) dated 25 Sep 2015 with enclosures.

I wish to inform you that approval, which will take effect from 31 Jan 2016, is hereby given to the following change(s) of registered particulars as detailed in your application(s):

a. Label
- unit package of 3 X 12 unit

Your attention is also drawn to Regulation 36(1B) of the Pharmacy and Poisons Regulations, Cap. 138 as follows:

"For the avoidance of any doubt, a pharmaceutical product or substance is registered with the Board, ..., if and only if its registrable particulars are those which correspond exactly with the registered particulars of a registered product or substance."

Please ensure complete withdrawal of all the old stocks of the above-named product(s) from the market before the effective date for the approved change(s) as they will no longer be registered on or after that effective date.

Yours faithfully,

Online Notification

Application Approval Notifi

Notification Date: 25.09.2015 21:33:2

Dear Certificate Holder,

We want to info you following applicati

Application Ref. No.	HK No.	Name of Product	Change Categories
CORP-HK26230-201550011-01	HK26230	NASUCAP DECONGESTANT CAP	2

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

CORP Application Status

Change Effective Date | Close

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

Application Reference No.:	CORP-HK26230-201550011-01	Application Status:	Application Approved
Application Batch No.:	CORP-HK26230-201550011-01	Application Type:	Certificate holder initiated - Response to clarification letter
HK No.:	HK26230	Previous App. Reference No.:	CORP-HK26230-201550011
Product Name:	NASUCAP DECONGESTANT CAP	DO Request Reference No.:	
Application Received Date:	25.09.2015	Client Date:	25.09.2015
Proposed Effective Date:	31.01.2016	Application Form Image:	No File Chosen
Hard Copy Received Date:		Justification (Urgent Application):	

Category 2 - Label Approved

Particulars Proposed to Change	Recall Required	Cert. Reprint Required	Evaluation Comment and Result
2.Label 2.1-Change in label Change Reason: change label design Effective Date: 31.01.2016	Yes	Not Required	OK, ACCEPTED Satisfactory | Unsatisfactory | Acknowledged | Withdrawn

Supporting Documents:

2.1 Change in label

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

Documents File Name	Remark	Screening Comment	Evaluation Comment
Label_highlighted copy.pdf	new design with highlight changed	label design out date	OK

Change Categories Allowed for Amendment:

Change Effective Date | Close

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Step 1: Selection of Products and Change Categories

Back Next

☐ Urgent Application (subject to decision by Drug Office)

Justification for urgent application

*Application Received Date: 25.09.2015

*Client Date: 25.09.2015

Certificate Holder Name:

ABC COMPANY LIMITED

Justification for changing the batch :

* Previous Approval Letter : Upload COP-Approval-letter.pdf

	HK No.	Product Name
☑	HK26230	NASUCAP DECONGESTANT CAP

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

Particulars Proposed to Change		Change Justification	New effective date
+ 1 Specification			
+ 2 Label		postpone to 01 June 2016 for market promation	01.06.2016
+ 3 Package Insert			
+ 4 Manufacturer			
+ 5 Registration Certificate Holder			
+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)			
+ 7 Excipients			
+ 8 Indication / Dosage / Route of Administration			
+ 9 Other	☐		

Back Next

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Step 2: Uploading Supporting Documents

Back | Cancel | Save & Close | Next

Application Type: Change of effective date of an approved CORP
Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	New effective date
1	HK26230	NASUCAP DECONGESTANT CAP	Cat. 2 : 01.06.2016

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

2 Label

2.1 Change in label

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

	Remark	Documents File Name
☐	new design with highlight changed	Upload Label_highlighted copy.pdf

Back | Cancel | Save & Close | Next

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Step 3: Change Product Particulars

Back | Cancel | Save & Close | Next

Application Type: Change of effective date of an approved CORP

Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	Changed Effective Date
1	HK26230	NASUCAP DECONGESTANT CAP	Cat. 2 : 01.06.2016

1.0.3 Indication, Route(s) of Administration and Dosage

Indication:

Dosage:

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

No. of Product Pack Size(s):* 1

1. Product Pack Size 3 X 12 unit

Prototype sales package* Upload No of File(s): 1

☑ Declare to change this pack size

Prototype package insert Upload No of File(s): 1

Component	Primary Container (container that is in direct contact with the product)		Proposed shelf life (months)*	Proposed storage conditions*	Stability Report		In-Use Stability Report
	Packaging Material (e.g. Glass)*	Type of container (e.g. box, bottle)*		(Temperature (°C) and Relative Humidity (RH))	Duration (Month)	Start Date	
1	Glass	bottle	36	Do not store over 15°C	24	10.12.2012	Upload No of File (s): 0
					Upload No of File(s): 1		

1.0.5 Legal Status

Proposed Dispensing Classification
○ Subject to prescription ◉ Not subject to prescription

Back | Cancel | Save & Close | Next

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Application Summary

Back | Cancel | Save & Close | Confirm & Submit

Application Type: Change of effective date of an approved CORP
Application Received Date: 25.09.2015

Product Selected:

#	HK No.	Product Name	New effective date
1	HK26230	NASUCAP DECONGESTANT CAP	Cat. 2 : 01.06.2016

Change Category:

Particulars Proposed to Change	Change Reason
2 Label	

Supporting Documents:

2 Label

2.1 Change in label

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

	Remark	Documents File Name
1	new design with highlight changed	Label_highlighted copy.pdf

Back | Cancel | Save & Close | Confirm & Submit

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Change of Registered Particulars (CORP) Application

Acknowledgement

Print Close

Thank you for using our service. Your application has been submitted to the Drug Office.

Application submitted should be subjected to our final approval.

For enquiries, please call us quoting this reference number.

General enquiries:

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

Tel: (852) 2319 8458

Email: prs2_info@dh.gov.hk

Application Received Date: 25.09.2015

Product Selected:

	HK No.	PR No.	PL No.	Product Name	Application Reference No.	New effective date
1	HK26230	PR1848/1985		NASUCAP DECONGESTANT CAP	CORP-HK26230-201550024	

Change Category:

Particulars Proposed to Change	Change Reason
2 Label	

Supporting Documents:

2 Label

2.1 Change in label

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

	Remark	Documents File Name
1	new design with highlight changed	Label_highlighted copy.pdf

Print Close

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Approved CORP Application: Change Of Implementation Date

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550024	CORP-HK26230-201550024	HK26230	NASUCAP DECONGESTANT CAP	2	Application Under Screening	Not Necessary
2	25.09.2015	CORP-HK26230-201550011-01	CORP-HK26230-201550011-01	HK26230	NASUCAP DECONGESTANT CAP	2	Application Approved	Not Necessary
3	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
12	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
13	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid

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Approved CORP Application: Change Of Implementation Date

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550024	CORP-HK26230-201550024	HK26230	NASUCAP DECONGESTANT CAP	2	Application Approved	Not Necessary
2	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
3	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
12	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid

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Approved CORP Application: Change Of Implementation Date

Dear Sir/Madam,

1. NASUCAP DECONGESTANT CAP (HK-26230)

I refer to your letter dated 25 Sep 2015 applying for change of effective date on the following change(s) of registered particulars:

a. Label
- unit package of 3 X 12 unit

Please be informed that approval is hereby given to the above change(s) of registered particulars with effect from 01 Jun 2016. The approval letter issued on 25 Sep 2015 is thereby superseded.

Your attention is also drawn to Regulation 36(1B) of the Pharmacy and Poisons Regulations, Cap. 138 as follows:

"For the avoidance of any doubt, a pharmaceutical product or substance is registered with the Board, ..., if and only if its registrable particulars are those which correspond exactly with the registered particulars of a registered product or substance."

Please ensure complete withdrawal of all the old stocks of the above-named product(s) from the market before the effective date for the approved change(s) as they will no longer be registered on or after that effective date.

Yours faithfully,

Online Notificatior

Application Approval N

Notification Date: 25.09.2015 22

Dear Certificate Holder,

We want to info you following application(s) have been approved. Please check attached approval letter for detail result.

Application Ref. No.	HK No.	Name of Product	Change Categories	Application Status
CORP-HK26230-201550024	HK26230	NASUCAP DECONGESTANT CAP	2	Application Approved

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Approved CORP Application: Change Of Implementation Date

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

CORP Application Status

Change Effective Date | Close

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

Application Reference No.:	CORP-HK26230-201550024	Application Status:	Application Approved
Application Batch No.:	CORP-HK26230-201550024	Application Type:	Change of effective date of an approved CORP application
HK No.:	HK26230	Previous App. Reference No.:	CORP-HK26230-201550011-01
Product Name:	NASUCAP DECONGESTANT CAP	DO Request Reference No.:	
Application Received Date:	25.09.2015	Client Date:	25.09.2015
Proposed Effective Date:		Application Form Image:	No File Chosen
Hard Copy Received Date:		Justification (Urgent Application):	
Previous Approval Letter:	COP-Approval-letter.pdf		

Category 2 - Label Approved

Particulars Proposed to Change	Recall Required	Cert. Reprint Required	Evaluation Comment and Result
2.Label Change Justification: postpone to 01 June 2016 for market promation 2.1-Change in label Effective Date: 01.06.2016	Yes	Not Required	OK, ACCEPTED Satisfactory | Unsatisfactory | Acknowledged | Withdrawn

Supporting Documents:

2.1 Change in label

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

Documents File Name	Remark	Screening Comment	Evaluation Comment
Label_highlighted copy.pdf	new design with highlight changed	label design out date	OK

Change Categories Allowed for Amendment:

Change Effective Date | Close

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CORP Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

Withdrawal of CORP Application

Withdraw Application

	Received	Ref. No.	HK No.	Product Name	Change Categories	Status
☑	25.09.2015	CORP-HK26230-201550011	HK26230	NASUCAP DECONGESTANT CAP	2	Application Submitted

Withdraw Application

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CORP Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

Withdrawal of CORP Application

Confirm to Withdraw | Close

Received	Ref. No.	HK No.	Product Name	Change Categories	Status
25.09.2015	CORP-HK26230-201550011	HK26230	NASUCAP DECONGESTANT CAP	2	Application Submitted

Reason(s) of Withdrawal: Keep original design

Confirm to Withdraw | Close

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CORP Application: Certificate Signature Fee Payment

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

New Submission

Initiate New CORP Application

Action Required

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Application Approved	Pending for Certificate Fee
2	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Application Approved	Pending for Certificate Fee
3	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Application Approved	Pending for Certificate Fee
4	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Application Approved	Pending for Certificate Fee
5	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Application Approved	Pending for Certificate Fee
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Application Approved	Pending for Certificate Fee
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Application Approved	Pending for Certificate Fee
8	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Application Approved	Pending for Certificate Fee
9	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Application Approved	Pending for Certificate Fee
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Application Approved	Pending for Certificate Fee
11	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Application Approved	Pending for Certificate Fee

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550011	CORP-HK26230-201550011	HK26230	NASUCAP DECONGESTANT CAP	2	Application Under Screening	Not Necessary

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CORP Application: Certificate Signature Fee Payment

Online Notification

Certificate Fee Notification

Notification Date: 25.09.2015 12:38:09
Notification Letter: CertPaymentNotification.pdf

Dear Certificate Holder,

We want to info you following application(s) have been

Application Ref. No.	HK No.	
CORP-HK26230-201550013	HK26230	NASU
CORP-HK39239-201550014	HK39239	UNI-M
CORP-HK47301-201550015	HK47301	PHEN
CORP-HK53968-201550016	HK53968	MARH
CORP-HK53969-201550017	HK53969	SUITA
CORP-HK53970-201550018	HK53970	RAMA
CORP-HK60174-201550019	HK60174	PRILI
CORP-HK60175-201550020	HK60175	PRILI
CORP-HK60186-201550021	HK60186	LEVO
CORP-HK60187-201550022	HK60187	LEVO
CORP-HK60507-201550023	HK60507	PROA

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

Date 日期: 25.09.2015

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] Change(s) of Registered Particulars 更改註冊詳情 (HK$155)	11	HK$1,705

Ref. 檔號:

HK26230, HK39239, HK47301, HK53968, HK53969, HK53970, HK60174, HK60175, HK60186, HK60187, HK60507

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CORP application: Certificate Payment

Supplement
+ Interview
+ Request to Cancel Product Registration
- Payment
Payment Pool
Payment History
Application History
+ User Profile
+ System
Logout

New Application Certificate Payment

Ready to Pay

	Application Received Date	PR No.	PL No.	Proposed Name of Product	Payment Status

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

CORP Updated Certificate Payment

Ready to Pay Close

	Application Received Date	Reference No.	HK No.	Name of Product	Change Categories	Payment Status
	25.09.2015	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Pending for Certificate Fee
	25.09.2015	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Pending for Certificate Fee
	25.09.2015	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Pending for Certificate Fee
	25.09.2015	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Pending for Certificate Fee
	25.09.2015	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Pending for Certificate Fee
	25.09.2015	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Pending for Certificate Fee
	25.09.2015	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Pending for Certificate Fee
	25.09.2015	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Pending for Certificate Fee
	25.09.2015	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Pending for Certificate Fee
	25.09.2015	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Pending for Certificate Fee
	25.09.2015	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Pending for Certificate Fee

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

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CORP application: Certificate Payment

GovHK 香港政府一站通

Online Payment Service

Help
Customer Service Hotline
2319 8461

Email
pharmweb @dh.gov.hk

Please select the payment method :

Type of Service	**DH Drug Office**
Transaction Date	**25-09-2015**
Transaction Reference Number	**DHPRS-201509251525-90007**
Total Amount	**HK$ 1,705.00**
Payment Method	VISA / MasterCard / PPS 繳費靈

Cancel Payment **Pay**

- Please take note of the transaction reference number or PRINT this page.
- After pressing the 'Pay' button, please do not leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful.
- Under exceptional conditions, a refund may need to be arranged. If the payment is made by Credit Card, the refund can normally be made to the Credit Card account that is used for the payment.
- Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use PPS to settle the payment. We apologise for any inconvenience caused.
- Different credit card issuers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please contact your card issuer if you want to learn more about the Verified by Visa and MasterCard SecureCode service.

HONG KONG

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Result of CORP Application Certificate Payment

DCO

Y... login as WONG
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- + Request to Cancel Product Registration
- - Payment
- Payment Pool
- Payment History
- Application History
- + User Profile
- + System
- Logout

Change of Registered Particular

Print Receipt | Close

Payment Reference No.: DHPRS-201509251525-90007

EGIS Reference No.: A201509252174288

Payment Method: PPS

Transaction Time: 25.09.2015 15:29:27

Delivery Method: Collect in Person in Drug Office

Certificate Collection Date: 01.12.2015

Application Received Date	Reference No.	HK No.	Product Name	Change Categories	Payment Status
25.09.2015 00:00	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid
25.09.2015 00:00	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid

The Drug Office acknowledges the receipt of your payment of HK$1,705.00 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

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CORP Application Certificate Payment

Name of Company 公司名稱	Payment Date 繳費日期
ABC COMPANY LIMITED	25.09.2015

Payment Reference No: 付款編號:	DHPRS-201509251525-90007
EGIS Reference No: EGIS編號:	A201509252174288
Payment Method: 付款方法:	PPS
Payment Amount: 付款金額:	HK$1,705.00

For Office use

____ certificate(s) collected on _____

Company Sta
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

Name of Company ABC COMPANY LIMITED
公司名稱
Payment Reference No: DHPRS-201509251525-90007
付款編號:

	Name of Product 製品/物質名稱	HK Reg. No 香港註冊號碼	Reference No. 參考編號
1	NASUCAP DECONGESTANT CAP	HK-26230	CORP-HK26230-201550013
2	UNI-MENADOL TAB 10MG	HK-39239	CORP-HK39239-201550014
3	PHENYTOIN INJ 250MG/5ML (HAMELN)	HK-47301	CORP-HK47301-201550015
4	MARKIST OINTMENT	HK-53968	CORP-HK53968-201550016
5	SUITANI OINTMENT	HK-53969	CORP-HK53969-201550017
6	RAMATIN OINTMENT	HK-53970	CORP-HK53970-201550018
7	PRILIGY TAB 30MG	HK-60174	CORP-HK60174-201550019
8	PRILIGY TAB 60MG	HK-60175	CORP-HK60175-201550020
9	LEVOXA TAB 500MG	HK-60186	CORP-HK60186-201550021
10	LEVOXA TAB 250MG	HK-60187	CORP-HK60187-201550022
11	PROACTIV SOLUTION KIT	HK-60507	CORP-HK60507-201550023

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CORP Application Certificate Payment

CORP_APPLICATION_STATUS

Change of Registered Particulars (CORP) Application

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

New Submission

Initiate New CORP Application

Action Required

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

Not Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK53970-201550012	CORP-HK53970-201550012	HK53970	RAMATIN OINTMENT	4	Application Saved	Not Necessary

Application Submitted

	Received	Batch No.	Ref. No.	HK No.	Product Name	Change Categories	Status	Payment Status
1	25.09.2015	CORP-HK26230-201550013	CORP-HK39239-201550014	HK39239	UNI-MENADOL TAB 10MG	5	Certificate Fee Paid	Certificate Fee Paid
2	25.09.2015	CORP-HK26230-201550013	CORP-HK47301-201550015	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	5	Certificate Fee Paid	Certificate Fee Paid
3	25.09.2015	CORP-HK26230-201550013	CORP-HK53970-201550018	HK53970	RAMATIN OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
4	25.09.2015	CORP-HK26230-201550013	CORP-HK26230-201550013	HK26230	NASUCAP DECONGESTANT CAP	5	Certificate Fee Paid	Certificate Fee Paid
5	25.09.2015	CORP-HK26230-201550013	CORP-HK53968-201550016	HK53968	MARKIST OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
6	25.09.2015	CORP-HK26230-201550013	CORP-HK60186-201550021	HK60186	LEVOXA TAB 500MG	5	Certificate Fee Paid	Certificate Fee Paid
7	25.09.2015	CORP-HK26230-201550013	CORP-HK60507-201550023	HK60507	PROACTIV SOLUTION KIT	5	Certificate Fee Paid	Certificate Fee Paid
8	25.09.2015	CORP-HK26230-201550013	CORP-HK60175-201550020	HK60175	PRILIGY TAB 60MG	5	Certificate Fee Paid	Certificate Fee Paid
9	25.09.2015	CORP-HK26230-201550013	CORP-HK53969-201550017	HK53969	SUITANI OINTMENT	5	Certificate Fee Paid	Certificate Fee Paid
10	25.09.2015	CORP-HK26230-201550013	CORP-HK60174-201550019	HK60174	PRILIGY TAB 30MG	5	Certificate Fee Paid	Certificate Fee Paid
11	25.09.2015	CORP-HK26230-201550013	CORP-HK60187-201550022	HK60187	LEVOXA TAB 250MG	5	Certificate Fee Paid	Certificate Fee Paid
12	25.09.2015	CORP-HK26230-201550011	CORP-HK26230-201550011	HK26230	NASUCAP DECONGESTANT CAP	2	Application Under Screening	Not Necessary

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Points to Note for CORP application

- Check all related change categories (e.g. package insert related to indication and dosage), if necessary, before application submission
- Upload highlighted copy as supporting document in step 2 and upload clean copy as product particulars in step 3
- Submit physical documents (GMP/Manufacturer License, Free Sale Certificate/CPP) after the application under evaluation
- Only application submitted via online channel is allowed to change implementation date via online channel
- Change of implementation date in only allowed before 10 working days of approved implementation date

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On-line Application for Registered Product Renewal

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Renewal Product via Online Channel

RENEWAL_STATUS

Renewal of Registration

Please allow at least 5 day(s) for the renewal application process before the expiry date of the product(s)

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Reply and Pay for Renewal of Registration

Renew | Not to Renew

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
☐	HK60175	PRILIGY TAB 60MG		24.11.2015	Batch Six
☐	HK60174	PRILIGY TAB 30MG		24.11.2015	Batch Six
☐	HK53968	MARKIST OINTMENT		13.01.2016	Batch One
☑	HK53970	RAMATIN OINTMENT		13.01.2016	Batch One
☑	HK53969	SUITANI OINTMENT		13.01.2016	Batch One

Payment Completed

	HK No.	Name of Product	Payment Date	Expiry Date	Batch No.
☐	HK60187	LEVOXA TAB 250MG	02.09.2015	24.11.2015	Batch Six

Product Confirmed Not to Renew

Reinstate

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
☐	HK60186	LEVOXA TAB 500MG	15.09.2015	24.11.2015	Batch Six

Requires Further Action Before Product Renewal

	HK No.	Name of Product	Reason	Expiry Date	Batch No.
☐	HK26230	NASUCAP DECONGESTANT CAP	Non Pharmaceutical Product	02.02.2016	Batch One
☐	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	BABE list	28.01.2016	Batch One
☐	HK60507	PROACTIV SOLUTION KIT	RSTR list	13.07.2016	Batch Four

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Renewal Product via Online Channel

RENEWAL_PROCESS_STATUS

Renewal of Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Pay for Renewal Certificate

Renew Product | Print Manual Renewal Form | Back

Certificate Holder	HK No.	PR No.	Name of Product
ABC COMPANY LIMITED	HK53970	PR0726/2005	RAMATIN OINTMENT
ABC COMPANY LIMITED	HK53969	PR0725/2005	SUITANI OINTMENT

No. of Product(s): 2

Fee type: Application Fee of Pharmaceutical Product Renewal

Payment Amount: HK$ 1150.0

Certificate Collect: ○ Collect in Person in Drug Office ◉ Received By Post

☑ 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.

Renew Product | Print Manual Renewal Form | Back

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Renewal Product via Online Channel

GovHK 香港政府一站通

Online Payment Service

Help

Customer Service Hotline 2319 8461

Email **pharmweb @dh.gov.hk**

Please select the payment method :

Type of Service	**DH Drug Office**
Transaction Date	**25-09-2015**
Transaction Reference Number	**DHPRS-201509250021-90004**
Total Amount	**HK$ 1,150.00**
Payment Method	VISA / MasterCard / PPS 繳費靈

Cancel Payment **Pay**

- Please take note of the transaction reference number or PRINT this page.
- After pressing the 'Pay' button, please do not leave this e-service until you receive the acknowledgement page, otherwise your transaction may not be successful.
- Under exceptional conditions, a refund may need to be arranged. If the payment is made by Credit Card, the refund can normally be made to the Credit Card account that is used for the payment.
- Some users may receive an error page or have to wait for several minutes before they get a response from the credit card payment gateway. If you experience such a problem, please wait a moment and retry, or change to use PPS to settle the payment. We apologise for any inconvenience caused.
- Different credit card issuers may have implemented different mechanisms to authenticate the cardholder's identity during online payment. Please contact your card issuer if you want to learn more about the Verified by Visa and MasterCard SecureCode service.

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Result of Renewal Certificate Payment

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Renewal

RENEWAL_PAYMENT
Print Receipt | Close

Payment Reference No.: DHPRS-201509250021-90004
EGIS Reference No.: A201509251004142
Type of Payment: Renewal
Transaction Time: 25.09.2015 00:23:37
Delivery Method: Received By Post

HK No.	Product Name	Expiry Date
HK53969	SUITANI OINTMENT	13.01.2016
HK53970	RAMATIN OINTMENT	13.01.2016

The Drug Office acknowledges the receipt of your payment of HK$1,150.00 for application fee regarding the above product(s). We will process your application and will provide response as soon as possible.

The certificate(s) will be mailed to the certificate holder

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

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Result of Renewal Certificate Payment

Name of Company 公司名稱	Payment Date 繳費日期
ABC COMPANY LIMITED	25.09.2015

Payment Reference No: 付款編號:	DHPRS-201509250021-90004
EGIS Reference No: EGIS編號:	A201509251004142
Payment Method: 付款方法:	VISA
Payment Amount: 付款金額:	HK$1,150.00

Name of Company ABC COMPANY LIMITED
公司名稱
Payment Reference No: DHPRS-201509250021-90004
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	SUITANI OINTMENT	HK53969	13.1.2016
2	RAMATIN OINTMENT	HK53970	13.1.2016

For Office use

____ **certificate(s) collected on** _____

Company Stamp:
公司印鑑: _____

Your company chose to collect the Certificate(s) of Drug/Product Registration (Certificate(s)) by the following method:

貴公司已選擇採用以下方式領取藥品/製品註冊證明書(證明書):

☐ **In Person 親自**

Please present this receipt on/after _____ for collection of certificates(s).

請於_____或以後,出示此收據領取證明書。

☒ **By Post 郵遞**

Certificates(s) will be posted to your company.
證明書將會以郵寄方式寄給貴公司。

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Renewal Product via Online Channel

RENEWAL_STATUS

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
24.09.2015 23:52

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

Renewal of Registration

Please allow at least 5 day(s) for the renewal application process before the expiry date of the product(s)

Reply and Pay for Renewal of Registration

Renew | Not to Renew

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
☐	HK60175	PRILIGY TAB 60MG		24.11.2015	Batch Six
☐	HK60174	PRILIGY TAB 30MG		24.11.2015	Batch Six
☐	HK53968	MARKIST OINTMENT		13.01.2016	Batch One

Payment Completed

	HK No.	Name of Product	Payment Date	Expiry Date	Batch No.
☐	HK60187	LEVOXA TAB 250MG	02.09.2015	24.11.2015	Batch Six
☐	HK53970	RAMATIN OINTMENT	25.09.2015	13.01.2016	Batch One
☐	HK53969	SUITANI OINTMENT	25.09.2015	13.01.2016	Batch One

Product Confirmed Not to Renew

Reinstate

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
☐	HK60186	LEVOXA TAB 500MG	15.09.2015	24.11.2015	Batch Six

Requires Further Action Before Product Renewal

	HK No.	Name of Product	Reason	Expiry Date	Batch No.
☐	HK26230	NASUCAP DECONGESTANT CAP	Non Pharmaceutical Product	02.02.2016	Batch One
☐	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	BABE list	28.01.2016	Batch One
☐	HK60507	PROACTIV SOLUTION KIT	RSTR list	13.07.2016	Batch Four

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Reply not to Renew Product via Online Channel

RENEWAL_STATUS

Renewal of Registration

Please allow at least 5 day(s) for the renewal application process before the expiry date of the product(s)

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

Reply and Pay for Renewal of Registration

Renew | Not to Renew

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
☐	HK60175	PRILIGY TAB 60MG		24.11.2015	Batch Six
☐	HK60174	PRILIGY TAB 30MG		24.11.2015	Batch Six
☑	HK53968	MARKIST OINTMENT		13.01.2016	Batch One

Payment Completed

	HK No.	Name of Product	Payment Date	Expiry Date	Batch No.
☐	HK60187	LEVOXA TAB 250MG	02.09.2015	24.11.2015	Batch Six
☐	HK53970	RAMATIN OINTMENT	25.09.2015	13.01.2016	Batch One
☐	HK53969	SUITANI OINTMENT	25.09.2015	13.01.2016	Batch One

Product Confirmed Not to Renew

Reinstate

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
☐	HK60186	LEVOXA TAB 500MG	15.09.2015	24.11.2015	Batch Six

Requires Further Action Before Product Renewal

	HK No.	Name of Product	Reason	Expiry Date	Batch No.
☐	HK26230	NASUCAP DECONGESTANT CAP	Non Pharmaceutical Product	02.02.2016	Batch One
☐	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	BABE list	28.01.2016	Batch One
☐	HK60507	PROACTIV SOLUTION KIT	RSTR list	13.07.2016	Batch Four

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Reply not to Renew Product via Online Channel

RENEWAL_STATUS

Renewal of Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

- Product(s) have been successfully set to not renew

Please allow at least 5 day(s) for the renewal application process before the expiry date of the product(s)

Reply and Pay for Renewal of Registration

Renew | Not to Renew

HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
HK60175	PRILIGY TAB 60MG		24.11.2015	Batch Six
HK60174	PRILIGY TAB 30MG		24.11.2015	Batch Six

Payment Completed

HK No.	Name of Product	Payment Date	Expiry Date	Batch No.
HK60187	LEVOXA TAB 250MG	02.09.2015	24.11.2015	Batch Six
HK53970	RAMATIN OINTMENT	25.09.2015	13.01.2016	Batch One
HK53969	SUITANI OINTMENT	25.09.2015	13.01.2016	Batch One

Product Confirmed Not to Renew

Reinstate

HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
HK60186	LEVOXA TAB 500MG	15.09.2015	24.11.2015	Batch Six
HK53968	MARKIST OINTMENT	25.09.2015	13.01.2016	Batch One

Requires Further Action Before Product Renewal

HK No.	Name of Product	Reason	Expiry Date	Batch No.
HK26230	NASUCAP DECONGESTANT CAP	Non Pharmaceutical Product	02.02.2016	Batch One
HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	BABE list	28.01.2016	Batch One
HK60507	PROACTIV SOLUTION KIT	RSTR list	13.07.2016	Batch Four

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Reinstate to Renew Product via Online Channel

RENEWAL_STATUS

Renewal of Registration

Please allow at least 5 day(s) for the renewal application process before the expiry date of the product(s)

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

Reply and Pay for Renewal of Registration

Renew | Not to Renew

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
☐	HK60175	PRILIGY TAB 60MG		24.11.2015	Batch Six
☐	HK60174	PRILIGY TAB 30MG		24.11.2015	Batch Six

Payment Completed

	HK No.	Name of Product	Payment Date	Expiry Date	Batch No.
☐	HK60187	LEVOXA TAB 250MG	02.09.2015	24.11.2015	Batch Six
☐	HK53970	RAMATIN OINTMENT	25.09.2015	13.01.2016	Batch One
☐	HK53969	SUITANI OINTMENT	25.09.2015	13.01.2016	Batch One

Product Confirmed Not to Renew

Reinstate

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
☐	HK60186	LEVOXA TAB 500MG	15.09.2015	24.11.2015	Batch Six
☑	HK53968	MARKIST OINTMENT	25.09.2015	13.01.2016	Batch One

Requires Further Action Before Product Renewal

	HK No.	Name of Product	Reason	Expiry Date	Batch No.
☐	HK26230	NASUCAP DECONGESTANT CAP	Non Pharmaceutical Product	02.02.2016	Batch One
☐	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	BABE list	28.01.2016	Batch One
☐	HK60507	PROACTIV SOLUTION KIT	RSTR list	13.07.2016	Batch Four

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Reinstate to Renew Product via Online Channel

RENEWAL_STATUS

Renewal of Registration

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 10:46

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

- Product(s) have been successfully reinstated

Please allow at least 5 day(s) for the renewal application process before the expiry date of the product(s)

Reply and Pay for Renewal of Registration

Renew | Not to Renew

	HK No.	Name of Product	Notify Date	Expiry Date	Batch No.
☐	HK60175	PRILIGY TAB 60MG		24.11.2015	Batch Six
☐	HK60174	PRILIGY TAB 30MG		24.11.2015	Batch Six
☐	HK53968	MARKIST OINTMENT		13.01.2016	Batch One

Payment Completed

	HK No.	Name of Product	Payment Date	Expiry Date	Batch No.
☐	HK60187	LEVOXA TAB 250MG	02.09.2015	24.11.2015	Batch Six
☐	HK53970	RAMATIN OINTMENT	25.09.2015	13.01.2016	Batch One
☐	HK53969	SUITANI OINTMENT	25.09.2015	13.01.2016	Batch One

Product Confirmed Not to Renew

Reinstate

	HK No.	Name of Product	Reply Date	Expiry Date	Batch No.
☐	HK60186	LEVOXA TAB 500MG	15.09.2015	24.11.2015	Batch Six

Requires Further Action Before Product Renewal

	HK No.	Name of Product	Reason	Expiry Date	Batch No.
☐	HK26230	NASUCAP DECONGESTANT CAP	Non Pharmaceutical Product	02.02.2016	Batch One
☐	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	BABE list	28.01.2016	Batch One
☐	HK60507	PROACTIV SOLUTION KIT	RSTR list	13.07.2016	Batch Four

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Online Notification of Product Renewal

#	Notification Type	Date of Issue
1	Renewal Notification	Around 6 months before the expiry of certificate
2	Renewal Reminder	1 month after issued renewal notification if certificate holder has no response
3	Expiry Notice (if certificate holder has replied “Not to Renew”)	1 month before the expiry of certificate
4	Expiry Notice (if certificate holder has no response)	The date after the expiry of certificate

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On-line Application for Registered Product Cancellation

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Initiate Application for Product Cancellation

EOL_APPLICATION_STATUS

Request to Cancel Product Registrations

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Submission

Initiate new EOL Application

Not Submitted

	Last Draft Date	Ref No.	HK No.	Product Name

Application Submitted

	Date Received	Ref No.	HK No.	Product Name	Status

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Initiate Application for Product Cancellation

Request to Cancel Product Registrations

Close | Next

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

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
HK53970	RAMATIN OINTMENT	13.01.2016	Recent Notification(s) on Change of Registered Product

* Effective Date : 01.01.2016

* Reason(s) of Product Cancellation :

No sales this procut anymore

Contact Information for Product Cancellation :

* Contact Person : Mr. Tang
* Phone No. : 22099653
* Email : Steven.tang@abc.com

* Address :

Unit : A
Floor : 4
Block : A
Building : DH BUILDING
Street No. : 382
Street Name : NACHENG
Sub-district : SHEK KIP MEI
Area : KOWLOON

Close | Next

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Initiate Application for Product Cancellation

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

Request to Cancel Product Registrations

Back | Save | Confirm & Submit

Step 2: Indicate the Return of Registration Certificate, and Confirm Submission of Your Request of Cancellation of Product Registration.

HK No.	Product Name	Return Registration Certification to Drug Office
HK53970	RAMATIN OINTMENT	☑

If "Return Registration Certificate to Drug Office" is checked, Drug Office will start to process your request when the registration certificate is received.

Effective Date: 01.01.2016

Reason(s) of Product Cancellation:
No sales this procut anymore

Contact Information for Product Cancellation:

Contact Person : Mr. Tang **Phone No. :** 22099653 **Email :** Steven.tang@abc.com

Address :
Unit : A **Floor :** 4 **Block :** A
Building : DH BUILDING
Street No. : 382 **Street Name :** NACHENG
Sub-district : SHEK KIP MEI
Area : KOWLOON

Warning:
The cancellation of registered product is subject to approval by Drug Office.
The cancellation of product registration cannot be revoked after the approval of cancellation by Drug Office.

Back | Save | Confirm & Submit

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Initiate Application for Product Cancellation

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

Request to Cancel Product Registrations

Print Close

Step 3: Acknowledgement

Thank you for using our service. Your request for cancellation of product registration is subject to approval of Drug Office.

You reference number is

DE-REG-HK53970-20150925

Please quote this 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) 2319 8458
Email:	prs2_info@dh.gov.hk

HK No.	Product Name
HK53970	RAMATIN OINTMENT

Print Close

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Initiate Application for Product Cancellation

EOL_APPLICATION_STATUS

Request to Cancel Product Registrations

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

New Submission

Initiate new EOL Application

Not Submitted

	Last Draft Date	Ref No.	HK No.	Product Name

Application Submitted

	Date Received	Ref No.	HK No.	Product Name	Status
1	25.09.2015	DE-REG-HK53970-20150925	HK53970	RAMATIN OINTMENT	Cancellation Request Submitted

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Product Cancellation Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

EOL Application Withdrawal

Withdraw Application

	Date Received	Ref No.	HK No.	Product Name	Status
☑	25.09.2015	DE-REG-HK53970-20150925	HK53970	RAMATIN OINTMENT	Cancellation Request Submitted

Withdraw Application

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Product Cancellation Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

- Online Notification
- My Product Search
- + New Registration
- + Change of Registered Particulars
- + Renewal of Registration
- + Submission of Other Post-registration Supplement
- + Interview
- - Request to Cancel Product Registration
  - Initiate EOL Application
  - Application Status
    - Not Submitted
    - Application Submitted
  - Withdraw application
- + Payment
- Application History
- + User Profile
- + System
- Logout

EOL Application Withdrawal

Confirm to Withdraw | Close

Date Received	Ref No.	HK No.	Product Name	Status
25.09.2015	DE-REG-HK53970-20150925	HK53970	RAMATIN OINTMENT	Cancellation Request Submitted

* Reason(s) of Withdrawal :

Keep this product, do not cancallation in this moment

Confirm to Withdraw | Close

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Miscellaneous Functions

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Miscellaneous Functions

- Online Notification

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

	Notification Date	Subject	Proposed Name of Product	PL No.	Payment Status
Open	25.09.2015 12:31:52	Application Payment Request	VITAMIN E TABLETS	PL0420/2015	Paid

On Going

	Notification Date	Subject	HK No.	Name of Product

CORP

	Notification Date	Subject	HK No.	Name of Product
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK60186	LEVOXA
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK53969	SUITANI
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK60187	LEVOXA
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK53970	RAMATIN
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK60507	PROACTIV
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK39239	UNI-MENADOL
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK60174	PRILIGY
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK47301	PHENTOIN (HAMELN)
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK60175	PRILIGY
Open	25.09.2015 15:29:21	Certificate Signature Fee Paid Notification	HK53968	MARKIST
Open	25.09.2015 12:38:09	Certificate Fee Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 12:38:08	Application Approval Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 11:30:36	Application Submitted Notification	HK26230	NASUCAP DECONGESTANT
Open	25.09.2015 00:12:17	Application Submitted Notification	HK26230	NASUCAP DECONGESTANT

Renewal of Registration

	Notification Date	Subject	Name of Product	No. of Renewals

Cancellation Request

	Notification Date	Subject	HK No.	Name of Product

Interview

	Notification Date	Subject

Non Pharmaceutical Product Alert

	Notification Date	Subject	HK No.	Name of Product

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Miscellaneous Functions

- Online Notification: Detailed Information

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Online Notification

ONLINE_NOTIFICATION_VIEW_01

New Product Registration

Notification Date :	25.09.2015 12:31:52
PL No. :	PL0420/2015
PR No. :	PR0386/2015
HK No. :	-
Proposed Name of Product (English) :	VITAMIN E TABLETS
Notification Detail :	NOTIFICATION_PRINT.pdf
Attachment(s) :	
1. Go To Application Payment :	Go

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

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

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

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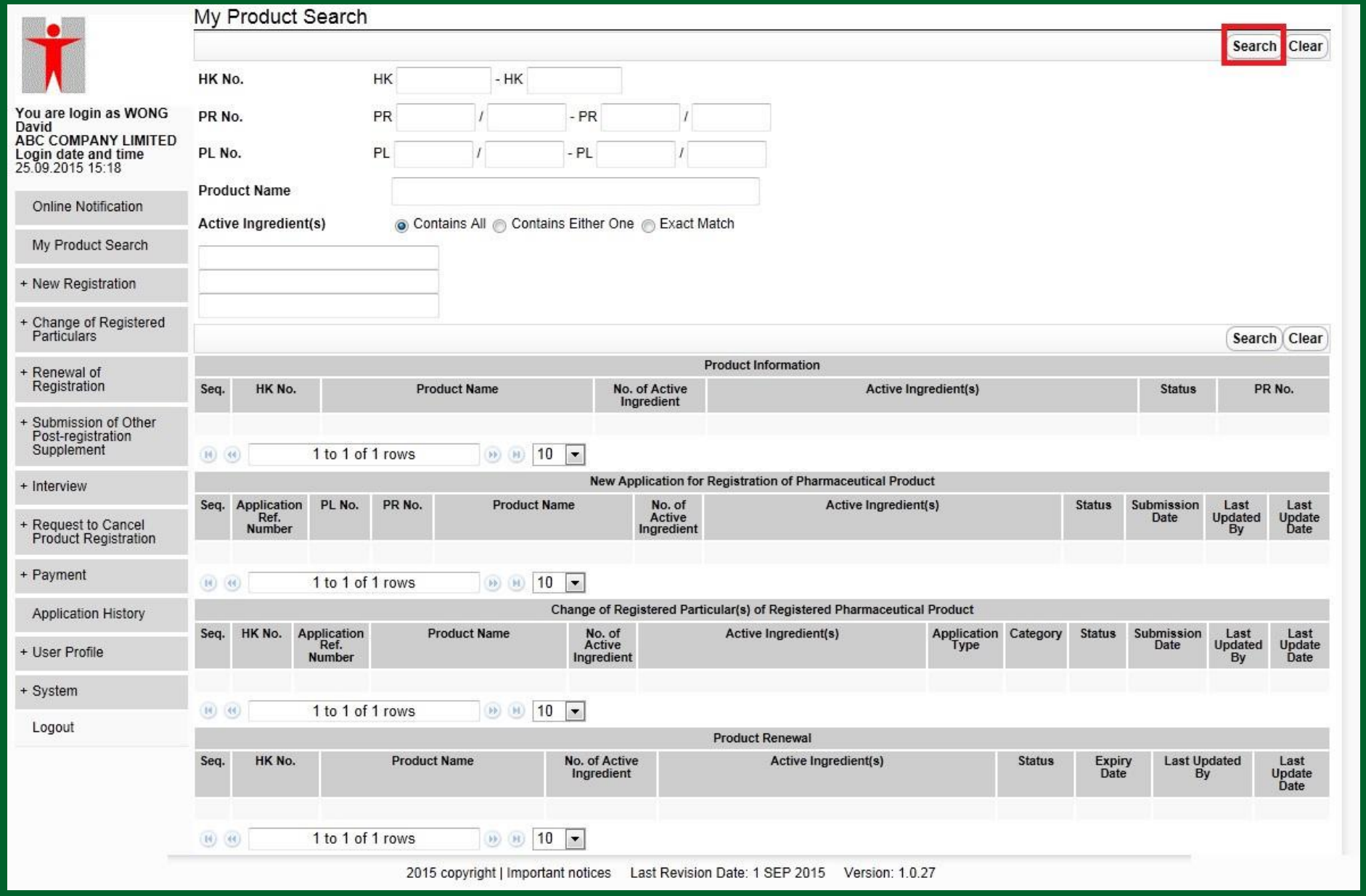
Miscellaneous Functions

- My Product Search



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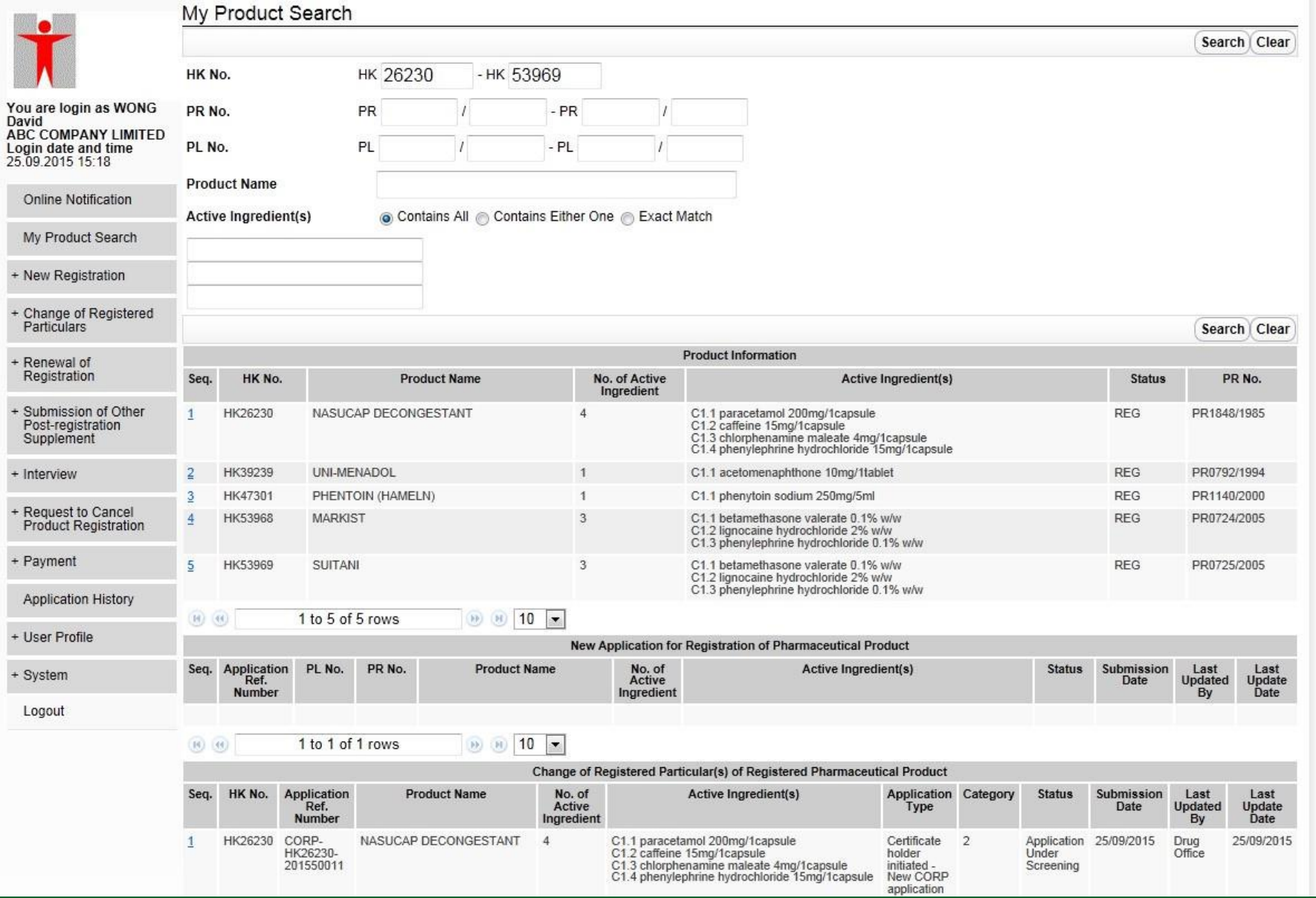
Miscellaneous Functions

- Search Result of My Product Search



My Product Search

Search Clear

HK No. HK 26230 - HK 53969

PR No. PR / - PR /

PL No. PL / - PL /

Product Name

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

Search Clear

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Product Information

Seq.	HK No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	PR No.
1	HK26230	NASUCAP DECONGESTANT	4	C1.1 paracetamol 200mg/1capsule C1.2 caffeine 15mg/1capsule C1.3 chlorphenamine maleate 4mg/1capsule C1.4 phenylephrine hydrochloride 15mg/1capsule	REG	PR1848/1985
2	HK39239	UNI-MENADOL	1	C1.1 acetomenaphthone 10mg/1tablet	REG	PR0792/1994
3	HK47301	PHENTOIN (HAMELN)	1	C1.1 phenytoin sodium 250mg/5ml	REG	PR1140/2000
4	HK53968	MARKIST	3	C1.1 betamethasone valerate 0.1% w/w C1.2 lignocaine hydrochloride 2% w/w C1.3 phenylephrine hydrochloride 0.1% w/w	REG	PR0724/2005
5	HK53969	SUITANI	3	C1.1 betamethasone valerate 0.1% w/w C1.2 lignocaine hydrochloride 2% w/w C1.3 phenylephrine hydrochloride 0.1% w/w	REG	PR0725/2005

1 to 5 of 5 rows 10

New Application for Registration of Pharmaceutical Product

Seq.	Application Ref. Number	PL No.	PR No.	Product Name	No. of Active Ingredient	Active Ingredient(s)	Status	Submission Date	Last Updated By	Last Update Date

1 to 1 of 1 rows 10

Change of Registered Particular(s) of Registered Pharmaceutical Product

Seq.	HK No.	Application Ref. Number	Product Name	No. of Active Ingredient	Active Ingredient(s)	Application Type	Category	Status	Submission Date	Last Updated By	Last Update Date
1	HK26230	CORP-HK26230-201550011	NASUCAP DECONGESTANT	4	C1.1 paracetamol 200mg/1capsule C1.2 caffeine 15mg/1capsule C1.3 chlorphenamine maleate 4mg/1capsule C1.4 phenylephrine hydrochloride 15mg/1capsule	Certificate holder initiated - New CORP application	2	Application Under Screening	25/09/2015	Drug Office	25/09/2015

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Miscellaneous Functions

- Application History

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 15:18

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

Application History

New Product Registration

Total Number of Application Records:0

Application Date	PL No.	PR No.	HK No.	Name of Product	Payment Status	Status	Last Updated Date

Change of Registered Particulars

Total Number of Application Records:0

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

Renewal of Registration

Total Number of Application Records:13

Expiry Date	HK No.	Name of Product	Application Status	Last Updated Date
13.01.2016	HK53969	SUITANI OINTMENT	Paid	25.09.2015
13.01.2016	HK53970	RAMATIN OINTMENT	Paid	25.09.2015
24.11.2015	HK60187	LEVOXA TAB 250MG	Paid	03.09.2015
17.09.2015	HK39239	UNI-MENADOL TAB 10MG	Paid	03.09.2015
02.02.2011	HK26230	NASUCAP DECONGESTANT CAP	Issue Certificate	11.02.2015
28.01.2011	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	Issue Certificate	11.02.2015
13.01.2011	HK53968	MARKIST OINTMENT	Issue Certificate	11.02.2015
13.01.2011	HK53970	RAMATIN OINTMENT	Issue Certificate	11.02.2015
13.01.2011	HK53969	SUITANI OINTMENT	Issue Certificate	11.02.2015
17.09.2010	HK39239	UNI-MENADOL TAB 10MG	Issue Certificate	11.02.2015
02.02.2006	HK26230	NASUCAP DECONGESTANT CAP	Issue Certificate	11.02.2015
28.01.2006	HK47301	PHENYTOIN INJ 250MG/5ML (HAMELN)	Issue Certificate	11.02.2015
17.09.2005	HK39239	UNI-MENADOL TAB 10MG	Issue Certificate	11.02.2015

Termination of Product Registration

Total Number of Application Records:0

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

Ongoing Request Application

Total Number of Application Records:0

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

Interview

Total Number of Application Records:1

Application Date	Subject	Application	Status
25.09.2015	Interview for CORP application (HK26230)	- CORP-HK26230-201550011	Declined

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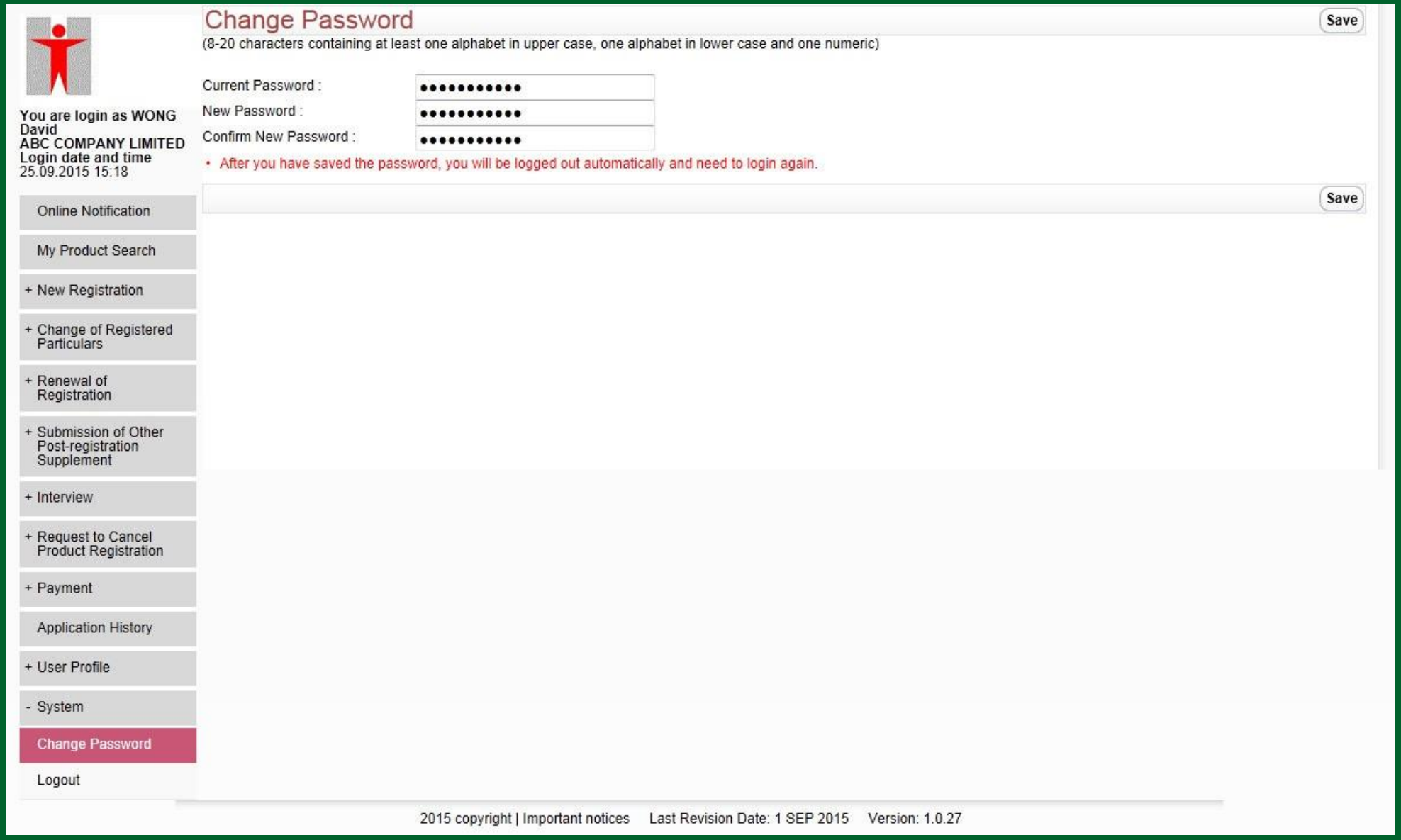
Miscellaneous Functions

- Change Password



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Roadmap for Termination of Manual Application Submission Mode

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Roadmap for Termination of Manual Application Submission

Stage	Type of Application	Date
1	Renewal (Stop sending letters for renewal of registered drugs, only be communicated via on-line notifications/reminders)	1 January 2016
2	New Registration (NCE) & CORP	1 January 2017 (Tentative)
3	New Registration (Generic)	1 April 2017 (Tentative)

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Points to Note for Termination of Manual Application Submission

- In-progress manual application will be continued to processed via manual mode after the cut-off date until the application is completed
- Besides the on-line payment (PPS/Credit Card), off-line payment (cash/cheque) will still be accepted

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PRS 2.0 Information on Drug Office Website

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PRS 2.0 Information on Drug Office Website

- Drug Office website (www.drugoffice.gov.hk)
- "Guidelines & Forms" -> "Drug Registration" -> "Pharmaceuticals Registration System (PRS 2.0)" section, the following content will be shown:
- Login to PRS 2.0 System
- Guidelines
  - Guidance Notes on Application for New-line Account Registration for PRS 2.0
  - PRS 2.0 User Manual
- Forms
  - Application Form for New On-line User Account Registration for PRS 2.0
- Frequently Asked Question

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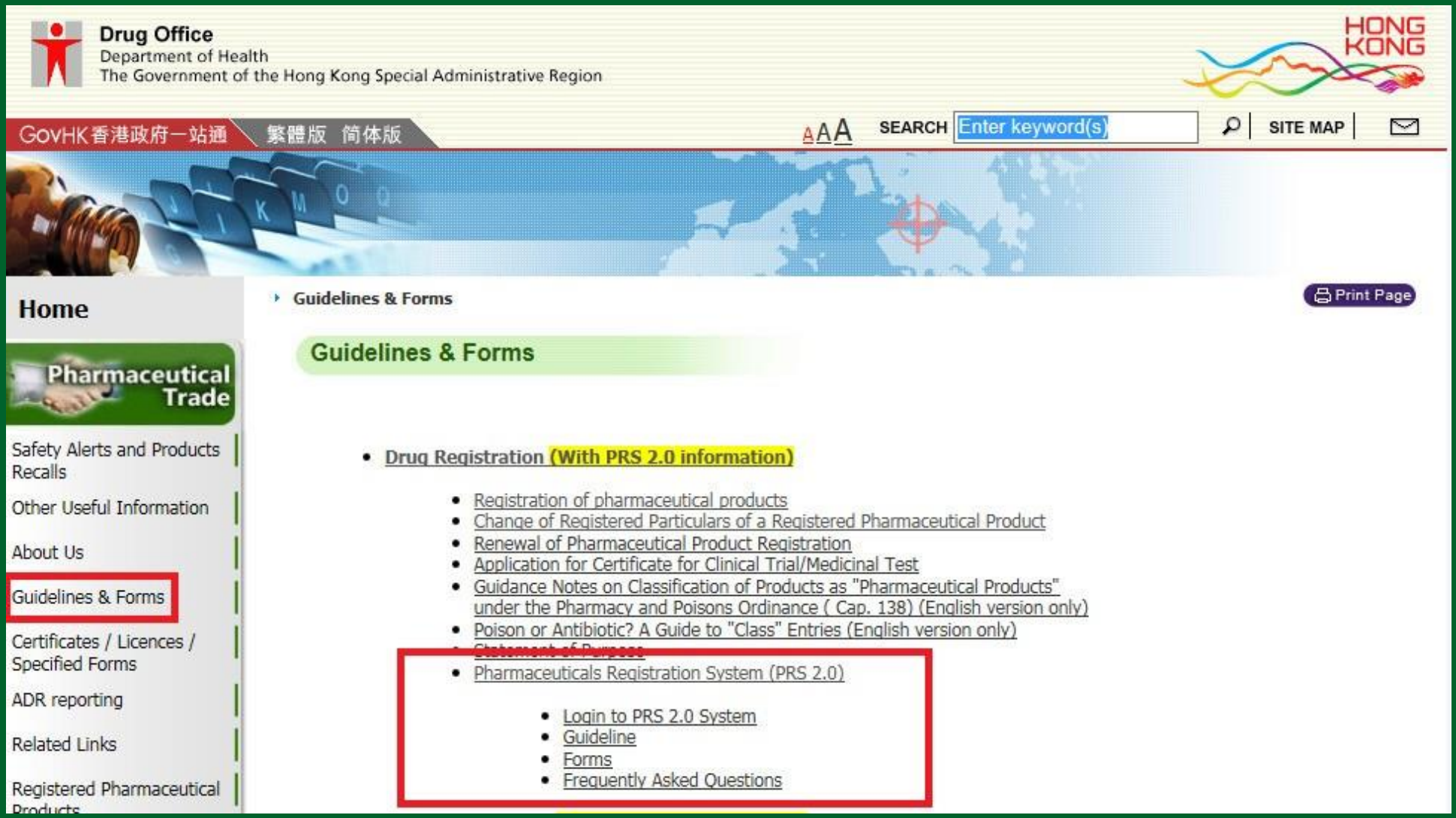
PRS 2.0 Information on Drug Office website



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PRS 2.0 Computer Training Workshops

- Provide hands-on training for operation staffs of drug registration to practice usage of PRS 2.0
- Starting from Nov 2015 to July 2016 (Monday-Friday, except Saturday, Sunday and public holidays)
- Half-day training (10:00 am – 1:00pm)
- Room 300a, 3/F Public Health Laboratory Centre, 382 Nam Cheong Street, Kowloon
- 1 session for each company
- Maximum 2 representatives
- Invitation letter and enrollment form will be sent by batch in each month

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PRS 2.0 Contact

- For supports or enquiries, please contact our PRS 2.0 help desk

  Phone: 3974-4195 (During office hours: Monday-Friday: 09:00-13:00 and 14:00-17:45)

  Email: prs2_info@dh.gov.hk

- Timothy Yu (PRS2.0 Team Head)

  Phone: 3974-4108

  Email: sm_do@dh.gov.hk

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Q & A

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Thank you

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