Launch of Pharmaceuticals Registration System 2.0 (PRS 2.0)

Briefing Session
Objectives of Briefing Session

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

System Requirements

• Web browser: Internet Explorer 9.0 or above
• Web browser settings: Accept cookies and enable JavaScript
• Java Runtime Environment (JRE) 1.6x or above (www.java.com)
  ➢ support for reading e-Cert file
• Adobe Flash Player 13 or above (www.adobe.com)
  ➢ support for uploading documents
Introduction to PRS 2.0

Pharmaceuticals Registration System (PRS2.0)

Applicant / Certificate Holder

New Application

Change of Registered Particular

Renewal

Ongoing Monitoring

Drug Office

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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*
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
Benefits of Using PRS 2.0
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
Benefits of Using PRS 2.0

- Certificate holder information being isolated
- Account access control for applications & products
Benefits of Using PRS 2.0

- On-line user registration & login with e-Cert for better security
Benefits of Using PRS 2.0

- On-line application submission & monitoring

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Benefits of Using PRS 2.0

- On-line application submission & monitoring
Benefits of Using PRS 2.0

- On-line notification for following up the application
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
Benefits of Using PRS 2.0

- Reminder/notification email delivery
Benefits of Using PRS 2.0

- On-line product/application information search
Benefits of Using PRS 2.0

- Application & payment history enquiry

### Application History

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<thead>
<tr>
<th>Application Date</th>
<th>PL No.</th>
<th>PR No.</th>
<th>HK No.</th>
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### Interview

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Benefits of Using PRS 2.0

- Application & payment history enquiry
Registration for On-line User Accounts & System Login
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
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)
Registration for On-line User Accounts & System Login

• Login of PRS 2.0

Welcome to Pharmaceuticals Registration System (PRS2.0)

Username: *
Organizational e-Cert File Location:* Please type full path of file, e.g. C:\cert.p12
e-Cert PIN:*
System Password:* 

Login Reset

Request for New Account
Registration for On-line User Accounts & System Login

- Terms and conditions for the use of PRS2.0

New User Registration

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

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 to 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 Location: Desktop\UAT-CertiWONG 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: 00871890-000

(e.g. 12345670-123)

* 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

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## New User Registration

**Step 3: Review and confirm the account details**

Please check your account details before submission.

<table>
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<tr>
<th>Field</th>
<th>Value</th>
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<tbody>
<tr>
<td>Username</td>
<td>david_wong</td>
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<tr>
<td>Email address</td>
<td><a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td>Name of Organization</td>
<td>ABC COMPANY</td>
</tr>
<tr>
<td>Business Registration Certificate Number</td>
<td>00671890-000</td>
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<tr>
<td>Name of Authorized User</td>
<td>WONG David</td>
</tr>
<tr>
<td>Contact Phone Number</td>
<td>22099423</td>
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<tr>
<td>Position</td>
<td>Manager</td>
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</table>
| 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 |

[Submit] Button
Registration for On-line User Accounts & System Login

• Acknowledgement for registration of account

New User Registration

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)
Registration for On-line User Accounts & System Login

• Registration Acknowledgement

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

Drug Office <prs2_info@dh.gov.hk> 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
Registration for On-line User Accounts & System Login

• Application Form for New On-line User Account Registration

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,
3F, Public Health Laboratory Centre,
362 Nam Cheong Street, Kwoloon.

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

Company Name
Company Address

BRC Number (five 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.

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Authorized User</th>
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<tr>
<td>Name of Authorized User</td>
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<td>Position</td>
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<td>Email Address</td>
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<td>Contact Phone Number</td>
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<tr>
<td>Facsimile Number (if any)</td>
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<tr>
<td>Proposed Login Username</td>
<td>(1. Length 1-20; 2. Case insensitive; 3. Accept character a-z, A-Z, 0-9, _-,#)</td>
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<tr>
<td>e-Certificate Expiry Date (dd/mm/yyyy)</td>
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<tr>
<td>Assign “User Administrator” Role?</td>
<td>Yes / No (Define as appropriate)</td>
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Registration for On-line User Accounts & System Login

• Application Form for New On-line User Account Registration

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<th>Authorized User</th>
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<td>Facsimile Number of any</td>
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<td>Proposed Login Username</td>
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<td>(i. Length 1-20; 2. Case insensitive; 3. Accept character a-z,A-Z,0-9, _, 4. No space)</td>
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<td>e-Certificate Expiry Date (yyyyy)</td>
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<tr>
<td>Assign &quot;User Administrator&quot; Role?</td>
<td>Yes / No (Delete as appropriate)</td>
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*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 their 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/chip signed by a director or a person with equivalent rank")

Name of Signatory: __________________________
Position: __________________________

Email Address: __________________________
Contact Telephone No.: __________________________
Facsimile Number: __________________________
(If any) Date: __________________________

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Registration for On-line User Accounts & System Login

- Approval Notification

![Email Approval Notification Image]
Registration for On-line User Accounts & System Login

- Login PRS2.0 with new registered account

![Welcome to Pharmaceuticals Registration System (PRS2.0)](image)

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Registration for On-line User Accounts & System Login

• Change password when first login

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

(8-20 characters containing at least one alphabet in upper case, one alphabet in lower case and one numeric)

Current Password: 
New Password: 
Confirm New Password: 

• After you have saved the password, you will be logged out automatically and need to login again.
Registration for On-line User Accounts & System Login

- Home page – online notification

### Online Notification

<table>
<thead>
<tr>
<th>New Product Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification Date</td>
</tr>
</tbody>
</table>

### On Going

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

### CORP

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

### 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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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
User Profiles Maintenance
User Profiles Maintenance

- User profiles

Maintain Company User Accounts

<table>
<thead>
<tr>
<th>Login User Name</th>
<th>User Name</th>
<th>Position</th>
<th>Phone Number</th>
<th>Supervisor Name</th>
<th>New App.</th>
<th>CORP</th>
<th>Renewal</th>
<th>All Product</th>
<th>User Admin.</th>
<th>Supervisor</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>david_wong</td>
<td>WONG David</td>
<td></td>
<td>22089423</td>
<td></td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Active</td>
</tr>
<tr>
<td>susan_cheung</td>
<td>CHEUNG Susan</td>
<td></td>
<td>22089443</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Active</td>
</tr>
<tr>
<td>kenny_liu</td>
<td>LIU Kenny</td>
<td></td>
<td>22089425</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Active</td>
</tr>
</tbody>
</table>
User Profiles Maintenance

- User profile details

User Account Detail

View Details

- Email Address of Authorized User: prs.kenny.liu@gmail.com
- Organization Name: ABC COMPANY LIMITED
- Business Registration Certificate Number: 00671890-000
- Authorized User Name: LIU Kenny
- Position: Contact Phone Number: 22099425
- Company Address: A 4/F ELK A DR BUILDING 382 NACKENS 10667 KOWLOON

Active Status: Active

Enable/Disabled the user account

Privileges Control

Supervisor: CHEUNG Susan

Product Information

- Application Submission:
  - New Product Registration: Allow
  - Change of Registered Particulars: Allow
  - Application: Deny
  - Renewal of Registration: Allow

- Senior Privileges:
  - User Administrator: Yes
  - Access All products: Yes
  - Supervisor: Yes

Setup the user application submission function

Setup the user management & product access right

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User Profiles Maintenance

- Grant product access right

Add Access Right

- All Products Add
- Application ID/PL No./PR No./HK No. Add
- User Account: WONG David prs.david.wong@gmail.com Add

<table>
<thead>
<tr>
<th>Application ID</th>
<th>PL No.</th>
<th>PR No.</th>
<th>HK No.</th>
<th>Name of Product</th>
<th>User Account</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NASUCAP DECONGESTANT</td>
<td>kenny_liu <a href="mailto:prs.kenny.liu@gmail.com">prs.kenny.liu@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>UNI-MENADOL</td>
<td>kenny_liu <a href="mailto:prs.kenny.liu@gmail.com">prs.kenny.liu@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PHENTOIN (MAMELK)</td>
<td>kenny_liu <a href="mailto:prs.kenny.liu@gmail.com">prs.kenny.liu@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL0874/2005</td>
<td>PR9724/2005</td>
<td>HK53868</td>
<td>MARKIST</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL0873/2005</td>
<td>PR9725/2005</td>
<td>HK53869</td>
<td>SUITANI</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL0872/2005</td>
<td>PR9726/2005</td>
<td>HK53870</td>
<td>RAMATIN</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL0958/2009</td>
<td>PR9702/2009</td>
<td>HK60174</td>
<td>PRILIGY</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL0555/2009</td>
<td>PR9703/2009</td>
<td>HK60175</td>
<td>PRILIGY</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL0426/2010</td>
<td>PR9425/2010</td>
<td>HK60186</td>
<td>LEVOXA</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
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<td>PR9426/2010</td>
<td>HK60187</td>
<td>LEVOXA</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
<tr>
<td></td>
<td>PL1445/2007</td>
<td>PR1058/2008</td>
<td>HK60507</td>
<td>PROACTIV</td>
<td>david_wong <a href="mailto:prs.david.wong@gmail.com">prs.david.wong@gmail.com</a></td>
</tr>
</tbody>
</table>

Add Access Right to...

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

Grant product access for all active users

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User Profiles Maintenance

- Revoke/transfer product access right

Add Access Right

<table>
<thead>
<tr>
<th>Application ID</th>
<th>PL No.</th>
<th>PR No.</th>
<th>HK No.</th>
<th>Name of Product</th>
<th>User Account</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR1846/1845</td>
<td>HK26230</td>
<td></td>
<td></td>
<td>NASUCAP DECONGESTANT</td>
<td>kenny_liu</td>
</tr>
<tr>
<td>PR1140/2000</td>
<td>HK47301</td>
<td></td>
<td></td>
<td>PHENTOIN (HAMELIN)</td>
<td>kenny_liu</td>
</tr>
<tr>
<td>PR0732/1994</td>
<td>HK39239</td>
<td></td>
<td></td>
<td>UNIMENADOL</td>
<td>kenny_liu</td>
</tr>
</tbody>
</table>

Remove/Transfer
# User Roles

<table>
<thead>
<tr>
<th>Role</th>
<th>(A) Maintain User Profiles</th>
<th>(B) Maintain Access of Functions</th>
<th>(C) Maintain Access of Products</th>
<th>(D) Accessible Functions</th>
<th>(E) Accessible Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Admin</td>
<td>All users</td>
<td>All users</td>
<td>All users</td>
<td>All functions</td>
<td>All products</td>
</tr>
<tr>
<td>Supervisor (User)</td>
<td>No</td>
<td>No</td>
<td>Staff in his team</td>
<td>Function granted by Admin</td>
<td>Products granted by Admin</td>
</tr>
<tr>
<td>Staff (User)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Function granted by Admin</td>
<td>Products granted by Admin/supervisor</td>
</tr>
</tbody>
</table>
On-line Registration
Application for New Product
### File Upload Size Limitation

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

* PRS 2.0 system just supports to upload documents in **PDF format** only.
Initiate New Product Registration Application
New Application Page 1 – Product Basic Information

Guidance

New Product Registration

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

Module 1 Module 2 Module 3 Module 4 Module 5

PL No.: PR No.: HK No.: 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:
- 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
- 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

- Proposed Name of Product (English)*
- Proposed Name of Product (Chinese), if any:
- Names / Proposed Names Used In Other Places

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

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

No. of Component(s)* 1

Active Ingredient:

Component 11. * vitamin E

2. Please Select
3. Please Select
4. Please Select

1.0.1.3 Application Type: (please select one)*

- Human biological pharmaceutical product
- Human chemical pharmaceutical product
- Human vaccine

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

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

Component: Dose Form of product:*  
1. Tablet

1.0.3 Indication, Route(s) of Administration and Dosage

Indication:*  
Please refer to pack insert

Dosage:*  
Please refer to pack insert

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. 3 x 12 Tablets

Component:  
1. Primary Container direct contact with the product:  
Packaging material (eg. Glass, plastic, aluminium, etc.): sellotape  
Type of container (eg. box, bottle, sachet):  
Proposed shelf life (months): 36  
Proposed storage conditions: Temperature (°C) and Relative Humidity (RH):  
Do not store over 25°C

Stability Report*  
Duration (Month): 36  
Start date: 01.04.2010

In-Use Stability Report  
No. of File(s): 1

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New Application Page 3 – Certificate Holder Information

### New Product Registration

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

#### 1.0.5 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 KIU LOUNG  
   - **Area:** KOV/LOON  
c. **BRC Number:** 00671890-000  
   - **Phone Number:** (852)  
   - **Fax Number:** (852)  
d. **Contact Person for this Application:**  
   - **Mr. Lee**  
   - **Phone No.:** 22099543  
   - **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:** Mandy Law  
b. **Contact Person HK Telephone No.:** (852) 22099533  
   - **Position:** Pharm  
   - **Email:** Mandy.law@abc.com
   - **(24 hours)**

---

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New Application Page 4 – Manufacturer Information

Guidance

New Product Registration

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.: 

Module 1 Module 2 Module 3 Module 4 Module 5

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

1.0.7 Manufacturers

1.0.7.1.a Manufacturer appeared on product label of finished product

Place/Region*: 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


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

Manufacturer Licence Number*: UK 8065 InsP GMP


1.0.7.1.b All Other Manufacturer(s) Involved in the preparation of the product/substrate

☐ Yes ☐ No

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

Guidance

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**New Application Page 5 – Ingredient Information**

**New Product Registration**

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Proposed Name of Product (English): VITAMIN E TABLETS

**1.0.8 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Name of Active Ingredient(s)*</th>
<th>Quantity</th>
<th>Strength Value*</th>
<th>Unit (Strength Unit)*</th>
<th>Dose Value*</th>
<th>Dose Unit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>vitamin E</td>
<td>200</td>
<td>mg</td>
<td>1</td>
<td>dose</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information

This component does not have any excipient.

<table>
<thead>
<tr>
<th>Excipient*</th>
<th>Quantity</th>
<th>Strength Value*</th>
<th>Unit (Strength Unit)*</th>
<th>Dose Value*</th>
<th>Dose Unit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>water</td>
<td>150</td>
<td>mg</td>
<td>1</td>
<td>dose</td>
<td></td>
</tr>
</tbody>
</table>

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

* @ No ☐ Yes

1.0.8.3 Does the product contain human plasma-derived ingredients?

* @ No ☐ Yes, please fill in the following.
## New Product Registration

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 to the files to Drug Office via CD/DVD if necessary.

### Proposed Name of Product (English): VITAMIN E TABLETS

#### 1.0.0 Annexed Documents/Information/sample

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

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New Application Page 8 – Annexed Documents

1.1.0 Annexed Documents/Information/samples

<table>
<thead>
<tr>
<th>Proposed Name of Product (English): VITAMIN E TABLETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PL #:</td>
</tr>
<tr>
<td>PR #:</td>
</tr>
<tr>
<td>HK #:</td>
</tr>
</tbody>
</table>

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

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

3. Evidence of the source of animals, the nature of the animal tissues used in manufacturing and production processes, 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)

4. 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 minimizing the risk of communicable diseases as stated in Guidance Notes on Registration of Pharmaceutical products. (Reference for 1.0.8 of Page 5)

5. 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)

6. 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)

7. 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)

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

9. Free sale certificate of the product issued by the country of origin (Manual submission of original or certified true copy 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)

10. Clinical and non-clinical overviews and overall summary

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

   (For NCE) List showing free sale certificate in other market(s)

   (For NCE) No of File(s): 0

   (For NCE) No of File(s): 0

   (For NCE) No of File(s): 0

   (For NCE) No of File(s): 0

   (For NCE) No of File(s): 0

   (For NCE) No of File(s): 0
New Application Page 9 – Annexed Documents

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

27.* (For Biological and Vaccine products)
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 1.0.5 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 5)

29.* (For NCE)
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 2)

30.* Method of analysis (detailed method of analysis for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)

31.* Certificate of analysis (showing results for all tests per finished product specifications) (Reference for 1.0.8 of Page 5)

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)

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

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).

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

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.

37. For capsule dose forms, please provide documentary evidence to substantiate the quality of gelatin / vacant capsule in compliance with pharmacopoeial standard.

38. Bioequivalence (BE) data for anti-epileptic drugs.

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

40. Others, please specify

Additional information of Product

Disclaimer: The information provided by the Department of Health ("DH") of the Government of the Hong Kong Special Administrative Region on this material ("the DH's information") is for reference only and is subject to change during the maintenance of PRS 2.0 project.
New Application Module 2 – Quality Overall Summary

New Product Registration

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

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<th>Module 1</th>
<th>Module 2</th>
<th>Module 3</th>
<th>Module 4</th>
<th>Module 5</th>
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<td>2.2 Introduction to Summary</td>
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<td>2.3 Quality Overall Summary</td>
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<td>2.3.5 Drug Substance (name, manufacturer)</td>
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New Application Module 3 – Quality

New Product Registration

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

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<th>Module 4</th>
<th>Module 5</th>
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| 3.1 Module 3 Table of Contents
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| 3.2.5.1 General Information
Remarks: |
| 3.2.5.1.1 Nomenclature
Remarks: |
| 3.2.5.1.2 Structure
Remarks: |
| 3.2.5.1.3 General Properties
Remarks: |
| 3.2.5.2.1 Manufacturer(s)
Remarks: |
| 3.2.5.2.2 Description of Manufacturing Process and Process Controls
Remarks: |
| 3.2.5.2.3 Control of Materials
Remarks: |
| 3.2.5.2.4 Controls of Critical Steps and Intermediates
Remarks: |

Disclaimer: The information provided by the Department of Health ("DH") of the Government of the Hong Kong Special Administrative Region on this material ("the DH's information") is for reference only and is subject to change during the maintenance of PRS 2.0 project.
New Application Module 4 – Non-clinical Study Reports

New Product Registration

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

4.1 Module 4 Table of Contents
Remarks:

4.2.1.1 Primary Pharmacodynamics
Remarks:

4.2.1.2 Secondary Pharmacodynamics
Remarks:

4.2.1.3 Safety Pharmacology
Remarks:

4.2.1.4 Pharmacodynamic Drug Interactions
Remarks:

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

4.2.2.2 Absorption
Remarks:

4.2.2.3 Distribution
Remarks:

4.2.2.4 Metabolism
Remarks:

Disclaimer: The information provided by the Department of Health (“DH”) of the Government of the Hong Kong Special Administrative Region on this material (“the DH’s information”) is for reference only and is subject to change during the maintenance of PRS 2.0 project.
## New Application Module 5 – Clinical Study Reports

### New Product Registration

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.

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<td>5.2.1 Bioavailability (BA) Study Reports</td>
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<tr>
<td>5.2.2 Comparative BA and Bioequivalence (BE) Study Reports</td>
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<td>5.2.3 In Vitro - In Vivo Correlation Study Reports</td>
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<tr>
<td>5.2.4 Reports of Bioanalytical and Analytical Methods for Human Studies</td>
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<td>5.2.5 Plasma Protein Binding Study Reports and Related Information</td>
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<td>5.2.6 Reports of Hepatic Metabolism and Drug Interaction Studies</td>
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<td>5.2.7 Reports of Studies Using Other Human Biomaterials</td>
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</table>
New Application – Application Form

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:
VITAMIN E TABLETS (*Delete as appropriate)

Dose Form / Package Size(s):

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<th>Component 1</th>
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</thead>
<tbody>
<tr>
<td>Package Size(s):</td>
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<tr>
<td>Tablet</td>
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<tr>
<td>Product Pack Size: 3 x 12 tablets</td>
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Detailed Qualitative and Quantitative Composition:

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<td>Name of Active Ingredient(s):</td>
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<td>vitamin E</td>
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<td>Unit (Strength Unit):</td>
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<tr>
<td>Reference / Monograph Standard</td>
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<tr>
<td>EP</td>
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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
New Application – Application Form

Business Address of Applicant: CHA KWO LING, KOWLOON
Tel No.: 22999453 (Contact Person: Mr. Lee)
Facsimile No.: 22999454 (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: FERRINO 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

<table>
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<th>Date Received</th>
<th>Legal Classification</th>
<th>Fees Paid</th>
<th>Registration Approved</th>
<th>Certificate Issued</th>
<th>Registration</th>
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</thead>
</table>

2015 copyright | Important notices | Last Revision Date: 10 SEP 2015 | Version: 1.0.28
Acknowledgement of New Registration Application Submission

Application ID: ANP20159000235
Submission Date: 2015.09.24

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

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

For enquiries, please quote 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)

Tel: (852) 2319 8458
Email: prs2_info@dh.gov.hk
**New Product Registration**

**New Submission**

Initiate New Product Registration

**Action Required**

<table>
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<th>Application Date</th>
<th>Application ID</th>
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<th>Application Status</th>
<th>Status Date</th>
<th>Payment Status</th>
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New Registration Application Fee Payment

**New Submission**

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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.pdf
- **Attachment(s):**
  1. Go To Application Payment:

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# New Registration Application Fee Payment

## New Application Payment

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## New Application Certificate Payment

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

---

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New Registration Application - Payment Gateway

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

1. Please take note of the transaction reference number or PRINT this page.
2. 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.
3. 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.
4. 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.
5. 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.
Result of New Registration Application Fee Payment

New Product Registration

Payment Reference No.: DHPRS-20150251504-90006
EGIS Reference No.: A20150251170473
Payment Method: MasterCard
Type of Payment: Application Fee
Transaction Time: 25.09.2015 15:07:04

Application Received Date: 25.09.2015 11:45
Reference No.: ANP20150000002
PR No.: PR0385/2015
Product Name: 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 5:00 pm on Monday)
(Closed on Saturdays, Sundays & Public Holidays)
Tel: (852) 23198458
Email: pr2_info@dh.gov.hk

2015 copyright | Important notices | Last Revision Date: | Version:
Result of New Registration Application Fee Payment

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<th>Payment Date</th>
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Payment Reference No: DHPRS-201509251504-90006
付款編號:

EGIS Reference No: A201509251170473
EGIS編號:

Payment Method: MasterCard
付款方法:

Payment Amount: HK$1,100.00
付款金額:

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# New Registration Application Reply Clarification

## New Product Registration

### New Submission

**Initiate New Product Registration**

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New Registration Application Reply Clarification

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
New Registration Application Reply Clarification

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:  Place: CANADA

Name:  Place: Please Select

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

No. of Component(s)*  1

Active Ingredient

Active Ingredient Appeared on Product Label

Component 1:  vitamin E

Component 2:

Component 3:

Component 4:

1.0.1.3 Application Type: (please select one)*

○ Human biological pharmaceutical product

○ Human chemical pharmaceutical product

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New Registration Application Reply Clarification

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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

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

d. Contact Person for this Application
   - Name: Mr. Lee
   - Phone No.: 22099423

   - Email: thomas.lee@abc.com
   - Fax No.: 22099424

   - 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)
New Registration Application Reply Clarification

### Application History

#### Proposed Name of Product (English): VITAMIN E TABLETS

**PL No.: PL0420/2015**

**PR No.: PR0380/2015**

**HK No.:**

#### Applications Require Action

**Module 1**

**Module 2**

**Module 3**

**Module 4**

**Module 5**

**Page 1**

**Page 2**

**Page 3**

**Page 4**

**Page 5**

**Page 6**

**Page 7**

**Page 8**

**Page 9**

**Application Form**

---

**1.0.7 Manufacturers**

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

<table>
<thead>
<tr>
<th>Place/Region</th>
<th>Name of Manufacturer</th>
<th>Chinese Name of Manufacturer</th>
<th>Address</th>
<th>Chinese Address</th>
<th>GMP Certificate</th>
<th>GMP Certificate Expiry Date</th>
<th>Manufacturer Licence</th>
<th>Manufacturer Licence Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNITED KINGDOM</td>
<td>LIVE SOURCE CO., LTD</td>
<td></td>
<td>332 PLACE PARK RD, YUKA CITY, UK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Manufacturing activities/role**

- Batch Release Manufacturer
- Manufacturer of Dosage Form
- Office
- Other
- Packaging Manufacturer
- QC Testing
- Stability testing

---

**Comments for page Page 4**

**Section 1.0.7.1a**

**Section 1.0.7.1b**

**Section 1.0.7.1c**

---

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

- Yes
- No

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

---

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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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Name of Active Ingredient(s)</th>
<th>Quantity</th>
<th>Unit (Strength Unit)</th>
<th>Strength Value</th>
<th>Dose Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 vitamin E</td>
<td>200</td>
<td>mg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional Information

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

- No
- Yes

1.0.8.3 Does the product contain human plasma-derived ingredients?

- No
- Yes, please fill in the following.
### Applications Require Action

#### 1.0.9 Other Marketing Authorization Applications

1. **1.0.9.1** Is there another country/region where an authorization is granted for the same product?
   - **No**
   - **Yes**

2. **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?
   - **No**
   - **Yes**

3. **1.0.9.3** Is there another countries/regions where an authorization was refused / suspended / revoked by the competent authorities for the same product?
   - **No**
   - **Yes**

4. **1.0.9.4** Please list marketing authorization application(s) for the same product in other country/region here:

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Status</th>
<th>Date of Authorization</th>
<th>Product Name</th>
<th>Free Sale Certificate (FSC) Attached</th>
<th>Authorization Number</th>
<th>Expire Date of FSC</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.A.</td>
<td>Approved</td>
<td>20.03.2014</td>
<td>VITAMIN E</td>
<td><img src="#" alt="Upload" /></td>
<td>USA 2014-038</td>
<td><img src="#" alt="Remove" /></td>
</tr>
<tr>
<td>CANADA</td>
<td>Approved</td>
<td>01.12.2014</td>
<td>GLOD VITAMIN</td>
<td><img src="#" alt="Upload" /></td>
<td>CDN 2014-684</td>
<td><img src="#" alt="Remove" /></td>
</tr>
</tbody>
</table>

---

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1. Prototype sales pack/outer and inner container labels (Reference for 1.0.4 of Page 2)
2. Package insert (Reference for 1.0.3 of Page 2)
3. For pharmaceutical substance, please provide a sample for Inspection. (Reference for 1.0.1.3 of Page 1)
4. Photo or scanned image of the product samples
5. Photo or scanned image of extra component(s) included in the sales pack apart from the drug product and package insert, e.g., measuring cups/spoons, syringe, connectors, alcohol swabs, etc. (if applicable) (Reference for 1.0.4 of Page 2)
6. Information on the overseas legal status of the product.
7. Copy of business registration certificate. (Reference for 1.0.6.1 of Page 3)
8. Authorization letter from the applicant authorizing a person/company to deal with the communication matters related to this application (if applicable)
9. Authorization letter from the manufacturer/marketing authorization holder authorizing the applicant to apply registration for its product.
10. An undertaking, given by the applicant to provide, at any stage of registration, any information and/or documents relating to the product/substance upon request within the prescribed timeframe.
11. Documentary evidence showing the compliance with GAP by the labeled manufacturer and the manufacturer to be shown on the label issued by competent authorities. (Manual submission of certified true copy(ies) is required). (Reference for 1.0.7 of Page 4)
12. An undertaking, given by the manufacturer(s) of the product/substance, to permit the premises where it is to be manufactured, and the operations carried on or to be carried on in the course of manufacturing it, to be inspected by or on behalf of the Pharmacy and Poisons (Regulation of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medical Test) Committee.
13. A declaration, given by the manufacturer of the product or substance, that, in relation to the manufacture of the product/substance any requirements imposed by or under the law of the country in which it is or is to be manufactured have been or will be complied with.
14. Flow chart indicating sequence and activities of the different sites involved in the manufacturing process, including testing site. (Reference for 1.0.7 of Page 4)
Due to security reason, your previous inputted sensitive data will not be shown.
You can re-input the sensitive data by un-tick 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)

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

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

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

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

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

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

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

23. *Free sale certificate of the product issued by the country of origin (Manual submission of original or certified true copy is required). (Reference for 1.0.9 of Page 6)

(F. N.E.)

Official evidence of registration approval of the product (e.g. original or certified true copies of free sale certificates) in two or more of the following countries: Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA (Reference for 1.0.9-4 of Page 6)

24. * (F. N.E.)

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

Evidence of the source of animals and/or human origin materials

Section 1.1.0-P2
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New Registration Application Reply Clarification

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:**
VITAMIN E TABLETS

**Dose Form / Package Size(s):**
- Dose Form
- Component 1
  - Package Size(s):
    - Product Pack Size: 3 x 12 tablets

**Detailed Qualitative and Quantitative Composition:**

<table>
<thead>
<tr>
<th>Component 1</th>
<th>Name of Active Ingredient(s)</th>
<th>Quantity (Strength Value)</th>
<th>Unit (Strength Unit)</th>
<th>Dose Value</th>
<th>Dose Unit</th>
<th>Reference / Monograph Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>vitamin E</td>
<td>200</td>
<td>mg</td>
<td>1</td>
<td>dose</td>
<td>EP</td>
</tr>
</tbody>
</table>

**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.:**
00571890-000

**In What Capacity the Applicant Makes This Application:**
Manufacturer

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New Registration Application Reply Clarification

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

For Office Use Only

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Legal Classification</th>
<th>Fees Paid</th>
<th>Registration Approved</th>
<th>Certificate Issued</th>
<th>Registration</th>
</tr>
</thead>
</table>

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Acknowledgement of New Registration Application Reply Clarification

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 8450

Email: pr2_info@dh.gov.hk
### New Product Registration

#### New Submission
- **Initiate New Product Registration**

#### Action Required
<table>
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<tr>
<th>Application Date</th>
<th>Application ID</th>
<th>PL No.</th>
<th>PR No.</th>
<th>Proposed Name of Product (English)</th>
<th>No. of submissions</th>
<th>Application Status</th>
<th>Status Date</th>
<th>Payment Status</th>
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<tbody>
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</table>

#### Not Submitted
<table>
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<tr>
<th>Application Date</th>
<th>Application ID</th>
<th>Proposed Name of Product (English)</th>
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<tbody>
<tr>
<td>25.09.2015</td>
<td>ANP20150000003</td>
<td>XWATER</td>
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#### Application Submitted
<table>
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<th>PR No.</th>
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<th>No. of submission</th>
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<th>Payment Status</th>
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### New Product Registration

#### New Submission

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<th>PR No.</th>
<th>Proposed Name of Product (English)</th>
<th>No. of submission</th>
<th>Application Status</th>
<th>Status Date</th>
<th>Payment Status</th>
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#### Not Submitted

<table>
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<tr>
<th>Latest Draft Date</th>
<th>Application ID</th>
<th>Proposed Name of Product (English)</th>
<th>Application Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.09.2015</td>
<td>ANP20159000003</td>
<td>X WATER</td>
<td>Pending</td>
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</tbody>
</table>

#### Application Submitted

<table>
<thead>
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<th>Application ID</th>
<th>PL No.</th>
<th>PR No.</th>
<th>Proposed Name of Product (English)</th>
<th>No. of submission</th>
<th>Application Status</th>
<th>Status Date</th>
<th>Payment Status</th>
</tr>
</thead>
</table>
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): 
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 newreg@pharaffirm.hk 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

NOTIFICATION OF PAYMENT
繳費通知書

Date 日期: 25.09.2015

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:

<table>
<thead>
<tr>
<th>Certificate(s) of Product Registration</th>
<th>Number</th>
<th>Total Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>營業製品註冊證明書 (HK$1,370)</td>
<td>1</td>
<td>HK$1,370</td>
</tr>
</tbody>
</table>

Ref. 檔號: PR0386/2015
New Registration Application Certificate Fee Payment

New Application Payment

New Application Certificate Payment

Certificate Collection: Received By Post

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New Registration Application Certificate Fee Payment

Please select the payment method:

<table>
<thead>
<tr>
<th>Type of Service</th>
<th>DH Drug Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transaction Date</td>
<td>25-09-2015</td>
</tr>
<tr>
<td>Transaction Reference Number</td>
<td>DHPRS-201509252137-90008</td>
</tr>
<tr>
<td>Total Amount</td>
<td>HK$ 1,370.00</td>
</tr>
<tr>
<td>Payment Method</td>
<td>VISA, MasterCard, PPS</td>
</tr>
</tbody>
</table>

1. Please take note of the transaction reference number or PRINT this page.
2. 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.
3. 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.
4. 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.
5. 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 New Registration Application Certificate Fee Payment

New Product Registration

Payment Reference No.: DHPRS-201509252137-90008
EGIS Reference No.: A20150925124443
Payment Method: VISA
Type of Payment: Certificate Fee
Delivery Method: Received By Post

Application Received Date | Reference No. | PR No. | Product Name
-------------------------------|---------------|--------|-----------------|
25.09.2015 11:45           | ANP201509000002 | 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
Print Receipt

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## Result of New Registration Application Certificate Fee payment

<table>
<thead>
<tr>
<th>Name of Company</th>
<th>Payment Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC COMPANY LIMITED</td>
<td>25.9.2015</td>
</tr>
</tbody>
</table>

**Payment Reference No:** DHPRS-201509252137-90008  
**Payment Method:** VISA  
**Payment Amount:** HK$1,370.00

---

### Certificate(s) Collection Method

Please tick your preferred collection method:

- [X] I would like to collect the Certificate(s) by post;  
  - 我/我等欲以郵遞方式領取證明書

Or

- [ ] I 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/我等欲在繳交費用後最少5個工作天起於上述地址領取證明書

---

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### Payment History of New Registration Application

#### New Product Registration

<table>
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<th>Name of Product</th>
<th>Payment Date</th>
<th>Amount (HK$)</th>
<th>Payment Ref No.</th>
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<tbody>
<tr>
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<td>VITAMIN E TABLETS</td>
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<td>DHPR2-20150925137-00001</td>
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<tr>
<td>PR0862015</td>
<td>VITAMIN E TABLETS</td>
<td>25.09.2015</td>
<td>Application Fee</td>
<td>DHPR2-201509251904-00001</td>
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</tbody>
</table>

#### Change of Registered Particulars Application

<table>
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<th>Payment Date</th>
<th>Amount (HK$)</th>
<th>Payment Ref No.</th>
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<tbody>
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<td>HK47391</td>
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<td>155.0</td>
<td>DHPR2-201509251525-90007</td>
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#### Renewal of Registration

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<td>HK53870</td>
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<td>25.09.2015</td>
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<td>DHPR2-201509252021-900024</td>
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New Registration Application Status Monitoring

### New Product Registration

#### New Submission

**Initiate New Product Registration**

<table>
<thead>
<tr>
<th>Action Required</th>
<th>Application Date</th>
<th>Application ID</th>
<th>PL No.</th>
<th>PR No.</th>
<th>Proposed Name of Product (English)</th>
<th>No. of submission</th>
<th>Application Status</th>
<th>Status Date</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
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<td>25.09.2015</td>
<td>NIP20159000003</td>
<td></td>
<td></td>
<td>X WATER</td>
<td></td>
<td>Pending</td>
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<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Not Submitted</th>
<th>Latest Draft Date</th>
<th>Application ID</th>
<th>Proposed Name of Product (English)</th>
<th>No. of submission</th>
<th>Application Status</th>
<th>Status Date</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25.09.2015</td>
<td>ANP20159000002</td>
<td>VITAMIN E TABLETS</td>
<td>2</td>
<td>Issue Certificate</td>
<td>25.08.2015</td>
<td>Yes</td>
</tr>
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</table>

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New Registration Application Withdrawal

You are login as WONG David
ABC COMPANY LIMITED
Login date and time
25.09.2015 08 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

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New Registration Application Withdrawal

Date of Withdrawal Request: 25.09.2015
Reason(s) of Withdrawal: No need to application

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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
On-line Application for Change of Registered Particulars
Initiate New CORP Application

Change of Registered Particulars (CORP) Application

New Submission

Initiate New CORP Application

Action Required

Not Submitted

Application Submitted

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Initiate New CORP Application

- Step 1 – Select products & change categories

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

<table>
<thead>
<tr>
<th>Particulars Proposed to Change</th>
<th>Change Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ 1 Specification</td>
<td></td>
</tr>
<tr>
<td>+ 2 Label</td>
<td></td>
</tr>
<tr>
<td>+ 2.1 Change in label</td>
<td>change label design</td>
</tr>
<tr>
<td>+ 3 Package Insert</td>
<td></td>
</tr>
<tr>
<td>+ 4 Manufacturer</td>
<td></td>
</tr>
<tr>
<td>+ 5 Registration Certificate Holder</td>
<td></td>
</tr>
<tr>
<td>+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)</td>
<td></td>
</tr>
<tr>
<td>+ 7 Excipients</td>
<td></td>
</tr>
<tr>
<td>+ 8 Indication / Dosage / Route of Administration</td>
<td></td>
</tr>
<tr>
<td>+ 9 Other</td>
<td></td>
</tr>
</tbody>
</table>
## Initiate New CORP Application

- **Step 2 – Upload supporting document(s)**

### Change of Registered Particulars (CORP) Application

**Step 2: Uploading Supporting Documents**

<table>
<thead>
<tr>
<th>#</th>
<th>HK No</th>
<th>Product Name</th>
<th>Proposed Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HK26230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>Expected Date: 31.01.2016</td>
</tr>
</tbody>
</table>

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

### 2 Label

#### 2.1 Change in label

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

<table>
<thead>
<tr>
<th>Remark</th>
<th>Documents File Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>new design with highlight changed</td>
<td>Upload Label_highlighted_copy.pdf</td>
</tr>
</tbody>
</table>

   ![Label change interface screenshot](image)
Initiate New CORP Application

- Step 3 – Change product particulars
### Initiate New CORP Application

- Review application summary

<table>
<thead>
<tr>
<th>#</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Proposed Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HK28230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>31.01.2018</td>
</tr>
</tbody>
</table>

### Change Category:

- **Particulars Proposed to Change**
  - 2.1 Change in label
    - Change Reason: change label design

### Supporting Documents:

- **Label**
  - 2.1 Change in label
    - Proposed label with the change(s) underlined or highlighted *
    - Remark: new design with highlight changed
    - Documents File Name: Label_highlighted copy.pdf

---

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Initiate New CORP Application

- Acknowledgement of CORP application submission

Change of Registered Particulars (CORP) Application

Acknowledgement

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

Application submitted should be subjected to our final approval.

For enquiries, please call us quoting this reference number.

General enquiries:

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

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

Application Received Date: 25.09.2015

Product Selected:

<table>
<thead>
<tr>
<th>HK No.</th>
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<th>PL No.</th>
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<th>Application Reference No.</th>
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Change Category:

2.1 Change in label

Supporting Documents:

2 Label

2.1 Change in label

Proposed label with the change(s) underlined or highlighted

Remark: new design with highlight changed

Documents: File Name

Label: highlighted copy.pdf
### Initiate New CORP Application

- CORP application status

#### Change of Registered Particulars (CORP) Application

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<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
<th>Payment Status</th>
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<td>Application Submitted</td>
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<td>1</td>
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<td>CORP-HK26230-201550011</td>
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<td>Application Status</td>
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<td>- Not Submitted</td>
<td>- Application Submitted</td>
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<tr>
<td>+ Submission of Other Post-registration Supplement</td>
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<td>+ Interview</td>
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<td>+ Request to Cancel Product Registration</td>
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<td>+ Payment</td>
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# Change of Registered Particulars (CORP) Application

## New Submission

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<th>Product Name</th>
<th>Change Categories</th>
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## Not Submitted

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<td>CORP-HKS370-201550012</td>
<td>HKS370</td>
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## Application Submitted

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<th>Change Categories</th>
<th>Status</th>
<th>Payment Status</th>
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<td>CORP-HK2620-201550013</td>
<td>CORP-HK47301-201550015</td>
<td>HK47301</td>
<td>PHENYTOIN INJ 250MG/5ML (HAMELIN)</td>
<td>5</td>
<td>Certificate Fee Paid</td>
<td>Certificate Fee Paid</td>
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<td>HK47301</td>
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<td>CORP-HK3696-201550016</td>
<td>HK3696</td>
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<td>Certificate Fee Paid</td>
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<td>Certificate Fee Paid</td>
<td>Certificate Fee Paid</td>
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<td>Certificate Fee Paid</td>
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<td>CORP-HK3696-201550016</td>
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<td>MARKIST OINTMENT</td>
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<td>Certificate Fee Paid</td>
<td>Certificate Fee Paid</td>
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<td>8</td>
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<td>HK3696</td>
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<td>Certificate Fee Paid</td>
<td>Certificate Fee Paid</td>
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<td>HK3696</td>
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<td>Certificate Fee Paid</td>
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<td>MARKIST OINTMENT</td>
<td>5</td>
<td>Certificate Fee Paid</td>
<td>Certificate Fee Paid</td>
</tr>
</tbody>
</table>

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Dear Sir/Madam,

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.

1. NASUCAP DECONGESTANT CAP (HK-26230)

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

Yours faithfully,

(Christy WONG)
Pharmacist
CORP Application Reply Clarification

Category 2 - Label Clarification Letter Sent

<table>
<thead>
<tr>
<th>Particulars Proposed to Change</th>
<th>Recall Required</th>
<th>Cert. Reprint Required</th>
<th>Evaluation Comment and Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Label</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Change in label</td>
<td>Yes</td>
<td>Not Required</td>
<td></td>
</tr>
</tbody>
</table>

Change Reason: change label design

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

Documents:
- Label highlight copy.pdf
  - new design with highlight changed
  - label design out date

Change Categories Allowed for Amendment:

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## CORP Application Reply Clarification

### Change of Registered Particulars (CORP) Application

**Step 1: Selection of Products and Change Categories**

- **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:**

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK26230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>change label design</td>
</tr>
</tbody>
</table>

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

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

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

**Product Selected:**
<table>
<thead>
<tr>
<th>#</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Proposed Effective Date</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>HK26230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>31.01.2016</td>
</tr>
</tbody>
</table>

**Change Category:**
- **Particulars Proposed to Change**
  - 2.1 Change in label
    - Change Reason: change label design

**Supporting Documents:**

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

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<tr>
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<td>Label highlighted copy.pdf</td>
</tr>
</tbody>
</table>
**Change of Registered Particulars (CORP) Application**

**Acknowledgement**

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

Application submitted should be subjected to our final approval.

For enquiries, please call us quoting this reference number.

**General enquiries:**

- **Office Hours:** Monday to Friday
  - 9:00 am - 1:00 pm
  - 2:00 pm - 5:45 pm
  - (up to 6:00 pm on Monday)
- **(Closed on Saturdays, Sundays & Public Holidays)**
- **Tel:** (852) 2319 8458
- **Email:** prs2_info@dh.gov.hk

**Application Received Date:** 25/09/2015

**Product Selected:**

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<th>HK No.</th>
<th>PR No.</th>
<th>PL No.</th>
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**Change Category:**

- **Particulars Proposed to Change**
  - 2.1 Change in label
  - Change Reason: change label design

**Supporting Documents:**

2 Label

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

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## Change of Registered Particulars (CORP) Application

### New Submission

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### Online Notification

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

---

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Approved CORP Application: Change Of Implementation Date

Change of Registered Particulars (CORP) Application

New Submission

Initiate New CORP Application

Action Required

Online Notification

My Product Search

+ New Registration

Not Submitted

Application Submitted

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

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© 2015 HP Confidential

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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,

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**Approved CORP Application: Change Of Implementation Date**

### CORP Application Status

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**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
  - Satisfactory

**Supporting Documents:**

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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
- Advertisement Required
- Not Submitted
- Application Submitted
+ Renewal of Registration
+ Submission of Other Post-registration Supplement
+ Interview
+ Request to Cancel Product Registration
+ Payment
Application History
+ User Profile
+ System

**Approved CORP Application: Change Of Implementation Date**

### Change of Registered Particulars (CORP) Application

#### Step 1: Selection of Products and Change Categories

- **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

- **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.

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<td>+ 4 Manufacturer</td>
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<tr>
<td>+ 5 Registration Certificate Holder</td>
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<td>+ 6 Quantity of the Dose Form in Unit Package (i.e. Package Size)</td>
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<td>+ 7 Excipients</td>
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</tr>
<tr>
<td>+ 8 Indication / Dosage / Route of Administration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 9 Other</td>
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**Postpone to 01 June 2016 for market promotion**

01.06.2016
## Change of Registered Particulars (CORP) Application

**Step 2: Uploading Supporting Documents**

<table>
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<th>Application Type:</th>
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</thead>
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**Product Selected:**

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### Change Category and Supporting Documents

(Only relevant supporting documents will be processed)

#### 2 Label

**2.1 Change in label**

1. Proposed label with the change(s) underlined or highlighted:

   - **Remark:** new design with highlight changed
   - **Documents File Name:** label_highlighted_copy.pdf

---

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**Approved CORP Application: Change Of Implementation Date**

**Change of Registered Particulars (CORP) Application**

**Step 3: Change Product Particulars**

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

**Product Selected:**

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<td>Cat. 2: 01.06.2016</td>
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</table>

**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
- **Product Pack Size:** 3 x 12 unit
- **Prototype sales package:**
  - **Prototype package insert:**

**Component**

- **Primary Container (container that is in direct contact with the product):**
  - **Packaging Material (e.g. Glass):** Glass
  - **Type of container (e.g. box, bottle):** Bottle
- **Proposed shelf life (months):** 36
- **Proposed storage conditions:**
  - Temperature (°C) and Relative Humidity (RH)
- **Stability Report**
  - **Duration (Month):** 24
  - **Start Date:** 10.12.2012

**1.0.5 Legal Status**

- **Proposed Dispensing Classification:**
  - Subject to prescription
  - Not subject to prescription

---

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### Change of Registered Particulars (CORP) Application

**Application Summary**

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

**Product Selected:**

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**Supporting Documents:**

**2 Label**

**2.1 Change in label**

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

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Change Category:

Particulars Proposed to Change

2 Label

Supporting Documents:

2 Label

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### Change of Registered Particulars (CORP) Application

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## Change of Registered Particulars (CORP) Application

### New Submission

**Initiate New CORP Application**

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- **Application Status**
  - **New Submission**
  - **Not Submitted**
  - **Application Submitted**
  - **Withdraw application**
  - **Renewal of Registration**
  - **Submission of Other Post-registration Supplement**
  - **Interview**
  - **Request to Cancel Product Registration**
  - **Payment**

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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.”

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## Approved CORP Application: Change Of Implementation Date

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<tr>
<td>Product Name:</td>
<td>NASUCAP DECONGESTANT CAP</td>
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<td></td>
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<td></td>
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<td>25.09.2015</td>
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<td>Previous Approval Letter:</td>
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<td>COP-Approval-letter.pdf</td>
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<td>Application Type:</td>
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<tr>
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<td>Client Date:</td>
<td>25.09.2015</td>
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<td>Application Form Image:</td>
<td>No File Chosen</td>
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</tr>
<tr>
<td>Justification (Urgent Application):</td>
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</tbody>
</table>

### Category 2 - Label Approved

#### 2. Label

**Change Justification:** Postpone to 01 June 2016 for market promotion.

<table>
<thead>
<tr>
<th>Required</th>
<th>Not Required</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

#### 2.1 Change in label

**Effective Date:** 01.06.2016

**Evaluation Comment and Result:**

- OK, ACCEPTED
- Satisfactory
- Unsatisfactory
- Acknowledged
- Withdrawn

**Supporting Documents:**

#### 2.1 Change in label

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

<table>
<thead>
<tr>
<th>Documents File Name</th>
<th>Remark</th>
<th>Screening Comment</th>
<th>Evaluation Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label_highlighted_copy.pdf</td>
<td>new design with highlight changed</td>
<td>label design out date</td>
<td>OK</td>
</tr>
</tbody>
</table>

**Change Categories Allowed for Amendment:**

- Change Effective Date
- Close
CORP Application Withdrawal

Withdrawal of CORP Application

<table>
<thead>
<tr>
<th>Date</th>
<th>Ref. No.</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.09.2015</td>
<td>CORP-HK28230-20150911</td>
<td>HK28230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>2</td>
<td>Application Submitted</td>
</tr>
</tbody>
</table>

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### Withdrawal of CORP Application

<table>
<thead>
<tr>
<th>Received</th>
<th>Ref. No.</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.09.2015</td>
<td>CORP-HK01230-201500011</td>
<td>HK01230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>2</td>
<td>Application Submitted</td>
</tr>
</tbody>
</table>

**Reason(s) of Withdrawal:** Keep original design

- **Confirm to Withdraw**
**CORP Application: Certificate Signature Fee Payment**

### Change of Registered Particulars (CORP) Application

#### Action Required

<table>
<thead>
<tr>
<th>Action Required</th>
<th>Batch No.</th>
<th>Ref. No.</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online Notification</td>
<td>CORP-HK2630-201550011</td>
<td>CORP-HK2630-201550011</td>
<td>HC26230</td>
<td>NASCUCAP DECONGESTANT CAP</td>
<td>2</td>
<td>Application Under Screening</td>
<td>Not Necessary</td>
</tr>
<tr>
<td>My Product Search</td>
<td>CORP-HK2630-201550011</td>
<td>CORP-HK2630-201550011</td>
<td>HC26230</td>
<td>NASCUCAP DECONGESTANT CAP</td>
<td>2</td>
<td>Application Under Screening</td>
<td>Not Necessary</td>
</tr>
<tr>
<td>New Registration</td>
<td>CORP-HK2630-201550011</td>
<td>CORP-HK2630-201550011</td>
<td>HC26230</td>
<td>NASCUCAP DECONGESTANT CAP</td>
<td>2</td>
<td>Application Under Screening</td>
<td>Not Necessary</td>
</tr>
<tr>
<td>Change of Registered Particulars</td>
<td>CORP-HK5998-201550016</td>
<td>CORP-HK5998-201550016</td>
<td>HK5998</td>
<td>MARKIST OINTMENT</td>
<td>5</td>
<td>Application Approved</td>
<td>Pending for Certificate Fee</td>
</tr>
<tr>
<td>Initiate CORP Application</td>
<td>CORP-HK5998-201550016</td>
<td>CORP-HK5998-201550016</td>
<td>HK5998</td>
<td>MARKIST OINTMENT</td>
<td>5</td>
<td>Application Approved</td>
<td>Pending for Certificate Fee</td>
</tr>
<tr>
<td>Application Status</td>
<td>CORP-HK5998-201550016</td>
<td>CORP-HK5998-201550016</td>
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<td>MARKIST OINTMENT</td>
<td>5</td>
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<td>Pending for Certificate Fee</td>
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<tr>
<td>Withdraw Application</td>
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<td>Pending for Certificate Fee</td>
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<td>MARKIST OINTMENT</td>
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<td>Pending for Certificate Fee</td>
</tr>
<tr>
<td>Submission of Other Post-registration Supplement</td>
<td>CORP-HK5998-201550016</td>
<td>CORP-HK5998-201550016</td>
<td>HK5998</td>
<td>MARKIST OINTMENT</td>
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<td>Application Approved</td>
<td>Pending for Certificate Fee</td>
</tr>
<tr>
<td>Interview</td>
<td>CORP-HK5998-201550016</td>
<td>CORP-HK5998-201550016</td>
<td>HK5998</td>
<td>MARKIST OINTMENT</td>
<td>5</td>
<td>Application Approved</td>
<td>Pending for Certificate Fee</td>
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#### Not Submitted

<table>
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<th>Ref. No.</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request to Cancel Product Registration</td>
<td>CORP-HK5998-201550016</td>
<td>CORP-HK5998-201550016</td>
<td>HK5998</td>
<td>MARKIST OINTMENT</td>
<td>5</td>
<td>Application Approved</td>
<td>Pending for Certificate Fee</td>
</tr>
</tbody>
</table>

#### Application Submitted

<table>
<thead>
<tr>
<th>Action Required</th>
<th>Batch No.</th>
<th>Ref. No.</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment</td>
<td>CORP-HK2630-201550011</td>
<td>CORP-HK2630-201550011</td>
<td>HC26230</td>
<td>NASCUCAP DECONGESTANT CAP</td>
<td>2</td>
<td>Application Under Screening</td>
<td>Not Necessary</td>
</tr>
</tbody>
</table>

---

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Certificate Fee Notification

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

Dear Certificate Holder,

We want to inform you that the following application(s) have been submitted:

<table>
<thead>
<tr>
<th>Application Ref. No.</th>
<th>HK No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORP-HK26230-201550013</td>
<td>HK26230</td>
</tr>
<tr>
<td>CORP-HK39239-201550014</td>
<td>HK39239</td>
</tr>
<tr>
<td>CORP-HK47301-201550015</td>
<td>HK47301</td>
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<tr>
<td>CORP-HK53968-201550016</td>
<td>HK53968</td>
</tr>
<tr>
<td>CORP-HK53969-201550017</td>
<td>HK53969</td>
</tr>
<tr>
<td>CORP-HK53970-201550018</td>
<td>HK53970</td>
</tr>
<tr>
<td>CORP-HK60174-201550019</td>
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<td>CORP-HK60175-201550020</td>
<td>HK60175</td>
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<tr>
<td>CORP-HK60186-201550021</td>
<td>HK60186</td>
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<tr>
<td>CORP-HK60187-201550022</td>
<td>HK60187</td>
</tr>
<tr>
<td>CORP-HK60507-201550023</td>
<td>HK60507</td>
</tr>
</tbody>
</table>

This is to notify you to pay for the following application(s)/registration(s):

A. Payment Particulars

<table>
<thead>
<tr>
<th>Number</th>
<th>Total Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HK$1,705</td>
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</tbody>
</table>

Change(s) of Registered Particulars

<table>
<thead>
<tr>
<th>Ref. 檔號:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK26230, HK39239, HK47301, HK53968, HK53969, HK53970, HK60174, HK60175, HK60186, HK60187, HK60507</td>
</tr>
</tbody>
</table>

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### New Application Certificate Payment

<table>
<thead>
<tr>
<th>Application Received Date</th>
<th>PR No.</th>
<th>PL No.</th>
<th>Proposed Name of Product</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received By Post</td>
<td>Collect in Person in Drug Office</td>
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</table>

### CORP Updated Certificate Payment

<table>
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<tr>
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<th>Reference No.</th>
<th>HK No.</th>
<th>Name of Product</th>
<th>Change Categories</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received By Post</td>
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</tbody>
</table>

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© 2015 HP Confidential
 Disclaimer: The information provided by the Department of Health ("DH") of the Government of the Hong Kong Special Administrative Region on this material ("the DH's information") is for reference only and is subject to change during the maintenance of PRS 2.0 project.
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

1. Please take note of the transaction reference number or PRINT this page.
2. 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.
3. 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.
4. 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.
5. 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.
Result of CORP Application Certificate Payment

Change of Registered Particular

Payment Reference No.: DHPRS-20150025152590007
EGS Reference No.: MA01506252174286
Payment Method: PPS
Transaction Time: 25.08.2015 15:29:27
Delivery Method: Collect in Person in Drug Office
Certificate Collection Date: 01.12.2015

<table>
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<tr>
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<th>Reference No.</th>
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<th>Product Name</th>
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<th>Payment Status</th>
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<tbody>
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<td>CORP-HK601887-201550022</td>
<td>HK60187</td>
<td>LEVOXA TAB 250MG</td>
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<td>Certificate Fee Paid</td>
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<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK39370-201550018</td>
<td>HK39370</td>
<td>RANATIN OINTMENT</td>
<td>5</td>
<td>Certificate Fee Paid</td>
</tr>
<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK20230-201550013</td>
<td>HK20230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>5</td>
<td>Certificate Fee Paid</td>
</tr>
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<td>25.09.2015 08:03</td>
<td>CORP-HK05057-201550023</td>
<td>HK05057</td>
<td>PROACTIV SOLUTION KIT</td>
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<td>Certificate Fee Paid</td>
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<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK39239-201550014</td>
<td>HK39239</td>
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<td>5</td>
<td>Certificate Fee Paid</td>
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<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK20174-201550019</td>
<td>HK20174</td>
<td>PRILIGY TAB 30MG</td>
<td>5</td>
<td>Certificate Fee Paid</td>
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<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK47361-201550015</td>
<td>HK47361</td>
<td>FENERYTOIN INJ 250MG/ML (HAMELIN)</td>
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<td>Certificate Fee Paid</td>
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<td>25.09.2015 08:03</td>
<td>CORP-HK600175-201550020</td>
<td>HK600175</td>
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<td>5</td>
<td>Certificate Fee Paid</td>
</tr>
<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK38380-201550016</td>
<td>HK38380</td>
<td>MARKUT OINTMENT</td>
<td>5</td>
<td>Certificate Fee Paid</td>
</tr>
<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK38396-201550021</td>
<td>HK38396</td>
<td>LEVOXA TAB 500MG</td>
<td>5</td>
<td>Certificate Fee Paid</td>
</tr>
<tr>
<td>25.09.2015 08:03</td>
<td>CORP-HK38396-201550017</td>
<td>HK38396</td>
<td>SUXTANI OINTMENT</td>
<td>5</td>
<td>Certificate Fee Paid</td>
</tr>
</tbody>
</table>

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: hps2_info@dh.gov.hk

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CORN Application Certificate Payment

Name of Company
ABC COMPANY LIMITED

Payment Date
25.09.2015

Payment Reference No:
DHPRS-201509251525-90007

EGIS Reference No:
A201509252174288

Payment Method:
PPS

Payment Amount:
HK$1,705.00

For Office use

Company Seal

Certification Collection Method

Please tick your preferred collection method:

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

☐ 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/我們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

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## Change of Registered Particulars (CORP) Application

### New Submission

**Action Required**

<table>
<thead>
<tr>
<th>Received</th>
<th>Batch No.</th>
<th>Ref. No.</th>
<th>HK No.</th>
<th>Product Name</th>
<th>Change Categories</th>
<th>Status</th>
<th>Payment Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Submitted</td>
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<table>
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<tr>
<td>10</td>
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<tr>
<td>11</td>
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</tbody>
</table>

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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
On-line Application for Registered Product Renewal
Renewal Product via Online Channel

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

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
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</thead>
<tbody>
<tr>
<td>HK60175</td>
<td>PRILIGY TAB 60MG</td>
<td>24.11.2015</td>
<td>Batch Six</td>
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</tr>
<tr>
<td>HK60174</td>
<td>PRILIGY TAB 30MG</td>
<td>24.11.2015</td>
<td>Batch Six</td>
<td></td>
</tr>
<tr>
<td>HK53968</td>
<td>MARKIST OINTMENT</td>
<td>13.01.2016</td>
<td>Batch One</td>
<td></td>
</tr>
<tr>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
<td>13.01.2016</td>
<td>Batch One</td>
<td></td>
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<tr>
<td>HK53969</td>
<td>SUTANI OINTMENT</td>
<td>13.01.2016</td>
<td>Batch One</td>
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</table>

Payment Completed

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Payment Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60187</td>
<td>LEVOXCA TAB 250MG</td>
<td>02.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
</tbody>
</table>

Product Confirmed Not to Renew

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reply Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60185</td>
<td>LEVOXCA TAB 500MG</td>
<td>15.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
</tbody>
</table>

Requires Further Action Before Product Renewal

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reason</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK26230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>Non Pharmaceutical Product</td>
<td>02.02.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK17301</td>
<td>PHENYTOIN INJ 250MG/6ML (HAMELN)</td>
<td>BABE list</td>
<td>28.01.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK60587</td>
<td>PROACTIV SOLUTION KIT</td>
<td>RISTR list</td>
<td>13.07.2016</td>
<td>Batch Four</td>
</tr>
</tbody>
</table>

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Renewal Product via Online Channel

Renewal of Registration

Pay for Renewal Certificate

<table>
<thead>
<tr>
<th>Certificate Holder</th>
<th>HK No</th>
<th>PR No</th>
<th>Name of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC COMPANY LIMITED</td>
<td>HK53970</td>
<td>PR0726/2005</td>
<td>RAMATIN OINTMENT</td>
</tr>
<tr>
<td>ABC COMPANY LIMITED</td>
<td>HK53969</td>
<td>PR0725/2005</td>
<td>SUITANI OINTMENT</td>
</tr>
</tbody>
</table>

- 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.

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Renewal Product via Online Channel

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:

1. Please take note of the transaction reference number or PRINT this page.
2. 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.
3. 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.
4. 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.
5. 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.
Result of Renewal Certificate Payment

Renewal

Payment Reference No.: DHPR-201509250021-90004
EGIS Reference No.: A201500251004142
Type of Payment: Renewal
Transaction Time: 25.09.2015 00:23:37
Delivery Method: Received By Post

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Product Name</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK53959</td>
<td>SUITANI OINTMENT</td>
<td>13.01.2016</td>
</tr>
<tr>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
<td>13.01.2016</td>
</tr>
</tbody>
</table>

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: prsj_prfo@dh.gov.hk

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Result of Renewal Certificate Payment

Name of Company
ABC COMPANY LIMITED

Payment Date
25.09.2015

Payment Reference No.
DHPRS-201509250021-90004

Payment Method
VISA

Payment Amount
HK$1,150.00

Name of Product
1. SUITANI OINTMENT
   HK53969
2. RAMATIN OINTMENT
   HK53970

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Renewal Product via Online Channel

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

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK50175</td>
<td>PRILIGY TAB 60MG</td>
<td>24.11.2015</td>
<td></td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK50174</td>
<td>PRILIGY TAB 30MG</td>
<td>24.11.2015</td>
<td></td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK50966</td>
<td>MARKIST OINTMENT</td>
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<td></td>
<td>Batch One</td>
</tr>
</tbody>
</table>

Payment Completed

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Payment Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK50187</td>
<td>LEVOXA TAB 250MG</td>
<td>02.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK30970</td>
<td>RAMATIN OINTMENT</td>
<td>25.09.2015</td>
<td>13.01.2016</td>
<td>Batch One</td>
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<tr>
<td>HK30860</td>
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Product Confirmed Not to Renew

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK50186</td>
<td>LEVOXA TAB 500MG</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
</tbody>
</table>

Requires Further Action Before Product Renewal

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reason</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK26230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>Non Pharmaceutical Product</td>
<td>02.02.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK47301</td>
<td>PHENYTOIN INJ 250MG/5ML (HAMELIN)</td>
<td>RSTR list</td>
<td>13.07.2016</td>
<td>Batch Four</td>
</tr>
</tbody>
</table>

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## 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

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60175</td>
<td>PRILUYG TAB 20MG</td>
<td>24/11/2015</td>
<td>24/11/2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK60174</td>
<td>PRILUYG TAB 20MG</td>
<td>24/11/2015</td>
<td>24/11/2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK53908</td>
<td>MARKIST OINTMENT</td>
<td>13/01/2016</td>
<td>13/01/2016</td>
<td>Batch One</td>
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</table>

### Payment Completed

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Payment Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60187</td>
<td>LEVOXIN TAB 250MG</td>
<td>02/08/2015</td>
<td>24/11/2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
<td>25/09/2015</td>
<td>13/01/2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK53969</td>
<td>SUJANCIID OINTMENT</td>
<td>25/09/2015</td>
<td>13/01/2016</td>
<td>Batch One</td>
</tr>
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</table>

### Product Confirmed Not to Renew

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reply Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60186</td>
<td>LEVOXIN TAB 500MG</td>
<td>15/06/2015</td>
<td>24/11/2015</td>
<td>Batch Six</td>
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</table>

### Requires Further Action Before Product Renewal

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reason</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK26230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>Not Pharmaceutical Product</td>
<td>02/02/2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK47301</td>
<td>PHENYTOIN INJ 250MG/5ML (HAMELON)</td>
<td>BABE list</td>
<td>28/01/2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK60597</td>
<td>PROACTIV SOLUTION KIT</td>
<td>RSTR list</td>
<td>13/07/2016</td>
<td>Batch Four</td>
</tr>
</tbody>
</table>

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## Renewal of Registration

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

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

### Reply and Pay for Renewal of Registration

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
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<tbody>
<tr>
<td>HK60175</td>
<td>PRILIGY TAB 60MG</td>
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<tr>
<td>HK60174</td>
<td>PRILIGY TAB 30MG</td>
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### Payment Completed

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Payment Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60187</td>
<td>LEVOXAZ TAB 250MG</td>
<td>02.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
<td>25.09.2015</td>
<td>13.01.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK53968</td>
<td>SUITANI OINTMENT</td>
<td>25.09.2015</td>
<td>13.01.2016</td>
<td>Batch One</td>
</tr>
</tbody>
</table>

### Product Confirmed Not to Renew

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60188</td>
<td>LEVOXAZ TAB 500MG</td>
<td>15.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK53968</td>
<td>MARKOT OINTMENT</td>
<td>25.09.2015</td>
<td>13.01.2016</td>
<td>Batch One</td>
</tr>
</tbody>
</table>

### Requires Further Action Before Product Renewal

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reason</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>Non Pharmaceutical Product</td>
<td>02.02.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK47301</td>
<td>PHENYTOIN INJ 250MG/5ML (HAMELIA)</td>
<td>BABE list</td>
<td>28.01.2016</td>
<td>Batch One</td>
</tr>
<tr>
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<td>PROACTIV SOLUTION KIT</td>
<td>RSTR list</td>
<td>13.07.2016</td>
<td>Batch Four</td>
</tr>
</tbody>
</table>

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## 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

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
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</thead>
<tbody>
<tr>
<td>HK00175</td>
<td>PRILOZY TAB 60MG</td>
<td></td>
<td>24.11.2015</td>
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<tr>
<td>HK00174</td>
<td>PRILOZY TAB 30MG</td>
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</table>

### Payment Completed

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Payment Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK00187</td>
<td>LEVOX TAB 250MG</td>
<td>02.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
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<td>13.01.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK53989</td>
<td>SUITAN OINTMENT</td>
<td>25.09.2015</td>
<td>13.01.2016</td>
<td>Batch One</td>
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</table>

### Product Confirmed Not to Renew

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reply Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK00106</td>
<td>LEVOX TAB 500MG</td>
<td>15.09.2015</td>
<td>24.11.2015</td>
<td>Batch Six</td>
</tr>
<tr>
<td>HK53968</td>
<td>MARKST OINTMENT</td>
<td>25.09.2015</td>
<td>13.01.2016</td>
<td>Batch One</td>
</tr>
</tbody>
</table>

### Requires Further Action Before Product Renewal

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reason</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td>02.02.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK47301</td>
<td>PHENYTOIN INJ 250MG/25ML (HAMELIN)</td>
<td>RSTR list</td>
<td>28.01.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK00507</td>
<td>PROACTIV SOLUTION KT</td>
<td></td>
<td>13.07.2016</td>
<td>Batch Four</td>
</tr>
</tbody>
</table>

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Reinstate to Renew Product via Online Channel

### Renewal of Registration

- Product(s) have been successfully reinstated

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

#### Reply and Pay for Renewal of Registration

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Notify Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60175</td>
<td>PRILIGY TAB 65MG</td>
<td>24.11.2015</td>
<td>Batch Six</td>
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<tr>
<td>HK60177</td>
<td>PRILIGY TAB 30MG</td>
<td>24.11.2015</td>
<td>Batch Six</td>
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</tr>
<tr>
<td>HK5968</td>
<td>MARKAT OINTMENT</td>
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<td>Batch One</td>
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</tbody>
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#### Payment Completed

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Payment Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK0187</td>
<td>LEVOXIA TAB 250MG</td>
<td>02.09.2015</td>
<td>Batch Six</td>
<td></td>
</tr>
<tr>
<td>HK5970</td>
<td>RAMATIN OINTMENT</td>
<td>25.09.2015</td>
<td>Batch One</td>
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</tr>
<tr>
<td>HK53080</td>
<td>SUTAN OINTMENT</td>
<td>25.09.2015</td>
<td>Batch One</td>
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</tr>
</tbody>
</table>

#### Product Confirmed Not to Renew

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reply Date</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK60188</td>
<td>LEVOXIA TAB 500MG</td>
<td>15.09.2015</td>
<td>Batch Six</td>
<td></td>
</tr>
</tbody>
</table>

#### Requires Further Action Before Product Renewal

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Name of Product</th>
<th>Reason</th>
<th>Expiry Date</th>
<th>Batch No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK06230</td>
<td>NASUCAP DECONGESTANT CAP</td>
<td>Non Pharmaceutical Product</td>
<td>02.02.2016</td>
<td>Batch One</td>
</tr>
<tr>
<td>HK47301</td>
<td>PHENTYNOIN INJ 250MG/5ML (HAMELIN)</td>
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<td>Batch One</td>
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<td>HK85587</td>
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<td>RSTR list</td>
<td>13.07.2016</td>
<td>Batch Four</td>
</tr>
</tbody>
</table>

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## Online Notification of Product Renewal

<table>
<thead>
<tr>
<th>#</th>
<th>Notification Type</th>
<th>Date of Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Renewal Notification</td>
<td>Around 6 months before the expiry of certificate</td>
</tr>
<tr>
<td>2</td>
<td>Renewal Reminder</td>
<td>1 month after issued renewal notification if certificate holder has no response</td>
</tr>
<tr>
<td>3</td>
<td>Expiry Notice (if certificate holder has replied “Not to Renew”)</td>
<td>1 month before the expiry of certificate</td>
</tr>
<tr>
<td>4</td>
<td>Expiry Notice (if certificate holder has no response)</td>
<td>The date after the expiry of certificate</td>
</tr>
</tbody>
</table>
On-line Application for Registered Product Cancellation
Initiate Application for Product Cancellation

## Request to Cancel Product Registrations

### New Submission

| Initiate new EOL Application |

<table>
<thead>
<tr>
<th>Not Submitted</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Submitted</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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

---

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### Initiate Application for Product Cancellation

#### Step 1: Enter Product(s) for Cancellation of Product Registration, Reason(s) of Product Cancellation and Contact Information.

**Select Product**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Expiry Date</th>
<th>Other Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAMATIN OINTMENT</td>
<td>13.01.2016</td>
<td><a href="#">Recent Notification(s) on Change of Registered Product</a></td>
</tr>
</tbody>
</table>

**Effective Date:** 01.01.2016

**Reason(s) of Product Cancellation:**

No sales this product 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

---

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Initiate Application for Product Cancellation

Request to Cancel Product Registrations

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

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Product Name</th>
<th>Return Registration Certification to Drug Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>HKS3970</td>
<td>RAMATIN OINTMENT</td>
<td>✔️</td>
</tr>
</tbody>
</table>

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 product anymore.

Contact Information for Product Cancellation:

Contact Person: Mr. Tang
Phone No.: 22099053
Email: Steven.tang@abc.com

Address:
Unit: A
Building: DH BUILDING
Street No.: 382
SUB-DISTRICT: SHEK KIP MEI
Area: KOWLOON

Street Name: NACHENG

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
Initiate Application for Product Cancellation

Request to Cancel Product Registrations

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) 2313 8459

Email: prs2_info@dh.gov.hk

<table>
<thead>
<tr>
<th>HK No.</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
</tr>
</tbody>
</table>

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Initiate Application for Product Cancellation

Request to Cancel Product Registrations

New Submission
Initiate new EOL Application

Not Submitted

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Ref No.</th>
<th>HK No.</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>25.09.2015</td>
<td>DE-REG-HK53970-2015/0925</td>
<td>HK53970</td>
<td>RAMATIN OINTMENT</td>
</tr>
</tbody>
</table>

Application Submitted

Cancellation Request Submitted

Disclaimer: The information provided by the Department of Health ("DH") of the Government of the Hong Kong Special Administrative Region on this material ("the DH's information") is for reference only and is subject to change during the maintenance of PRS 2.0 project.
You are login as WONG David
ABC COMPANY LIMITED
Login date and time 22.09.2015 15:10

Product Cancellation Application Withdrawal

EOL Application Withdrawal

- Date Received: 25.09.2015
- Ref No.: DE-REG-HK5370-20150925
- HK No.: HK5370
- Product Name: RAMATIN OINTMENT

Reason(s) of Withdrawal:

Keep this product, do not cancellation in this moment

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Miscellaneous Functions
Miscellaneous Functions

- Online Notification

Online Notification

New Product Registration

<table>
<thead>
<tr>
<th>Notification Date</th>
<th>Subject</th>
<th>Proposed Name of Product</th>
<th>PL No.</th>
<th>Payment Status</th>
</tr>
</thead>
</table>

On Going

<table>
<thead>
<tr>
<th>Notification Date</th>
<th>Subject</th>
<th>HK No.</th>
<th>Name of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK01156</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK03969</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK01230</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK03157</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK03957</td>
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<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK05057</td>
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<td>HK03030</td>
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<tr>
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<td>HK010174</td>
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<td>HK047901</td>
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<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK060175</td>
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<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK05058</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK26230</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK26230</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Signature Fee Paid Notification</td>
<td>HK26230</td>
</tr>
</tbody>
</table>

Renewal of Registration

<table>
<thead>
<tr>
<th>Notification Date</th>
<th>Subject</th>
<th>HK No.</th>
<th>Name of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Fee notification</td>
<td>HK060175</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Fee notification</td>
<td>HK060175</td>
</tr>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Fee notification</td>
<td>HK060175</td>
</tr>
</tbody>
</table>

Cancellation Request

<table>
<thead>
<tr>
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<th>Subject</th>
<th>HK No.</th>
<th>Name of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
<td>Certificate Fee notification</td>
<td>HK060175</td>
</tr>
</tbody>
</table>

Interview

<table>
<thead>
<tr>
<th>Notification Date</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>25.09.2015 10:21:21</td>
</tr>
</tbody>
</table>

Non Pharmaceutical Product Alert

<table>
<thead>
<tr>
<th>Notification Date</th>
<th>Subject</th>
<th>HK No.</th>
<th>Name of Product</th>
</tr>
</thead>
</table>

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**Miscellaneous Functions**

- **Online Notification: Detailed Information**

### Online Notification

**New Product Registration**

- **Notification Date:** 25.09.2015 12:31:52
- **PL No.:** PL04202015
- **PR No.:** PR03852015
- **HK No.:** -
- **Proposed Name of Product (English):** VITAMIN E TABLETS
- **Notification Detail:** [NOTIFICATION_PRINT.pdf](#)
- **Attachment(s):**
  1. Go To Application Payment:

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

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

   For enquirers, 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
Miscellaneous Functions

- Search Result of My Product Search

My Product Search

<table>
<thead>
<tr>
<th>HK No.</th>
<th>PR No.</th>
<th>PL No.</th>
<th>Product Name</th>
<th>Active Ingredient(s)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>HK 26230</td>
<td></td>
<td></td>
<td>NASUCAP DECONGESTANT</td>
<td>C1.1 paracetamol 200mg/capsule</td>
<td>REG</td>
</tr>
<tr>
<td>HK 53960</td>
<td></td>
<td></td>
<td></td>
<td>C1.2 caffeine 15mg/capsule</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C1.3 chlorphenamine maleate 4mg/capsule</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C1.4 phenylephrine hydrochloride 15mg/capsule</td>
<td></td>
</tr>
</tbody>
</table>

- Change of Registered Particulars

- Removal 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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Miscellaneous Functions

- Application History
Miscellaneous Functions

• Change Password

Change Password

(8-20 characters containing at least one alphabet in upper case, one alphabet in lower case and one numeric)

Current Password: 
New Password: 
Confirm New Password: 

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

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Roadmap for Termination of Manual Application Submission Mode
# Roadmap for Termination of Manual Application Submission

<table>
<thead>
<tr>
<th>Stage</th>
<th>Type of Application</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Renewal (Stop sending letters for renewal of registered drugs, only be communicated via online notifications/reminders)</td>
<td>1 January 2016</td>
</tr>
<tr>
<td>2</td>
<td>New Registration (NCE) &amp; CORP</td>
<td>1 January 2017 (Tentative)</td>
</tr>
<tr>
<td>3</td>
<td>New Registration (Generic)</td>
<td>1 April 2017 (Tentative)</td>
</tr>
</tbody>
</table>
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
PRS 2.0 Information on Drug Office Website
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
PRRS 2.0 Information on Drug Office website

Guidelines & Forms

Drug Registration (With PRS 2.0 information)

- Registration of pharmaceutical products
- Change of Registered Particulars of a Registered Pharmaceutical Product
- Renewal of Pharmaceutical Product Registration
- Application for Certificate for Clinical Trial/Medical Test
- Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138) (English version only)
- Poison or Antibiotic? A Guide to "Class" Entries (English version only)
- Statement of Purpose

- Pharmaceuticals Registration System (PRS 2.0)
  - Login to PRS 2.0 System
  - Guideline
  - Forms
  - Frequently Asked Questions
**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
**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
Q & A
Thank you