



For Drug Office Use Only

Date Received _____

Officer Name _____

Successful Application Yes No

Application Form for New / Update / Terminate 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 3974 4195 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) v1.2".

(See http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/PRS2.0_TC_en_2016.04.01_v1.2.pdf)

Please send the completed application form to:

Project Manager – PRS2.0 Drug
Registration Unit, Drug Office,
Department of Health,
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon.

Note :

¹ The same email address must be included in the e-Certificate during e-Certificate application. Upon successful PRS2.0 account application, the login password will be sent to the individual applicant through a confirmation email.

² User Administrator Role: Each company must assign at least one or more administrator(s) in the PRS2.0 system. Administrator(s) has the right to grant privileges to other colleagues or subordinates under his/her organization for rights to access various system functions, such as application for new product registration or submission of CORP application or confirming renewal of registered products.

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

Organization Name _____

Branch Name (if any) _____

Organization Address _____

Telephone No. _____

Email Address _____

Business Registration No.

(First 11 digits)

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Business Registration

Certificate 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.

<input type="checkbox"/> Create a new account / <input type="checkbox"/> Update account / <input type="checkbox"/> Terminate account	
Particulars	Authorized User
Name of Authorized User	
Position	
Email Address ¹	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username <small>(1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)</small>	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role ² ?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

<input type="checkbox"/> Create a new Account / <input type="checkbox"/> Update account / <input type="checkbox"/> Terminate account	
Particulars	Authorized User
Name of Authorized User	
Position	
Email Address ¹	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username <small>(1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)</small>	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role ² ?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

<input type="checkbox"/> Create a new account / <input type="checkbox"/> Update account / <input type="checkbox"/> Terminate account	
Particulars	Authorized User
Name of Authorized User	
Position	
Email Address ¹	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username <small>(1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)</small>	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role ² ?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

<input type="checkbox"/> Create a new account / <input type="checkbox"/> Update account / <input type="checkbox"/> Terminate account	
Particulars	Authorized User
Name of Authorized User	
Position	
Email Address ¹	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username <small>(1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)</small>	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role ² ?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

<input type="checkbox"/> Create a new account / <input type="checkbox"/> Update account / <input type="checkbox"/> Terminate account	
Particulars	Authorized User
Name of Authorized User	
Position	
Email Address ¹	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username <small>(1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)</small>	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role ² ?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

<input type="checkbox"/> Create a new Account / <input type="checkbox"/> Update account / <input type="checkbox"/> Terminate account	
Particulars	Authorized User
Name of Authorized User	
Position	
Email Address ¹	
Contact Phone Number	
Facsimile Number (if any)	
Proposed Login Username <small>(1. Length: 5 - 20 ; 2. Case insensitive ; 3. Accept character: a-z, A-Z, 0-9, -, _ ; 4. No space)</small>	
e-Certificate Expiry Date (dd/mm/yyyy)	
Assign "User Administrator" Role ² ?	<input type="checkbox"/> Yes / <input type="checkbox"/> No

C. Confirmation by Applicant on behalf of the Company

Please tick the checkboxes and confirm the following:

- Please provide a copy of the valid Business Registration Certificate.

- 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.

- I have read through the content of this application form and agree with the Terms and Conditions (including the Privacy Policy) for the Use of Pharmaceuticals Registration System 2.0 (PRS 2.0).

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

Name of Signatory: _____ Position: _____

Email Address: _____ Contact Telephone No.: _____

Facsimile No: _____ Date: _____
(If any)

D. Authorization Letter (for company to authorize the parent company or subsidiary to access and use the services of PRS 2.0 if required)

I would like to appoint the company below as the Authorized Representative Company, on behalf of the authorizing company to access and use the services of Pharmaceuticals Registration System (PRS 2.0) provided by the Department of Health.

Authorized Representative Company Name	Business Registration No. §

Authorizing Company Name	Business Registration No. §

Authorized Signature: _____
(Authorizing Company) (Stamped with "for and on behalf of" company chop and signed by a director or a person with equivalent rank)

Name of Signatory: _____ Position: _____

Email Address: _____ Contact Telephone No.: _____

Facsimile No.: _____ Date: _____
(If any)

§ Please provide a copy of the valid Business Registration Certificate.

1. Privacy Policy

- 1.1 PRS2.0 consists of a website for submitting online applications for registration of pharmaceutical products or substances, change of registered particulars of registered products or substances and renewal of registration certificates pursuant to the Pharmacy and Poisons Regulations (Cap. 138A) (“**Applications**”) and its User may use any of the services provided therein (“**Services**”) in accordance with these Terms.
- 1.2 The Government will handle all personal data submitted through and stored in PRS2.0 in accordance with the Personal Data (Privacy) Ordinance (Cap. 486).
- 1.3 Personal Information Collection Statement
- (a) Information (including any personal data) collected will be used for the purposes of processing your Applications and providing the Services to you.
 - (b) Information (including any personal data) kept in the user profile of your PRS2.0 account may be retained by the Government after termination of your PRS2.0 account for matters arising out of or in relation to your use of the Services before termination of the account.
 - (c) Any personal data contained in your Application may be retained by the Government so long as (i) the Application is in progress, or (ii) the pharmaceutical product or substance concerned is registered under the Pharmacy and Poisons Regulations (Cap. 138A).
- 1.4 By creating a user profile under PRS2.0 you are regarded to have agreed to, and to have obtained consent from each individual whose personal data is provided in the user profile for, the disclosure, use and further disclosure by the Government of the personal data for the purposes mentioned in Clause 1.3.
- 1.5 You hereby give consent to the Government and DH for:
- (a) the transfer or use of information (including any personal data) kept in the user profile of your PRS2.0 account for the purpose of using any Services of PRS2.0;
 - (b) the use of information (including any personal data) in the digital certificate attached to your PRS2.0 account for the purpose of authenticating the identity of the User;
 - (c) the retention of information (including any personal data) contained in the user profile of your PRS2.0 account after termination of the account for matters arising out of or in relation to the use of your PRS2.0 account and the Services; and
 - (d) the retention of any personal data contained in your Application so long as (i) the Application is in progress or (ii) the pharmaceutical product or substance concerned is registered under the Pharmacy and Poisons Regulations (Cap. 138A).
- 1.6 Access and correction of personal data
- (a) You may access and correct the information (including any personal data) kept in the user profile via the application menu “User Profile → Maintain Company’s User Accounts” of PRS2.0.
 - (b) If your PRS2.0 account is terminated and personal data kept in the user profile of the account are retained by the Government (see Clause 1.3 (b)), you may request access to or correction of your personal data, by sending a data access request to the PRS2.0 Service Team via email at ‘prs2_info@dh.gov.hk’.
 - (c) Enquiries concerning personal data collected by means of PRS2.0, including the making of access and corrections, may be made by sending e-mail to PRS2.0 Service Team of DH at ‘prs2_info@dh.gov.hk’.