DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION

Guidance Notes on
New On-line User Account Registration for Pharmaceuticals Registration
Systems 2.0 (PRS 2.0)

In order to use the system, your company is required to have organizational
e-certificate(s) which is/are specific to each authorized user within your company
and to create new account(s) via our external system. The “e-Cert (Organizational)
application form” can be downloaded from the following website:
and please forward the completed application form (in section A7 of the application
form “e-Cert Storage Medium”, please choose “e-Cert File USB”; in section D
“Particulars of Authorized Users”, the email address must be included in the
e-Cert) to post office for processing. Please be advised that each intended user for
the PRS2.0 system requires applying the organizational e-certificate individually.

Please follow the steps below after successful application for the
e-certificate(s) (which will normally take about 1-2 months) to proceed with the
PRS2.0 new user account registration:

Step 1-5 for each authorized PRS2.0 user of your company to register his/her
new on-line user account(s)

1. Install and configure the required software:
   a. Web browser: Internet Explorer 9.0 or above
   b. Web browser settings: Accept cookies and enable JavaScript
   c. Java Runtime Environment (JRE) 1.6.x or above
   d. Adobe Flash Player 13 or above

2. The PRS2.0 external platform can be accessed via the following
   hyperlink:

3. Click the “Request for New Account” button.

4. Read and agree the “Terms and Conditions for the Use of the PRS2.0” in
   order to proceed.

5. Fill in the information under the “New User Registration” page. An
   acknowledgement email will be sent to the applicant after submission.

Step 6 to be completed by your company

6. Please complete and return the attached “Application form for new
online user account registration for PRS2.0” (“application form”) to Drug Office. Each company should submit ONE application form only. In the application form, please specify which user(s) is/are to be assigned with the “User Administrator” role. PRS2.0 user(s) with such role 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.

7. Upon receiving the application form and verification of information by the Drug Office, the login user name and password will be sent to each user by his/her stated email. User can then login to his/her account in PRS2.0 with:

(a) the login user name and password (sent from the Drug Office); and
(b) his/her e-certificate and the e-certificate PIN.