

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.

3. Services provided in PRS2.0

3.1 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.

3.2 For the purposes of the Terms, “pharmaceutical product”, “substance”, “registered particulars” and “registered product or substance” shall have the same meaning as that assigned to them in the Pharmacy and Poisons Ordinance and Regulations (Cap. 138).

3.3 Users should make reference to the Guidance Notes on Registration of Pharmaceutical Products/Substances when using the Services in accordance with these Terms.

3.4 Notwithstanding anything herein to the contrary, the Government may from time to time modify, suspend and/or terminate any Services at its own discretion without giving any prior notice to any User.

4. Disclaimers

4.1 The contents of PRS2.0 and the Services are provided to you on an “as is” basis without any expressed or implied warranty or representation of any kind, including without limitation, warranty or representation as to the accuracy, completeness, fitness for any particular purpose, non-infringement, reliability, security, timeliness of such contents or Services.

4.2 In particular, the Government does not warrant or represent that:

- (a) the quality of any Services or information provided by PRS2.0 will meet your requirements or expectation;
- (b) PRS2.0 or the server or any files or any software available for downloading through PRS2.0 are free of computer viruses or any other harmful components, defects, errors, infection, Trojan horses or any other script, program or code that manifests contaminating or destructive properties;
- (c) your access to or any Services of PRS2.0 (and any linked websites) will be uninterrupted, timely, secure, reliable or error-free;
- (d) any defects in PRS2.0 will be corrected; or
- (e) any information, records, or documents generated by PRS2.0 will be reliable or accurate.

4.3 No representation, information or advice, whether written or oral, obtained by you from us through or from PRS2.0 shall create any warranty or representation or other obligation not expressly stated in these Terms.

5. Limitation of Liability

5.1 Your use of PRS2.0 and the Services therein is at your own risk.

5.2 The Government is not liable for any damage or loss arising in any manner from or in respect of any use or misuse of or reliance on the contents of, or inability to access or use, the PRS2.0 or the Services therein.

5.3 Any material, file or software downloaded or otherwise obtained through the use of PRS2.0 is done at your own risk and discretion and that the Government will not be responsible for any damage to your computer system or loss of data that results from or related to the download of any such material, file or software.

5.4 In particular, the Government will not be liable for any direct, indirect, special, incidental, consequential or exemplary damages, including but not limited to, damages for loss of profits, use, data, goodwill, or other intangible losses (even if the Government have been advised of the possibility of such damages), resulting from:

- (a) any information, data or Services obtained or messages received or transactions entered into through or from PRS2.0;
- (b) statements or conduct of any third party on PRS2.0;
- (c) the use or the inability to use PRS2.0;
- (d) the inability to gain access in whole or in part to PRS2.0;
- (e) unauthorised access to or alteration of your transmissions or data;
- (f) the use of any material, file or software downloaded or obtained through the use of PRS2.0;
- (g) any delays, failures, mis•delivery or non•delivery of any Services;
- (h) any errors, defects, inaccuracies, omissions, interruptions, deletions, computer viruses or communication line failures in connection with PRS2.0;
- (i) any destruction, damage, theft, or unauthorised access to your computer system or network;
or
- (j) any other matter whatsoever in connection with PRS2.0.

6. Disclaimer in respect of links from PRS2.0 to other websites

PRS2.0 may contain hyperlinks to websites that are not maintained by the Government. The Government is not responsible for the contents of those websites. Providing or assistance in providing links to those websites does not constitute any statement, representation or warranty, express or implied, that the Government agrees or does not agree with the contents of any such website. Nor does such provision or assistance constitute any form of co-operation or affiliation with the Government and the operator of any such website. The Government is not liable for any damage or loss arising in any manner from or in respect of any use or misuse of or reliance on the contents of, or inability to access or use, any such website.

7. Use of PRS2.0

7.1 Usage Control of the Services

7.1.1 PRS2.0 may block malicious web sites or other internet resources.

7.1.2 The Government reserves the right to withhold the provision of Services to any User violating the Terms.

7.2 System Logging of User Activities

7.2.1 Your activities under PRS2.0 are subject to logging and review by the Government for the following purposes:

- (a) System diagnosis and trouble-shooting;
- (b) Capacity planning and service improvement;
- (c) Identification of Users abusing the Services;
- (d) Provision of information upon DH's request; and
- (e) Provision of information upon request of court or as required by law.

7.2.2 The log retention period is 6 months.

7.3 Users' Obligations and Responsibilities in using the Services

7.3.1 You will be held fully accountable for all activities, and the consequences of such activities, conducted by using your user account for access to PRS2.0 (“**PRS2.0 account**”).

8. Conduct of User

8.1 You agree and undertake not to use PRS2.0 to:

- (a) upload, post, e-mail, otherwise transmit or post links to any contents which are defamatory, offensive, unlawful, obscene, abusive, harmful, pornographic, threatening, tortuous, or otherwise objectionable;
- (b) upload, post, e-mail, otherwise transmit or post links to any information or software which contains any computer viruses, worms, Trojan horses or any other harmful computer codes, programs or files;
- (c) access, use, break into, or attempt to access, use or break into any other parts of PRS2.0 and /or data areas which you have not been authorised to use;
- (d) access, collect or store personally identifiable information about other Users; or
- (e) upload, post, e-mail, otherwise transmit or post links to any promotional material, unauthorised advertising, chain letters, pyramid schemes or any unsolicited commercial communication.

8.2 You are responsible for any damage that you cause to PRS2.0 or to any of its electronic facility or data. You should not cause damage to PRS2.0 or to any of its electronic facility or data through the knowing transmission of any program, information, code or command.

8.3 You are responsible for ensuring that your own computer is secure, including taking all reasonable steps to:

- (a) prevent unauthorised access to your computer system or your PRS2.0 account for access to PRS2.0 by any other person, and

- (b) ensure your computer system and data are free of computer viruses, worms, Trojan horses, any other harmful computer codes, programs or files and all other forms of corruption.

8.4 You agree to keep the user name and passwords for PRS2.0 confidential and shall not disclose the user name and passwords to any other person. We will not be liable for any loss or damage arising from your failure to comply with this clause.

8.5 You shall not use or knowingly allow any other person to use or access PRS2.0 for or in connection with any illegal purpose or activity.

9. Warranty regarding information submitted through PRS2.0 etc.

9.1 You represent, warrant and undertake to the Government that:

- (a) any information, communication or material submitted to the Government through PRS2.0 is true and accurate and not misleading, incomplete or false;
- (b) any information, communication or material submitted to the Government through PRS2.0 by means of the User's user name and password shall be deemed to be submitted by the User; and
- (c) you shall comply with all applicable laws, regulations and orders when using PRS2.0 and the Services.

9.2 You acknowledge that a registered product or substance may be deregistered if it is discovered that incomplete or inaccurate information has been provided in connection with the relevant Application.

10. Indemnity

You shall indemnify and keep indemnified the Government against all claims, actions, proceedings, liabilities, demands, charges, damages, costs, losses or expenses arising out of or resulting from the use or attempted use of PRS2.0 and the Services to the extent that the same are or have been caused by

any negligent or reckless conduct, wilful misconduct, omission, defamation, breach of statutory duty or breach of any of the Terms by you. This provision survives termination of your PRS2.0 account.

11. Links to this website

You may not create a link to any page of the website of PRS2.0 without the Government's prior written consent.

12. Privacy Policy

12.1 The Government will handle all personal data submitted through and stored in PRS2.0 in accordance with the Personal Data (Privacy) Ordinance (Cap. 486).

12.2 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).

12.3 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 12.2.

12.4 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).

12.5 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 12.2 (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’.

13. System Requirement

13.1 Web Browser

- (a) PRS2.0 supports Google Chrome web browser 96.0.4664 or above.
- (b) You should access PRS2.0 using above supporting web browsers to achieve the best performance of PRS2.0.

13.2 Cookies

The Government will record visits to PRS2.0 by using cookies. A cookie is a small amount of data created in a computer when a person visits a website through the computer. It often includes an anonymous unique identifier. A cookie can be used to identify a computer, or to temporarily store non-personal information required by an online service. It is not used by PRS2.0 to collect any personal information. If you configure your browser to reject cookies, you will not be able to use PRS2.0.

13.3 JavaScript

PRS2.0 requires JavaScript to function properly. If you disable JavaScript on your computer, you will not be able to use PRS2.0.

14. Security

- 14.1 You must log out your PRS2.0 account and close all your browser windows after use to prevent misuse of your PRS2.0 account by third parties.
- 14.2 You must refer to the information security best practices as stipulated in the Infosec website of the Government (<http://www.infosec.gov.hk/english/technical/guidelines.html>) to keep your information, software and equipment secured from misuse by third parties.

15. Intellectual Property Rights

- 15.1 For the purpose of the Terms, “Intellectual Property Rights” means patents, trade marks, service marks, trade names, design rights, copyrights, domain names, database rights, rights in know-how, new inventions, designs or processes, and other intellectual property rights, in each case whether now known or created in future, regardless of whatever nature and wherever arising, and whether registered or unregistered, and including applications for the grant of any such rights.
- 15.2 You acknowledge that PRS2.0 and all of its contents are proprietary to the Government and all the Intellectual Property Rights therein are owned by the Government. All contents (inwhole or in part) of PRS2.0 may not be used, copied, sold, transferred, transmitted, adapted, modified, published, made available to the public, distributed, stored or otherwise exploited, for any purpose without the Government’s prior written consent.
- 15.3 You represent, warrant and undertake to the Government that any information, communication or material submitted to the Government through PRS2.0 shall not and will not infringe the Intellectual Property Rights of any person.
- 15.4 By submitting any information, communication or material through PRS2.0 to the Government, the User grants a non-exclusive, royalty-free, transferable, perpetual and irrevocable licence to the Government to use such information, communication or material for the purpose of providing the Services and all corresponding and related purposes for the functioning and monitoring of the PRS2.0 by the Government.

16. Modifications of the Terms

The Government may from time to time vary, modify, delete and/or add any terms or conditions on the Terms at its own discretion without prior notice to any person.

17. Severability

If at any time any provision of these Terms is or becomes illegal, invalid or unenforceable in any respect, the legality, validity and enforceability of the remaining provisions of these Terms shall not be affected or impaired thereby.

18. Language

These Terms have been translated into Chinese. If there is any inconsistency or ambiguity between the English version and the Chinese version, the English version shall prevail.

19. Governing Law

These Terms shall be governed and constructed in accordance with the laws of Hong Kong. You agree to submit to the exclusive jurisdiction of the courts of Hong Kong.

20. Contact and Enquiry

If you have any enquiries concerning PRS2.0, you may contact PRS2.0 Service Team of DH at Tel. (852) 3974-4195 during office hours (Monday: 09:00-18:00; Tuesday-Friday: 09:00-17:45; lunch hours: 13:00-14:00) or via e-mail to 'prs2_info@dh.gov.hk' .

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