

**Business Facilitation Advisory Committee
Wholesale and Retail Task Force**

*E-services for Wholesale and Retail Licences/Certificate for Medicines
under the “Be the Smart Regulator” Programme*

Purpose

This paper aims to brief members of the Wholesale and Retail Task Force (WRTF) on the e-services for wholesale and retail licences/certificate for medicines provided by the Department of Health (DH) under the “Be the Smart Regulator” (BTSR) Programme.

Background

2. The Government is fully committed to creating an environment for all businesses to thrive. To sustain improvement in Hong Kong’s regulatory environment, the Government launched in 2007 the BTSR Programme, which aims to reduce the compliance costs to business and enhance the licensing process through regulatory review and improving the efficiency, transparency and business-friendliness of Hong Kong’s business licensing services.

3. Under the “new normal”, the Government adopts innovation and technology and streamlines business processes to meet the rising expectations and changing needs of businesses and the public. In general, DH has been providing e-services for its licences under the BTSR Programme.

E-services for Wholesale and Retail Licences/Certificate

4. In order to provide greater convenience to trade, DH provides e-services for seven wholesale and retail licences/certificate for medicines, including three licences related to Chinese medicines and four licences/certificate related to Western medicines. The scope of e-services includes e-submission, e-payment and issuance of e-licence upon application approval. E-services provide an

alternative means to the paper-mode applications. Traders can save time from visiting the office in person and handle their licence applications more conveniently and efficiently. The seven wholesale and retail licences/certificate for medicines issued by the DH include –

Licence	Issuing Office
Wholesaler Licence in Chinese Herbal Medicines	Chinese Medicine Regulatory Office, DH
Retailer Licence in Chinese Herbal Medicines	
Wholesaler Licence in Proprietary Chinese Medicines	
Wholesale Dealer Licence	Drug Office, DH
Wholesale Dealer's Licence to Supply Dangerous Drugs	
Licence for Listed Sellers of Poisons	
Certificate of Registration of Premises of an Authorized Seller of Poisons	

Chinese Medicine Regulatory Office (CMRO)

5. The CMRO of the DH is, among others, responsible for the enforcement of the Chinese Medicine Ordinance (Cap. 549) which regulates the practice of Chinese medicine practitioners and the use, manufacture and trading of Chinese medicines. The CMRO also provides professional and administrative support to the Chinese Medicine Council of Hong Kong (CMCHK), a statutory body established under Cap. 549 which is responsible for implementing regulatory measures for Chinese medicine.

6. According to Cap. 549, any person who wish to engage in the business of retail and wholesale of Chinese herbal medicines (Chm) as well as the wholesale and manufacturing business of proprietary Chinese medicines (pCm) shall obtain the relevant licence issued by the Chinese Medicines Board of the CMCHK before carrying on such business.

7. The e-services for Chinese medicines licences were rolled-out on 30 June 2022, in parallel with the existing mode of application and payment for the trade.

e-submission and e-payment

8. The CMRO has subscribed to the Office of the Government Chief Information Officer (OGCIO) Central e-Form Services. Applicants can use the web forms for application of Chinese medicines licences via the websites of CMCHK, CMRO or GovHK Portal. Upon completion of filling the web form and uploading the required supporting documents, applicants are allowed to submit applications with their e-certificates (organisational) for digital signing. Subject to the approval of application, the licence fees can be settled by electronic means, e.g. via PPS, e-Cheque, FPS or internet banking.

e-licence

9. Trader applicants will receive paper licence by post regardless of their ways of application submission, i.e., by e-submission or by paper-mode. If the applicant have also provided email address in the paper application, upon approval of the application, the applicant will receive both the paper licence by post and the e-licence via email. By scanning the QR code printed on each licence, licence information can be retrieved in the webpage of the CMCHK.

Promotion of e-services and Customer Satisfaction Survey

10. In order allow traders to have a better understanding on the implementation of e-services and to promote the wider use of e-services, CMRO has sent letters and promotion pamphlets to the Chinese medicines trade associations. The e-service has also been introduced through the monthly pCm registration seminars and briefing sessions. Besides, relevant information and promotional materials, such as leaflets, newsletter, etc., have been uploaded to the websites of CMCHK and CMRO. Users of e-services are also invited to participate in the customer satisfaction survey on the ease of use, processing speed and user satisfaction for further service improvement.

Drug Office (DO)

11. The DO of the DH is the law enforcement agency over the legislations concerning medicines. It also provides for the procurement and dispensing of medicines at the clinics of DH. The Licensing and Compliance Division under the DO has worked towards achieving e-submission of application, e-payment and issuance of e-licence for all licences, except those currently with legal and operational constraints, for BTSR programme. On this, the Wholesale Dealer Licence, Wholesale Dealer's Licence to Supply Dangerous Drugs, Licence for Listed Seller of Poisons (LSP) and Certificate of Registration of Premises of an

Authorized Seller of Poisons (ASP) have been implemented with e-licensing option in June 2022, in parallel with the existing mode of application and payment for the industry.

e-submission

12. Application for traders' licences can be submitted via DO's website. All supporting documents can be submitted via email in PDF format. Each application will be timely reviewed and if outstanding or supplementary documents are required, the applicant shall be contacted for re-submission via e-services at DO's website. The application together with all supporting documents and application fee (if applicable) is assessed in accordance with the established procedures and requirements. If approval of application is granted, the applicant would be notified for settling the licence fees via e-payment.

e-payment

13. For application of LSP licence, a Government demand note will be issued via the General Demand Note System and sent to an applicant via email upon receipt of a completed application dossier. For application of other traders' licences, a Government demand note will be issued via the same General Demand Note System and sent to an applicant via email upon approval of the application by the respective Licensing Committee or the Pharmacy and Poisons Board. The applicant can then settle the payment by electronic means, e.g. via PPS, e-Cheque, FPS or internet banking. DO will check settlement of the demand note before issuance of the licence to the applicant

e-licence

14. Upon approval of the application by the respective body, a digitally signed licence in PDF format with electronic certification issued by Hongkong Post, a recognised Certification Authority in Hong Kong, will be generated and sent to the email designated by the applicant to receive the e-licence. In compliance with the legal requirements, the licensed LSP or ASP can display the e-licence via a monitor in a conspicuous place for public awareness. The e-licence for Traders' licences has been rolled-out on 29 June 2022.

Benefits of the e-services

15. The provision of electronic licensing services benefits the traders and the DH. It can minimise the need or save the time for the applicant to travel to the government office for submission of application and its supporting document.

All in all, it fosters better efficiency of work, enhances transparency and communication which ultimately leads to higher customer satisfaction of our licensing services. It also reduces paper printouts and introduce more eco-friendly office practice.

Advice Sought

16. Members are invited to note the implementation progress of e-services in DH and offer comments, if any.

Department of Health
December 2022