WRTF Paper 52

Business Facilitation Advisory Committee
Wholesale and Retail Task Force

Update on Progress of Enhancement of Pharmaceuticals Licence Application and Movement Monitoring System (Phase II)

Purpose

This paper updates the Wholesale and Retail Task Force (WRTF) of the progress of enhancement work of Pharmaceuticals Licence Application and Movement Monitoring System (hereafter referred as PLAMMS), an electronic licensing system for the import and export of pharmaceutical products.

Background

2. To strengthen the tracking system for pharmaceutical products imported for re-export purpose as recommended by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong in 2009, an electronic licensing system for the import and export of unregistered pharmaceutical products, PLAMMS Phase I, was rolled out on 7 January 2015 with full phase out of manual application from 1 July 2016 onwards for importing unregistered pharmaceutical products solely for re-export purpose. The scope of PLAMMS Phase I covers business processing automation functions relating to import and export licensing system, including drug enlisting, import and export licences application for unregistered pharmaceutical products, report shipment of the unregistered pharmaceutical products, account suspension, and ledger balance of the unregistered pharmaceutical products.

3. PLAMMS Phase I enable the Department of Health (DH) to retrieve shipment information more efficiently and keep track of the amount imported and the amount intended to be exported to prevent illegal diversion of pharmaceutical products imported for re-export purpose into the local market. Apart from enhancing traceability of imported pharmaceutical products and facilitating law enforcement actions, the new electronic system

also facilitates the trade on import and export of pharmaceutical business by reducing the courier services and shortening the processing time to obtain the import and export licences approval within the same day upon completion of inputting all the necessary application details for unregistered pharmaceutical products enlisted in the automatic system.

4. Since the launching of PLAMMS Phase I on 7 January 2015 and up to October 2018, DH has processed over 9,770 applications for the purpose of enlisting unregistered pharmaceutical products from over 270 traders and issued over 410,000 import and export licences.

Enhancement and Implementation Arrangement

5. In November 2016, further enhancement work of PLAMMS (Phase II) has been initiated to extend the scope of licence processing to unregistered pharmaceutical products for other purposes (e.g. pharmaceutical products for treatment of a particular patient, etc.), locally registered pharmaceutical products, dangerous drugs and psychotropic substances (Please refer to the table as below). The scope of licences/certificates covered in PLAMMS Phase I and Phase II are listed at **Annex**.

6. To enhance the trade acceptance and utilization of the new system and at the same time collect ongoing feedback from PLAMMS Phase I users for further improvement, DH has been communicating and consulting with the trade by carrying out various initiatives and activities, including briefing sessions in 2018 and 2019, invitation of key stakeholders for user acceptance test and trial run, new web page to provide latest news and guidance notes, soft-launching approach, small group training workshops, help desk for troubleshooting and technical support, and Kiosk fitted with PC workstations for the trade.

7. On 20 June and 4 July 2018, DH held two identical briefing sessions attended by around 260 key stakeholders to brief them the functions and implementation arrangement of PLAMMS Phase II as well as the fundamental workflow for relevant licences and certificates. DH will continue to implement the enhancement of PLAMMS Phase II with ongoing communication with the trade.

8. As planned, the User Acceptance Test (UAT) of PLAMMS Phase II will be conducted between September 2018 and April 2019.

Tentatively, the enhancement is planned to be completed and rolled out in Q4 2019. In parallel, DH will continue to monitor the implementation of PLAMMS Phase I and fine tune the system with the feedback received from the trade.

Advice Sought

9. Members are invited to note the enhancement progress and offer comments, if any.

Department of Health
December 2018

Annex

List of Licences/Certificates Processed through Pharmaceuticals Licence Application and Movement Monitoring System

Phase I (2 types of licences/certificates)	**Phase II** (22 types of licences/certificates)
Import Licence	
Unregistered drugs imported for re-export	Unregistered drugs imported for re-export
	Unregistered drugs imported for particular patient
	Unregistered drugs imported for particular animal
	Unregistered drugs imported for clinical trial / medicinal test
	Unregistered drugs imported for local manufacturer
	Registered drugs
	Psychotropic substances which is also pharmaceutical product
	Dangerous drugs which is also pharmaceutical product
Export Licence	
Unregistered drugs imported for re-export	Unregistered drugs imported for re-export
	Unregistered drugs locally manufactured for export
	Return of unregistered drugs imported for particular patient / animal (for licensed trader only)
	Return of unregistered drugs imported for clinical trial / medicinal test
	Registered drugs
	Psychotropic substances which is also pharmaceutical product
	Dangerous drugs which is also pharmaceutical product
Import Certificate	
	Controlled Item
	Psychotropic Substances
	Dangerous Drugs
Dangerous Drugs (DD) Licence	
	DD Import Licence
	DD Export Licence
	DD Removal Licence
	DD Diversion Licence