Guidance Notes on Application of Import & Export Licences for <u>unregistered pharmaceutical products for re-export purpose</u>

- 1. Pharmaceuticals Licence Application and Movement Monitoring System (PLAMMS) has a function to facilitate the application for import and export licences for the purpose of **re-exporting of unregistered pharmaceutical products or medicines**. Registered Users can apply the import/export licence online and print the approved licence by themselves without the need to collect the approved licence from Drug Office of the Department of Health.
- 2. PLAMMS allows round-the-clock import and export licence application with selfprinting of approved licences for traders. This document aims to introduce the major steps and features of PLAMMS in facilitating licence application for import and re-export of unregistered pharmaceutical products and medicines. The following diagram shows the workflow of using PLAMMS for application of import and export licences of unregistered pharmaceutical products (UPP).

Workflow of PLAMMS



3. User Registration – Applicants are required to become a registered user of PLAMMS so that he/she can login and be able to use the system's functions including on-line application of import/export licence and printing of automated licence approval. Applicant can submit application for user registration by filling in the 'Account Registration Form' of PLAMMS which can be downloaded from Drug Office's website:_

https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Account_Registra_tion_Form_(PLAMMS)_E.pdf?v=e84xa

Completed Account Registration Form should be sent by post or delivered by hand to the Drug Office at:

PLAMMS Service Team Drug Import/Export Control Unit Department of Health Suites 2002-05, 20/F AIA Kowloon Tower, Landmark East 100 How Ming Street, Kwun Tong Kowloon, Hong Kong Tel. 3974 4159

After your application for user registration has been approved, user account and password will be sent to you by email to login the system. (Note: Your company must be holder of appropriate drug dealer's licence(s) and an e-Cert (organizational) of the Hongkong Post.

- 4. **Drug Enlisting** A registered user of PLAMMS can apply for enlisting of UPP in the system by using "Drug Enlisting" function of PLAMMS. Application and functions of 'Drug Enlisting' are described in the PLAMMS User Guide. When UPP has been enlisted in PLAMMS, a registered user must initiate the 'Opening Balance' function and then apply for import/export licence of the enlisted UPP.
- 5. Opening Balance A registered user is required to provide an opening balance for each newly enlisted UPP under "Opening balance" function of PLAMMS. Application and functions of 'Opening Balance' are described in the PLAMMS User Guide. The user cannot make an application for import and export licence via PLAMMS for any enlisted drug unless the opening balance of the corresponding UPP has been initiated.
- 6. **Import Licence Application** A registered user can apply for import licences online via the "Import/Export Licence" function of PLAMMS. User can create, preview and submit import licence application of enlisted drugs for the automated verification process. Application and functions of 'Import Licence Application' are described in the PLAMMS User Guide. For each successful application, the system will generate a new licence number and the approved licence can be printed via PLAMMS.

- 7. Report Shipment (Import) A registered user should report the actual imported shipment within 14 days after the importation of the UPP via the "Report Shipment (Import)" function of PLAMMS. Under this function, the actual imported quantity of the concerned pharmaceutical product as well as its batch number and expiry date are required to be entered into the system. Functions of 'Report Shipment' are described in the PLAMMS User Guide. After completion of each shipment report, the quantity of corresponding batch information of the enlisted UPP will be updated in the ledger of PLAMMS.
- 8. **Export Licence Application** A registered user can apply for export licence online via the "Import/Export Licence" function of PLAMMS. User can create, preview and submit export licence application of enlisted drugs for the automated verification process. Application and functions of 'Export Licence Application' are described in the PLAMMS User Guide. For each successful application, the system will generate a new licence number and the approved licence can be printed via PLAMMS. [Please note that unless you void the export licence on or before the departure date via PLAMMS, the quantity of UPP as per export licence would be automatically deducted from the ledger after the departure date].
- 9. Ledger Ledger in PLAMMS captures the import and export transactions of each batch of the enlisted UPP. Users can check and view the balance and transactions of each enlisted drugs via PLAMMS. The functions of 'Ledger' are described in the PLAMMS User Guide.
- 10. The importer/exporter must print out the **<u>original</u>** of the appropriate licence and comply with the conditions of issue specified on the licence.
- 11. These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular use. Please refer to the Pharmacy and Poisons Ordinance and Import and Export Ordinance for the relevant legal provisions.

Drug Information and Import/Export Control Division Department of Health Drug Office May 2024