INTRODUCTION TO PHARMACEUTICALS LICENCE APPLICATION AND MOVEMENT MONITORING SYSTEM (PLAMMS) PHASE II

DRUG OFFICE,
DEPARTMENT OF HEALTH

20 June and 4 July 2018

Presentation Outline

- Introduction to PLAMMS
- Development and Scope of PLAMMS Phase II
- General Workflow and Enhanced Functions
- Transition Arrangement and Facilitation Measures for Implementation of PLAMMS Phase II
- Interface with Trade Single Window
- Q&A Session

Legal Framework

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Under the Pharmacy and Poisons Ordinance (PPO) (Cap. 138):-

- pharmaceutical products must be registered with the Pharmacy and Poisons Board (PPB) before sale or distribution in Hong Kong;
- pharmaceutical products imported for re-export are exempted from registration;
- the importer or exporter must have the appropriate traders' licences under Section 28A, Cap 138.

Legal Framework (II)

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Under the Import and Export Ordinance (Cap. 60)

- No person shall import or export any pharmaceutical products except under and in accordance with an import or export licence issued under Section 3, Cap.60;
- Each consignment must be covered by the corresponding Import Licence or Export Licence;
- Any person who contravenes shall be guilty of an offence and shall be liable on conviction to a fine of **$500,000** and to imprisonment for **2 years**.

PHARMACEUTICALS LICENCE APPLICATION AND MOVEMENT MONITORING **S**YSTEM (**PLAMMS**)

Before Implementation of PLAMMS Phase I

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- Paper Licences of Trade & Industry Department
  - Form 3 (Import Licence) ($24/20 sets);
  - Form 6 (Export Licence) ($20/20 sets)
- Traders must submit each application and pick up approved licences/certificates in person after one working day for Customs clearance within the validity of the licence
  - 6 months from issue date for Import Licence
  - 28 days from issue date for Export Licence

Sample and Flowchart

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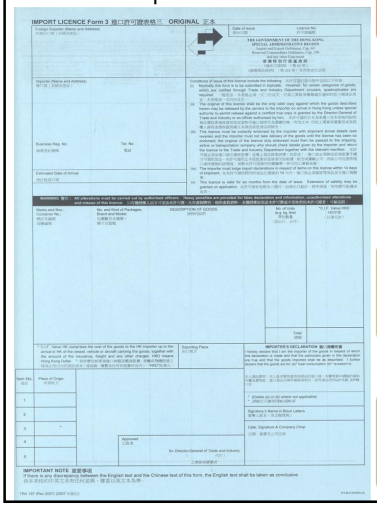
Form 3
Import Licence



DHDO Office
- Procure application forms
- Apply and collect IE licences in person

Trader
- Original IE licences to be provided to cargo/shipping company

Cargo/Shipping Company
- Customs Clearance

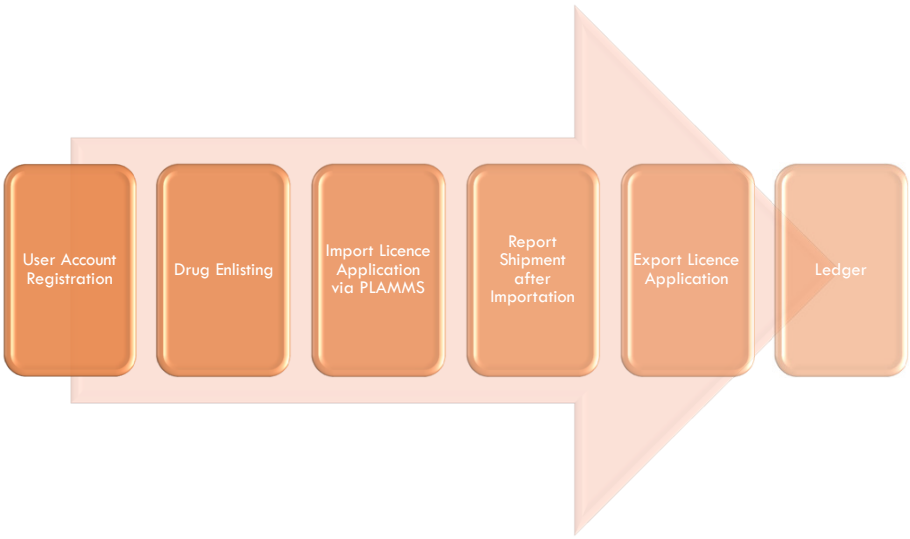
Trader
Report actual shipment with 14 days of arrival or departure

Form 6 Export
Licence

Introduction to PLAMMS

- Review Committee on the Regulation of Pharmaceutical Products in Hong Kong
- PLAMMS is an automatic licensing system to process import and export licences applications and monitor drug movement of unregistered drug products for re-export;
- PLAMMS Phase I rolled out in August 2014 and mandatory Implementation on 1 July 2016;
- Currently, only electronic applications of import licence for the purpose of re-exporting of unregistered pharmaceutical products will be accepted.

Process Flow of PLAMMS Phase I



Introduction to PLAMMS -User Account Registration

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1) Traders must have appropriate trader licence;
2) Traders should first apply for e-certificate from Hongkong Post;
3) Then, sign-in using Hongkong Post e-certificate (Organisational);
4) Traders must manually register an account first;
5) Traders should enlist each pharmaceutical product intended for re-export prior to application of IE licences; and
6) After that, traders may submit import or export licence application and print the licence at your office.

Introduction to PLAMMS -Drug Enlisting

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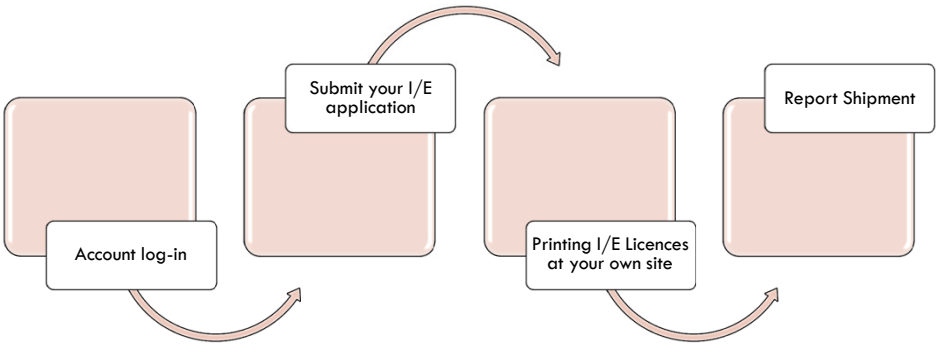
- Drug Enlisting-
  - A step to enlist an unregistered pharmaceutical product in the system with "Drug Enlisting" function;
  - Drug Enlisting only necessary for the first import of the unregistered pharmaceutical product for the purpose of re-export;
  - Once the item is enlisted, registered users are allowed to apply IE licences online and then print the approved licences at their own site.

Introduction to PLAMMS -After Drug Enlisting



Points to note-

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- Each licence is valid for one shipment only. No partial shipment is allowed.
- Section 3 (Operations) of the Code of Practice for Holder of Wholesale Dealer Licence (WDL) stipulated-
  - *A WDL holder should report to the DH the actual import and export of pharmaceutical products within 14 days of the arrival and departure of the shipment of the products upon the implementation of the DH's online import/export licence issuing system;*
  - *For pharmaceutical products imported for export purpose, a WDL holder should export the products within 1 year from the date of importation unless otherwise approved by the DH;*

Points to note

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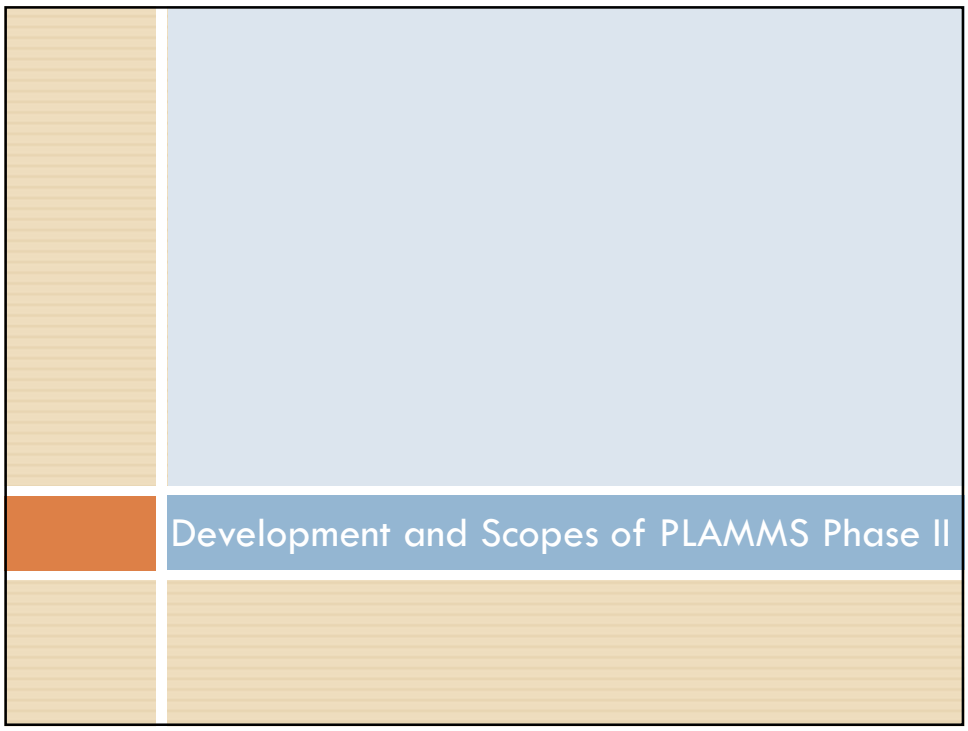
- If the holder of WDL who contravened a code of practice applicable to the licensed wholesale dealer, the Committee may revoke or suspend a WDL, issue a warning letter or vary a condition of the licence.

(Sec. 26, PPR, Chapter 138)



Development and Scopes of PLAMMS Phase II

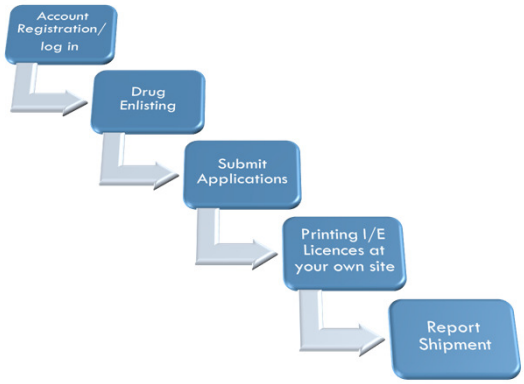
- Further enhancement of PLAMMS to extend the scope of import and export licences/certificates, including
  - registered and unregistered pharmaceutical products;
  - psychotropic substances; and
  - dangerous drugs;
- Tentatively, Phase II will be rolled out in **Q4 2019**.

Development and Scopes of PLAMMS Phase II

PLAMMS Phase I (Import and export licence for)	PLAMMS Phase II (Import or export licence for)
Unregistered pharm. products imported for re-export	1. Unregistered pharm. products imported for re-export; 2. Unregistered pharm. products imported for a particular patient and animal; 3. Unregistered pharm. products imported for clinical trial and medicinal test; 4. Unregistered pharm. products imported for own manufacturing by local manufacturer; 5. Registered pharm. products for local sale or distribution;
	Import certificate for controlled items, e.g. Pseudoephedrine, Phenylpropanolamine, Testosterone, etc.
	Import certificate for psychotropic substances
	Import certificate for dangerous drugs
	Removal licence for dangerous drugs
	Diversion licence for dangerous drugs

Development and Scopes of PLAMMS Phase II

- Steps for using PLAMMS Phase II include-
  - Applies to products import for re-export and import for own manufacturing



Development and Scopes of PLAMMS Phase II

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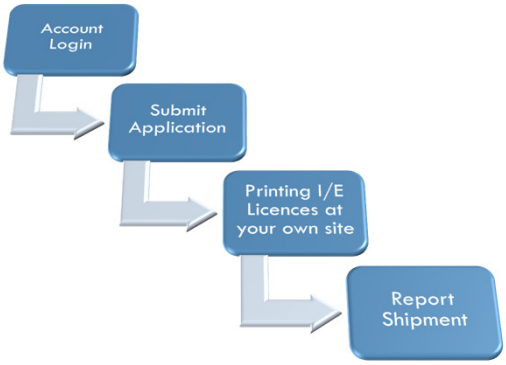
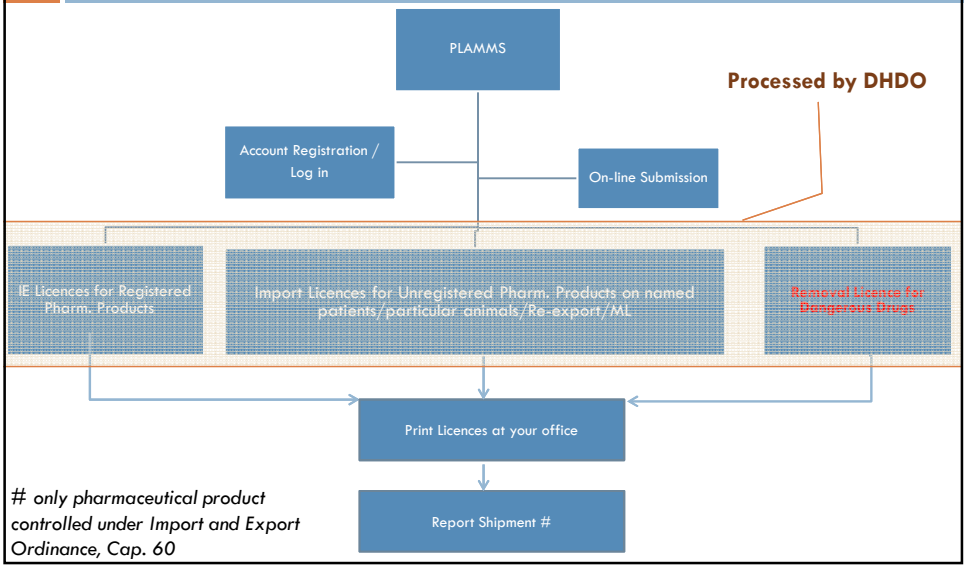
- Steps for using PLAMMS Phase II include-
  - Other IE licences applications under Chapter 60,

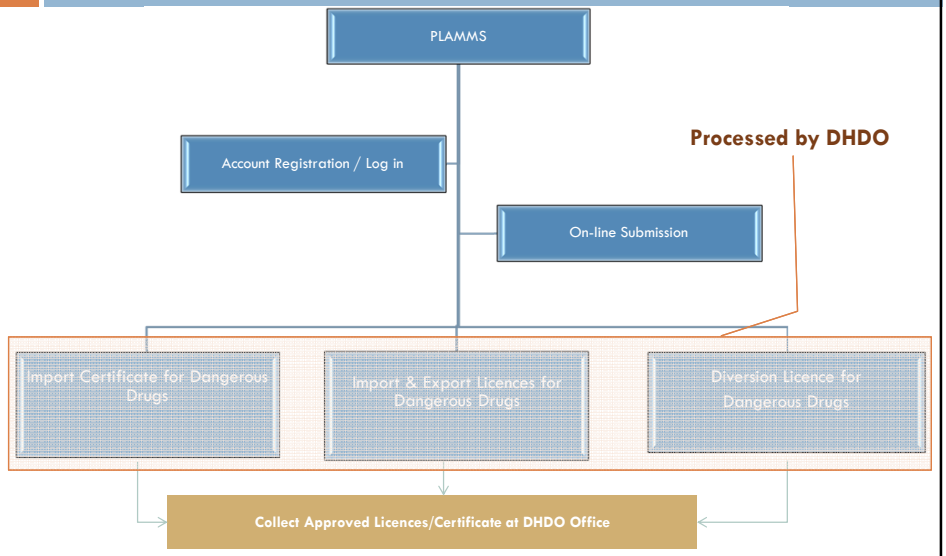


Scope of PLAMMS (Phase II) PLAMMS



 # only pharmaceutical product controlled under Import and Export Ordinance, Cap. 60

Scope of PLAMMS (Phase II)
PLAMMS



Features of PLAMMS

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- Full automation of the IE licences application and approval process;
- Apply IE licences in 24 hours for every day;
- Almost real-time approval of IE licences;
- Allow application very close to the goods arrival;
- Printing of approved licences online by traders at their own site and no longer required visit DHDO for collection, including Removal Licence for Dangerous Drugs;

Features of PLAMMS

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- Resources Saving;
  - no need to buy paper IE licence forms;
  - no travel expenses;
  - saving time is saving money; etc.
- Licence information kept in the system for easy retrieval;
- Ledger function to keep drug IE records and balance;
- Function for traders to retrieve the licence data to TDEC system for trade declaration;

Features of PLAMMS

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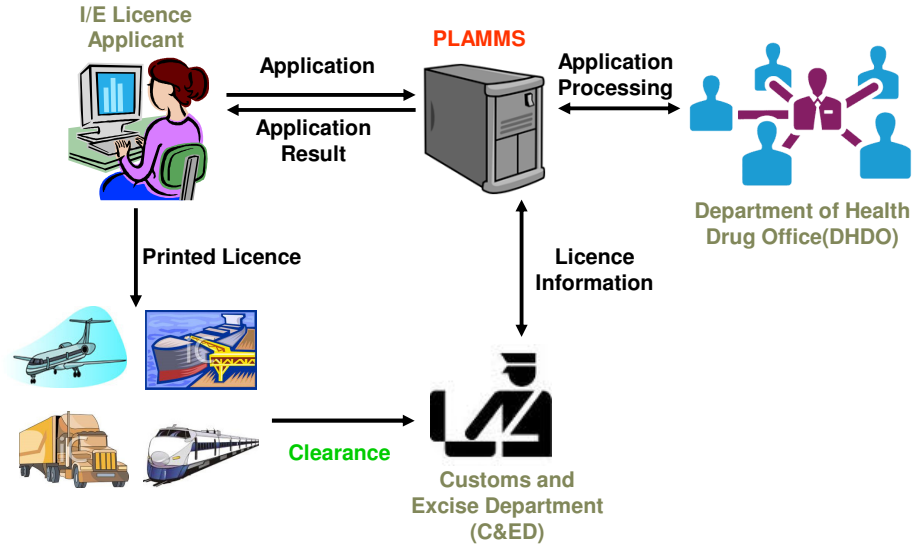
- A function for traders to report actual shipment quantity within 14 days after each shipment
- System monitors the ledge balance of each unregistered drugs for re-export
- Alert applicant to export any remaining unregistered drugs 9 months after importation
- Traders submit Disposal Plan for the outstanding drugs
- Verification of licence information online by C&ED

PLAMMS Phase II

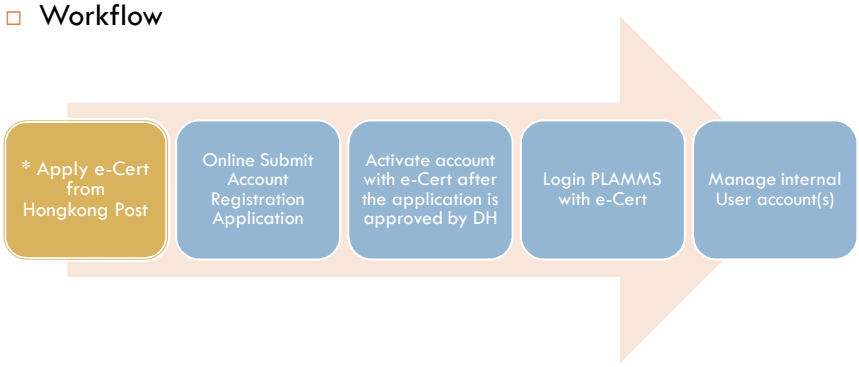
General Workflow and Enhanced Functions

General Workflow



Account Registration and User Account Creation

- Workflow



* Organizational e-Cert is applicable to trader/cert. holder company; and Personal e-Cert is applicable to medical practitioners, dentists, veterinary surgeons, Government Chemist, and laboratory in-charge of universities.

Drug Enlisting

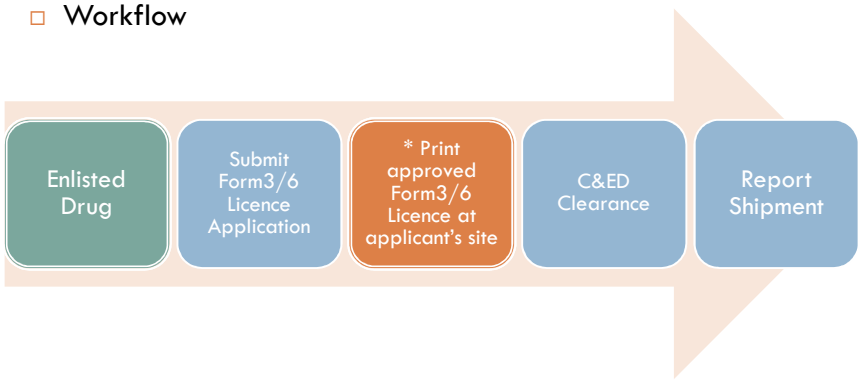
- Workflow

* Necessary for each product prior to the first application of I/E licence.

* It's applicable to the following drugs (except containing controlled substance) :
  - Unregistered drugs imported for re-export (PLAMMS Phase I)
  - Unregistered drugs imported for own manufacturing
  - Unregistered drugs locally manufactured for export

Import and Export Licences for unregistered Drugs for re-export (PLAMMS I)

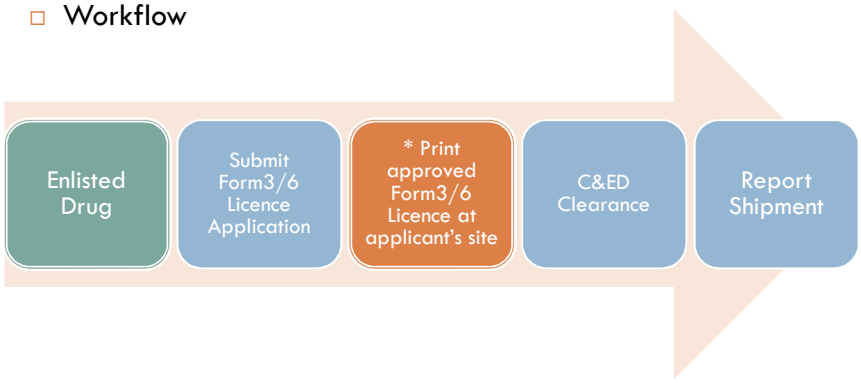
- Workflow



* Not applicable to late submission case or drugs containing controlled substance.

Import and Export Licences for unregistered pharmaceutical products for own manufacturing / locally manufactured for export

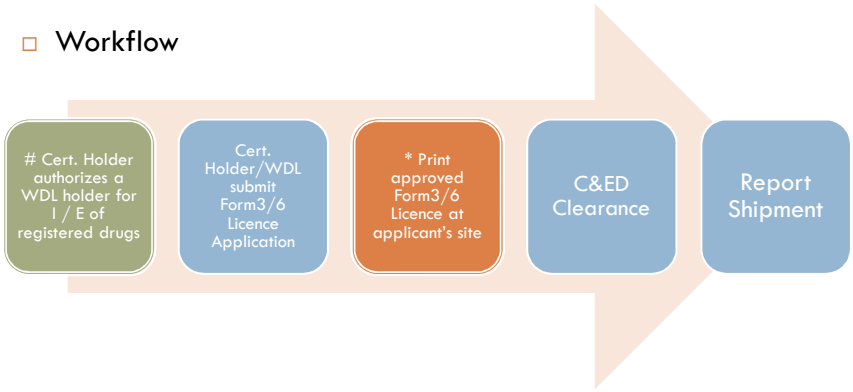
- Workflow



* Not applicable to late submission case or drugs containing controlled substance.

Import and Export Licences for registered pharmaceutical products

- Workflow

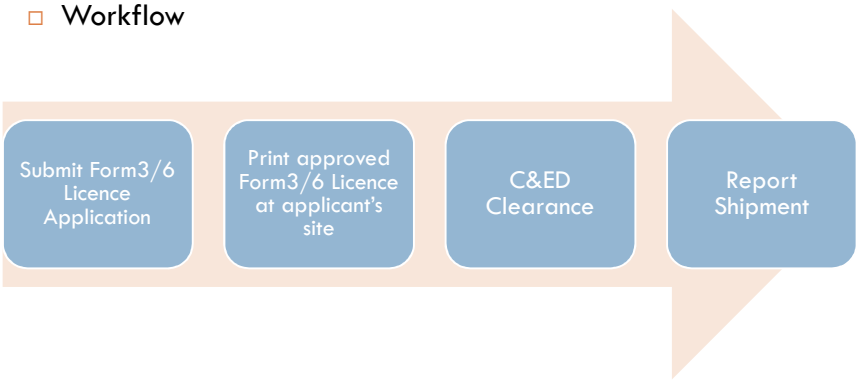


Only applicable if a Cert. Holder authorizes a licensed Wholesaler Dealer to import/export registered drugs. Authorization Letter will not be required for licence application.

* Not applicable to late submission case or drugs containing controlled substance.

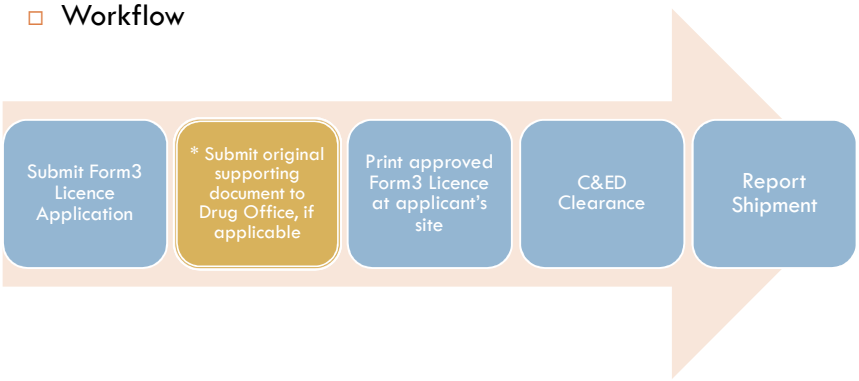
Import and Export Licences for unregistered pharmaceutical products for clinical trial/medicinal test

- Workflow



Import Licence for unregistered pharmaceutical products for particular patients/animals

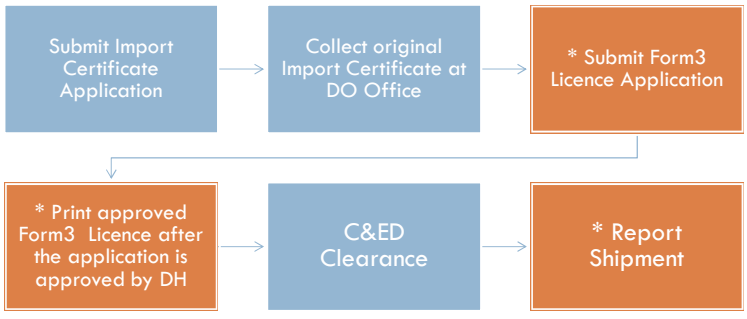
- Workflow



* Original supporting document, e.g. Signed doctor's/vet. surgeon's letter, etc., is required ONLY when the application is submitted by WDL on behalf of doctors/vet. surgeons.

Import of Psychotropic Substance / Controlled Item

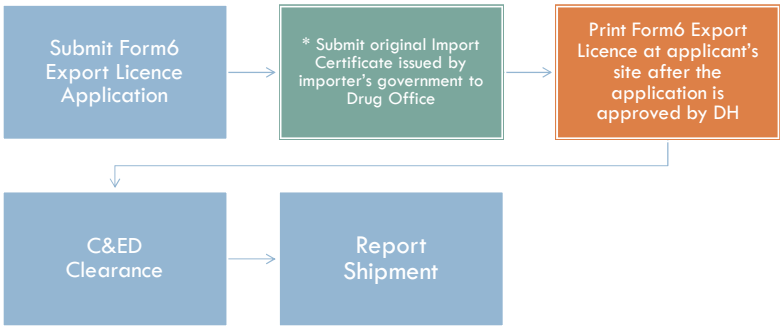
- Workflow



* Only applicable to Psychotropic Substance/Controlled Item which is also Pharmaceutical Product.

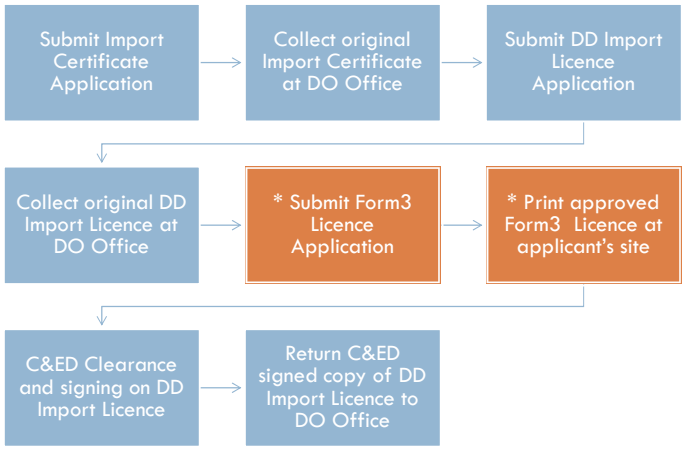
Export of Psychotropic Substance which is also Pharmaceutical Product

- Workflow



Import Licence for Dangerous Drugs (DD)

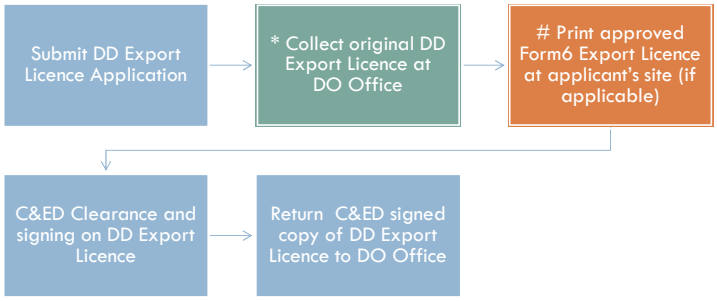
- Workflow



* Only applicable to DD which is also a pharmaceutical product.

Export Licence for Dangerous Drugs (DD)

- Workflow

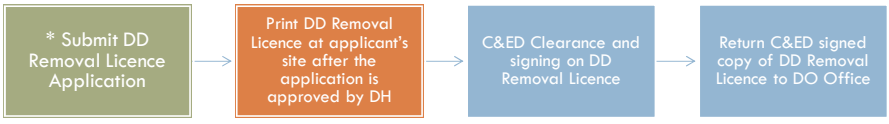


* Original copy of Import Certificate issued by importer's government is required when collecting DD Export Licence.

Only applicable to DD which is also Pharmaceutical Product.

Removal Licence for Dangerous Drugs (DD)

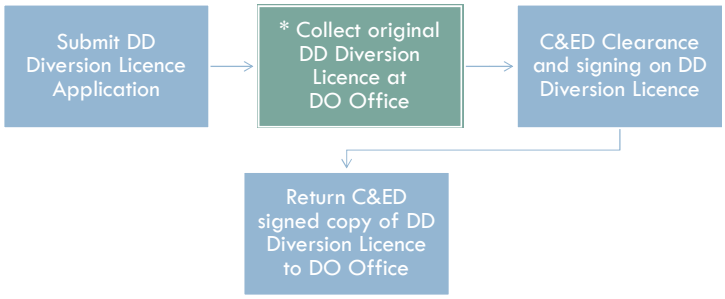
- Workflow



* Applicable to logistics companies only.

Diversion Licence for Dangerous Drugs (DD)

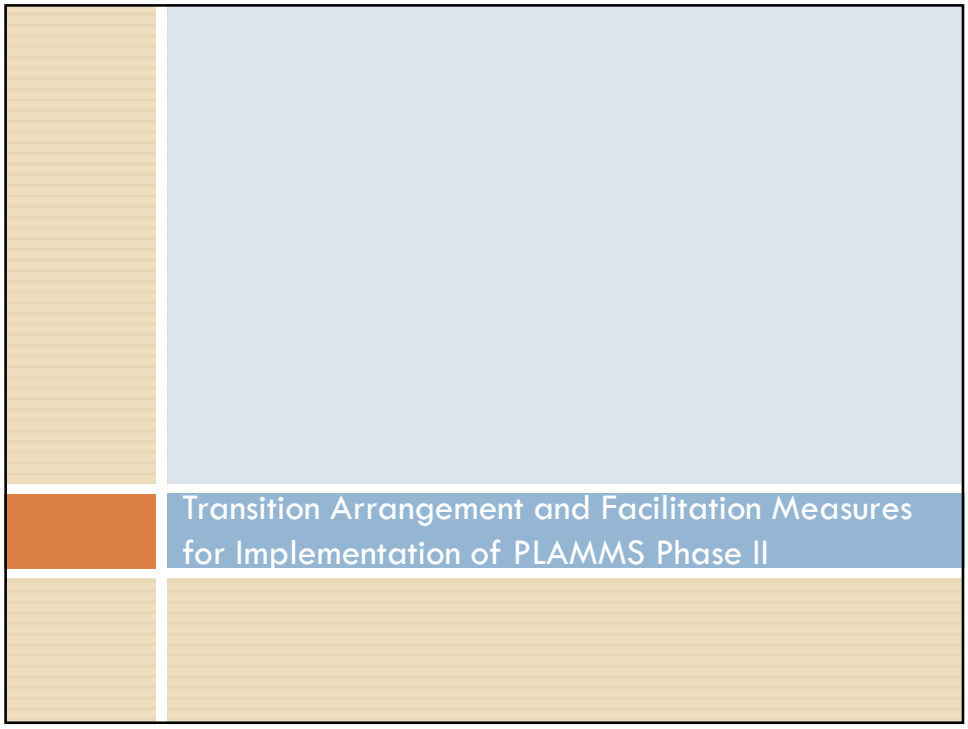
- Workflow



* Original copy of Import Certificate issued by new importer's government is required when collecting DD Diversion Licence.

Enhanced Functions

- PLAMMS Phase II also provides a number of add-on and improved functions-
  - User account interface and management;
  - Licence/certificate preview before submission;
  - Submit new application by copying from application records;
  - Enhanced system notification;
  - Enhanced search function;
  - Enhanced processing flow and data maintenance from dedicated servers;
  - service down-time and communication stoppage minimization.



Transition Arrangement and Facilitation Measures for PLAMMS Phase II

Proposed timeframe for each activity	Trade engagement activities
June & July 2018	Briefing Seminars for introduction of PLAMMS Phase II; Transition arrangement; and Services and support to the trade;
Q2 2019	(1) Briefing Seminar for users operation and utilization of PLAMMS Phase II; and (2) Invitation of interested stakeholders for user acceptance tests;
Q3 2019	New web page for PLAMMS Phase II in DO Website, providing latest news, new user guides and notes for each licence/certificate, letters to trade, faq, etc.

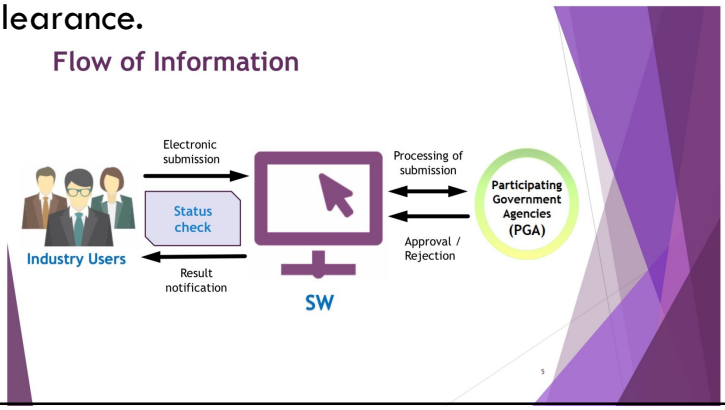
Transition Arrangement and Facilitation Measures for PLAMMS Phase II

Proposed timeframe for each activity	Trade engagement activities
Q4 2019	PLAMMS Phase II roll out;
Q4 2019 and ongoing (After Roll-out)	(1) Invitation of stakeholders for trial run; (2) Small group workshops/User training for interested stakeholders; (3) Help desk for troubleshooting and general assistance; and (4) Kiosk terminals will be provided at DHDO Office.

Interface with Trade Single Window

Interface with Trade Single Window

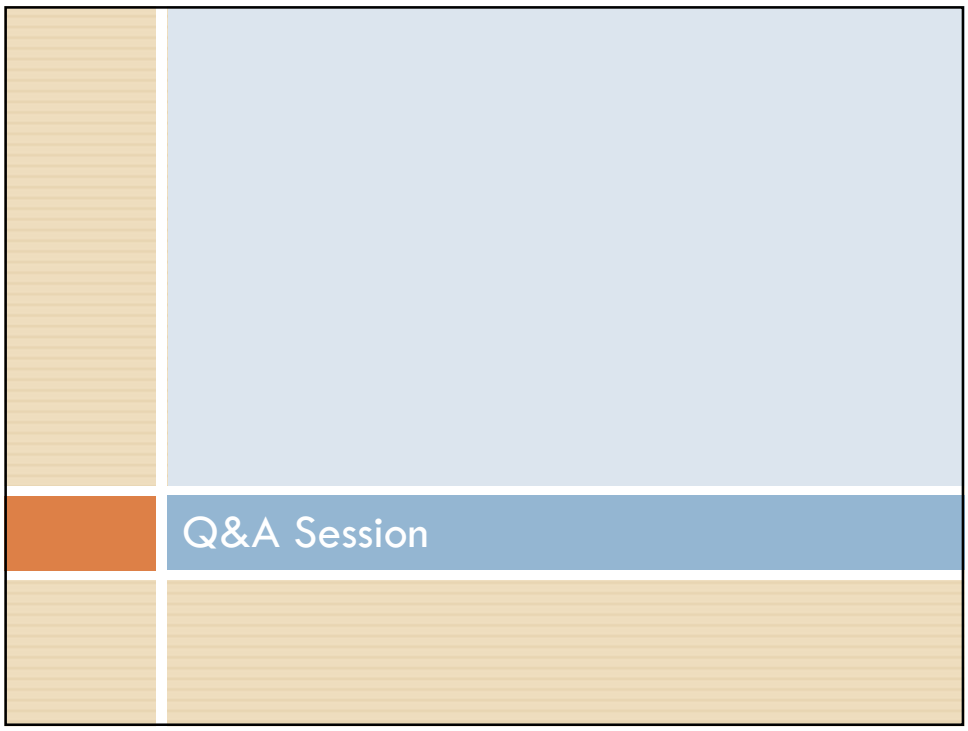
- A one-stop platform for the lodging of Business-to-Government trade documents and submission with Government for trade declaration and customs clearance.



Interface with Trade Single Window

- Trade Single Window (TSW) would save time and cost of the trading community as no longer need to approach different government agencies individually and can lodge IE trade documents electronically round the clock through this centralized platform.

- Common platform for government agencies
  - Better risk-profiling
  - More effective goods tracing


Q&A Session