
Guidance on Application of Import and Export Licences — Advanced Therapy Products

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(Draft for comment)

Drug Office
Department of Health

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1. Introduction

1.1 In Hong Kong, Advanced Therapy Products (“ATPs”) are regulated as pharmaceutical products under the Pharmacy and Poisons Ordinance, Cap. 138 (“PPO”).

1.2 Under the PPO, “pharmaceutical product”—

- (a) means a substance or combination of substances that—
 - (1) is presented as having properties for treating or preventing disease in human beings or animals; or
 - (2) may be used in or administered to human beings or animals with a view to—
 - (A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
 - (B) making a medical diagnosis; and
- (b) includes an advanced therapy product.

1.3 “Advanced Therapy Product” means any of the following products that is for human use—

- (a) a gene therapy product;
- (b) a somatic cell therapy product;
- (c) a tissue engineered product;

1.4 Definitions of gene therapy product, somatic cell therapy product and tissue engineered product are appended at Appendix 1.

1.5 Under sections 6C(1) and 6D(1) of the Import and Export Ordinance, Cap. 60 (“IEO”), no person shall import or export pharmaceutical products and medicines except under and in accordance with a licence issued by the Director-General of Trade and Industry. Any person who contravenes sections 6C(1) and 6D(1) shall be guilty of an offence and shall be liable on conviction to a fine of \$500,000 and to imprisonment for two years.

1.6 The power of issuance of the import and export licence of pharmaceutical products has been delegated to the Department of Health. The Drug Evaluation and Import/Export Control Division of the Drug Office, Department of Health (“DH DO”) is responsible for receiving such application.

1.7 Under sections 28A(1) of the PPO, a person must not carry on business as an importer of

pharmaceutical products unless—

- (a) the person is a licensed wholesale dealer; or
- (b) the person is a licensed manufacturer and the products are imported by the person for the purpose of manufacturing the person's own pharmaceutical products.

1.8 Under sections 28A(2) of the PPO, a person must not carry on business as an exporter of pharmaceutical products unless—

- (a) the person is a licensed wholesale dealer; or
- (b) the person is a licensed manufacturer and the products to be exported are manufactured by the person.

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2. Purpose of this Guidance

2.1 This guidance outlines the requirements and procedures for the application of import and export licences for ATPs and import of pharmaceutical products for ATP manufacturing.

2.2 In addition, this guidance also highlights some of the legislations that may be relevant to the import and export of ATPs and their starting and raw materials for ATP manufacturing owing to their nature.

3. Scope

3.1 This guidance applies to applicants for the import licences for—

- ATPs which are registered pharmaceutical products ("Registered ATPs")
- ATPs which are not registered pharmaceutical products for ("Unregistered ATPs")—
 - (1) clinical trial;
 - (2) the treatment of a particular patient; and
 - (3) re-export; and
- pharmaceutical products as starting and raw materials for ATP manufacturing.

3.2 In addition, this guidance applies to applicants for the export licences for ATPs.

4. Import of Registered ATPs

4.1 For every single importation, the importer needs to submit an application for an Import Licence to the Drug Evaluation and Import/Export Control Division of DH DO.

Applicants

4.2 The applicants for the import licence for registered ATPs should be—

- a licensed wholesale dealer who is the holder of the registration certificate of the product to be imported; or
- a licensed wholesale dealer with a written authorization from the holder of the registration certificate of the product to be imported.

4.3 For details on the application procedures, please refer to [Section 8](#).

4.4 Depending on the nature of the ATPs, other legislative requirements may be applicable to their import. For details, please refer to [Section 9](#).

5. Import of Unregistered ATPs

5.1 According to regulation 36(1) of the Pharmacy and Poisons Regulations, Cap. 138A ("PPR"), pharmaceutical products must be registered before they can be sold, offered for sale or distributed or possessed for the purposes of sale, distribution or other use in Hong Kong.

5.2 The above requirement is not applicable in the case of possession or use where the pharmaceutical product or substance—

- (a) is to be administered for the purposes of a clinical trial that is to be conducted in accordance with a clinical trial certificate issued under regulation 36B(3) of the PPR;
- (b) is possessed or is to be used for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient; or
- (c) has been imported into Hong Kong to be exported outside Hong Kong.

5.3 Since ATPs are regulated as pharmaceutical products, the above exemptions apply to ATPs as well.

5.4 The requirements for application of import licence for unregistered ATPs in the above situations are set out in the subsequent sections.

Import for Clinical Trial

5.5 Under Regulation 36B of the PPR, a certificate for clinical trial/medicinal test is required for the purpose of conducting a clinical trial on human beings. The regulation applies to ATPs.

5.6 Please be reminded that application for the certificate for clinical trial/medicinal test should be made for conducting any clinical trial on human beings. For details of the application, please visit our website at http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/clinicaltrial.html.

5.7 For every single importation of ATPs for clinical trial, the importer needs to submit an application for an Import Licence to the Drug Evaluation and Import/Export Control Division of DH DO.

Applicants

5.8 The applicants for the import licence for unregistered ATPs for clinical trial should be—

- a licensed wholesale dealer who is or on behalf of the holder of the certificate for clinical trial/medicinal test; or
- the holder of the certificate for clinical trial/medicinal test.

5.9 For details on the application procedures, please refer to **Section 8**.

5.10 Depending on the nature of the ATPs, other legislative requirements may be applicable to their import. For details, please refer to **Section 9**.

Import for the Treatment of a Particular Patient

5.11 For every single importation of unregistered ATPs for the treatment of particular patient(s), the importer needs to submit an application for an Import Licence to the Drug Evaluation and Import/Export Control Division of DH DO.

5.12 The application would be considered on a case by case basis.

5.13 The importer should make sure and providing an undertaking that—

- (a) the patient has been or would be properly informed that—
 - (1) the product is not registered in Hong Kong and its safety, efficacy and quality have not been evaluated by the Pharmacy and Poisons Board;
 - (2) the risk of the product, including risk of treatment failure and potential impact of the treatment on future therapies typical for the diagnosis or treatment of the disease;
 - (3) the irreversible nature of the ATP, where applicable;
 - (4) the need for long-term follow-up and commitment, where applicable;
 - (5) if the ATP includes a bacterial or viral vector, the risk and precautionary measures for potential shedding; and
 - (6) any other information applicable to the ATPs; and
- (b) appropriate patient follow-up will be arranged if the ATP has the potential for prolonged biological activity after administration.

5.14 In addition, the product should be manufactured in accordance with the standard of Good Manufacturing Practice.

5.15 With regard to the appropriateness of using the unregistered pharmaceutical product for the purpose of treatment of particular patient, the responsible medical practitioner should observe relevant guidelines and code of professional conduct.

Applicants

5.16 The applicants for the import licence for unregistered ATPs for the treatment of particular patient(s) should be—

- a registered medical practitioner or dentist; or
- a licensed wholesale dealer on behalf of a registered medical practitioner or dentist.

Supporting Documents

5.17 The following documents are required for the application—

- (a) letter of a registered medical practitioner or a registered dentist stating the drug name, required quantity, patient's information (at least with his or her full name) and the rationale for the use of the unregistered ATP;
- (b) if the product has been registered in other countries,
 - (1) proof of that registration; and
 - (2) the product insert;
- (c) if the product has not been registered anywhere in the world, documents supporting the therapeutic use and safety of the product; and
- (d) evidence indicating that the product is manufactured in accordance with the standard of Good Manufacturing Practice.
- (e) a copy of certificate of analysis of the product issued by the manufacturer; if certificate of analysis could not be provided, an undertaking stating the justification(s).

5.18 For details on the application procedures, please refer to Section 8.

5.19 Depending on the nature of the ATPs, other legislative requirements may be applicable to their import. For details, please refer to Section 9.

Special Requirements on Safety Monitoring and ADR Reporting

5.20 The importer and the registered medical doctor or dentist are required to engage in the safety monitoring of this ATP and should report suspected adverse drug reactions occurring in patients taking the above drug to the Drug Office.

5.21 For details of the adverse drug reaction reporting, please visit our website at <http://www.drugoffice.gov.hk/adr.html>.

Import for Re-Export

5.22 For every single importation, the importer needs to submit an application for an Import Licence to the Drug Evaluation and Import/Export Control Division of DH DO.

Applicants

5.23 The applicants for the import licence for unregistered ATPs for re-export should be a licensed wholesale dealer.

Supporting Document

5.24 For the application, the applicant is required to provide supporting documents showing the details of the product, including product name, product description, indication, strength, dose form, unit dose, pack size, name of manufacturer and the country of origin.

5.25 For details on the application procedures, please refer to [Section 8](#).

5.26 Depending on the nature of the ATPs, other legislative requirements may be applicable to their import. For details, please refer to [Section 9](#).

5.27 Please note that approval of the import licence application does not necessarily mean that a subsequent export licence application for re-export of the goods to the country you have indicated will be approved.

6. Import for Manufacture of ATPs

6.1 The licensed manufacturer may import starting and raw materials for manufacturing of their own ATPs.

Import of Pharmaceutical Products for own Manufacturing

6.2 Some starting and raw materials for manufacturing of ATPs may fall within the definition of pharmaceutical product and ATPs. Examples include human albumin and growth factors that—

- is presented as having properties for treating or preventing disease in human beings or animals; or
- may be used in or administered to human beings or animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

6.3 For every single importation of pharmaceutical product for own manufacturing, the importer needs to submit an application for an Import Licence to the Drug Evaluation and Import/Export Control Division of DH DO.

Applicants

6.4 The applicants for the import licence for pharmaceutical product for manufacture should be a licensed manufacturer and the import should be for the purpose of manufacturing the applicants' own ATPs.

6.5 For details on the application procedures, please refer to [Section 8](#).

6.6 However, depending on the nature of the materials, other legislative requirements may be applicable to their import. For details, please refer to [Section 9](#).

Import of Starting and Raw Materials that are not Considered as Pharmaceutical Products

6.7 Submission of an application for an Import Licence to the Drug Evaluation and Import/Export Control Division of DH DO is not required for the importation of materials that are not considered as pharmaceutical products for manufacturing of ATPs.

6.8 Examples of these starting and raw materials include—

- blood or cells for the manufacturing of ATPs; and
- culture media, scaffold, culture media for the manufacturing of ATPs.

6.9 However, depending on the nature of the materials, other legislative requirements may be applicable to their import. For details, please refer to [Section 9](#).

7. Export of ATPs and Starting or Raw Materials for Manufacture of ATPs

Export of ATPs

7.1 For every single exportation of ATPs, the exporter needs to submit an application for an Export Licence to the Drug Evaluation and Import/Export Control Division of DH DO.

Applicants

7.2 The applicants for the export licence for ATPs should be—

- a licensed wholesale dealer, or
- a licensed manufacturer by whom the product to be exported is manufactured

7.3 For details on the application procedures, please refer to [Section 8](#).

Export of Starting or Raw Materials for Manufacture of ATPs

7.4 Submission for an application for an Export Licence to the Drug Evaluation and Import/Export Control Division of DH DO is not required for the exportation of materials that are not considered as pharmaceutical products (for example, blood, cells and tissues) for manufacturing of ATPs overseas.

7.5 However, depending on the nature of the materials, other legislative requirements may be applicable to their export. For details, please refer to [Section 9](#).

8. Application and Issuance of Import and Export Licences

8.1 The application for the import and export licence for ATPs can be made—

- through the electronic system, namely Pharmaceuticals Licence Application and Movement Monitoring System ("PLAMMS"); or
- in person with the completed Import and Export Licence Forms (except the applications for unregistered ATPs for re-export purpose)

8.2 With effect from 1 July 2016, applications for import and export licences for unregistered pharmaceutical products for re-export purpose can only be made through the PLAMMS.

8.3 The scope of import/export licence processing using the PLAMMS has been extended in two stages –

- from 30 September 2019 onwards, all applications for import and export licences of registered pharmaceutical products; and
- from 30 December 2019 onwards, all applications for import and export licences of the following products or substances –
 - Registered pharmaceutical products;
 - Unregistered pharmaceutical products for the treatment of particular patients by a registered medical practitioner or dentist;
 - Pharmaceutical products for the purpose of clinical trials; and
 - Pharmaceutical products or substances imported by a pharmaceutical manufacturer for the purpose of manufacture of pharmaceutical products.

8.4 Manual submission of Import and Export Licence Forms for the above applications will still be accepted during the transition period until further notice. For further details on the implementation of PLAMMS, you may wish to visit the DH DO webpage at http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_for_ms.html.

8.5 Applications for import and export licences for ATPs are free of charge.

8.6 Please note that applications for Import Licence of unregistered ATPs for the treatment of particular patient(s) are considered on a case-by-case basis. The application should be lodged well before the estimated date of arrival to allow sufficient time for the application to be processed and approved.

Through PLAMMS

8.7 The PLAMMS can be used for submitting applications for import and export licences of ATPs.

8.8 The application procedures are summarised in the subsequent sections. For further details on how to use the PLAMMS, please refer to the PLAMMS User Guide, available at http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/PLAMMS_User_Guide.pdf?v=zc53od, and the DH DO Webpage at http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_for_ms.html.

User Registration (for First Time User Only)

8.9 Applicants are required to become a registered PLAMMS user before they can use the various functions of the PLAMMS.

8.10 In order to use the system, the applicants are required to have—

- for company applicants, a Hongkong Post e-Cert (Organisational) which is specific to each intended user(s) in supervisor role within your company; or
- for registered medical practitioners or dentists, a Hongkong Post e-Cert (Personal).

8.11 After successful application for the relevant e-Cert, the applicants are required to complete an PLAMMS Account Registration Form available at [http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Account_Registration_Form_\(PLAMMS\)_E_n_TC.pdf?v=rj520l](http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Account_Registration_Form_(PLAMMS)_E_n_TC.pdf?v=rj520l).

8.12 In order to proceed the registration, the applicant should provide—

- for company applicants, a copy of their business registration certificate; or
- for registered medical practitioners or dentists, a copy of their certificate of registration.

8.13 If an account registration form is used, the completed form, together with the copy of document mentioned in 8.11, should be submitted by post, delivery or in person to the below address—

PLAMMS Service Team

Drug Evaluation and Import/Export Control Division

Drug Office, Department of Health

Suites 2002-05, 20/F
AIA Kowloon Tower, Landmark East
100 How Ming Street
Kwun Tong, Kowloon

8.14 Upon successful application, a confirmation of registration with a PLAMMS user account and log-in password will be sent to the applicant's email provided in the PLAMMS account registration application.

Drug Enlisting and Setting Opening Balance (for Importing Unregistered ATPs for Re-export Only)

8.15 For importing an unregistered ATPs for re-export purpose for the first time, the registered PLAMMS users are required to enlist the product to the PLAMMS by using the "Drug Enlisting" function of the system. Once a product has been enlisted in PLAMMS by a PLAMMS user, that user and other users of the same company are not required to enlist the same product to the PLAMMS again for the subsequent import and export licence application.

8.16 The steps for enlisting a product to PLAMMS are described in section 3 of the PLAMMS User Guide.

8.17 Information required for enlisting includes—

- drug name;
- dosage form;
- pack size;
- manufacturer;
- country of origin;
- active ingredient(s);
- supporting documents showing the details of the product, including product name, product description, indication, strength, dosage form, unit dose, pack size, name of manufacturer and the country of origin; and
- Hong Kong Harmonized System (HS) code – the HS code could be searched at the Census and Statistics Department website (<https://www.censtatd.gov.hk/trader/hrcode/index.jsp>).

8.18 After enlisting the product to the PLAMMS, the registered PLAMMS users are required to provide an opening balance for each newly enlisted product.

8.19 The steps for setting opening balance in PLAMMS are described in section 7 of the PLAMMS User

Guide.

8.20 Please note that applications for import and export licences for a product could not be made unless the opening balance of that product has been initiated.

Import and Export Licence Application

8.21 Registered PLAMMS users can apply for the import and export licence online via the "Import/Export Licence" function of the PLAMMS.

8.22 The steps for application of the import and export licence in PLAMMS are described in Section 4 of the PLAMMS User Guide.

8.23 The below supporting documents are required to be uploaded to the PLAMMS during the licence application.

Licence	Products	Documents required
Import Licence	Registered ATPs	<ul style="list-style-type: none">● If the applicant is not the holder of the registration certificate holder of the product to be imported, a written authorization from the relevant product registration certificate holder to support the application
	Unregistered ATPs for clinical trial	<ul style="list-style-type: none">● Copy of Certificate of registration for clinical trial/medical test of the product(s) to be imported
	Unregistered ATPs for the treatment of a particular patient	<ul style="list-style-type: none">● Letter of a registered medical practitioner or a registered dentist stating the drug name, required quantity, patient's information (at least with his or her full name) and the rationale for the use of the unregistered ATP● If the product has been registered in other countries,<ul style="list-style-type: none">■ proof of that registration; and■ the product insert.● If the product has not been registered anywhere in the world, documents supporting the therapeutic use of the product● Evidence indicating that the product is manufactured in accordance with the standard of Good Manufacturing Practice

8.24 Condition(s) may be specified on the licence. The importer or exporter must comply with the condition(s) specified on the licence.

8.25 Please note that approval of the import licence application for re-export of ATPs does not necessarily mean that a subsequent export licence application for re-export to the country you have indicated will be approved.

Reporting Shipment (for Importing Unregistered ATPs for Re-export Only)

8.26 The registered PLAMMS users should report actual imported shipment via the "Report Shipment (Import)" function of the PLAMMS within 14 days after the importation of unregistered ATPs for re-export.

8.27 The actual imported quantity of the ATPs as well as their batch number and expiry date are required to be entered into the PLAMMS.

8.28 The steps for reporting shipment are described in Section 4.5 of the PLAMMS User Guide.

In-person Licence Application

8.29 For the in-person licence application, applicants are required to complete an Import Licence Form (Form 3) or Export Licence Form (Form 6).

Import and Export Licence Forms

8.30 The Import Licence Form (Form 3) (TRA 187) or Export Licence Form (Form 6) (TRA 394) are available for sale at the following locations—

- Trade and Industry Department
Room 1309, 13/F, Trade and Industry Tower, 3 Concorde Road, Kowloon City, Kowloon
Telephone number: 2398 5325
- Shroff Office of the Drug Evaluation and Import/Export Control Division, DH DO
Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon
Telephone Number: 3974 4178

8.31 Detailed notes on how to complete the Import and Export Licence Forms are set out in Appendix 2 and the specimen copy of a completed Import Licence Form and Export Licence Form are appended at Appendices 3 and 4 respectively.

8.32 The following notes should be made on the Import and Export Licence Form—

Licence	Products	Note(s)
Import Licence	Registered ATPs	Mark the Hong Kong Registration Number in the "Description of Goods" section of the Licence Form
Import Licence	Unregistered ATPs for re-export	Make a declaration that the goods are for "re-export" in the "Importer's Declaration" section of the Licence Form
	Unregistered ATPs for clinical trial	State "for the purpose of clinical trial" on the Licence Form in the "Importer's Declaration" section of the Licence Form
	Unregistered ATPs for the treatment of a particular patient	State "for the purpose of treatment by a registered medical practitioner of a particular patient" or "for the purpose of treatment by a registered dentist of a particular patient" in the "Importer's Declaration" section of the Licence Form

	Pharmaceutical Products for manufacture	State "for the purpose of manufacture or the compounding of pharmaceutical preparations" in the "Importer's Declaration" section of the Licence Form
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Supporting Documents

8.33 The below supporting documents are required to be submitted for the application.

Licence	Products	Documents required
Import Licence	Registered ATPs	<ul style="list-style-type: none"> ● A copy of certificate of registration of the product(s) to be imported ● A copy of wholesale dealer's licence of the applicant ● If the applicant is not the holder of the registration certificate holder of the product to be imported, a written authorization from the relevant product registration certificate holder to support the application
Export Licence		<ul style="list-style-type: none"> ● A copy of wholesale dealer's licence of the applicant ● A copy of valid manufacturer's licence of the applicant if the ATPs to be exported are manufactured by the applicant.
Import Licence	Unregistered ATPs for clinical trial	<ul style="list-style-type: none"> ● A copy of certificate of registration for clinical trial/medical test of the product(s) to be imported ● If the applicant is a licensed wholesale dealer, a copy of the wholesale dealer's licence ● If the applicant is a registered medical practitioner or dentist, a copy of the certificate of registration
	Unregistered ATPs for the treatment of a particular patient	<ul style="list-style-type: none"> ● Letter of a registered medical practitioner or a registered dentist stating the drug name, required quantity, patient's information (at least with his or her full name) and the rationale for the use of the unregistered ATP ● If the product has been registered in other countries, <ul style="list-style-type: none"> ■ proof of that registration; and ■ the product insert. ● If the product has not been registered anywhere in the world, documents supporting the therapeutic use of the

		product <ul style="list-style-type: none"> ● Evidence indicating that the product is manufactured in accordance with the standard of Good Manufacturing Practice ● If the applicant is a licensed wholesale dealer, a copy of the wholesale dealer's licence ● If the applicant is a registered medical practitioner or dentist, a copy of the certificate of registration
	Pharmaceutical Products for manufacture	<ul style="list-style-type: none"> ● A copy of valid manufacturer's licence of the applicant.

Submission of Application

8.34 The duly completed Import Licence Form (Form 3) or Export Licence Form (Form 6) together with the required supporting documents mentioned in 8.33 should be submitted to —

Drug Evaluation and Import/Export Control Division
 Suites 2002-05, 20/F
 AIA Kowloon Tower, Landmark East
 100 How Ming Street
 Kwun Tong, Kowloon

8.35 Upon receipt of the application, a numbered receipt will be issued to the applicant.

Collection of Licence

8.36 Provided that all the submitted documents are satisfactory after review, the applicants could collect the processed applications at the above office with the numbered receipt.

8.37 A licence with condition(s) may be issued. The importer or exporter must comply with the condition(s) specified on the licence.

Presentation of Licence to Carrier

8.38 For the import licence application, the applicant will be given the original and duplicate of licence. The original is to enable the licensee to take delivery of the goods from the carrier (shipping company, airline or transportation company). Please note that under Section 8 of the IEO, the original must be presented to the carrier within 7 days after importation of the goods, irrespective of whether delivery of the goods is taken. The duplicate is for the applicant's retention.

8.39 For the export licence application, the applicant will be given only the original, which should be surrendered to the carrier. Please note that under Section 10 of the IEO, without the original export licence, the carrier is forbidden from accepting the goods for export.

9. Other Relevant Legislation

9.1 Depending on the nature of the ATPs and starting and raw materials for ATP manufacturing, other legislative requirements may be applicable to their import and export.

9.2 This section serves only as a general guide and must not be treated as a complete or authoritative statement of the law on any particular case. You are advised to refer to the IEO and other relevant legislations at Hong Kong e-Legislation (<http://www.elegislation.gov.hk>). Should you have any question when interpreting the legislation, please obtain legal advice or consult relevant expert.

Import of ATPs or Starting or Raw Materials containing Infectious Agents (e.g. Biological Materials)

9.3 For ATPs or starting or raw materials for ATP manufacturing (e.g. biological materials) containing or consisting of infectious agents (e.g. viral vectors) or suspected to be containing infectious agents, an additional import or transshipment permit may be required under the Prevention and Control of Disease Regulation, Cap. 599A.

9.4 Further details including the relevant application form can be found at the website of the Port Health Division of the Department of Health (https://www.dh.gov.hk/english/main/main_ph/main_ph.html).

Import of ATPs or Starting or Raw Materials containing Animal Products

9.5 For ATPs or starting or raw materials containing or consisting of parts or derivatives of a dog, a cat (e.g. dog skin, canine plasma, etc.), or any animal that has been infected with rabies, an additional import licence may be required under the Rabies Regulation, Cap. 421.

9.6 Further details can be found at the website of the Agriculture, Fisheries and Conservation Department (<http://www.afcd.gov.hk/eindex.html>).

Import of Starting or Raw Materials containing Genetically Modified Organisms

9.7 Under the Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607, shipments containing Genetically Modified Organisms ("GMOs") (including those intended for release into environment¹ and contained use²), when being imported or exported, have to be accompanied with prescribed documents to enable easy identification of the GMOs and to provide the contact points for further information. The detailed documentation requirements are laid down in the Genetically Modified Organisms (Documentation for Import and Export) Regulation, Cap. 607A.

9.8 In addition, no one is allowed to release a GMO into the environment, import a GMO intended for release into the environment or maintain the life of a GMO that is in state of being released into the environment unless—

- (a) the GMO has been approved and any condition for the approval has been complied with; or
- (b) the GMO has been exempted by the Secretary for the Environment from the restriction and any condition for the exemption has been complied with.

9.9 Even though the above ordinance does not apply to or in relation to a GMO that is a pharmaceutical product for use by human being, the above ordinance may apply to starting and raw materials containing or consisting of GMOs.

9.10 For details, please refer to the website of the Agriculture, Fisheries and Conservation Department (<http://www.afcd.gov.hk/eindex.html>).

¹ According to section 3(1) of the Genetically Modified Organisms (Control of Release) Ordinance (Cap. 607), a GMO is released into the environment if (a) it is not in contained use; and (b) it is exposed to a condition in which it may grow or reproduce.

² According to section 3(2) of the Genetically Modified Organisms (Control of Release) Ordinance (Cap. 607), a GMO is in contained use if (a) it is involved in an operation that is undertaken within a facility, installation or other physical barrier; and (b) it is controlled by specific measures that effectively limit its contact with, and its impact on, the environment.

10. Enquiries

10.1 For enquiries relating to the import and export licence application for pharmaceutical products, please contact the Drug Evaluation and Import/Export Control Division, DH DO—

Address:

Suites 2002-05, 20/F

AIA Kowloon Tower, Landmark East

100 How Ming Street

Kwun Tong, Kowloon

Email: pharmgeneral@dh.gov.hk

Telephone Number: 3974 4180

Office Hours:

Monday to Friday

9:00 a.m. to 1:00 p.m.

2:00 p.m. to 5:45 p.m.

(up to 6:00 p.m. on Monday)

(Closed on Saturdays, Sundays and

Public Holidays)

10.2 For enquiries relating to the PLAMMS, please contact the PLAMMS Service Team of the above division—

Email: plammsinfo@dh.gov.hk

Telephone Number: 3974 4159

Appendix 1 Definitions of Advanced Therapy Products (Proposed)

Gene Therapy Product

Gene therapy product—

- (a) means a product—
 - (1) that contains an active substance containing or consisting of a recombinant nucleic acid that may be used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and
 - (2) the therapeutic, prophylactic or diagnostic effect of which relates directly to—
 - (A) the recombinant nucleic acid sequence it contains; or
 - (B) the product of genetic expression of that sequence; but
- (b) does not include a vaccine against an infectious disease.

Somatic Cell Therapy Product

Somatic cell therapy product means a product that—

- (a) contains or consists of any of the following cells or tissues—
 - (1) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
 - (2) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and
- (b) is presented as having properties for, or may be used in or administered to human beings with a view to—
 - (1) treating, preventing or diagnosing a disease; or
 - (2) restoring, correcting or modifying physiological functions,through the pharmacological, immunological or metabolic action of those cells or tissues.

Tissue Engineered Product

Tissue engineered product—

- (a) means a product that—
 - (1) contains or consists of any of the following cells or tissues—
 - (A) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement have been altered;

-
- (B) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and
 - (2) is presented as having properties for, or may be used in or administered to human beings with a view to, regenerating, repairing or replacing a human tissue; but
- (b) does not include a product that—
- (1) contains or consists of exclusively non-viable human or animal cells or tissues; and
 - (2) does not act principally by pharmacological, immunological or metabolic action.

Substantial Manipulation

Substantial manipulation, in relation to cells or tissues, does not include the manipulation processes set out in the Schedule of the Pharmacy and Poisons Ordinance (Cap. 138).

Under the Schedule of Cap. 138, the following manipulation processes are not substantial manipulations—

1. Cutting
2. Grinding
3. Shaping
4. Centrifugation
5. Soaking in antibiotic or antimicrobial solutions
6. Sterilization
7. Irradiation
8. Cell separation, concentration or purification
9. Filtering
10. Lyophilization
11. Freezing
12. Cryopreservation
13. Vitrification

Appendix 2 Notes on Completing the Import and Export Licence Forms for ATPs

Please follow this guidance for completing the import and export licence forms for ATPs.

General Instructions

2. Import Licence Form (Form 3) and Export Licence Form (Form 6) are printed on NCR (No-Carbon-Required) paper. Traders will only need to complete/sign on the first (original) copy and the application particulars/signatures will come out on the other copies. Please apply company chop on each and every page of the licence form (Note (n)).
3. No erasure or correction fluid should be used on licence forms. Errors should be clearly and tidily crossed out. Please initial, date and apply your company's amendment chop against all amendments, defacements, additions or deletions made. No more than 3 amendment chops are allowed for each application. Any amendments of the licence after issue could only be made by the Department upon receipt of written applications for amendments by the licensees concerned.

Notes on Particular Fields

4. The alphabets given to each note correspond to the note alphabets in the specimen import and export licence form at Appendices 3 and 4 respectively. Unless otherwise specified, the notes apply to both the import and export licence applications for ATPs.
- (a) Name and Address of Importer/Exporter
 - Please give the company name and full address.
 - P.O. Box number or 'Company A on behalf of Company B' is not accepted.
 - (b) Business Registration Number
 - If the applicant is an individual and not a company or firm, the Hong Kong identity card number or passport number of the applicant should be provided.
 - (c) Name and Address of Foreign Exporter (for Import Licence Form)
 - Please give the name and full address.
 - P.O. Box number or 'Company A on behalf of Company B' is not accepted.
 - The country must be clearly specified and should tally with the exporting place (Note (o)) stated on the application.
 - (d) Name and Address of Consignee (for Export Licence Form)
 - Please give the name and full address.
 - P.O. Box number or 'Company A on behalf of Company B' is not accepted.
 - The country must be clearly specified and should tally with the destination (Note (p)) stated on the application.

(e) Arrival/Departure Date

- Please give the date of arrival/departure.
- If the exact date is not known, an intended date is acceptable.
- Licence application should be lodged well before the intended date of arrival/departure to allow sufficient time for the application to be processed and approved.

(f) Vessel/Flight/Vehicle Number

- Please state the mode of transport (by air, sea or land, etc.).
- Please give the name of vessel and voyage, flight or vehicle number, if available.

(g) Marks and Nos.; Container No.

- Please give the shipping marks and numbers and container number.
- If there are no shipping marks and numbers, please state 'No marks'.

(h) No. and Kind of Packages

- Please indicate the number of packages/cartons, etc. in both words and numerals and specify the type/mode/form of packages, e.g. Two (2) cartons

(i) Description of Goods

- Please give a full product description for each item of the goods including the brand name where applicable.
- The common name should also be given.
- For registered pharmaceutical products, please specify the Hong Kong registration number (HK-XXXXX).
- Use of abbreviations and in-house terms should be avoided.
- Please enter no more than five items on each application.
- Blank space beneath the last goods to be declared must be crossed out.

(j) No. of Units

- Please put 1 asterisk immediately in front of and behind the numeral showing the quantity of the goods and give the appropriate unit, e.g. ml, gram, bottles, boxes, etc. in which the quantity of the goods is expressed, e.g. *24*bottles.

(k) Importer's Declaration (for Import Licence Form)

- Please indicate whether the goods are for local consumption or for re-export. If the goods are for re-export, please name the country to which the goods will subsequently be re-exported.

(l) Signatory's Name

- Please give the signatory's name in block letters.
- Initials are not accepted.

(m) Date and Signature

- Please insert the date and sign the application.
- The declaration must be signed by an authorized official of the company.
- Declaration cannot be made on behalf of another company.

(n) Company Chop

- Please apply company chop on each and every page of the application.
- The company chop should be clear and legible.

(o) Exporting Country

- The exporting country should tally with the country of the foreign exporter in Note (c).

(p) Destination Country and Code

- The destination country should tally with the country of the consignee in Note (d).
- The code numbers need not be given, if unknown.

(q) Origin Country/Place of Origin

- Please name the place of origin for each item of goods.
- This is the place where the goods are manufactured and is not necessarily the exporting place.

(r) Code Numbers of Place of Origin and Destination (for Export Licence Form)


- The code numbers need not be given, if unknown.

(s) Name and Address of HK Manufacturer/Processor (for Export Licence Form)

- Please give the name and address of the Hong Kong manufacturer or processor.
- If the goods are not of Hong Kong origin, the box can be left blank.

Appendix 3 Specimen Import Licence Form (Form 3)

IMPORT LICENCE Form 3 進口許可證表格三 ORIGINAL 正本

Foreign Exporter (Name and Address) 外地出口商 (名稱及地址) XYZ Co Ltd 123 First Street Washington D. C. 12345 U. S. A.		Date of Issue 發出日期 		Licence No. 許可證編號 THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION Import and Export Ordinance, Cap. 60 Reserved Commodities Ordinance, Cap. 296 and any other Enactment 香港特別行政區政府 《進出口條例》(第60章) 《儲備商品條例》(第296章)及其他成文法例	
Importer (Name and Address) 進口商 (名稱及地址) ABC Co Ltd Room 10, ABC Building 3000 Nathan Road Kowloon, Hong Kong		Conditions of issue of this licence include the following 本許可證的發出條件包括以下各項: (i) Normally this form is to be submitted in triplicate. However, for certain categories of goods, which are notified through Trade and Industry Department circulars, quadruplicates are required. 一般而言, 本表格必須一式三份呈交, 但就工業貿易署通告通知的若干類貨品而言, 本表格須一式四份呈交。 (ii) The original of this licence shall be the only valid copy against which the goods described herein may be released by the carriers to the importer on arrival in Hong Kong unless special authority to permit release against a certified true copy is granted by the Director-General of Trade and Industry or an officer authorised by him. 本許可證的正本為承運人在本表格所說明貨品運抵香港後發給指定貨物予進口商時作為憑據的唯一有效文本, 但如工業貿易署署長或其授權人員特准憑該真確文本發給該批貨品則除外。 (iii) This licence must be correctly endorsed by the importer with shipment arrival details (see reverse) and the importer must not take delivery of the goods until the licence has been so endorsed, the original of the licence duly endorsed must then be passed to the shipping, airline or transportation company who should check details given by the importer and return the licence to the Trade and Industry Department together with the relevant manifest. 本許可證必須由進口商正確地批署, 並填上貨品抵埠詳情(見背頁), 進口商必須將妥此項批署手續方可領取貨品。本許可證的正本經批署妥當後須交給船運、航空或運輸公司, 而該公司在查核進口商所填報的詳情後, 須將本許可證連同有關輪單一併交回工業貿易署。 (iv) The importer must lodge import declarations in respect of items on this licence within 14 days of shipment. 在本許可證所開列的貨品付運後的14天內, 進口商必須就該等貨品呈交進口報關單。 (v) This licence is valid for six months from the date of issue. Extension of validity may be granted on application. 本許可證有效期為六個月, 由發出日起計。經申請後, 有效期可能獲准延長。			
Business Reg. No. 12345678-000 Note (b) Tel. No. 2123 4567 商業登記號碼 電話					
23 August 2019 Note (e)					
By Air, Flight No. XX 100 Note (f)					
WARNING 警告: All alterations must be carried out by authorized officers. Heavy penalties are provided for false declaration and information, unauthorized alterations and misuse of this licence. 只有獲授權人員方可更改本許可證。凡作虛假聲明、提供虛假資料、未經授權而更改本許可證或不當地利用本許可證者, 可被懲罰。					
Marks and Nos. Container No. 標記及編號 貨櫃編號 ABC 123456 Container No. 1-2 Note (g)	No. and Kind of Packages; Brand and Model, 包裝數目及種類 牌子及型號 Two (2) cartons Note (h)	DESCRIPTION OF GOODS 貨物的說明 1. XYZ (xxxleucel) 0.5 - 5 x 10 ⁸ cells dispersion for infusion 10-50 ml (HK-XXXX1) 2. ZYY (yyyleucel) 0.5 - 5 x 10 ⁸ cells dispersion for infusion 10-50 ml (HK-XXXX2) Note (i)		No. of Units 單位數量 *3*bags *1*bag Note (j)	*C.I.F. Value HKD *到埠價 (以港元計) 100,000 100,000
Note (i) SPECIMEN					
				Total 總額 200,000	
* C.I.F. Value HKD comprises the cost of the goods to the HK importer up to the arrival in HK of the vessel, vehicle or aircraft carrying the goods, together with the amount of the insurance, freight and any other charges. HKD means Hong Kong Dollar. * 到岸價包括香港進口商截至載貨船隻、車輛或飛機抵港之時為止所付出的貨品成本(連保險、運費及任何其他費用在內)。* HKD 指港元。		Exporting Country 出口國 U.S.A. Note (o)		IMPORTER'S DECLARATION 進口商聲明書 I hereby declare that I am the importer of the goods in respect of which this declaration is made and that the particulars given in this declaration are true and that the goods imported shall be as described. I further declare that the goods are for (a) local consumption (供本地消費) 本人謹此聲明: 本人是本聲明書所指貨品之進口商, 本聲明書中填報的資料均屬真實無訛。進口貨品亦與所填報者相同。該等貨品用作(a)本地消費。 Note (k)	
Item No. 項目 1 2 3 4 5	Origin Country 來源國家 U.S.A. U.S.A. Note (q)	Approved 已批准 for Director-General of Trade and Industry (代行) 工業貿易署署長			
		Signatory's Name in Block Letters 簽署人姓名(用正楷填寫) CHAN MAN Note (l)			
		Date, Signature & Company Chop 日期、簽署及公司印章 1 August 2019 Note (n)			

IMPORTANT NOTE 重要事項


If there is any discrepancy between the English text and the Chinese text of this form, the English text shall be taken as conclusive.

倘本表格的中英文本有任何差異, 應以英文本為準。

TRA 187 (Rev 2007) (2007年修訂)

Appendix 4 Specimen Export Licence Form (Form 6)

EXPORT LICENCE Form 6 進口許可證表格六 ORIGINAL 正本

Exporter (Name and Address) 出口商 (名稱及地址) ABC Co Ltd Room 10, ABC Building 3000 Nathan Road Kowloon, Hong Kong Note (a)		Date of issue 發出日期 		Licence No. 許可證編號	
Business Reg. No. 商業登記號碼 12345678-000 Note (b)		Tel. No. 電話號碼 2123 4567		THE GOVERNMENT OF THE HONG KONG SPECIAL ADMINISTRATIVE REGION Import and Export Ordinance, Cap. 60 Reserved Commodities Ordinance, Cap. 298 and any other Enactment 香港特別行政區政府 《進出口條例》(第60章) 《儲備商品條例》(第298章)及其他成文法例	
Consignee (Name and Address) 收貨人 (名稱及地址) XYZ Co Ltd 123 First Street Washington D. C. 12345 U. S. A. Note (d)		Conditions of issue of this licence include the following:- 本許可證的發出條件包括以下各項:- (i) Normally the form is to be submitted in duplicate. However for certain categories of goods, which are notified through Trade and Industry Department circulars, triplicates are required. 一般而言, 本表格必須一式兩份呈交, 但就工業貿易署轉達通知的若干類別貨品而言, 本表格須一式三份呈交。 (ii) Any number of items in licensable categories may be entered on this form provided all are shipped at the same time on the same vessel, aircraft or vehicle. 須領取出口許可證的不同類別貨品, 如在同一時間全部由同一船隻、飛機或車輛裝運, 可在本表格內一併填報, 貨品數量不限。 (iii) The original must be given to the shipping, airline or transportation company for return to the Trade and Industry Department together with the relevant manifest. 本許可證的正本須交給船運、航空或運輸公司, 由該公司將本許可證連同有關單文交回工業貿易署。 (iv) The exporter must lodge export declarations in respect of items on this licence within 14 days of shipment. 在本許可證所開列的貨品付運後的14天內, 出口商必須就該等貨品呈交出口報關單。 (v) The name and address of the Hong Kong manufacturer or processor must be provided for locally produced commodities covered by this licence. 對於本許可證所開列的本地製造商品, 必須提供香港製造商或加工商的名稱及地址。 (vi) In case of re-exports, condition (v) does not apply. However, the country of origin of the items must be shown in the box provided for the purpose of this licence. 第(v)項條件不適用於轉口貨品, 但必須在本許可證特設的空格內填報該等貨品的產地來源國。 (vii) This licence is valid for twenty eight days from the date of issue. 本許可證有效期為二十八天, 由發出日期起計。 (viii) HKD means Hong Kong Dollar. "HKD"指港元。			
Departure Date 離境日期 30 August 2018 Note (e)		Vessel/Flight/Vehicle No. 船隻/班機/車輛編號 By Air, Flight No. XX 100 Note (f)			
WARNING: All alterations must be carried out by authorized officers. Heavy penalties are provided for false declaration & information, unauthorized alterations & misuse of this licence. 警告: 只有獲授權人員方可更改本許可證。凡作虛假聲明、提供虛假資料、未經授權而更改本許可證或不當地使用本許可證者, 可被重罰。					
Marks and Nos., Container No. 標記及編號, 貨櫃編號 ABC 123456 Container No. 1-2 Note (g)		No. and Kind of Packages Brand and Model, 包裝數目及種類, 牌子及型號 Two (2) cartons Note (h)		DESCRIPTION OF GOODS 貨品的說明 1. XYZ (xxxleucel) 0.5 - 5 x 10 ⁸ cells dispersion for infusion 10-50 ml (HK-XXXX1) 2. ZYY (yyyleucel) 0.5 - 5 x 10 ⁶ cells dispersion for infusion 10-50 ml (HK-XXXX2) Note (i)	
				No. of Units 單位數量 *3*bags *1*bag Note (j)	
				F.O.B. Value HKD 離岸價 (以港元計) 100,000 100,000	
				Total 總額 200,000	
		Destn. Country & Code 目的國家及代碼 U.S.A. Note (o)		EXPORTER'S DECLARATION 出口商聲明書 I hereby declare that I am the exporter of the goods in respect of which this declaration is made and that the particulars given in this declaration are true and that the value declared above is the full value. 本人謹此聲明: 本人是上述聲明書所指貨品的出口商, 本聲明書中所填報的資料均屬真實無訛, 而且上開填報的價值為全部價值。 Signature and Date 簽署及日期 Chan 1 August 2019 Note (m) Signatory's Name in Block Letters 簽署人姓名 (用正楷填寫) CHAN MAN Note (l)	
Item No. 項目		Origin Country 來源國家		Origin Country Code 來源國家代碼	
1		Hong Kong			
2		Hong Kong			
3		Note (p)		Note (q)	
4				Approved 已批准	
5				() for Director-General of Trade and Industry 工業貿易署署長	
		Name and Address of HK Manufacturer/Processor 香港製造商/加工商名稱及地址 1&2. ABC Factory Co Ltd Room 20, ABC Building 3000 Nathan Road Kowloon, Hong Kong Note (r)		Company Chop 公司印章 Note (n)	
				ABC Co Ltd	

IMPORTANT NOTE 重要事項

If there is any discrepancy between the English text and the Chinese text of this form, the English text shall be taken as conclusive.

倘本表格的中英文本有任何差異, 應以英文本為準。

TRA 394 (Rev 2007) (2007年修訂)

Appendix 5 Statement of Purposes

Purpose of Collection

This personal data are provided by applicants for the purposes of application for Import and Export Licences for pharmaceutical products under the Import and Export Ordinance. The personal data provided will be used by DH for the following purposes:

- (a) Proof of eligibility
- (b) Processing of applications for licence

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to prove your eligibility for the licences, or to process the relevant application.

Classes of Transferees

3. The personal data you provide are mainly for use within DH. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making of access and corrections should be addressed to:

Senior Pharmacist
Drug Evaluation and Import/Export Control Division
Drug Office, Department of Health
Suites 2002-05, 20/F
AIA Kowloon Tower, Landmark East
100 How Ming Street
Kwun Tong, Kowloon
Tel: 3974 4180

Document Information

Version	Date	Description of Change
1.0	29.10.2019	First version (Draft for comment)
1.0.1	13.1.2020	First version (Draft for comment) <ul style="list-style-type: none">● Update of contact information

DRAFT