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

Version 1.0

Drug Office

Department of Health

CONTENTS

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 Relevant definitions of gene therapy product, somatic cell therapy product and tissue engineered product are set out in section 2 of the PPO.

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 authority to issue import and export licence of pharmaceutical products has been delegated by the Director-General of Trade and Industry to the Department of Health. The Drug Evaluation and Import/Export Control Division of the Drug Office, Department of Health (the "Division") is responsible for receiving such application and issuing the licences upon approval.

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.

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"; section 4)
- ATPs which are not registered pharmaceutical products ("Unregistered ATPs"; section 5), for –
    - clinical trial
    - the treatment of a particular patient
    - re-export
- pharmaceutical products as starting and raw materials for ATP manufacturing (section 6).

3.2 In addition, this guidance applies to applicants for the export licences for ATPs (section 7).

4. Import of Registered ATPs

4.1 For every single importation, an importer needs to submit an application for Import Licence (Form 3) to the Division.

Applicants

4.2 Applicant for Import Licence for a Registered ATP should be any of the following:

- a licensed wholesale dealer who is the holder of the registration certificate of the product to be imported
- 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 ATP, other legislative requirements may be applicable to its 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 an import licence for the 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, Certificate for Clinical Trial/Medicinal Test[1] is required for the purposes of conducting a clinical trial on human beings. This regulation applies to ATPs.

5.6 For every single importation of Unregistered ATPs for clinical trial, an importer needs to submit an application for Import Licence (Form 3) to the Division.

Applicants

5.7 Applicant for Import Licence for an Unregistered ATP for a clinical trial should be (any of the following)–

- a licensed wholesale dealer who is or on behalf of the holder of Certificate for Clinical Trial/Medicinal Test
- a holder of Certificate for Clinical Trial/Medicinal Test

5.8 For details on the application procedures, please refer to section 8.

5.9 Depending on the nature of the ATP, other legislative requirements may be applicable to their import. For details, please refer to section 9.

[1] Application for Certificate for Clinical Trial/Medicinal Test should be made for conducting any clinical trial on human beings. For details of application, please visit our website at: http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/clinicaltrial.html

Import for the Treatment of a Particular Patient

5.10 For every single importation of Unregistered ATPs for the treatment of particular patients, an importer needs to submit an application for Import Licence (Form 3) to the Division.

5.11 Applications would be considered on a case by case basis.

5.12 Undertakings from the importer and responsible treating medical practitioner or dentist, as appended at Appendices 1 and 2, should be provided.

5.13 In addition, evidence should be provided showing that the products to be imported are complying with the standard of Good Manufacturing Practice and other relevant quality requirements.

5.14 With regard to the appropriateness of using unregistered pharmaceutical product for the purpose of treatment of a particular patient, the responsible medical practitioner or dentist should observe relevant guidelines and codes of professional conduct/discipline.

Applicants

5.15 Applicant for Import Licence for an Unregistered ATP for the treatment of a particular patient(s) should be a licensed wholesale dealer on behalf of a registered medical practitioner or dentist.

Supporting Documents

5.16 The following documents are required for the application–

(a) letter of a registered medical practitioner or a registered dentist stating–

(1) the drug name;

(2) the required quantity;

(3) patient's information (at least with his or her full name);

(4) the rationale for the use of the Unregistered ATP; and

(5) for ATPs containing cells or tissues, hospital or Day Procedure Centre[2] where the product is to be administered to the patient;

(b) undertakings from importer and the treating medical practitioner or dentist;

(c) product information (e.g. product insert, description of manufacturing process (if applicable), etc.);

(d) if the product is an ATP containing cells or tissues, information on the hospital or Day Procedure Centre where the product is to be administered to the patient;

(e) if the product has been registered overseas, proof of that registration;

(f) if the product has not been registered anywhere in the world, documents supporting the therapeutic use and safety of the product;

(g) evidence indicating that the product is manufactured in accordance with the standard of Good Manufacturing Practice;

(h) copy of the certificate of analysis of the product issued by the manufacturer; or if a certificate of analysis could not be provided, an undertaking stating the justification.

5.17 For details on the application procedures, please refer to section 8.

[2] Definition of "day procedure centre" in accordance to section 2 of the Private Healthcare Facilities Ordinance (Cap. 633).

5.18 Depending on the nature of the ATP, other legislative requirements may be applicable to its importation. For details, please refer to section 9.

Special Requirements on Safety Monitoring and ADR Reporting

5.19 The importer and the registered medical practitioner 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 product to the Drug Office.

5.20 For details of adverse drug reaction reporting, please visit our website at: https://www.drugoffice.gov.hk/adr.html

Import for Re-Export

5.21 For every single importation, an importer needs to submit an application for Import Licence (Form 3) to the Division.

Applicant

5.22 Applicant for Import Licence for an Unregistered ATP for re-export should be a licensed wholesale dealer.

Supporting Documents

5.23 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.

5.24 For details on the application procedures, please refer to section 8.

5.25 Depending on the nature of the ATP, other legislative requirements may be applicable to its importation. For details, please refer to section 9.

5.26 Please note that approval of an Import Licence application does not necessarily mean that the 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 Licensed manufacturers may import starting and raw materials for manufacturing of their own ATPs. The requirements for the import depend on whether the starting and raw materials fall within the definition of pharmaceutical product.

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 or ATP. Examples include human albumin and growth factors that—

- is presented as having properties for treating or preventing disease in human beings or animals
- 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

6.3 For every single importation of pharmaceutical product for own manufacturing, the importer needs to submit an application for Import Licence (Form 3) to the Division.

Applicants

6.4 Applicant for Import Licence for a pharmaceutical product for manufacture should be a licensed manufacturer, and manufacturing the applicants' own ATPs should be the purpose of the import.

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 Division 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
- culture media or scaffold 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 Export Licence (Form 6) to the Division.

Applicants

7.2 Applicant for Export Licence for an ATP should be (any of the following)—

- a licensed wholesale dealer
- 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 Division is not required for the exportation of materials (for example, blood, cells and tissues) that are not considered as pharmaceutical products 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 applications for the import and export licences for ATPs can be made–

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

[**With effect from 31 December 2021**, the Division will no longer accept in-person application submission for import and export licences and applications for import and export licences for registered pharmaceutical products submitted via the Electronic Services. Only applications submitted online via the PLAMMS will be processed.]

8.2 All applications[3] for import and export licences for unregistered pharmaceutical products (i.e. those that are not registered) 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 –

(a) from 30 September 2019 onwards, all applications for import and export licences of registered pharmaceutical products; and

(b) 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

[3] For product with stringent import and export control, only manual application is accepted for processing.

- pharmaceutical products or substances imported by a pharmaceutical manufacturer for the purpose of manufacture of pharmaceutical product

8.4 For further details on implementation of the PLAMMS, you may wish to visit the webpage of Drug Office, Department of Health at: http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html

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

8.6 Please note that applications for Import Licence (Form 3) for 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.

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, and the webpage of Drug Office, Department of Health at: http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html.

User Registration (for First Time User Only)

8.9 Applicants are required to become registered PLAMMS users to login and use the various functions of the PLAMMS.

8.10 Users of the PLAMMS are required to have—

- for company users, a Hongkong Post e-Cert (Organisational) which is specific to each intended user(s) in supervisory role within the company
- for registered medical practitioners or dentists, a Hongkong Post e-Cert (Personal)

8.11 With suitable e-Certs, applicants are required to complete the PLAMMS Account Registration Form available at: http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Account_Registration_Form_(PLAMMS)_E.pdf.

8.12 In order to proceed the registration, applicants should provide –

- for company users, a copy of their business registration certificate
- for registered medical practitioners or dentists, a copy of the certificate of registration of their profession

8.13 The completed Account Registration Form, together with the document mentioned in paragraph 8.12, 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 Unregistered ATPs for re-export purpose at the first time, registered PLAMMS users are required to enlist that product to the PLAMMS by using the "**Drug Enlisting**" function of the system. Once a product has been enlisted in the PLAMMS, the enlisting user and other PLAMMS users of the same company are not required to enlist the same product to the PLAMMS again in subsequent import and export licence applications.

8.16 The steps for enlisting a product to the 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

- Hong Kong Harmonized System (HS) code – the HS code could be searched at the Census and Statistics Department website: http://www.censtatd.gov.hk/trader/hscode/index.jsp

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

8.19 The steps for setting opening balance in the 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 Applications

8.21 Registered PLAMMS users can apply for the Import and Export Licences online via the "**Import/Export Licence**" function of the PLAMMS.

8.22 The steps for the applications are described in section 4 of the PLAMMS User Guide.

8.23 The following supporting documents are required to be uploaded to the PLAMMS during the licence applications.

Licence	Products	Documents required
Import Licence	Registered ATPs	● If the applicant is not the holder of the registration certificate of the product to be imported, a written authorization from the product registration certificate holder to support the application

	Unregistered ATPs for clinical trial	● Copy of Certificate for Clinical Trial/Medical Test of the product(s) to be imported
	Unregistered ATPs for the treatment of a particular patient	● Letter of a registered medical practitioner or a registered dentist stating– ■ the drug name ■ the required quantity ■ patient's information (at least with his or her full name) ■ the rationale for the use of the unregistered ATP ■ for ATPs containing cells or tissues, hospital or Day Procedure Centre where the product is to be administered to the patient ● Undertakings from importer and the treating medical practitioner or dentist ● Product information (e.g. product insert, description of manufacturing process (if applicable), etc.) ● If the product is an ATP containing cells or tissues, information on the hospital or Day Procedure Centre where the product is to be administered to the patient ● If the product has been registered overseas, proof of that registration ● If the product has not been registered anywhere in the world, documents supporting the therapeutic use and safety of the product ● Evidence indicating that the product is manufactured in accordance with the standard of Good Manufacturing Practice ● A copy of certificate of analysis of the product issued by the manufacturer; or if certificate of

		analysis could not be provided, an undertaking stating the justification

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 an 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 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 the Import Licence Form (Form 3) or Export Licence Form (Form 6).

[**With effect from 31 December 2021**, the Division will no longer accept in-person application submission for import and export licences and applications for import and export

licences for registered pharmaceutical products submitted via the Electronic Services. Only applications submitted online via the PLAMMS will be processed.]

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
  Tel: 2398 5325
- Shroff Office of the 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 4178

8.31 Detailed notes on how to complete the Import and Export Licence Forms are set out in Appendix 3, and the specimen copies of the completed Import Licence Form and Export Licence Form are appended at Appendices 4 and 5 respectively.

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

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" 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

Supporting Documents

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

Licence	Products	Documents required
Import Licence	Registered ATPs	• A copy of registration certificate of the product(s) to be imported • A copy of the wholesale dealer 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 product registration certificate holder to support the application
Export Licence		• A copy of wholesale dealer licence of the applicant • If the ATPs to be exported are manufactured by the applicant, a copy of a valid licence to manufacture pharmaceutical products of the applicant
Import Licence	Unregistered ATPs for clinical trial	• A copy of Certificate 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 licence

		● If the applicant is a registered medical practitioner or dentist, a copy of the certificate of registration of the profession
	Unregistered ATPs for the treatment of a particular patient	● A copy of the wholesale dealer licence of the applicant ● Letter of a registered medical practitioner or a registered dentist stating– ■ the drug name ■ the required quantity ■ patient's information (at least with his or her full name) ■ the rationale for the use of the unregistered ATP ■ for ATPs containing cells or tissues, hospital or Day Procedure Centre where the product is to be administered to the patient ● Undertakings from importer and the treating medical practitioner or dentist ● Product information (e.g. product insert, description of manufacturing process (if applicable), etc.) ● If the product is an ATP containing cells or tissues, information on the hospital or Day Procedure Centre where the product is to be administered to the patient ● If the product has been registered overseas, proof of that registration ● If the product has not been registered anywhere in the world, documents supporting the therapeutic use and safety of the product ● Evidence indicating that the product is manufactured in accordance with the standard of

		Good Manufacturing Practice ● A copy of certificate of analysis of the product issued by the manufacturer; or if certificate of analysis could not be provided, an undertaking stating the justification
	Pharmaceutical products for manufacture	● A copy of a valid licence to manufacture pharmaceutical products of the applicant.

Submission of Applications

8.34 The duly completed Import Licence Form (Form 3) or Export Licence Form (Form 6) together with the required supporting documents mentioned in paragraph 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 Licences

8.36 Provided that all the submitted documents are satisfactory after review, applicants may collect the licence 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 at:
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 (e.g. biological materials) for ATP manufacturing containing or consisting of infectious agents (e.g. viral vectors) or suspected to be containing infectious agents, an additional import or transhipment 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:
http://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. 421A.

9.6 Further details can be found at the website of the Agriculture, Fisheries and Conservation Department:
http://www.afcd.gov.hk/english/index.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 environment[4] and contained use[5]), 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–

[4] 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.

[5] 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.

(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 Genetically Modified Organisms (Control of Release) 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/english/index.html

10. Enquiries

10.1 For enquiries relating to the import and export licence applications for pharmaceutical products, please contact the Division—

Address:	Office hours:
Suites 2002-05	Monday to Friday
20/F AIA Kowloon Tower, Landmark East	9 am to 1 pm and 2 pm to 5:45pm
100 How Ming Street	(up to 6 pm on Monday)
Kwun Tong, Kowloon	(Closed on Saturdays, Sundays and
Email: pharmgeneral@dh.gov.hk	Public Holidays)
Tel: 3974 4180	

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

Email: plammsinfo@dh.gov.hk

Tel: 3974 4159

Appendix 1 Undertaking by a Licensed Wholesale Dealer as an Importer

As an importer of an unregistered pharmaceutical product which is an advanced therapy product, namely _____ ("unregistered ATP"), for the purpose of treatment to be provided to a particular patient, named _____ ("named patient"), by the registered medical practitioner/dentist*, named _____, I am fully aware of the below obligations and requirements.

*(*Please delete as appropriate.)*

(Please put a "√" in the relevant box below)

Availability of Registered Product

☐ Maintain a system to check against the availability of any registered pharmaceutical products in Hong Kong or overseas which can meet the special needs of the patient before submitting the application for importation of the unregistered ATP.

Patient Consent

☐ Ensure that the treating medical practitioner or dentist must inform the patient of—

- the unregistered ATP having not been registered;
- the risk of the use of the unregistered ATP;
- irreversible nature of the unregistered ATP and the need for long-term follow-up and commitment, where applicable;
- if the unregistered ATP includes a bacterial or viral vector, the risk and precautionary measures for potential shedding; and
- any other information applicable to the unregistered ATP.

Safety Monitoring

- ☐ Report all serious or unexpected adverse drug reactions occurring in the named patient taking the unregistered ATP to Drug office of the Department of Health in accordance with 'Guidance for Pharmaceutical Industry—Adverse Drug Reaction Reporting Requirements'.
- ☐ Ensure that the treating medical practitioner or dentist would arrange follow-up of the named patient if there is a potential for prolonged biological activity after administration.

Traceability

- ☐ Ensure that a system is in place enabling bidirectional tracking of any cells or tissues contained in the unregistered ATP from donation, through manufacturing to the delivery of the finished product to the use of a medical practitioner or dentist.
- ☐ The transaction record, shipping and other supporting documents must be kept and retained for 30 years after the expiry date of the product.

Dealing with Out-of-specification Product

- ☐ If the unregistered ATP to be supplied for use is out-of-specification, before the importation —
  - inform the treating medical practitioner or dentist in writing of the event and the associated risks assessed and provided by the manufacturer;
  - ensure that the treating medical practitioner or dentist has informed the patient about the risk of using the out-of-specification unregistered ATP and has obtained the consent from the patient;
  - obtain a written confirmation from the treating medical practitioner or dentist that he/she accepts the out-of-specification unregistered ATP for use; and
  - report the supply of the out-of-specification unregistered ATP to the Drug Office within 48 hours

Breaching the above obligations and requirements may result in the case being referred to the Pharmacy and Poisons (Wholesale Licences) Committee for consideration of disciplinary actions.

Signature	Signatory's name in block letters	
Date (DD/MM/YY)	Office capacity of signatory	Company stamp

Appendix 2 Undertaking by a Treating Medical Practitioner/Dentist

Referring to the application for the importation of an unregistered pharmaceutical product which is an advanced therapy product, namely _____ ("unregistered ATP"), for the purpose of treatment to be provided to a particular patient under my care, named _____ ("named patient"), I am fully aware of the below obligations and requirements.

(Please put a "√" in the relevant box below)

Patient Consent

☐ Obtain informed consent from the named patient, including but not limited to, informing the patient of—

- the unregistered ATP having not been registered and the safety, efficacy and quality having not yet been evaluated by the Pharmacy and Poisons Board;
- the risk of use of the unregistered ATP, including risk of treatment failure and potential impact of the treatment on future therapies;
- irreversible nature of the unregistered ATP, where applicable;
- the need for long-term follow-up and commitment, where applicable;
- if the unregistered ATP includes a bacterial or viral vector, the risk and precautionary measures for potential shedding; and
- any other information applicable to the unregistered ATP.

Appropriate Use of Product and Patient Care

☐ Take responsibility for prescribing the unregistered ATP, for overseeing the patient's care and any follow-up treatment in accordance with the applicable code of professional conduct or discipline.

Safety Monitoring

- ☐ Report all serious or unexpected adverse drug reactions occurring in the named patient taking the unregistered ATP to Drug Office of the Department of Health within 15 calendar days.
- ☐ Arrange follow-up of the named patient if there is a potential for prolonged biological activity after administration.

Traceability

- ☐ Keep the record of treatment involving the use of the unregistered ATP in accordance with the 'Guidance on Record Keeping for Medical Practitioners, Dentists and Institutions providing Advanced Therapy Product Treatment.

Dealing with Out-of-specification Product

- ☐ In case I have been informed by the importer of the unregistered ATP that the product to be supplied for use is out-of-specification, before the importation of this unregistered ATP, I should—
  - consider the associated risks assessed and provided by the manufacturer;
  - inform the patient about the risk of using the out-of-specification unregistered ATP;
  - if the patient does not accept the unregistered ATP for use—
    - obtain the patient's consensus of not accepting the unregistered ATP for use and inform the importer accordingly;
  - if the patient accepts the unregistered ATP for use—
    - obtain the patient's consent of using the unregistered ATP; and
    - provide a written confirmation to the importer confirming the acceptance of the out-of-specification unregistered ATP for use.

I am fully aware of the above obligations and requirements, and understand that relevant codes of professional conduct issued by the Medical Council or the Dental Council, as well as the codes of practice for the Licensed Private Healthcare Facilities issued by the Department of Health, where applicable, should be followed.

Signature	Signatory's name in block letters (Registration No.:)	Date (DD/MM/YY)

Appendix 3 Notes on Completing the Import and Export Licence Forms for ATPs

1. 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 4 and 5 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' are not acceptable.

(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' are not acceptable.
- 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' are not acceptable.
- 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 Numbers.; Container Number

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

(h) Number 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) Number 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 4 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.

Note (c)

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）及其他成文法則

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

Note (a)

Business Reg. No. 商業登記號碼 12345678-000 Note (b) Tel. No. 電話 2123 4567

23 August 2019 Note (e)

By Air, Flight No. XX 100 Note (f)

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，但就工業貿易署藉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放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核證真確文本發放該批貨品則除外。

(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），進口商必須辦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艙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。

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、未獲授權而更改本許可證或不當地利用本許可證者，可被重罰。

Marks and Nos.; Container No.; 標記及編號 貨櫃編號	No. and Kind of Packages; Brand and Model; 包裹數目及種類；牌子及型號	DESCRIPTION OF GOODS 貨物的說明	No. of Units 單位數量	*C.I.F. Value HKD *到岸價（以港元計）
ABC 123456 Container No. 1-2 Note (g)	Two (2) cartons Note (h)	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)	*3*bags *1*bag Note (j)	100,000 100,000
		Note (i) SPECIMEN		
			Total 總額	200,000

* C.I.F. Value HK 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載貨船隻、車輛或飛機抵達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 Note (o) U.S.A.

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 (~~b)*re-export~~)

本人謹此聲明：本人是本聲明書所指貨品的進口商，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)*本銷 (~~b)*轉口~~)

Note (k)

* (Delete (a) or (b) where not applicable)
* 請刪去不適用的(a)或(b)項

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

Chan Note (m)

1 August 2019 Note (n)

ABC Co Ltd

Item No. 項目	Origin Country 來源國家
1	U.S.A.
2	U.S.A.
3	Note (q)
4	
5	

Approved 已批准

for Director-General of Trade and Industry (代行)
工業貿易署署長

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，應當以英文本為準。

TRA 187 (Rev 2007) (2007 年修訂)

Appendix 5 Specimen Export Licence Form (Form 6)

EXPORT LICENCE Form 6 出口許可證表格六 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)

Business Reg. No. 商業登記號碼 12345678-000 Note (b)
Tel. No. 電話號碼 2123 4567

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)

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)

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）及其他成文法則

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，但就工業貿易署藉通告通知的若干類貨品而言，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艙單交回工業貿易署。

(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 on this licence. 第(v)項條件不適用於轉口貨品，但必須在本許可證特備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。

WARNING 警告： All alterations must be carried out by authorized officers. Heavy penalties are provided for false declaration & information, unauthorized alterations & 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、未獲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	No. and Kind of Packages Brand and Model, 包裹數目及種類，牌子及型號	DESCRIPTION OF GOODS 貨品的說明	No. of Units 單位數量	F.O.B. Value HKD 離岸價（以港元計）
ABC 123456 Container No. 1-2 Note (g)	Two (2) cartons Note (h)	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)	*3*bags *1*bag Note (j)	100,000 100,000
		Note (i) SPECIMEN		
			Total 總額	200,000

Destn. Country & Code 目的國家及代碼 U.S.A. Note (o)

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		
5		

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)

Approved 已批准
(代行)
for Director-General of Trade and Industry 工業貿易署署長

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：本人是本聲明書所指貨品的出口商，本聲明書中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)

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，應當以英文本為準。
TRA 394 (Rev 2007) (2007 年修訂)

Appendix 6 Statement of Purposes

Purpose of Collection

1. 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 Department of Health 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 Department of Health. 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	1 August 2021	(Issued in August 2021)

[End of Document]