

Regulatory Update on Advanced Therapy Products in Hong Kong



Department of Health

The Government of the Hong Kong Special Administrative Region

August 2021

Content



- **What** is **ATP**?
- **Regulation** of ATP
 - **Pharmacy and Poisons (Amendment) Ordinance 2020**
- **Scope** of ATP Regulation
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 - **Record Keeping**
 - **Labelling**
 - **Manufacture**
 - **ADR reporting**
 - **Import & Export**
 - **Product Registration**
 - **Clinical Trial**

What is Advanced Therapy Product?



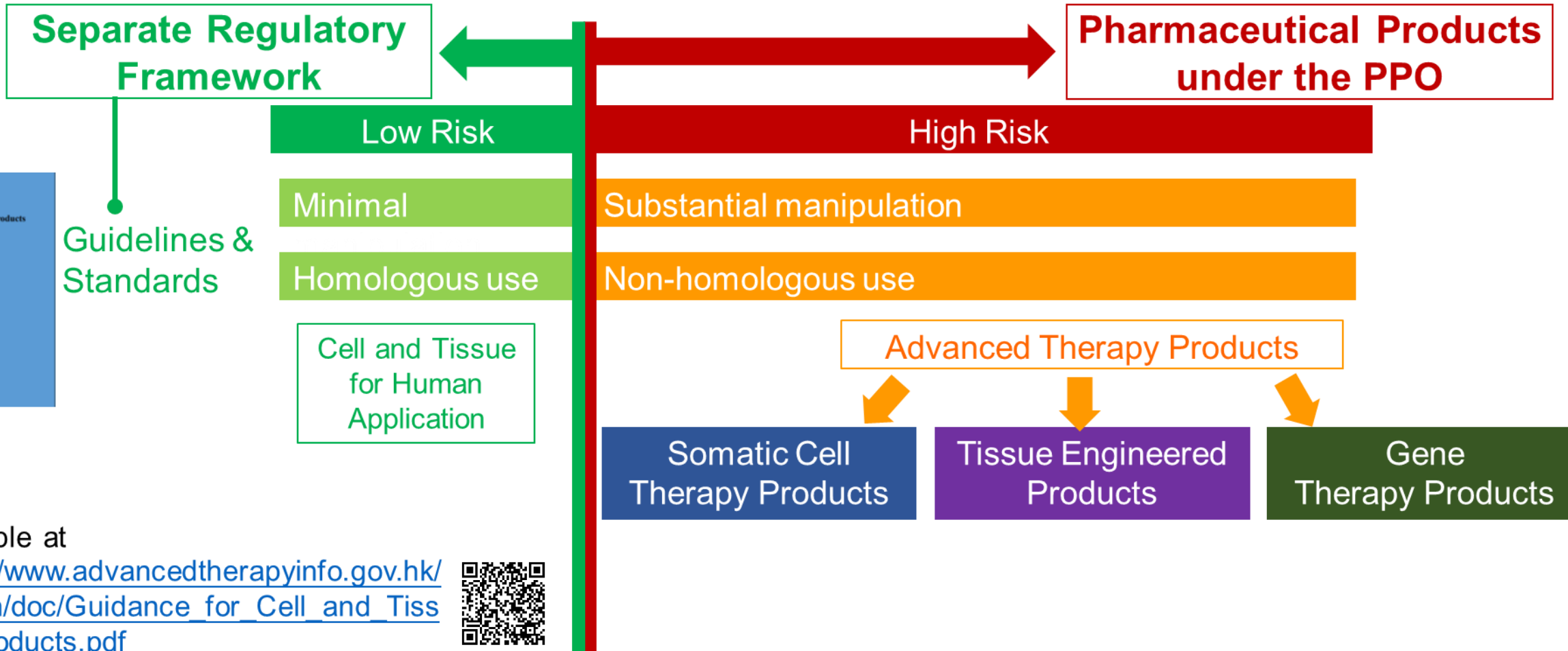
- **ATPs*** are **innovative** medicinal products based on **genes**, **cells** and **tissues**
- **Scientific advancement** in ATP may offer **great medical potential**
- **Risks** and **long-term side effects** need to be carefully managed due to their **complicated nature** and the **limited knowledge** about these products

* The exact legal definition of “Advanced Therapy Product” is set out in the section 2 of the Pharmacy and Poisons Ordinance (Cap. 138), which is available at <https://www.elegislation.gov.hk>

Regulation of Cells & Tissues Products



Risk-based Approach



Pharmacy and Poisons (Amendment) Ordinance 2020



Pharmacy and Poisons (Amendment) Ordinance 2020

Ord. No. 19 of 2020
A1635

Pharmacy and Poisons (Amendment) Ordinance 2020

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Pharmacy and Poisons (Amendment) Ordinance 2020

Ord. No. 19 of 2020
A1637

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Amendment Ordinance

- **Amended Pharmacy and Poisons Ordinance** to regulate ATP
- **Passed** by **LegCo** and gazetted in **July 2020**
- **Come into operation** on **1 August 2021**

Available at

<https://www.gld.gov.hk/egazette/pdf/20202430/es12020243019.pdf>



Scopes of ATP Regulation



Classification
of ATP

Record
Keeping

Labelling

Manufacture

ADR
Reporting

Import &
Export

Product
Registration

Clinical
Trial

Amend
PPO

s.2 of PPO
(Definition of
PP)

r.28, 35 & 39
of PPR
(Record
keeping by
manufacturer/
wholesaler /
Keeping Period)

r.31 of PPR
(Labelling by
manufacturer)

s.2 of PPO
(Definition of
Manufacture)

Other
means

Licensing
Conditions
+
Guidelines

Existing Requirements
+
ATP Specific Requirements

Relevant Guidance



**Drug Office**
Department of Health
The Government of the Hong Kong Special Administrative Region



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繁體版 简体版

AAA

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SITE MAP

**Pharmaceutical Trade**

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Home

Safety Alerts and Products Recalls

Other Useful Information

About Us

Code of Practice

Guidelines & Forms

Certificates / Licences / Specified Forms

ADR reporting

Drug Shortage Notification (English Only)

Related Links

Regulation of Advanced Therapy Products

Print Page

Regulation of Advanced Therapy Products

- Pharmacy and Poisons (Amendment) Ordinance 2020
- Guidance for Industry
 - Classification of Advanced Therapy Products
 - Manufacture
 - Drug Registration
 - Clinical Trial
 - Import and Export
 - Labelling of Advanced Therapy Product
 - Record Keeping
 - Adverse Drug Reaction Reporting
 - Other Guidance applicable to Pharmaceutical Products
- Guidance for Healthcare Professionals
 - Classification of Advanced Therapy Products
 - Record Keeping
 - Adverse Drug Reaction Reporting
 - Clinical Trial
 - Import for the Treatment of a Particular Patient
- List of Registered Advanced Therapy Products

Available at

https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html



Classification of ATP

Classification of ATP

To include ATP in PP Definition (S.2)



Existing

pharmaceutical product (藥劑製品) and **medicine** (藥物) mean any substance or combination of substances—

- (a) presented as having properties for treating or preventing disease in human beings or animals; or
- (b) that may be used in, or administered to, human beings or animals, either with a view to—
 - (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
 - (ii) making a medical diagnosis;

Amended Version

pharmaceutical product (藥劑製品)—

(a) means a substance or combination of substances that—

- (i) is presented as having properties for treating or preventing disease in human beings or animals; or
- (ii) 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;

medicine (藥物) has the same meaning as in the definition of **pharmaceutical product**;

Classification of ATP

Definition of ATP (S.2)



New Provision

”**Advanced therapy product**” (先進療法製品) 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**;

Classification of ATP

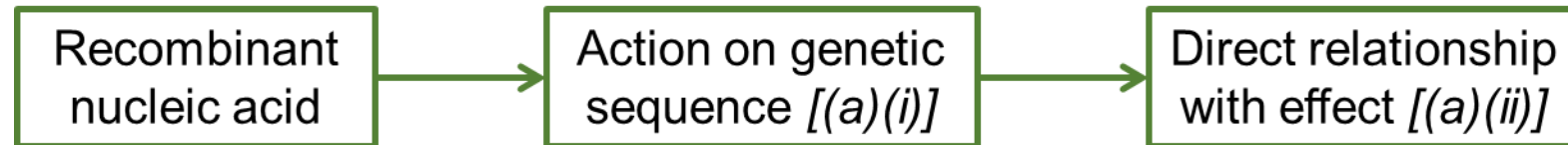
Definition of Gene Therapy Product (S.2)



New Provision

Gene therapy product (基因療法製品)—

- (a) means a product—
 - (i) 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
 - (ii) 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**



Classification of ATP

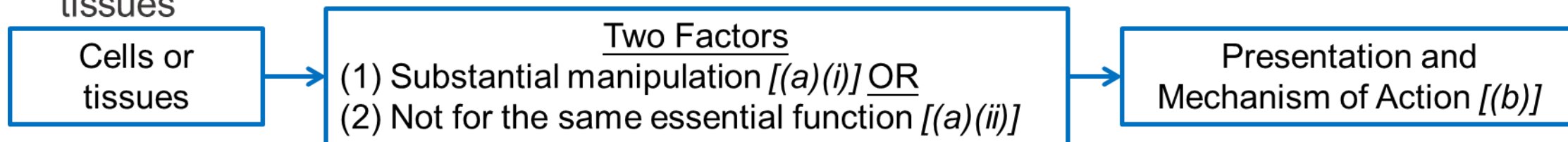
Definition of Somatic Cell Therapy Product (S.2)



New Provision

Somatic cell therapy product (體細胞療法製品) means a product that—

- (a) contains or consists of any of the following cells or tissues—
 - (i) 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;
 - (ii) 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—
 - (i) **treating, preventing or diagnosing a disease**; or
 - (ii) **restoring, correcting or modifying physiological functions**,through the **pharmacological, immunological or metabolic action** of those cells or tissues



Classification of ATP

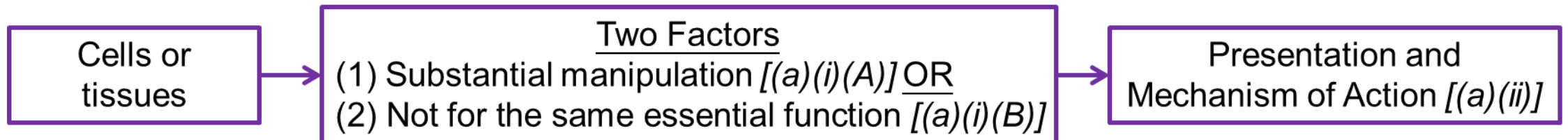
Definition of Tissue Engineered Product (S.2)



New Provision

Tissue engineered product (組織工程製品)—

- (a) means a product that—
 - (i) 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
 - (ii) 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—
 - (i) contains or consists of **exclusively non-viable** human or animal cells or tissues; and
 - (ii) does **not act principally by pharmacological, immunological** or **metabolic action**



Classification of ATP

Schedule for “Non-substantial” Manipulation



New Provision

S.2

substantial manipulation (實質處理), in relation to cells or tissues, does **not** include the manipulation processes **set out in the Schedule**;

Schedule

Manipulation Processes that are **Not Substantial Manipulations**

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

S.38 Amendment of Schedule

The **Director of Health** may, by notice published in the Gazette, amend the Schedule.

Guidance on Classification of ATP



Guidance on Classification of Advanced Therapy Products

Version 1.0

Pharmacy and Poisons Board of Hong Kong

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Can be found at

[https://www.drugoffice.gov.hk/eps/do/en/
pharmaceutical_trade/atp_regulation.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html)



Record Keeping

Record Keeping

- Aim to ensure **traceability**
- To require retention of record on
 - **Distribution**
 - **Practitioner** responsible for use of productfor **30 years** after expiry date
- Provisions for **bankruptcy/wound up/dissolution** and **cessation** of licence
 - Transfer specified documents to **Pharmacy and Poisons Board** within **specified timeframes**
- **Guidance** to **Medical Practitioners, Dentists** and **Institutions**

Record Keeping

Guidance on Record Keeping for Licensed Manufacturers and Licensed Wholesale Dealers



Guidance on Record Keeping for Licensed Manufacturers and Licensed Wholesale Dealers – Advanced Therapy Products

Version 1.0

Pharmacy and Poisons Board of Hong Kong

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Can be found at

[https://www.drugoffice.gov.hk/eps/do/en/
pharmaceutical_trade/atp_regulation.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html)





Record Keeping

Transaction Records by WDL and ML

(Section 5 of the Guidance)

- Required under regulation 28 of the PPR
- Record of particulars of **acquisition** (r. 28(1)) and **disposal** (r.28(2)) of PPs (including ATPs) and Poisons

- 
- (a) the date of the transaction;
 - (b) the name of the supplier;
 - (c) the name of the poison or pharmaceutical product;
 - (ca) the batch number, pack size and unit of quantity of the poison or pharmaceutical product;
 - (d) the total quantity of the poison or pharmaceutical product;
 - (e) the nature of the transaction; and
 - (f) a reference to the invoice or other documents supporting the transaction.

- 
- (a) the date of the transaction;
 - (b) the nature of the transaction;
 - (c) the name of the person to whom the poison or pharmaceutical product is supplied;
 - (ca) for an ATP supplied for use by a registered medical practitioner or registered dentist – the name and address of the practitioner or dentist;
 - (d) the total quantity of the poison or pharmaceutical product;
 - (e) a reference to the invoice or other documents supporting the transaction;
 - (f) the name of the poison or pharmaceutical product;
 - (fa) the batch number, pack size and unit of quantity of the poison or pharmaceutical product;
 - (g) the balance of the poison or pharmaceutical product remaining in his possession after the transaction.

- Same requirement as other PPs, except
 - **r. 28(2)(ca)** for **disposal** of **ATPs**
 - Duration – **30 years** after the expiry date of the product
 - **Transfer** to **the Board** if **cessation** of operation (Section 6 of the Guidance)

* ML should also refer to requirements in the GMP Guide if applicable.



Labelling

Labelling

- **Labelling** of ATPs with
 - **Product code**
 - **Unique donation identifier (UDI)**
 - For **autologous** product
 - **Unique recipient identifier (URI)**
 - **“For autologous use only”** or **“只供自體使用”**
- Code and Identifiers assigned according to **Code of Practice**
- International recognized systems
 - **ISBT 128** standard
 - Single **E**uropean **C**ode (**SEC**)

Labelling

Guidance on Labelling Requirements of Product Code, UDI and URI for ATP



Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for Advanced Therapy Products

Version 1.0

Pharmacy and Poisons Board of Hong Kong

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Can be found at

[https://www.drugoffice.gov.hk/eps/do/en/
pharmaceutical_trade/atp_regulation.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html)



Labelling

Product Code & Unique Donation Identifier



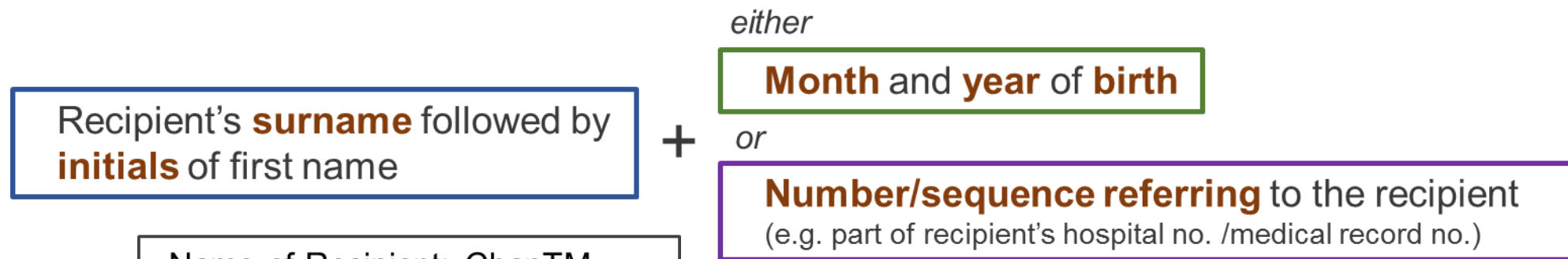
- **Product Code**
 - Coding sequence for **identification** of **cell and tissue types** contained in an ATP
- **Unique Donation identifier (UDI)**
 - **Unique** sequence attributed to **specific donation** of cells or tissues for unique identification
- Two widely accepted coding systems for human cells and tissues
 - **ISBT 128** by ICCBBA
 - **Single European Code (SEC)** – for EU
 - Both systems include two components – **Product Code** + **UDI**
- For ATPs containing human cells or tissues
 - Either **ISBT 128** or **SEC** could be used to meet both the Product Code and UDI requirement
 - If **NOT**, assigned according to **section 4 (Product Code)** and **section 5 (UDI)** of the Guidance

Labelling

Unique Recipient Identifier (URI)



- Applies only to ATPs for **autologous use***
- **Combination** of **recipient information** sufficient for healthcare professionals to **verify** the **identity** of the intended recipient
- URI should consist of at least **2 sets** of information



- Example:

Name of Recipient: ChanTM
Month and Year of Birth: 01/1960
 - Should ensure HCP fully understand how to interpret and use the URI to verify the identity of the recipient
 - Should comply with the Personal Data (Privacy) Ordinance (Cap. 486) requirements
- * ATPs for autologous use should also be labelled with “**For autologous use only**” or “**只供自體使用**”



Manufacture

Manufacture

- **Manufacturing Licence** is required for ALL facilities
 - that involve **substantial manipulation** of cells or tissues in production process, including **institutions**
 - for the production of **GTP**
 - for **affixing** to the container of ATP a **label*** stating –
 - **Product code**
 - **Unique donation identifier (UDI)**
 - **Unique recipient identifier (URI)**
 - **“For autologous use only”** or **“只供自體使用”**

* Licence for Manufacturer (Secondary Packaging) if **only involves** labelling, re-labelling, cartoning, re-cartoning or adding additional information to PP which are already enclosed in the container in which they are to be sold or supplied.

ADR Reporting

ADR Reporting

- **Existing** requirements to report ADR
- **Guidance** for **industry** & **HCP**
 - **Industry**
 - to **report** all **serious** OR **unexpected** ADR
 - **Traceability**
 - Include the **Batch number**
 - System in place capable of linking ADR reports with other traceability data
 - **List** of potential **ADR** of **concern**

Guidance for
Pharmaceutical Industry -
Adverse Drug Reaction
Reporting Requirements

Version 1.0
Pharmacy and Poisons Board of Hong Kong

Guidance for Healthcare
Professionals – Adverse
Drug Reaction Reporting

Version 2.0

Drug Office
Department of Health

ADR Reporting

Guidance for **Pharmaceutical Industry** – Adverse Drug Reaction Reporting Requirements

Guidance for Pharmaceutical Industry - Adverse Drug Reaction Reporting Requirements

Version 1.0

Pharmacy and Poisons Board of Hong Kong



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ADR Reporting

Guidance for Healthcare Professionals – Adverse Drug Reaction Reporting



Guidance for Healthcare Professionals – Adverse Drug Reaction Reporting

Version 2.0

Drug Office

Department of Health

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ADR Reporting

Potential ADR of Concern (Section 6.1 of the Guidance)



6.1 Potential Adverse Drug Reactions of Concern

Some potential adverse drug reactions of concern are listed below. Nevertheless, not all of the adverse drug reactions listed below are unique to ATPs. The list serves to provide examples to stimulate further considerations.

- adverse drug reactions related to quality characteristics of the product
 - transmission of diseases (e.g. viral, bacterial or parasitical infections and infestations) in relation to the origin of cells or tissues
 - tumourigenesis due to the alteration of differentiation capacity of the cells during the manufacturing process, “off target” mutations and unintended “on target” mutations in relation to gene editing, etc.
- adverse drug reactions related to the storage and distribution of the product
 - treatment failure due to impact on the biologic activity in related to preservation, freezing and thawing and breaking the controlled temperature conditions
- adverse drug reactions related to patient associated conditions/disease or underlying disease, or concomitant treatment/ interactions with other medicinal products
 - unwanted immunogenicity and the consequences
 - adverse drug reactions related to conditioning of patient, e.g. chemotherapy in case of CAR T-cell therapy
 - adverse drug reactions related to both intended and unintended genetic modification of the patient’s cells

- early and late consequences of homing, grafting, differentiation, migration and proliferation
- infection with vectors used in gene therapy medicinal products
- adverse drug reactions related to clinical follow-up, e.g. immunosuppression associated with the co-medication
- adverse drug reactions related to reconstitution procedures
 - dosing errors and maladministration
- adverse drug reactions related to administration procedures and re-administration
- adverse drug reactions related to persistence of the product in the patient
 - later complications (e.g. malignancies and autoimmunity)
 - adverse drug reactions related to non-specific integration into other cells with the potential of tumourigenicity
 - adverse drug reactions related to germ line integration of transgene or other genetic transformation of the germ line
- transmission of virus or vector to healthcare professionals, care givers, offspring and other close contacts
- adverse drug reactions occurring in offspring due to:
 - foetal transmission of vectors, biologically active substances, cells, infectious agents, etc.
 - transmammary exposure of children for lactating women (to vectors, biologically active substances, cells, infectious agents, etc.)

Import & Export

Import/Export

- **Same** requirements as other **pharmaceutical products** + **Considerations** specific to **ATPs**
- Requires an **Import/Export licence** to import/export of pharmaceutical products
 - Under the Import and Export Ordinance, (Cap. 60)
- Person carrying on **business** as an **importer** or **exporter** of PP –
 - **Licensed wholesale dealer** or
 - **Licensed manufacturer** (import for own manufacturing or export of own manufactured product)

Guidance on Application of Import and Export Licences

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

Version 1.0

Drug Office

Department of Health



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Can be found at




https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html

Scope of the Guidance



- **Registered** ATPs
- **Unregistered** ATPs for –
 - Clinical Trial  Same as other PPs – Requires a certificate for clinical trial/medicinal test
 - Treatment of a particular patient
 - Re-export  Same as other PPs
- **Starting** and **raw materials** for ATP **manufacturing**
- **Other relevant legislations**

Other relevant Legislation (Section 9 of the Guidance)

Subject Matter	Materials	Examples	Legislation	Responsible Department/ Office	Website	
Infectious agents	Biological materials containing or consisting of or suspected to be containing of infectious agents (e.g. viral vectors)	Viral Vector	Prevention and Control of Disease Regulation (Cap. 599A)	Port Health Division of Department of Health	https://www.dh.gov.hk/english/main/main_ph/main_ph.html	
Animal Products (Rabies)	Materials containing or consisting of parts or derivative of a dog, a cat or any animal that has been infected with rabies	Dog skin, canine plasma	Rabies Regulation (Cap. 421A)	Agriculture, Fisheries and Conservation Department (AFCD)	https://www.afcd.gov.hk/english/quarantine/qua_ie/qua_ie.html	
Genetically Modified Organisms (GMO)	Starting and raw materials containing or consisting of GMOs <i>* Not applicable to GMO that is a PP for use by human being</i>	GM viral vector	Genetically Modified Organisms (Control of Release) Ordinance (Cap. 607)		https://www.afcd.gov.hk/english/conservation/con_gmo/con_gmo.html	

Product Registration

Product Registration

Guidance on Application of Certificate of Drug/Product Registration

Guidance on Application of Certificate of Drug/Product Registration — Advanced Therapy Products

Version 1.0

Pharmacy and Poisons Board of Hong Kong



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Can be found at

[https://www.drugoffice.gov.hk/eps/do/en/
pharmaceutical_trade/atp_regulation.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html)



Product Registration

Requirements specific to ATPs



- Registration **approval** of the product in **two or more** of the following countries* –
 - Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK and USA

* Approval from the **EU countries** must be issued from **EMA**
- Submission of **ICH CTD Modules 2 – 5**
 - **Specific requirements** to ICH CTD Modules 3 (Quality), 4 (Nonclinical) and 5 (Clinical) in **Appendices 1 – 3** of guidance
- Description of **traceability system**
 - Bidirectional traceability from donor to medical practitioner/dentist using the ATP and vice versa
- Product **label**
 - Should comply with “**Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for ATPs**”
 - Should **specify** the **coding system** adopted

Product Registration

Regulated Product under HOTO



- “**Organ**” is subject to the regulatory control under **Human Organ Transplant Ordinance** (Cap. 465) (**HOTO**), including the **prohibition** of **commercial dealings**.
- The **Director of Health** may, on **application**, **exempt** a **regulated product** from the application of the whole or any part(s) of the HOTO if **certain criteria** have been met.

Section 7A of HOTO

Regulated product (受規管產品) means a product containing any structured arrangement of tissues that—
(i) falls within paragraph (a)(iii) of the **definition of organ** in section 2; and
(ii) has been **subjected to processing**.

Section 7A of HOTO

Processing (加工處理), in relation to any structured arrangement of tissues, means any **activity** performed on the tissues which **alters** the **biological characteristics**, **function** or **integrity** of the **tissues**, but does not include recovering or preparing the tissues, preserving the tissues for storage, or removing the tissues from storage.

- If an **ATP** falls within the definition of “**regulated product**” in HOTO, the application **dossier for exemption** may be submitted to **Drug Office** together with **product registration**.
- For details of application for exemption of **regulated product**, please refer to DH website.
 - https://www.dh.gov.hk/english/useful/hot_exemption.html



Clinical Trial

Clinical Trial

Guidance on **Application** of Certificate for **Clinical Trial**

Guidance on Application of Certificate for Clinical Trial - Advanced Therapy Products

Version 1.0

Pharmacy and Poisons Board of Hong Kong



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Can be found at

[https://www.drugoffice.gov.hk/eps/do/en/
pharmaceutical_trade/atp_regulation.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html)



Clinical Trial

Considerations specific to ATPs



- **Traceability**

- Ensure **bidirectional** traceability **from donor to subject** and **from subject to donor**
- **Sponsor** should –
 - Ensure that the **manufacturer** has set up a **system** that enables bidirectional tracking of cells or tissues contained in ATPs
 - Provide the **investigator** with detailed **instructions** to ensure traceability
- Data should be kept for **30 years** after the expiry date of the product

- **Informed consent**

- Where applicable, **subject** should be **informed** of –
 - Irreversible nature of ATP
 - Risk to close contacts and off-springs
 - If the treatment could compromise future pregnancies
 - The need for long-term follow-up and seeking subject commitment

- **Long-term follow-up**

- **Scheme** for long-term follow-up where applicable

Thank You