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

Version 1.1

Pharmacy and Poisons Board of Hong Kong

## CONTENTS

## 1. Purpose

1.1 This guidance outlines the requirements for handling the following records required by the Pharmacy and Poisons Regulations, Cap. 138A (PPR) in relation to Advanced Therapy Products (ATPs)–

- records stipulated in regulation 35(1) of the PPR (the "Regulation 35(1) Records"), applicable to licensed manufacturers
- transaction record stipulated in regulation 28(1) & (2) of the PPR (the "Transaction Record"), applicable to both licensed manufacturers and licensed wholesale dealers

1.2 This guidance is only a general guide for keeping relevant records and must not be treated as a complete or authoritative statement of the law on any particular case.

1.3 Licensed manufacturers and licensed wholesale dealers should also refer to their applicable code of practice and for licensed manufacturers, the Good Manufacturing Practice (GMP) Guide[1] as well.

[1] The 'Guide to Good Manufacturing Practice for Medicinal Products' published by the Pharmaceutical Inspection Co-operation Scheme (PIC/S GMP Guide PE 009-17) was adopted by the Pharmacy and Poisons Board and is available at:
https://www.ppbhk.org.hk/eng/files/PIC-S_GMP_Guilde_eng.pdf

## 2. Scope

2.1 This guidance is relevant to–

- licensed manufacturers which manufacture and/or distribute ATPs
- licensed wholesale dealers which distribute ATPs

2.2 ATPs referred in this guidance mean 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.

## 3. Background

3.1 ATPs are innovative medical products based on genes, cells and tissues. The rapid scientific advancement in the research and development of ATP offers great medical potential for benefiting patients. At the same time, due to their complicated nature and our limited knowledge and experience, the risks and long-term side effects of ATPs need to be carefully managed.

3.2 In some situations, the safety and quality issues of ATPs may only be identified after the ATPs has been administered to patients. Additional health information about the donor, possible contamination of materials and consumables used in the processing of the cells or tissues as well as the defective equipment and testing kits that may imply the safety and quality issues of the ATPs sometimes come up after the administration of ATPs.

3.3 As such, an effective and efficient traceability system covering from the donation through processing to the end use is essential to allow determination of which ATPs and patients could potentially be affected for the necessary patient follow-up and recall of the affected ATPs in case of any safety and quality issues identified.

3.4 On the other hand, some safety and quality issues can only be revealed long after the use of ATPs. For example, unpredictable risks of malignancies and effects to offspring may appear many years after the use of ATPs. As such, records relevant to traceability must be kept for extended period sufficient to enable the tracking and tracing the donation, processing and the recipient of the ATPs for the possible follow-up actions if necessary.

3.5 The anonymity and privacy of the donor and recipient should not be compromised by the need to comply with the traceability requirements. Licensed manufacturers and licensed wholesale dealers should prevent the disclosure of confidential information to unauthorised

persons, and at the same time, ensure that the information relating to donation, procurement, processing, storage and distribution of the cells and tissues and the use of ATP could be effectively and efficiently traceable.

3.6 In Hong Kong, ATP are regulated as pharmaceutical product under the Pharmacy and Poisons Ordinance (PPO). Record keeping requirements for licensed manufacturers and licensed wholesale dealers applicable to pharmaceutical products as well as those additional requirements specific to ATPs and relevant to the traceability are stated in the PPR.

3.7 The PPR requires two types of records to be maintained by licensed manufacturers and licensed wholesale dealers–

- Regulation 35(1) Records, applicable to licensed manufacturers only (outlined in section 4 of this Guidance)
- Transaction Record, applicable to both licensed manufacturers and wholesale dealers (outlined in section 5 of this Guidance)

3.8 Failure to meet the above record keeping requirements is an offence punishable by the maximum penalty of a fine at level 6 of the Criminal Procedure Ordinance, Cap. 221 and two years' imprisonment.

## 4. 'Regulation 35(1) Records' by Licensed Manufacturer for ATP

4.1 Under regulation 35(1) of the PPR, licensed manufacturer must maintain adequate records in respect of each pharmaceutical product prepared by him, showing[2]–

**(a) the quantities of all substances used in the manufacture of the product;**

**(b) the quantity of the product manufactured;**

**(c) the name and the address of the person to whom the pharmaceutical product was sold or supplied**;

**(ca) for an ATP sold or supplied for use by a registered medical practitioner or registered dentist – the name and address of the practitioner or dentist**;

(d) the nature and results of tests made on each lot or batch of raw or bulk materials used in the product;

(e) the nature and results of tests made on each batch of finished product;

(f) any complaints received relating to the product and the action taken on the complaints by the manufacturer;

(g) the nature and result of any tests made on the samples retained; and

**(h) for an ATP containing or consisting of cells or tissues–**

**(i) the name and address of the person from whom the cells or tissues used for the preparation of the product were obtained; and**

**(ii) the unique donation identifier assigned in accordance with the codes of practice issued by the Pharmacy and Poisons Board (the "Board").**

4.2 In maintaining the abovementioned records, the licensed manufacturer must comply with the GMP principles laid down in applicable sections of the GMP Guide, in particular, Chapter 4 'Documentation' and Annex 11 'Computerised Systems'.

[2] The bold types of record must be kept or retained by licensed wholesale dealers and licensed manufacturers for a period of 30 years after the expiry date of the product according to regulation 39 of the PPR. For details, please refer to paragraph 4.8.

## Specific Guidance for Particular Regulation 35(1) Records

Items (c) and (ca)

4.3 For items (c) and (ca) in paragraph 4.1 in relation to the name and address of the person the product is sold or supplied, they should be included into the Transaction Record mentioned in section 5 of this document.

Item (h)

4.4 The following information should be recorded to facilitate the bidirectional tracking of human cells and tissues contained in the ATPs from the point of donation, through manufacturing, to the delivery of the finished product to the recipient–

(a) the name and address of the person from whom the cells or tissues used for the preparation of the product were obtained:

- if the cells or tissues are obtained from a hospital, private healthcare facility or tissue establishment (local or overseas), the name and address of that hospital, private healthcare facility or tissue establishment should be entered
- if the cells or tissues are obtained directly by the licensed manufacturer from a donor/patient at a site other than a hospital, private healthcare facility or tissue establishment, the name and address of that donor/patient;

(b) the unique donation identifier assigned in accordance with 'Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for Advanced Therapy Products'[3].

[3] 'Guidance on Labelling Requirements of Product Code, Unique Donation Identifier and Unique Recipient Identifier for Advanced Therapy Products' is available at the webpage: https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/atp_regulation.html

## Computerised Systems for Record Keeping

4.5 If the licensed manufacturer intends to use a computerised system for keeping records under paragraph 4.1, the computerised system should be validated in accordance with the requirements laid down in the GMP Guide, in particular, but not limited to, Annex 11 'Computerised Systems'.

## Time Limits for Completion of Record

4.6 The time limits for completion of the records mentioned in paragraph 4.1 are stipulated in regulations 35(2), (3) and (4) and listed below–

(a) A record showing the matters mentioned in paragraph 4.1(a), (b), (d), (e), (g) and (h) must be completed when the manufacturing process or test concerned is being carried out;

(b) A record showing the matters mentioned in paragraph 4.1(c) and (ca) must be completed within 72 hours after the transaction concerned takes place;

(c) A record showing a complaint mentioned in paragraph 4.1(f) must be completed within 72 hours after the complaint is received by the licensed manufacturer;

(d) A record showing an action taken in respect of a complaint mentioned in paragraph 4.1(f) must be completed within 72 hours after the action is taken.

## Duration of Record Keeping

4.7 For ATPs, according to regulation 39 of the PPR, licensed manufacturers must preserve all books, records and documents required to be kept or retained in respect of the product under regulations 35(1)(a), (b), (c), (ca) and (h) (i.e. the bold types of record in paragraph 4.1) for a period of 30 years after the expiry date of the product.

4.8 For other records and documents required under regulation 35, they must be preserved for a period of 2 years from the date of the last entry or in relation to a document, for a period of 2 years from the date of the transaction[5].

[5] Please also refer to specific requirements on retention of documents stated in Chapter 4 'Documentation' of the GMP Guide.

## 5. Transaction Record by Licensed Wholesale Dealers and Licensed Manufacturers for ATPs

5.1 Under regulation 28 of the PPR, licensed wholesale dealer or licensed manufacturer must record the particulars specified in regulations 28(1) and (2) for each transaction by which any pharmaceutical product is acquired by him and disposed of.

5.2 For each transaction by which an ATP is acquired by the licensed wholesale dealer or licensed manufacturer whether by way of import, purchase, gift or otherwise, particulars to be recorded include–

(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.

5.3 For each transaction by which an ATP is disposed of, whether the disposition is by way of export, sale, gift or otherwise –

(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; and

(g) the balance of the poison or pharmaceutical product remaining in his possession after the transaction.

5.4 In addition, according to regulation 28(6) of the PPR, records of sales or supplies must be supported by documents signed by the purchaser.

5.5 Licensed wholesale dealer and licensed manufacturer should follow the good documentation practices in keeping the Transaction Record. Handwritten entries should be made in clear, legible, indelible way. Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.

5.6 The handling of the personal data should also comply with the Personal Data (Privacy) Ordinance, Cap. 486.

**Time Limits for Recording the Transaction**

5.7 According to regulation 28(5) of the PPR, every transaction to which regulations 28(1) and (2) relates must be recorded within 72 hours after the time it took place.

**Format of Transaction Record**

5.8 The Transaction Record must be in the specified form unless the Pharmacy and Poisons (Wholesale Licences) Committee of the Board (the "Committee") approves another system

of recording. The specified form in relation to transactions involving ATPs is appended in Appendix 1[6].

5.9 The Transaction Record can be in an electronic format; however, approval from the Committee of the Board should also be sought prior to the adoption of an electronic format other than the specified form. In such case, the following requirements are to be satisfied[7]–

- the electronic recording system must be able to record all particulars specified in regulations 28(1) and (2) (the "Stored Data")
- the Stored Data should be secured by physical or electronic means and protected against accidental or unauthorised modifications
- the Stored Data should be checked periodically for accessibility
- the Stored Data should be protected by backing up at regular intervals. Backup data should be retained for the period stated in paragraph 5.12 at a separate and secure location
- it should be possible to obtain clear printed copies of the Stored Data

5.10 The application for adopting an electronic format other than the specified form for Transaction Record should be submitted to the respective regulatory unit of the DH DO for the Committee's prior approval–

- Manufacturers Regulatory Unit
- Wholesalers Regulatory Unit

[6] The specified form appended in Appendix 1 is only applicable to transactions involving ATPs. For transactions involving pharmaceutical products and Part 1 poisons other than ATPs, another specified form entitled "Form of Records of Transactions involving Poisons in Part 1 of the Poison List or Pharmaceutical Products to be kept by Licensed Wholesale Dealers or Licensed Manufacturers" ("Another Specified Form") should be used. This Another Specified Form is available at the webpage:
https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/certificates_licences_specified_forms/certificates_licences_specified_forms.html
For ATPs that are also Part 1 poisons, only the specified form appended in Appendix 1 should be used and no duplicate entries are required to be made on a record using Another Specified Form.

[7] Please also refer to Annex 11 'Computerised Systems' of the GMP Guide if applicable.

5.11 The application should include–

- a description of the electronic recording system
- written policies or procedures for data security, periodic data accessibility checking and data backup
- a sample of printed record

**Duration of Record Keeping**

5.12 For ATPs, according to regulation 39 of the PPR, licensed wholesale dealers or licensed manufacturers must preserve all books, records and documents required to be kept or retained in respect of the product under regulations 28 for a period of 30 years after the expiry date of the product.

## 6. Handling of Record upon Cessation of Operation

6.1 It is anticipated that licensed manufacturers and licensed wholesale dealers may cease to operate due to the following situations –

(a) withdrawal, revocation or expiry of the manufacturing licence or wholesale dealer licence;

(b) winding up or dissolution of the company.

6.2 In these situations, the record should be transferred to the Board –

(a) within 14 days after the cessation of operation as a licensed manufacturer or licensed wholesale dealer; or

(b) in case of winding up or dissolution of the company, as soon as practicable after the commencement of the winding up or dissolution.

### Format of the Record

6.3 If the record is made in a written form, the original record should be submitted.

6.4 On the other hand, if the record is made in an electronic format or using a computerised system, all data must be converted to file(s) in a commonly readable and printable format (for example, pdf, Microsoft® Word, Excel) and softcopy of all files in printable format (for example, files contained in CD-ROM) (preferred) should be submitted. Alternatively, a legible printed copy could be submitted.

6.5 A cover letter listing all the documents or files to be submitted should be provided.

6.6 In addition, the documents or files to be submitted should be labelled clearly to indicate each type of records (for example, transaction record).

**Submission of Record**

6.7 The DH DO is an executive arm of the Board. The record should be submitted via the respective regulatory unit of the DH DO –

- Manufacturers Regulatory Unit

  Address: Room 2550, Wu Chung House, 213 Queen's Road East, Wanchai, Hong Kong

  Email: pharmgeneral@dh.gov.hk

- Wholesalers Regulatory Unit

  Address: Room 2001-2002, 20/F, Dah Sing Financial Centre, 248 Queen's Road East, Wanchai, Hong Kong

  Email: pharmgeneral@dh.gov.hk

## Appendix 1 Form of Records of Transactions Involving Advanced Therapy Products to be kept by Licensed Wholesale Dealers or Licensed Manufacturers

[regulation 28(4)]
[第 28(4)條]

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例

(Chapter 138)
(第 138 章)

FORM OF RECORDS OF TRANSACTIONS INVOLVING ADVANCED THERAPY PRODUCTS
TO BE KEPT BY LICENSED WHOLESALE DEALERS OR LICENSED MANUFACTURERS
持牌批發商或持牌製造商須備存的涉及先進療法製品的交易紀錄格式

| Name of Advanced Therapy Product<br>先進療法製品名稱 | | | | Pack Size<br>包裝大小 | | Unit of Quantity<br>數量單位 | |
|---|---|---|---|---|---|---|---|
| Date of Transaction<br>交易日期 | Nature of Transaction<br>交易性質 | Supplier or to whom supplied<br>供應人或獲供應的人 | Name and Address of Registered Medical Practitioner or Registered Dentist (if supplied for use by them)<br>註冊醫生或註冊牙醫的姓名及地址（如供應予他們使用） | Invoice Number<br>發票號碼 | Batch Number<br>批次編號 | Total Quantity<br>總數量 | Balance after Transaction<br>交易後的餘量 |
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## Document Information

| Version | Date | Description of Change |
|---|---|---|
| 1.0 | 1 August 2021 | (First version issued in June 2021) |
| 1.1 | 1 July 2025 | Reformatting of version 1.0 |

**[End of Document]**