Guidance on Record Keeping for Medical Practitioners, Dentists and Institutions Providing Advanced Therapy Product Treatment

Version 1.0
(Draft for comment)

Drug Office
Department of Health

Contents

1. Purpose

1.1 This document provides guidance on record keeping in relation to the provision of treatment involving the use of advanced therapy products ("ATP treatment") by medical practitioners and dentists. It covers the type of records to be kept as well as the handling and the retention period of such records.

2. Scope

2.1 This guidance is relevant to –

(a) Registered medical practitioners and dentists who provide the ATP treatment to their patients; and

(b) "Institutions" defined in section 2 of the Pharmacy and Poisons Ordinance, Cap. 138 ("PPO") where the ATP treatments are provided. Private healthcare facilities licensed under the Private Healthcare Facilities Ordinance, Cap. 633 ("the licensed private healthcare facilities") would also be regarded as "institutions" under the PPO.

2.2 Advanced Therapy Products ("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; and

(c) A tissue engineered product.

2.3 [Proposed] Definitions of gene therapy product, somatic cell therapy product and tissue engineered products are appended at Appendix 1.

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 ATPs 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. Thus, enhanced record keeping requirements with longer retention period ensure sufficient monitoring and tracing of the patients who received an ATP treatment in case of any safety and quality issues identified.

3.2 In Hong Kong, ATPs are regulated as pharmaceutical products under the PPO. Under the [proposed amendment of] Pharmacy and Poisons Regulations, Cap. 138A, licensed wholesalers and manufacturers are required to record the name and address of the practitioners or dentists to whom ATPs are supplied for use.

3.3 In order to allow the complete tracing of ATP treatment from the licensed manufacturers or the licensed wholesalers to the patients who have received a particular ATP for quality or safety reasons , it is important for the following **"ATP users"** providing the ATP treatment to maintain a register or a tracing system to record the details of the use and application of the product –

(a) medical practitioners;

(b) dentists;

(c) healthcare institutions, including the Hospital Authority and private healthcare facilities registered under the Private Healthcare Facilities Ordinance (Cap.633).

3.4 This document serves to provide guidance on such record keeping.

4. Who is Responsible for Record Keeping?

4.1 In principle, the ATP treatment record is part of patients' medical record. Accordingly, medical practitioners, dentists and private healthcare facilities are responsible for keeping ATP treatment record in the same manner as the other medical records. Relevant codes of professional conduct issued by the Medical Council and the Dental Council, as well as the codes of practice for private healthcare facilities issued by the Department of Health, should be followed.

4.2 If the medical practitioner or dentist is employed by an institution to provide the ATP treatment, the medical practitioner or dentist providing the treatment should ensure that the record is properly kept in that institution.

5. What Record should be Kept?

A Register or a Tracing System ("the ATP Record")

5.1 Under section 28 of the PPO, for a medicine supplied by a registered medical practitioner or a registered dentist for the purpose of treatment, particulars relating to the supply should be entered in the record of treatment or other document. These particulars include –

(d) the date on which the medicine was supplied;

(e) the name and address of the person to whom or on whose behalf it was supplied; and

(f) the ingredients of the medicine and the quantity, dosage and duration of supply.

5.2 Failure to enter the above particulars in the record of treatment or other document is an offence punishable by the maximum penalty of a fine of $100,000 and two years' imprisonment.

5.3 In addition to the record keeping requirements under section 28 of the PPO, ATP users providing the ATP treatment are recommended to maintain a register containing the patient and treatment information listed in Section 5.7.

5.4 As a substitute to the aforementioned register, an alternative tracing system could be used. The alternative tracing system should enable the identification of those patients who received a particular batch of an ATP. In addition, the information listed in Section 5.7 could also be traceable through that system or other records (e.g. medical record).

5.5 The register mentioned in Section 5.3 and the alternative tracing system mentioned in Section 5.2 are referred as **"the ATP record"** in this Guidance.

Information Required

5.6 The information included in the ATP record should enable the identification of patient who received a particular batch of an ATP and the treatment details.

5.7 The ATP record should contain the following information –

(a) Identifier of the patient;

(b) Details of the ATP applied –

(1) Name;

(2) Batch number, ISBT 128 code or Single European Code (SEC)[1];

(3) Supplier name, and manufacturer name if different from the supplier;

[1] Both ISBT 128 (maintained by the Council for Commonality in Blood Banking Automation ("ICCBBA")) and SEC (established under the Commission Directive (EU) 2015/565) are internationally recognized coding systems for identification of the medical products containing cells or tissues for tracing purpose. Some ATPs may use the ISBT 128 or SEC to encode the product and in such case, a unique ISBT 128 code or SEC could be found on the label of each container of the ATPs containing cells or tissues. The code on each container is different and unique. Samples of labels are appended in Appendices 2 (ISBT 128) and 3 (SEC). For ATPs encoded with a system other than ISBT 128 and SEC, batch number could be entered in the ATP record instead.

(c) Date of treatment; and

(d) Medical practitioner or dentist responsible for the use of the product if the record is kept by an institution.

Format and Data Handling

5.8 The ATP record can be in electronic or written format. Where the ATP record is in an electronic format, there should be a mechanism to provide an audit trail on any amendments made on the record.

5.9 The ATP record should be protected from unauthorized access, alteration or loss. If electronic recording system is used, regular back-ups or archive should be performed.

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

6. Duration of Record Keeping

6.1 To be in line with the record keeping requirements for the ATP manufacturers and wholesalers[2], the general principle is that the ATP record should be kept for 30 years after the use of the product.

6.2 Notwithstanding Section 6.1, ATP users can determine the duration of record keeping taking into account individual circumstances of the case. For instance, ATP users may apply a shorter record keeping duration for deceased patients. On the other hand, for gene therapy products that carry the risk of germline alteration, ATP users should assess whether a longer record keeping duration is needed for monitoring the effects of the patients' offspring.

7. Handling of Record upon Cessation of Practice or Provision of Service in the Healthcare Facilities

7.1 It is anticipated that a medical practitioner or dentist may cease their professional practice or a healthcare facility may cease to operate during the long record retention period. In these situations, it is important that the ATP record is properly handled and preserved in order to maintain the traceability of those patients who received a particular batch of an ATP.

7.2 As with the requirements by their respective code of professional conduct, in these situations, it is the responsibility of the medical practitioner or dentist providing the ATP treatment to ensure that the records are properly handled and kept. Medical practitioners, dentists and licensed private healthcare facilities should have due regard to their responsibilities and liabilities under the Personal Data (Privacy) Ordinance, Cap. 486, when considering how to handle these records.

[2] Under the [proposed amendment of] Pharmacy and Poisons Regulation, Cap. 138A, licensed wholesalers and manufacturers are required to keep the record for each transaction of disposition for 30 years after the expiry date of the product.

7.3 If a medical practitioner or dentist intends to stop practising medicine, that medical practitioner or dentist should make follow-up arrangement for affected patients. The medical records including ATP record should be transferred to another medical practitioner or dentist who is, in his or her opinion, competent to look after the patient. The transfer of such record should comply with the requirements set out in their respective code of professional conduct.

7.4 If a medical practitioner or dentist ceases to provide service in an institution but continue to take care of the patient, he or she should obtain a copy of the ATP record from that institution.

7.5 If a facility ceases to operate, that facility should make follow-up arrangement to affected patients. The institution should ensure that the relevant medical practitioners, dentists and patients can have access to medical records, including ATP records, in the recommended record keeping period.

8. Enquiries

8.1 For enquiries, please contact the Advanced Therapy Products Unit of the Drug Office, Department of Health –

Address:	Room 1856, 18/F, Wu Chung House, 213 Queen's Road East
	Wan Chai, Hong Kong
Email:	pharmgeneral@dh.gov.hk
Telephone:	2961 8162

Appendix 1 (Proposed) Definition of Gene Therapy Product, Somatic Cell Therapy Product and Tissue Engineered Product

Gene Therapy Product

Gene therapy product—

(a) means a product—

(1) that contains an active substance containing or consisting of a recombinant nucleic acid that may be used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and

(2) the therapeutic, prophylactic or diagnostic effect of which relates directly to—

(A) the recombinant nucleic acid sequence it contains; or

(B) the product of genetic expression of that sequence; but

(b) does not include a vaccine against an infectious disease.

Somatic Cell Therapy Product

Somatic cell therapy product means a product that—

(a) contains or consists of any of the following cells or tissues—

(1) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

(2) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and

(b) is presented as having properties for, or may be used in or administered to human beings with a view to—

(1) treating, preventing or diagnosing a disease; or

(2) restoring, correcting or modifying physiological functions,

through the pharmacological, immunological or metabolic action of those cells or tissues.

Tissue Engineered Product

Tissue engineered product—

(a) means a product that—

(1) contains or consists of any of the following cells or tissues—

(A) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement have been altered;

(B) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and

(2) is presented as having properties for, or may be used in or administered to human beings with a view to, regenerating, repairing or replacing a human tissue; but

(b) does not include a product that—

(1) contains or consists of exclusively non-viable human or animal cells or tissues; and

(2) does not act principally by pharmacological, immunological or metabolic action.

Substantial Manipulation

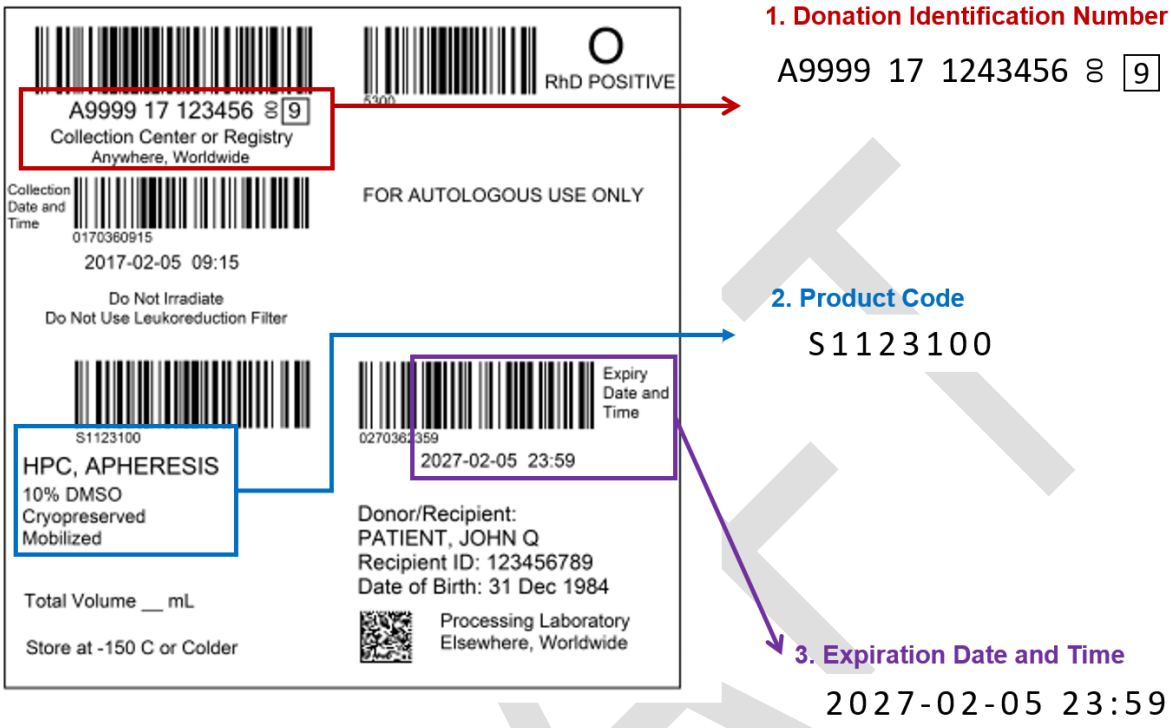
Substantial manipulation, in relation to cells or tissues, does not include the manipulation processes set out in the Schedule of the Pharmacy and Poisons Ordinance, Cap. 138.

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

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

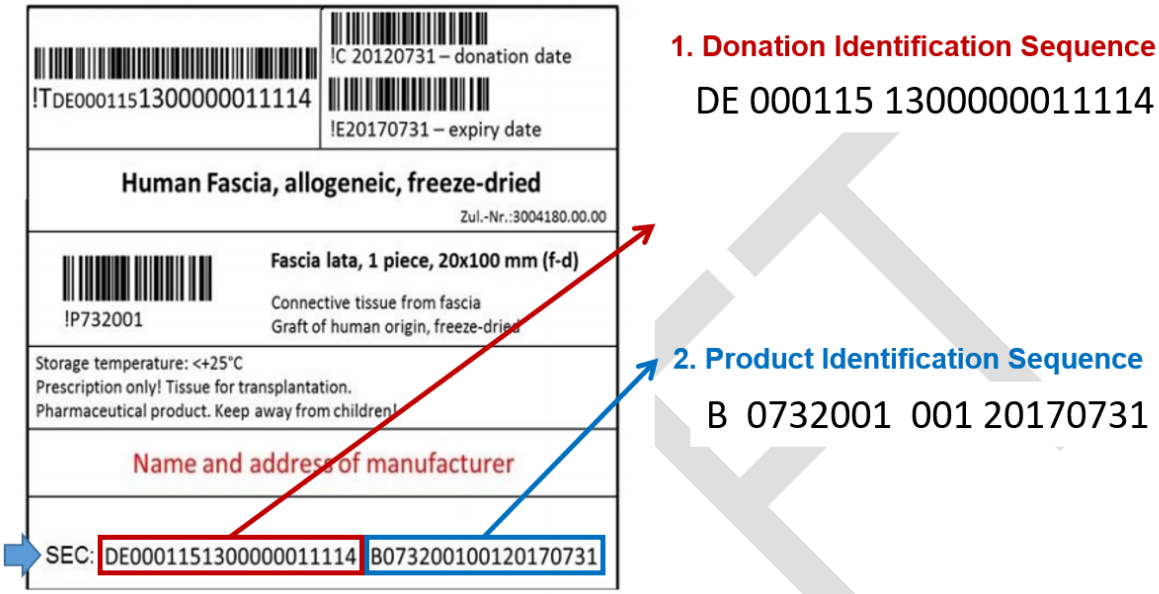
Appendix 2 Sample of Labels containing ISBT 128 Code

ISBT 128 code contains three components – Donation Identification Number (DIN), product code and expiration date and time. Sample label below shows the location where the three components of the ISBT 128 code could be found.



Appendix 3 Sample of Labels containing Single European Code (SEC)

SEC contains two components – Donation identification sequence and product identification sequence. SEC on the product label precedes with the letters "SEC:" and follows with two alphanumeric sequences. Sample label below shows the location where the two components of the SEC could be found.



Document Information

Version	Date	Description of Change
1.0	4/11/2019	First version (Draft for comment)