Code of Practice for Holder of Wholesale Dealer Licence

For consultation

2026

Pharmacy and Poisons Board of Hong Kong

CONTENT

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INTRODUCTION

Under section 4B of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance), the Pharmacy and Poisons Board (the Board) may issue codes of practice that it considers suitable for providing practical guidance in respect of the Ordinance.

Pursuant to such power under section 4B of the Ordinance, the Board issues this Code of Practice for Holder of Wholesale Dealer Licence (the Code) for the purpose of providing guidance on the roles and responsibilities of the holders of Wholesale Dealer Licence (WDL) and setting out, in addition to those in the relevant Guide to Good Distribution Practice for Pharmaceutical Products (the GDP Guide) issued by the Board, the minimum standards that a WDL holder has to meet in the distribution of pharmaceutical products. For the purpose of the Code, wholesale distribution of pharmaceutical products refers to all activities consisting of procuring, holding, supplying, importing or exporting pharmaceutical products, apart from suppling pharmaceutical products to the public.

WDL holders shall comply with the Ordinance (Cap.138), the Code, the GDP Guide and other relevant guidance documents issued by the Board which are available at the following link: https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html , as well as any other requirements related to pharmaceutical products imposed under the Laws of Hong Kong, including but not limited to:

a. Dangerous Drugs Ordinance (Cap. 134);
b. Antibiotics Ordinance (Cap. 137);
c. Import and Export Ordinance (Cap. 60);
d. Public Health and Municipal Services Ordinance (Cap. 132);
e. Undesirable Medical Advertisements Ordinance (Cap. 231);
f. Trade Descriptions Ordinance (Cap. 362); and
g. Waste Disposal Ordinance (Cap. 354).

Contravention of the Code may lead to revocation or suspension of the WDL for such period as the Pharmacy and Poisons (Wholesale Licences) Committee (the Committee) thinks fit.

The Board has engaged the assistance of the Department of Health in implementing the various requirements under the Code.

The Code does not apply to the trade in non-medicinal poisons, for example chemical reagents, hair-dyes, and industrial chemicals such as cyanide and

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sulphuric acid as well as medical devices containing poisons. However, all WDL holders shall ensure that their operations comply with the legal requirements stipulated in the Ordinance, and its subsidiary regulations.

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SECTION 1: GENERAL RESPONSIBILITIES OF HOLDER OF WHOLESALE DEALER LICENCE

1.1 A WDL holder shall furnish any information relating to its licence as reasonably required by the Committee.

1.2 A WDL holder shall nominate in writing a person to take charge of poisons and/or pharmaceutical products, and may nominate in writing one or more deputies to act during the temporary absence of the person in charge. A WDL holder shall obtain approval from the Committee prior to any change in the person in charge of the poisons and/or pharmaceutical products or his deputies and the Committee shall not approve the change unless it considers the person nominated fit and proper.

1.3 A WDL holder shall notify the Committee in writing of any change in its proprietor, partner(s) or director(s) within one month from the date of change.

1.4 A WDL holder shall not sell or deal in any listed psychotropic substances set out in Appendix A unless under the supervision of a registered pharmacist.

1.5 A WDL holder shall ensure that all activities relating to pharmaceutical products or poisons are conducted in a manner that complies with applicable legislation, the Code, the GDP Guide and other relevant guidance documents issued by the Board.

1.6 A WDL holder shall provide designated storage facility for storing pharmaceutical products. All storage facilities of pharmaceutical products shall be approved by the Committee prior to the commencement of use.

1.7 All Part 1 poisons shall be properly locked in the storage facility.

1.8 Poisons shall only be kept in a container impervious to the poison stored and sufficiently stout to prevent leakage from the container arising from the ordinary risks of handling.

1.9 In addition to the requirements by the Customs and Excise Department, a WDL holder shall report to the DH the actual import of unregistered pharmaceutical products within 14 days of the arrival of the shipment of the products.

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1.10 For pharmaceutical products imported for export purpose, a WDL holder shall export the products within 1 year from the date of importation unless otherwise approved by the DH.

1.11 Within a reasonable time frame after a drug incident, the WDL holder who imported those drugs from overseas manufacturer for sale or supply must make available to the DH a batch sample of the drug concerned so as to facilitate any investigation into the incident required by the DH.

1.12 A WDL holder must not sell or supply a poison to any person other than the following:

a. a licensed wholesale dealer;
b. a licensed manufacturer;
c. an authorized seller of poisons;
d. a registered pharmacist;
e. a registered medical practitioner, a registered dentist or a registered veterinary surgeon;
f. persons who require the poison for the purpose of their trade or business;
g. a Government department or public officer requiring the article for the purposes of public service;
h. a person or an establishment concerned with education or scientific research, if the article is required for the purposes of such education or research;
i. an institution;
j. purchasers outside Hong Kong; or
k. a Listed Seller of Poisons (provided that only Part 2 poisons may be sold or supplied).

If the product handled is a dangerous drug or an antibiotic, a WDL holder must also comply with the Dangerous Drug Ordinance (Cap. 134) or the Antibiotics Ordinance (Cap. 137) in its sale or supply of the product.

1.13 When a verbal order for pharmaceutical products that contain Part 1 poisons, dangerous drugs or antibiotics is received from a purchaser, a WDL holder shall obtain an order in writing from the purchaser before completion of a sale of these products in order to avoid ambiguity or miscommunication which may otherwise lead to wrongful delivery.

Written orders in paper format or by means of an electronic

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message, such as email, are acceptable.

A WDL holder may accept an order of medicines placed by a representative of the purchaser but shall exercise due diligence to ensure the authenticity of the order.

1.14 Particulars of registered pharmaceutical products sold or distributed in Hong Kong shall correspond exactly with those registered with the Pharmacy and Poisons Board.

1.15 A WDL holder shall not consign any poison for transport unless the poison is sufficiently stoutly packed to avoid leakage arising from the ordinary risks of handling and transport.

1.16 Pharmaceutical products intended to be destroyed shall be handled in accordance with relevant legislations and guidelines issued by the Environmental Protection Department, if any. A WDL holder shall notify the DH in advance of the destruction of dangerous drugs, and the destruction shall be witnessed by a pharmacist of the DH. Record of destruction of any pharmaceutical products shall be kept for inspection and investigation by the DH.

1.17 A WDL holder shall maintain documentation related to the licensed activities, including those required in the Code, the GDP Guide and ensure the documents are readily available for inspection when required by the DH.

1.18 A WDL holder shall keep record of all transactions of Part 1 poisons or pharmaceutical products and the records shall contain the following particulars:

a. the name of the poison or pharmaceutical product;
b. the batch number, pack size and unit of quantity of the poison or pharmaceutical product;
c. the date of the transaction;
d. the nature of the transaction;
e. the name of supplier or the person to whom the poison or pharmaceutical product is supplied;
f. for an advanced therapy product (ATP) supplied for use by a registered medical practitioner or registered dentist – the name and address of the practitioner or dentist;
g. the invoice number;
h. the total quantity received or supplied; and
i. the balance of the poison or pharmaceutical product kept after

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the transaction.

There shall be a separate entry in the record for each Part 1 poison or pharmaceutical product and every transaction shall be recorded within 72 hours after the time it took place.

All records of transactions must be in the specified form (see Appendices B and C) unless the Committee approves another system of recording.

Records of sales or supplies maintained under Pharmacy and Poisons Regulations shall be supported by documents signed by the purchaser. In the case of an import or export transaction, a WDL holder must retain all shipping and other documents supporting the transaction.

1.19 A WDL holder shall collect the signed receipts of sale or supply of Part 1 poisons or pharmaceutical products within 72 hours after the transaction.

1.20 Electronic record may only be used if it can be readily retrieved and printed out for inspection.

1.21 A WDL holder shall retain the supporting records and documents for each transaction of Part 1 poisons or pharmaceutical products, which include but are not limited to invoice, written order, signed receipt, import and export licence, import and export declaration form, batch release certificate and certificate of analysis.

1.22 A WDL holder shall state the batch number of the Part 1 poisons or pharmaceutical products supplied in the invoice for the transaction.

1.23 All books or other form of records and documents required to be kept or retained by a WDL holder shall be preserved in the premises in which the transaction recorded took place-

a. for a period of 2 years from the date of the last entry therein; or
b. in relation to a certificate or document, for a period of 2 years from the date of the transaction.

1.24 For an ATP, all books, records and documents required to be kept or retained ("specified documents") in respect of the product must be preserved by the WDL holder for a period of 30 years after the expiry date of the product. If a WDL holder ceases to operate as a WDL holder before the period aforementioned expires, the specified documents must be transferred to the Board within 14 days after the

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cessation.

1.25 Any other records and documents mentioned in the Code shall be kept or retained by a WDL holder for at least two years from the date of completion of the record or document.

1.26 Records and documents required to be maintained under the Code shall be reviewed regularly. In the event of irregularities and/or deficiencies found in maintaining the records and documents, the causes of irregularities and/or deficiencies shall be investigated and any corrective and preventive actions taken shall be documented.

1.27 A WDL holder shall carefully review all the documents before their proper disposal to avoid mistaken destruction.

1.28 A WDL holder shall carefully investigate and document any complaints and information concerning potentially defective pharmaceutical products supplied. In case of a complaint or problem of pharmaceutical products that leads to a recall not initiated by the DH, a WDL holder shall report the recall to the DH, and implement the recall as instructed or endorsed by the DH in accordance with the "Pharmaceutical Products Recall Guidelines" published at the following website link:

http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Pharmaceutical_Products_Recall_Guidelines.pdf

A recall of pharmaceutical products may be initiated by the DH, the manufacturer, wholesaler, importer or registration certificate holder of the concerned pharmaceutical products.

1.29 If a WDL holder is also the registration certificate holder of a pharmaceutical product, the WDL holder shall closely liaise with the local or overseas manufacturer of the product for any significant changes or conditions which may affect the safety, efficacy or quality of the pharmaceutical products. Any notification of such changes or conditions received from the manufacturer shall be promptly reported to the DH.

1.30 Once a WDL holder is aware of an Adverse Drug Reaction (ADR) related to the products it has supplied, it shall investigate into, document and report the same to the Drug Office of the DH in accordance with the "Guidance for Pharmaceutical Industry –

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Adverse Drug Reaction Reporting Requirements" published at the following website:

https://www.drugoffice.gov.hk

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SECTION 2: SPECIFIC REQUIREMENT FOR HANDLING ADVANCED THERAPY PRODUCTS

2.1 Apart from the record keeping requirements as provided under Section 1, a WDL holder handling advanced therapy products (ATPs) must ensure the specific requirements stipulated in this section are met.

Traceability

2.2 A WDL holder should ensure a system that enables the bidirectional tracking of cells/tissues contained in ATPs from the point of donation, through manufacturing, to the delivery of the finished product to the use by a medical practitioner or dentist is in place.

Product Labelling

2.3 Notwithstanding other labelling requirements applicable to pharmaceutical products, a WDL holder shall ensure that the ATPs they supply should be labelled with:

a. a product code and a unique donation identifier assigned in accordance with Appendix D; and
b. For ATPs for autologous use only, the product should be labelled with a unique recipient identifier assigned in accordance with Appendix E, and the English words "For autologous use only" or the Chinese characters "只供自體使用".

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GLOSSARY

"advanced therapy product"
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.

"Adverse Drug Reaction (ADR)"
A response to a pharmaceutical product which is noxious and unintended.

"antibiotics"
Substances to which the Antibiotics Ordinance (Cap.137) applies.

"authorized seller of poisons (ASP)"
This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap.138).

"batch"
A defined quantity of pharmaceutical products processed in a single process or series of processes so that the products produced are expected to be homogenous.

"The Board"
The Pharmacy and Poisons Board.

"certificate of analysis"
A certificate which certifies whether or not a sample of poison or pharmaceutical product complies with certain specifications after a list of test procedures meeting specified criteria are applied to the sample.

"The Code"
The Code of Practice for Holder of Wholesale Dealer Licence.

"Committee"
The Pharmacy and Poisons (Wholesale Licences) Committee established by the Pharmacy and Poisons Board.

"container"
The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product and secondary if they are not.

"dangerous drugs"

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The drugs and substances specified in Part I of the First Schedule of the Dangerous Drugs Ordinance (Cap.134).

"DH"
The Department of Health

"expiry date"
In relation to a pharmaceutical product, it is the date determined, on the basis of the product's specifications registered under Regulation 36(3)(a)(ii) of the Pharmacy and Poisons Regulations, by the manufacturer as the date after which the product should not be used, assuming that the product is stored under conditions suitable to the product.

"The GDP Guide"
The Guide to Good Distribution Practice for Pharmaceutical Products issued by the Pharmacy and Poisons Board.

"gene therapy product"
(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.

"institution"
This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap.138).

"Listed Seller of Poisons"
This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap.138).

"manufacture" and "manufacturer"
These have the same meaning assigned to them under the Pharmacy and Poisons Ordinance (Cap.138).

"The Ordinance"
The Pharmacy and Poisons Ordinance (Cap.138).
"pharmaceutical product"

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(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.

"Part 1 poison"
A substance which is specified in Part 1 of the Poisons List (Cap.138A Schedule 10).

"Part 2 poison"
A substance which is specified in Part 2 of the Poisons List (Cap.138A Schedule 10).

"poison"
A substance which is specified in the Poisons List (Cap.138A Schedule 10).

"procure"
Obtain, acquire, purchase or buy pharmaceutical products from manufacturers, importers or other wholesale distributors.

"product recall"
A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, and/or complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit.

"psychotropic substance"
Any substances specified in the List of poisons which are Psychotropic Substances (see Appendix A) maintained and updated by the Drug Office of the Department of Health in accordance with the Convention on Psychotropic Substances, 1971.

"registered"
This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap.138).

"returned pharmaceutical product"

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Finished product sent back to a holder of Wholesale Dealer Licence.

"somatic cell therapy product"
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.

"specification"
A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

"storage"
The storing of pharmaceutical products up to the point of use.

"tissue engineered product"

(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.

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“wholesale distribution of pharmaceutical products”
It is all activities consisting of procuring, holding, supplying, importing or exporting pharmaceutical products, apart from supplying pharmaceutical products to the public.

“WDL”
The Wholesale Dealer Licence

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APPENDIX A

List of poisons which are psychotropic substances based on the United Nations 1971 Convention on Psychotropic Substances

1. Allobarbital
2. Amineptine
3. Amobarbital
4. Buprenorphine
5. Butalbital
6. Butobarbital
7. Cyclobarbital
8. Ethchlorvynol
9. Ethinamate
10. Fencamfamin
11. Glutethimide
12. Lefetamine
13. Mazindol
14. Meprobamate
15. Methylphenobarbital
16. Methyprylon
17. Pemoline
18. Pentazocine
19. Pentobarbital
20. Phenobarbital
21. Pipradrol
22. Pyrovalerone
23. Secbutabarbital
24. Vinylbital
25. Zolpidem
26. any salt or preparation of any of the above

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APPENDIX B

[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
POISONS IN PART 1 OF THE POISONS LIST OR ANY PHARMACEUTICAL 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毒藥表第 1 部毒藥或任何藥劑製品的交易紀錄格式

Name of Poison/ Pharmaceutical Product 毒藥/藥劑製品名稱				Pack Size 包裝大小		Unit of Quantity 數量單位
Date of Transaction 交易日期	Nature of Transaction 交易性質	Supplier or to whom supplied 供應人或獲供應的人	Invoice Number 發票號碼	Batch Number 批次編號	Total Quantity 總數量	Balance after Transaction 交易後的餘量

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APPENDIX C

[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 先進療法製品名稱				Pack Size 包裝大小		Unit of Quantity 數量單位	
Date of Transaction 交易日期	Nature of Transaction 交易性質	Supplier or to whom supplied 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) 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 發票號碼	Batch Number 批次編號	Total Quantity 總數量	Balance after Transaction 交易後的餘量

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APPENDIX D: PRODUCT CODE AND UNIQUE DONATION IDENTIFIER FOR ADVANCED THERAPY PRODUCTS

D.1 According to regulation 31(1)(g)(i) of the Pharmacy and Poisons Regulations, Cap. 138A (PPR), a licensed manufacturer shall label the container of the advanced therapy product (ATP) with the Product Code and the Unique Donation Identifier (UDI) assigned in accordance with the codes of practice issued by the Board. This appendix sets out the requirements for assignment of the product code and the UDI.

D.2 Product Code is a set of coding sequence for identification of cell and tissue types that an ATP contains or consists of. UDI is a unique sequence attributed to the specific donation of the cells or tissues for unique identification.

D.3 ISBT 128 (Information Standard for Blood and Transplant) standard by the International Council for Commonality in Blood Banking Automation (ICCBBA) and Single European Code (SEC) in the European Union (EU) are two widely accepted coding systems for human cells and tissues. Both systems include two components – coding for identification of the cell and tissue type and coding for the identification of the donation – which could be used to facilitate traceability of the cells and tissues from donation to products, and vice versa.

D.4 Either one of the systems mentioned in section D.3 could be used in labelling ATPs containing or consisting of human cells or tissues to meet the requirements of Product Code and UDI required under regulation 31(1)(g)(i) of the PPR.

D.5 If the ATPs containing or consisting of human cells or tissues are not labelled in accordance with one of the systems mentioned in section D.3, Product Code and UDI could be assigned in accordance with section D.7 to D.12 and section D.13 to D.15 respectively.

D.6 Since both internationally recognized systems are applicable to human cells and tissues only, for ATPs that do not contain or consist of any human cells or tissues, the product should be labelled with the following particulars in order to meet the Product Code and UDI requirement under regulation 31(1)(g)(i) of the PPR –

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- product name;
- international non-proprietary name (INN), if any; and
- for ATPs containing or consisting of animal cells or tissues, information reflecting the animal species, the country of origins and the types of cells or tissues that they contain or consist of.

Product Code

D.7 If neither ISBT 128 standard nor SEC is adopted for labelling the ATPs containing or consisting of human cells and tissues, a set of coding sequence should be assigned according to section D.8 to D.12 and labelled on the product as the Product Code.

D.8 The Product Code consists of two parts – the Product Coding System Identifier and the Product Number. The structure and the format of the Product Code are as follows:

Product Code	
Product Coding System Identifier	Product Number
1 character (alphabetic)	7 characters (alphanumeric)

D.9 Currently there are three product coding systems available globally which are widely used for describing human cells and tissues. They are the ISBT 128 standard product code by the ICCBBA, the Eurocode and the EU Tissue and Cell Product Compendium (EUTC). One of the three coding systems should be adopted for assigning the Product Code for ATPs supplied in Hong Kong.

D.10 Product Coding System Identifier is a 1-alphabetic character indicating the coding system adopted for labelling ATPs supplied in Hong Kong of which "A" is assigned to the ISBT 128 standard product code, "B" is assigned to the Eurocode and "E" is assigned to the EUTC.

D.11 Product Number is 7-alphanumeric characters revealing the type of cells or tissues that an ATP contains or consists of. The most appropriate product number must be chosen from the adopted coding system to describe the type of cells or tissues that an ATP contains

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or consists of. If the product number is less than 7 characters, it should be padded with leading zeros.

D.12 Subject to consideration and approval by the respective committees of the Board, the requirement of product code may be deemed to have fulfilled if an ATP, that is not labelled with the product code assigned according to section D.4 or section D.8 to D.11, is labelled with sufficient information that specifically identifies the types of cells or tissues that the ATP contains or consists of.

Unique Donation Identifier (UDI)

D.13 If neither ISBT 128 standard nor SEC is adopted for labelling the ATPs containing or consisting of human cells and tissues, a set of coding sequence should be assigned according to section D.14 to D.15 and labelled on the product as UDI.

D.14 For human cells or tissues obtained from a tissue establishment in the EU and already assigned with a SEC or donation identification sequence of a SEC (SEC-DI), the SEC-DI part of that SEC could be adopted as the UDI of the ATPs manufactured from them.

D.15 For human cells or tissues without any assigned SEC (or SEC-DI), for example, those obtained from a non-European country or collected locally, the ISBT 128 standard should be adopted. The Donation Identification Number (DIN) part of the ISBT 128 standard of those cells and tissues should be labelled on the ATPs manufactured from them as a UDI. If the human cells or tissues obtained has already been assigned with a DIN of the ISBT 128 standard, this DIN could be used and labelled on the ATPs manufactured from them as a UDI. For human cells or tissues without any assigned DIN of the ISBT 128 standard, licensed manufacturers should assign a DIN or SEC-DI to the cells and tissues obtained according to ISBT 128 standard or SEC-DI (if applicable) respectively.

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APPENDIX E: UNIQUE RECIPIENT IDENTIFIER FOR ADVANCED THERAPY PRODUCTS FOR AUTOLOGOUS USE

E.1 According to regulation 31(1)(g)(ii) of the PPR, an ATP for autologous use should be labelled with a Unique Recipient Identifier (URI) assigned in accordance with the codes of practice issued by the Board. This appendix sets out the requirements for assignment of the URI.

E.2 The URI is a combination of recipient information sufficient for healthcare professionals to verify the identity of the intended recipient of the product. The URI should consist of at least two sets of information including the recipient's surname followed by initials of the first name plus either –

- Month and year of birth; or
- Any other numeric or alphanumeric number/sequence that is referring to the recipient (e.g. Part of recipient's hospital number/medical record number).

E.3 A WDL holder should ensure that healthcare professionals who use the ATPs fully understand how to interpret and use the recipient information contained in the URI to verify the identity of the recipient.

E.4 In addition, a WDL holder should comply with the requirements in the Personal Data (Privacy) Ordinance, Cap. 486 (PDPO) when handling personal data.

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