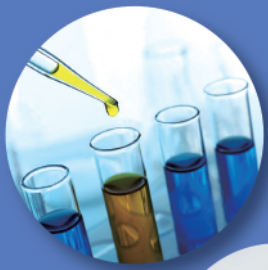
Code of Practice

for Licensed Manufacturers and Registered Authorized Persons

持牌製造商及註冊獲授權人執業守則



Pharmacy and Poisons Board of Hong Kong
香港藥劑業及毒藥管理局
2021

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Section 1 Background
第 1 條 背景

Licensed Manufacturers

1.1 According to regulation 29(1) of the Pharmacy and Poisons Regulations (Cap.138A, Laws of Hong Kong), no person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products ("manufacturer licence") on those premises. Manufacture of pharmaceutical products includes secondary packaging, which means the labelling, re-labelling, cartoning, re-cartoning or adding additional information (including inserts) to pharmaceutical products which are already enclosed in the container in which they are to be sold or supplied.

1.2 The issuing authority for manufacturer licence is the Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee") of the Pharmacy and Poisons Board ("the Board").

持牌製造商

1.1 根據《藥劑業及毒藥規例》（香港法例第138A章）第29(1)條，任何人不得在任何處所製造藥劑製品，但如該人持有牌照在該處所製造藥劑製品（「製造商牌照」），則屬例外。藥劑製品的製造包括外包裝，外包裝指為已密封在容器內將予銷售或供應的藥劑製品加上標籤、重新加上標籤、裝盒、重新裝盒或加上補充資料（包括說明書）。

1.2 製造商牌照的簽發當局是藥劑業及毒藥管理局（「管理局」）轄下藥劑業及毒藥（製造商牌照）委員會（「委員會」）。

Registered Authorized Persons

1.3 According to regulation 30A of the Pharmacy and Poisons Regulations, a Licensed Manufacturer must ensure that at least one Authorized Person is employed to be responsible for, in relation to the pharmaceutical products manufactured under the licence, ensuring and certifying that:

a. each batch of the pharmaceutical products has been manufactured and checked in accordance with the GMP Guide; and

b. the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products.

1.4 The GMP Guides issued by the Board for Licensed Manufacturers of pharmaceutical products ("Pharmaceutical Manufacturers") and those carrying out only secondary packaging of pharmaceutical products ("Secondary Packaging Manufacturers") respectively require that batches of pharmaceutical products should only be released for sale or supply after certification by an Authorized Person.

註冊獲授權人

1.3 根據《藥劑業及毒藥規例》（香港法例第138A章）第30A條，持牌藥劑製品製造商必須僱用至少一位獲授權人負責就其製造的藥劑製品確保及證明：

a. 每批藥劑製品，均已按照生產質量管理規範指引製造和檢查；及

b. 每批藥劑製品的須註冊詳情，均與該等製品的註冊詳情完全相符。

1.4 根據管理局發出有關持牌藥劑製品製造商（「藥物製造商」）及只為藥劑製品進行外包裝的製造商（「外包裝製造商」）的生產質量管理規範指引，每批藥劑製品須經獲授權人證明，方可放行銷售或供應。

1.5 To ensure compliance with the required standards in the manufacture of pharmaceutical products, the registered Authorized Person employed by Pharmaceutical Manufacturers, and the registered Authorized Person employed by Secondary Packaging Manufacturers, who is referred to as the Quality Assurance Officer, must be suitably qualified, experienced and competent for the types of manufacturing and packaging operations undertaken by the company that he or she works for.

1.5 為確保符合製造藥劑製品的標準要求，藥物製造商所僱用的註冊獲授權人，以及外包裝製造商所僱用的註冊獲授權人（即品質保證主任），必須具備就其受僱公司進行的各種製造及包裝程序而言屬適當的資格、經驗及技能。

Section 2 Purpose of this Code of Practice
第 2 條 本執業守則的目的

2.1 This Code of Practice sets out, in addition to those in the relevant GMP guide issued by the Board, the minimum standards, obligations and requirements to be followed by Licensed Manufacturers and registered Authorized Persons. Its purpose is to provide Licensed Manufacturers and registered Authorized Persons with practical guidance and directions for manufacturing of pharmaceutical products with a view to safeguarding the interest of the public.

2.2 Compliance with this Code is one of the conditions upon which the Committee issues a manufacturer licence as well as conditions of registration of Authorized Person. All Licensed Manufacturers and registered Authorized Persons must observe the standards set out in this Code and be aware of the consequences of non-compliance.

2.1 本執業守則列明持牌製造商及註冊獲授權人，除由管理局發出相關的生產質量管理規範指引外，須遵從的最低標準、責任及規定，目的是向持牌製造商及註冊獲授權人提供有關製造藥劑製品的實際指引及指示，以保障公眾利益。

2.2 遵從本守則的規定，是委員會發出製造商牌照的其中一項條件，亦是獲授權人的註冊條件。所有持牌製造商及註冊獲授權人必須遵循本守則所列明的標準，以及知悉不遵從規定的後果。

Section 3 Scope
第 3 條 涵蓋範圍

3.1 Part I of this Code of Practice applies to Licensed Manufacturers, including the Secondary Packaging Manufacturers.

3.2 Part II of this Code of Practice applies to registered Authorized Persons employed by the Pharmaceutical Manufacturers, including registered Authorized Persons employed by Secondary Packaging Manufacturers, namely the Quality Assurance Officer.

3.1 本執業守則第I部適用於持牌製造商，包括外包裝製造商。

3.2 本執業守則第 II 部適用於藥物製造商所僱用的註冊獲授權人，包括外包裝製造商所僱用的註冊獲授權人（稱為品質保證主任）。

Part I 第 I 部

Section 4 Obligations and Requirements for Licensed Manufacturers
第 4 條 持牌製造商須履行的責任及遵從的規定

Licensed Manufacturers of pharmaceutical products must ensure that the following obligations and requirements are met:

4.1 Pharmaceutical products are manufactured and packaged in a manner which will ensure that they are fit for their intended use and will not place patients at risk due to inadequate safety, quality or efficacy of the pharmaceutical products.

4.2 All manufacturing processes, packaging processes, and activities conducted on their licensed premises are carried out in a manner compliant with the relevant legislation, which include but are not limited to:

a. the Import and Export Ordinance (Cap.60);

b. the Pharmacy and Poisons Ordinance (Cap.138);

c. the Dangerous Drugs Ordinance (Cap.134);

d. the Antibiotics Ordinance (Cap.137);

持牌藥劑製品製造商必須確保履行下列責任及規定：

4.1 藥劑製品的製造及包裝方式，須確保藥劑製品適合用於擬作的用途，並且不會因藥劑製品的安全、品質或效能欠佳而令病人蒙受風險。

4.2 所有製造工序、包裝工序及在其持牌處所進行的活動，均以符合相關法例的方式進行。有關法例包括但不限於：

a.《進出口條例》（第60章）；

b.《藥劑業及毒藥條例》（第138章）；

c.《危險藥物條例》（第134章）；

d.《抗生素條例》（第137章）；

e. the Public Health and Municipal Services Ordinance (Cap.132);

f. the Undesirable Medical Advertisements Ordinance (Cap.231); and

g. the Trade Descriptions Ordinance (Cap.362).

4.3 Pharmaceutical products are manufactured, packaged and tested in accordance with the conditions specified on the manufacturer licence.

4.4 Notwithstanding other labelling requirements applicable to pharmaceutical products, advanced therapy products are labelled with a product code and a unique donation identifier assigned in accordance with Appendix A of this Code of Practice.

4.5 For advanced therapy products for autologous use only, the products are labelled with a unique recipient identifier assigned in accordance with Appendix B of this Code of Practice, and the English words "For autologous use only" or the Chinese characters "只供自體使用".

e.《公眾衞生及市政條例》（第132章）；

f.《不良廣告(醫藥)條例》（第231章）；以及

g.《商品說明條例》（第362章）。

4.3 藥劑製品已按照製造商牌照載明的條件製造、包裝和測試。

4.4 儘管有其他適用於藥劑製品的標籤要求，先進療法製品須加上按照本執業守則附錄A編配的製品代碼及獨特捐贈標識符標籤。

4.5 就只供自體使用的先進療法製品而言，製品須加上按照本執業守則附錄B編配的獨特受贈者標識符標籤，以及"For autologous use only"的英文字句或"只供自體使用"的中文字樣標籤。

4.6 All parts of the Quality Management System referred to in the current GMP guide issued by the Board are adequately resourced with competent personnel and suitable and sufficient premises, equipment and facilities.

4.6 管理局發出的現行生產質量管理規範指引所提及的品質管理系統的各個部分，均獲提供足夠資源，包括稱職的人員，以及合適和充足的處所、設備及設施。

4.7 Approval from the Committee has been obtained prior to any change in key personnel. The key personnel include the registered Authorized Person, Head of Production and Head of Quality Control, or, for Secondary Packaging Manufacturers, the Quality Assurance Officer and the Person-in-charge of secondary packaging.

4.7 關鍵人員如有任何變更，須先獲委員會批准。關鍵人員包括註冊獲授權人、生產部主管及品質控制部主管；或就外包裝製造商而言，關鍵人員為品質保證主任及外包裝負責人。

4.8 Approval from the Committee has been obtained prior to any change in manufacturing premises that may affect the quality of the product.

4.8 製造處所如有任何影響產品品質的變更，須先獲委員會批准。

4.9 An Authorized Person registered by the Board is employed to, inter alia, take responsibility for the quality of pharmaceutical products manufactured or packaged on the premises and to authorise the release for sale or distribution of each batch of finished pharmaceutical products, including certifying that each batch

4.9 僱用經管理局註冊的獲授權人，負責確保在處所製造或包裝的藥劑製品品質，以及批准放行銷售或分發每批藥劑製品製成品等工作，包括證明每批製品已遵照管理局發出的現行藥劑製品生產質

of product has been manufactured or packaged in compliance with the requirements of the current GMP guide issued by the Board in respect of pharmaceutical products and the registrable particulars correspond with the registered particulars for that product.

量管理規範指引的規定製造或包裝，以及藥劑製品的須註冊詳情與該製品的註冊詳情相符。

4.10 The registered Authorized Person is either:

a. appointed as a board member of the Licensed Manufacturer; or

b. invited to attend board meetings of the Licensed Manufacturer and allowed to speak on matters where safety, efficacy and quality issues of products are concerned and his or her remarks will be put on record.

The Licensed Manufacturer should provide its registered Authorized Person with the necessary authority for and provide every support to the decisions of the registered Authorized Person made in the performance of his or her duties.

4.10 註冊獲授權人：

a. 獲委任為持牌製造商董事局成員；或

b. 獲邀出席持牌製造商董事局會議，並獲准就關乎製品安全、效能及品質問題的事宜發言，其意見會記錄在案。

持牌製造商須給予註冊獲授權人在執行職責時所需的權力，並為註冊獲授權人在執行職責時所作的決定提供一切支援。

4.11 All key personnel have appropriate qualifications and experience as required by the Board.

4.11 所有關鍵人員均具備管理局所規定的適當資格及經驗。

4.12 Key personnel and company staff are provided with training necessary to enable them to undertake their respective duties in accordance with the GMP requirements and appropriate records of such training are maintained.

4.12 向關鍵人員及公司員工提供所需的培訓，使他們能夠按照生產質量管理規範的規定履行各自的職責，並就有關培訓備存適當記錄。

4.13 For advanced therapy products, supply sites of human cells and tissues used as starting materials must be authorized, licensed or accredited in their place of origin. The authorization or licensing by a competent authority, accreditation by a competent body or otherwise the compliance with relevant good practice guides is verified as part of the starting material supplier management.

4.13 就先進療法製品而言，作為起始物料的人類細胞及組織的供應場所，必須在來源地取得授權、許可或認可。起始物料供應商管理須包括驗證主管當局的授權或許可，或主管機構的認可，或遵守相關優良規範指引。

4.14 A system that enables the bidirectional tracking of cells or tissues contained in advanced therapy products from the point of donation, through manufacturing, to the delivery of finished product to the use by a medical practitioner or dentist is in place.

4.14 須備有一套系統能夠從捐贈點，經製造，至交予醫生或牙醫使用，雙向追踪先進療法製品中包含的細胞或組織。

4.15 Records of all transactions of Part 1 poisons or pharmaceutical products are kept and contain the following particulars:

a. the name of the poison or pharmaceutical product;

4.15 須備存所有第1部毒藥或藥劑製品的交易記錄，而該等記錄須載有下列詳情：

a. 毒藥或藥劑製品名稱；

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 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 the transaction.

There shall be a separate entry in the record for each Part 1 poison or pharmaceutical product. All records of transactions must be in the specified form (see Appendix C for Part 1 poisons or pharmaceutical products or Appendix D for advanced therapy products) unless the Pharmacy and Poisons (Wholesale Licences) Committee established by the Board approves another system of recording.

b. 毒藥或藥劑製品的批次編號、包裝大小及（如屬毒藥）分量單位或（如屬藥劑製品）數量單位 ；

c. 交易日期；

d. 交易性質；

e. 供應人或獲供應毒藥或藥劑製品的人的姓名；

f. 就供應予註冊醫生或註冊牙醫使用的先進療法製品而言 — 該醫生或牙醫的姓名及地址；

g. 發票號碼；

h. 獲取或供應的總數量；以及

i. 毒藥或藥劑製品交易後的餘量。

每種第1部毒藥或藥劑製品須有獨立的記錄，所有交易記錄，均須符合指明格式（見與第1部毒藥或藥劑製品相關的附錄C或與先進療法製品相關的附錄D ），但如管理局下設的藥劑業及毒藥（批發牌照）委員會批准使用另一種記錄制度，則屬例外。

4.16 For an advanced therapy product, all books, records and documents required to be kept or retained in respect of the product under regulations 28 and 35(1)(a), (b), (c), (ca) and (h) of the Pharmacy and Poisons Regulations ("specified documents"), including those records in section 4.15 and those showing the following particulars, must be preserved by the Licensed Manufacturer for a period of 30 years after the expiry date of the product:

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;

d. for an advanced therapy product sold or supplied for use by a registered medical practitioner or registered dentist – the name and address of the practitioner or dentist;

e. for an advanced therapy product 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

4.16 就先進療法製品而言，根據《藥劑業及毒藥規例》（香港法例第138A章）第28及35(1)(a)、(b)、(c)、(ca)及(h)條規定就該製品而備存或保留的所有簿冊、紀錄及文件（「指明文件」），包括4.15條所提及的紀錄及列明以下詳情的紀錄，須由有關持牌製造商保存，保存期為該製品的使用期限後的30年:

a. 用於製造製品的所有物質的分量；

b. 所製造的製品的數量；

c. 獲售予或獲供應藥劑製品的人的姓名或名稱及地址；

d. 就銷售予或供應予註冊醫生或註冊牙醫使用的先進療法製品而言 — 該醫生或牙醫的姓名及地址；

e. 就含有細胞或組織（或由細胞或組織組成）的先進療法製品而言 -

i. 提供配製該製品的細胞或組織的人的姓名或名稱，以及其地址；及

ii. the unique donation identifier assigned in accordance with Appendix A.

If the Licensed Manufacturer ceases to operate as a Licensed Manufacturer before the aforementioned period expires, the specified documents must be transferred to the Board within 14 days after the cessation.

4.17 Any defect impacting on the quality of products released for sale or distribution, including products intended for markets other than Hong Kong, is assessed, investigated and documented.

4.18 Report to the Drug Office adverse drug reactions in accordance with the "Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements" issued by the Board.

4.19 Report to the Drug Office any conditions or significant changes or deviations which may affect the quality, safety or efficacy of a pharmaceutical product, including significant changes to key personnel, facilities, equipment, systems, procedures, etc.

ii. 按照附錄A而編配的獨特捐贈標識符。

如持牌製造商在前提述的期間屆滿之前停止以持牌製造商身分營運，則須在停止營運後的14日內，將指明文件移交管理局。

4.17 把任何影響已放行銷售或分發的製品品質的問題，一一評估、調查和記錄在案，當中包括擬於香港以外市場銷售或分發的製品。

4.18 按照管理局的「藥劑業界指引—呈報藥品不良反應的要求」，向藥物辦公室呈報藥品不良反應。

4.19 向藥物辦公室呈報任何可能影響藥劑製品品質、安全或效能的情況或重大變更或偏離，包括關鍵人員、設施、設備、系統及程序等的重大變更。

4.20 Report to the Drug Office before or upon commencement of a product recall, submit pertinent product information related to the recall and comply with the current "Pharmaceutical Products Recall Guidelines".

4.21 Any quality control testing required to be contracted out is contracted out to:

a. a Licensed Manufacturer certified as a GMP manufacturer by the Committee; or

b. a laboratory:

i. accredited in accordance with ISO 17025, or other suitable quality standards, for the tests required to be performed; or

ii. inspected by inspectors of the Drug Office and the result of the inspection has shown to the satisfaction of the Committee that the laboratory has complied with such parts of GMP relevant to the quality control testing to be contracted out.

4.20 展開製品回收行動前或其時，向藥物辦公室呈報，以及提交與該回收行動有關的相關製品資料，並且遵從現行的《藥劑製品回收指引》。

4.21 把任何需要外判的品質控制測試外判予：

a. 獲委員會證明為符合生產質量管理規範製造商的持牌製造商；或

b. 實驗所：

i. 該實驗所已按照 ISO 17025，或其他合適的品質標準獲認可進行所需的測試；或

ii. 藥物辦公室督察已對該實驗所進行視察，而視察結果證明並令委員會信納，實驗所已遵從生產質量管理規範有關外判品質控制測試的各部分。

4.22 Allow public officers authorised by the Chairman of the Board to carry out inspections and to take samples, photos and copies of documentation as may be necessary for the purpose of inspection and, where inspection referred to in section 4.21(b)(ii) is required, to make relevant arrangement with the laboratory for the inspection.

4.22 准許獲管理局主席授權的公職人員進行視察，並為進行視察而按需要提取樣本、拍攝照片及複製文件。此外，如須進行第4.21(b)(ii)條所提及的視察，應就有關視察與實驗所作出相關安排。

4.23 Not wilfully delay or obstruct authorised public officers in the carrying out of their duties during the course of inspection and investigation.

4.23 在視察及調查過程中，不得故意延誤或妨礙獲授權公職人員執行職責。

4.24 In case of suspected product quality defects, suspend distribution of or recall any defective products according to instruction of the Drug Office.

4.24 如懷疑製品品質有問題，須按藥物辦公室的指示暫停分發或回收任何有問題的製品。

4.25 An order in writing issued by the purchaser has been obtained before the completion of the sale of Part 1 poisons, dangerous drugs and antibiotics. Electronic communications (such as e-mail), fax and mail are accepted forms of written order. The order in writing should be kept for at least two years from the date of issue of the order.

4.25 須於完成銷售第1部毒藥、危險藥物及抗生素前，取得由購買人發出的書面訂單。電子通訊（例如電郵）、傳真及信件是可接受的書面訂單形式。書面訂單應由訂單發出日期起計，備存至少兩年。

Section 5 Consequence of Breaching Section 4 of this Code of Practice
第 5 條 違反本執業守則第4條的後果

5.1 Licensed Manufacturers found to have breached section 4 of this Code of Practice will be reported to the Committee for appropriate action.

5.2 Depending on the severity of individual case, the Committee may revoke the licence or suspend it for such period as it thinks fit, vary the licence condition(s) or issue a warning letter to the Licensed Manufacturer if, in its opinion, the Licensed Manaufacturer has failed to comply with section 4 of this Code of Practice.

5.3 Any Licensed Manufacturer aggrieved by a decision of the Committee may appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

5.1 如發現持牌製造商違反本執業守則第4條，會向委員會舉報，以採取適當行動。

5.2 視乎個別個案的嚴重程度，委員會如認為持牌製造商沒有遵從本執業守則第4條的規定，可撤銷有關牌照，或在其認為合適的期間內暫時吊銷該牌照、更改牌照條件、或向持牌製造商發出警告信。

5.3 任何持牌製造商如因委員會的決定而感到受屈，可就該決定向藥劑業及毒藥上訴審裁處提出上訴。

Part II 第II部

Section 6 Obligations and Requirements for Registered Authorized Persons
第 6 條 註冊獲授權人須履行的責任及遵從的規定

Registered Authorized Persons employed by Licensed Manufacturers in Hong Kong must ensure that the following obligations and requirements are met:

本港持牌製造商所僱用的註冊獲授權人，必須確保履行下列責任及規定：

6.1 He or she is listed on the Register of Authorized Persons maintained by the Board.

6.1 他或她名列管理局備存的獲授權人名冊。

6.2 Take responsibility for the quality of the pharmaceutical products manufactured or packaged on the premises of the manufacturer.

6.2 負責確保在製造商處所製造或包裝的藥劑製品品質。

6.3 Authorise the release for sale or distribution of each batch of finished pharmaceutical products manufactured or packaged, including certifying before the release that each batch of the products has been manufactured or packaged in compliance with the requirements of the current GMP guide issued by the Board in respect of pharmaceutical products and the registrable particulars correspond with the registered particulars for the products.

6.3 批准放行銷售或分發所製造或包裝的每批藥劑製成品，包括在放行前證明每批製品已遵照管理局發出的現行藥劑製品生產質量管理規範指引的規定製造或包裝，以及藥劑製品的須註冊詳情與該製品的註冊詳情相符。

6.4 Maintain a register (or equivalent document) as a record of product batches certified prior to batch release.

6.4 備存登記冊（或同等文件），記錄在批次放行前經證明的製品批次。

6.5 The appropriate senior management is made fully aware of any manufacturing and/or testing difficulties which may cast doubt on

6.5 如有任何製造及／或測試問題，可能令人質疑批次證明，或可能導致事後需要回

the certification of batches or which may post facto require a product recall and, where there is any aspect of manufacturer's Quality Management System which is not in compliance with the current GMP guide issued by the Board, such non-compliance is brought to the attention of the senior management and appropriate corrective measures are taken.

收製品，須全面告知適當的高層管理人員。此外，如製造商品質管理系統的任何方面沒有遵從管理局發出的現行生產質量管理規範指引，須通知高層管理人員有關違規情況，並採取適當糾正措施。

6.6 Authorised public officers are not wilfully delayed or obstructed in the carrying out of their duties during the course of inspection and investigation.

6.6 在視察及調查過程中，不得故意延誤或妨礙獲授權公職人員執行職責。

6.7 Keep knowledge, experience and competence up-to-date through continuing professional development in accordance with the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong" issued by the Board.

6.7 按照管理局發出的《香港持牌製造商獲授權人及其他關鍵人員的資格、經驗與培訓要求指引》（"Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong"），通過持續專業進修，增進知識、經驗及技能。

Guidance on how some of the above obligations and requirements for registered Authorized Persons can be met is listed in Appendix E and Appendix F to this Code of Practice.

有關註冊獲授權人如何履行上述某些責任及規定的指引，載列於本執業守則附錄E及附錄F。

Section 7 Consequence of Breaching Section 6 of this Code of Practice
第 7 條 違反本執業守則第6條的後果

7.1 Registered Authorized Persons found to have breached section 6 of this Code of Practice, or found to be incompetent, will be reported to the Committee for appropriate action.

7.2 Depending on the severity of individual case, the Committee may cancel the registration or suspend the registration for a period of time, vary the registration condition(s) or issue a warning letter to the registered Authorized Person, if, in its opinion, the registered Authorized Person has breached section 6 of this Code of Practice or is incompetent.

7.3 Any registered Authorized Person aggrieved by a decision of the Committee may appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

7.1 如發現註冊獲授權人違反本執業守則第6條或不稱職，會向委員會舉報，以採取適當行動。

7.2 視乎個別個案的嚴重程度，委員會如認為註冊獲授權人沒有遵從本執守則第6條或並不稱職，可取消或在其認為合適的期間內暫時吊銷該註冊獲授權人的註冊、更改註冊條件，或向該註冊獲授權人發出警告信。

7.3 任何註冊獲授權人如因委員會的決定而感到受屈，可就該決定向藥劑業及毒藥上訴審裁處提出上訴。

Appendices 附 錄

Appendix A : Product Code and Unique Donation Identifier for Advanced Therapy Products

附錄 A : 先進療法製品的製品代碼及獨特捐贈標識符

A.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.

A.1 根據《藥劑業及毒藥規例》（第138A章）（《規例》）第31(1)(g)(i)條，持牌製造商須在盛載先進療法製品的容器上，加上標籤，標明按照管理局發出的執業守則而編配的製品代碼和獨特捐贈標識符。本附錄列出有關編配製品代碼和獨特捐贈標識符的要求。

A.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.

A.2 製品代碼是一組編碼序列，用於標識先進療法製品中含有或組成的細胞和組織類型。獨特捐贈標識符是一組獨特序列，用作獨特標識細胞或組織的特定捐贈。

A.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.

A.3 國際血庫自動化委員會（「ICCBBA」）的ISBT 128（血液和移植資料標準）標準和歐洲聯盟（「歐盟」）的歐洲單一代碼（「SEC」）是兩個獲廣泛接受的人類細胞和組織編碼系統。這兩個系統都包含兩個組成部分 — 用以標識細胞和組織類型的編碼和用以標識捐贈的編碼 — 這些編碼可便於追溯細胞和組織從捐贈到製品整個過程，反之亦然。

A.4 Either one of the systems mentioned in section A.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.

A.4 任何一個於A.3提及的系統均可用於標明含有人類細胞或組織或由其組成的先進療法製品，以符合《規例》第31(1)(g)(i)條對於製品代碼和獨特捐贈標識符的要求。

A.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 A.3, Product Code and UDI could be assigned in accordance with section A.7 to A.12 and section A.13 to A.17 respectively.

A.5 若未有按照A.3提及的其中一個系統標明含有人類細胞或組織或由其組成的先進療法製品，則可按照A.7至A.12及A.13至A.17分別為製品編配製品代碼和獨特捐贈標識符。

A.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 –

- 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.

A.6 由於這兩個國際認可系統僅適用於人類細胞和組織，因此對於不含任何人類細胞或組織或由其組成的先進療法製品，應標明以下詳情以符合《規例》第31(1)(g)(i)條的要求 -

- 製品名稱；
- 國際非專利藥品名稱（INN）（如有）；及
- 對於含有動物細胞或組織或由其組成的先進療法製品，可反映動物物種、原產國和所含有或組成的細胞或組織類型的資料。

Product Code

A.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 A.8 to A.12 and labelled on the product as the Product Code.

A.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)

A.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.

製品代碼

A.7 若未有採用ISBT標準或SEC標明含有人類細胞和組織或由其組成的先進療法製品，則應根據A.8至A.12為該製品編配一組編碼序列並標明在該製品作為製品代碼。

A.8 製品代碼由兩部分組成 — 製品編碼系統標識符和製品編號。製品代碼的結構和格式如下：

製品代碼	
製品編碼系統標識符	**製品編號**
1 個字符（字母）	7 個字符（字母數字）

A.9 目前全球有三個製品編碼系統獲廣泛用作描述人類細胞和組織，分別是 ICCBBA 的ISBT 128標準製品代碼、歐洲編碼（Eurocode）和歐盟組織和細胞製品綱要（EU Tissue and Cell Product Compendium，「EUTC」）。應從以上三個編碼系統中選擇一個用作編配在香港供應的先進療法製品的製品代碼。

A.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.

A.10 製品編碼系統標識符由一個字母字符組成，表明在香港供應的先進療法製品標籤上所採用的編碼系統，其中「A」代表採用了ISBT 128標準的製品代碼系統，「B」代表採用了歐洲編碼系統，「E」代表採用了EUTC系統。

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

A.11 製品編號由7個字母數字字符組成，表明先進療法製品所含有或組成的細胞或組織類型。必須從所採用的編碼系統中選擇最合適的製品編號，以描述先進療法製品中所含有或組成的細胞或組織類型。如製品編號少於7個字符，則應在編號前加上零字補足。

A.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 A.4 or section A.8 to A.11, is labelled with sufficient information that specifically identifies the types of cells or tissues that the ATP contains or consists of.

A.12 若先進療法製品未有標明按照A.4或A.8至A.11編配的製品代碼，但標明了足夠的資料以明確標識製品所含有或組成的細胞或組織類型，則經管理局相應委員會考慮及批准，可視為已符合製品代碼的要求。

Unique Donation Identifier (UDI)

A.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 A.14 to A.17 and labelled on the product as UDI.

A.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.

獨特捐贈標識符

A.13 若未有採用 ISBT 128 標準或 SEC 標明含有人類細胞和組織或由其組成的先進療法製品，則應按照A.14至A.17編配一組編碼序列並將其標明在製品上作為獨特捐贈標識符。

A.14 對於從歐盟組織機構獲得並已編配有SEC或SEC的捐贈標識序列「SEC-DI」的人類細胞或組織，可採用SEC的SEC-DI部分為由該等細胞或組織製造的先進療法製品的獨特捐贈標識符。

A.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.

A.15 對於沒有編配任何 SEC（或 SEC-DI）的人類細胞或組織，例如從非歐洲國家獲得或在本地收集的細胞或組織，應採用 ISBT 128 標準進行編碼。ISBT 128 標準的捐贈標識碼「DIN」部分可標明為由該等細胞或組織製造的先進療法製品的獨特捐贈標識符。若所獲得的人類細胞或組織已編配有 ISBT 128 標準的DIN，該DIN可標明為由該等細胞或組織製造的先進療法製品的獨特捐贈標識符。對於未編配任何 ISBT 128 標準的DIN的人體細胞或組織，持牌製造商應按照 ISBT 128 標準或 SEC-DI（如適用）為所獲得的細胞或組織編配一個 DIN 或 SEC-DI。

A.16 If Licensed Manufacturers pool the human cells or tissues labelled with different DINs of the ISBT 128 standard or SEC-DI, the Licensed Manufacturers should assign a UDI using the ISBT 128 standard to the ATPs manufactured from those pooled cells or tissues. The Licensed Manufacturers must ensure that individual donation information remains traceable after the new UDI has been assigned.

A.16 若持牌製造商將標有不同的ISBT 128 標準的 DIN 或 SEC-DI 的人類細胞或組織匯集，該持牌製造商應使用 ISBT 128 標準為該等匯集細胞和組織製造的先進療法製品編配一個獨特捐贈標識符。該持牌製造商必須確保在編配了新的獨特捐贈標識符後，個別的捐贈資料仍然可追溯。

A.17 Licensed Manufacturers should ensure that the facility from where the human cells or tissues are obtained implements a system enabling the tracing of the following donation information in case a particular UDI is provided —

- name and address of the donation site;
- identifier of the donor;
- date of donation; and
- types of cells or tissues donated.

A.17 持牌製造商應確保其獲得人類細胞或組織的設施使用具可追溯性的系統，以便在獲提供一個特定的獨特捐贈標識符時，可對以下捐贈資料進行追溯 –

- 捐贈地點的名稱和地址；
- 捐贈者的標識符；
- 捐贈日期；及
- 捐贈細胞或組織類型。

Appendix B : Unique Recipient Identifier for Advanced Therapy Products for Autologous Use
附錄 B : 供自體使用的先進療法製品的獨特受贈者標識符

B.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.

B.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).

B.1 根據《規例》第31(1)(g)(ii)條，供自體使用的先進療法製品須以標籤標明按照管理局發出的執業守則而編配的獨特受贈者標識符。本附錄列出有關編配獨特受贈者標識符的要求。

B.2 獨特受贈者標識符是為專業醫護人員提供的受贈者資料組合，使其能核實製品的預期受贈者的身分。獨特受贈者標識符應至少由兩組資料組成，包括受贈者的姓氏後跟名字的首字母及以下其中一項資料 –

- 出生年月；或
- 代表受贈者的任何其他數字或字母數字編號／序列（例如受贈者的醫院編號／病歷編號其中一部分）。

B.3 Licensed Manufacturers 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.

B.4 In addition, Licensed Manufacturers should comply with the requirements in the Personal Data (Privacy) Ordinance, Cap. 486 ("PDPO") when handling personal data.

B.3 持牌製造商應確保使用先進療法製品的專業醫護人員完全了解如何詮釋和使用獨特受贈者標識符中包含的受贈者資料以核實受贈者身分。

B.4 此外，持牌製造商須遵守《個人資料（私隱）條例》（第486章）的要求處理個人資料。

Appendix C : 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

附錄 C : 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

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例

[regulation 28(4)]
[第28(4)條]

(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

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

附錄 D : 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

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例

[regulation 28(4)]
[第28(4)條]

(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

Appendix E : Duties of Registered Authorized Person Relating to Release of Finished Products
附錄 E : 註冊獲授權人在放行製成品方面的職責

Each batch of finished product must be certified by a registered Authorized Person before being released for sale or supply. The certification should **ensure** that the following requirements have been met:

(The meaning of the word "ensure" in this context is that the registered Authorized Person must be confident that various actions, which may not be under his or her direct control, have in fact been taken).

每批製成品須先經註冊獲授權人證明，方可放行銷售或供應。有關證明應**確保**符合下列規定：

（「確保」一詞在此的意思，是註冊獲授權人必須肯定，各項可能不由其直接控制的行動，已確實執行。）

E.1 The licensing conditions of the manufacturer licence have been met for the batch concerned and the registrable particulars of each batch of the pharmaceutical products correspond with the registered particulars of the products.

E.1 有關批次符合製造商牌照的發牌條件及藥劑製品的須註冊詳情均與該等製品的註冊詳情完全相符。

E.2 The current GMP guide issued by the Board have been followed in all manufacturing, packaging, testing and warehousing activities.

E.2 所有製造、包裝、測試及存倉活動已遵循管理局發出的現行生產質量管理規範指引。

E.3 Critical manufacturing processes and quality control test methods have been validated.

E.3 關鍵的製造工序及品質控制測試方法已獲驗證。

E.4 All the necessary quality control checking and testing have been performed, and account has been taken of the manufacturing and packaging conditions including a review of the batch records.

E.4 已進行所有必要的品質控制檢查及測試，並已考慮製造及包裝情況，包括檢閱批次記錄。

E.5 Any changes or deviations in manufacturing, packaging or quality control have been processed in accordance with well-defined systems, including reporting of such changes or deviations to the Authorized Person before any product batch is released.

E.5 已按照明確的制度處理任何製造、包裝或品質控制方面的變更或偏離，包括在放行任何製品批次前，向獲授權人呈報有關變更或偏離。

E.6 Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover changes or deviations in manufacturing, packaging or quality control.

E.6 已進行或提出進行任何額外抽樣、視察、測試及檢查（視何者適用而定），以涵蓋製造、包裝或品質控制方面的變更或偏離。

E.7 All necessary manufacturing, packaging and associated documentation have been completed and endorsed by suitably authorised staff trained in the concept of Quality Management and GMP.

E.7 所有必要的製造、包裝及相關文件記錄，已由曾接受品質管理及生產質量管理規範概念培訓的適當獲授權員工完成及批簽。

E.8 Regular audits, self-inspections and spot checks have been carried out by experienced staff.

E.8 已由經驗豐富的員工進行定期審核、自行視察及抽樣檢查。

E.9 All relevant factors including any factor not specifically associated with the output batch directly under review (e.g. calibration and maintenance records, environmental monitoring, etc.) have been considered.

E.9 已考慮所有相關因素，包括任何與直接接受檢閱的生產批次沒有具體關係的因素（例如校正及保養記錄、環境監察等）。

E.10 The registered Authorized Person should recognise the need to consult other company's experts in a specific area so as to reinforce his or her knowledge on appropriate points when a doubtful situation arises (e.g. stability, unusual analytical results, process or equipment changes, potential environmental or microbiological risks, re-labelling, abnormal yields, cross contamination risks, etc.).

E.10 當出現可疑情況（例如穩定性問題、不尋常分析結果、工序或設備有所更改、潛在環境或微生物風險、重新加上標籤、異常產量、交叉感染風險等）時，註冊獲授權人有需要向其他公司的特定領域專家徵詢意見，以加強其在有關方面的知識。

E.11 A register (or equivalent document) is maintained as a record of product batches certified by the registered Authorized Person prior to batch release.

E.11 備存登記冊（或同等文件），記錄在批次放行前經註冊獲授權人證明的製品批次。

E.12 Reference samples and/or retention samples of each product batch are retained for a period of time specified in the current GMP guide issued by the Board in respect of pharmaceutical products.

E.12 保存每批製品的對照樣本及／或留存樣本，為期如委員會發出的現行藥劑製品生產質量管理規範指引所載明。

E.13 *[Not applicable to Quality Assurance Officer]* If the registered Authorized Person is not involved in the on-going stability testing program or the preparation of Product Quality Review ("PQR"), he or she should at least have access to the full results of such testing program and review (since the registered Authorized Person must consider the results of both as part of the release for sale/ distribution process).

E.13 *[不適用於品質保證主任]* 如註冊獲授權人沒有參與持續進行的穩定性測試計劃或製品品質檢討的準備工作，他或她至少應獲准查閱持續進行的穩定性測試及製品品質檢討的詳細結果（因註冊獲授權人在放行銷售／分發的過程中，必須考慮兩者的結果）。

In considering how to perform the above duties, the registered Authorized Person should take into account the nature and size of the operations involved. For example, registered Authorized Person employed to work in a very small company manufacturing a limited range of products may have to take direct responsibility for some or all of the duties outlined above, whereas the registered Authorized Person working in larger organisations may have to be more dependent upon the knowledge and expertise of his or her colleagues in undertaking some or all of such duties.

在考慮如何履行上述職責時，註冊獲授權人應顧及所涉及運作的性質及規模。舉例說，受僱於一家製造有限種類製品的非常小型公司的註冊獲授權人，可能直接負責上述部分或全部工作。至於在較大型機構工作的註冊獲授權人，則較依賴同事的知識及專長進行部分或全部工作。

In any event, it is of paramount importance that the registered Authorized Person must take steps, within a well-planned Quality Management System, to assure himself or herself that the tasks allocated are being performed satisfactorily. The duties of the registered Authorized Person depend very much upon a team effort wherein the individuals involved realise the position and responsibility of the registered Authorized Person and provide every support.

在任何情況下，註冊獲授權人必須在規劃完善的品質管理系統內，採取措施確保自己妥善進行獲分配的工作，這點至關重要。註冊獲授權人的職責，十分依賴團隊努力，參與人士須了解註冊獲授權人的崗位及責任，並提供一切支援。

A registered Authorized Person who failed to discharge his or her duties relating to release of finished products may be subjected to disciplinary actions.

註冊獲授權人如未能履行在放行製成品方面的職責，可能會遭紀律處分。

Appendix F : Continuing Professional Development
附錄 F : 持續專業進修

F.1 Registered Authorized Persons have a personal and professional duty to keep up-to-date their knowledge and experience on the current state of pharmaceutical quality management, regulatory aspects and GMP standards, product manufacturing and control technology, and general work practices.

F.1 註冊獲授權人有個人及專業責任，不斷增進其在藥劑品質管理、規管事宜及生產質量管理規範標準、製品製造及監控科技，以及一般工作實務的現況方面的知識及經驗。

F.2 Records of continuing professional development should be kept to reflect the registered Authorized Person's continued performance of professional duties.

F.2 應備存持續專業進修記錄，以顯示註冊獲授權人持續履行專業職責。

F.3 In the event of a significant change in a registered Authorized Person's professional responsibilities, for example changing employment from one with a company making only non-sterile oral solid dosage forms to one with a company making a wider range of products including sterile products; or from one with a company packaging oral solid dosage forms to one with a company packaging parenternal products requiring cold chain management, the registered Authorized Person and the senior management of the company involved should recognise the need for receiving additional training/education and demonstrate that adequate steps have been taken to receive or provide such additional training/education, which should have been undertaken before the registered Authorized Person commences his or her work in the new positions.

F.3 如註冊獲授權人的專業責任有重大改變，例如由受僱於一家只製造非無菌口服固體劑型的公司，轉為受僱於一家製造多種製品（包括無菌製品）的公司；或由一家為口服固體劑型進行包裝的公司，轉為受僱於一家為注射用製品進行包裝並需要冷鏈管理的公司，註冊獲授權人及所涉的公司高層管理人員應知道需要接受額外培訓或教育，並證明已採取充分步驟接受或提供該等額外培訓或教育。有關培訓或教育應在註冊獲授權人展開新崗位的工作前進行。

Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局

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