Good Distribution Practice ("GDP") for Pharmaceutical Products in Hong Kong

香港藥劑製品良好分銷規範

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Contents 內容

BACKGROUND背景

Background 背景

What is Good Distribution Practice ("GDP")? 什麼是良好分銷規範?

Pharmaceutical Inspection Co-operation Scheme ("PIC/S") –

GDP is that part of **quality assurance** which ensures that the **quality** of pharmaceutical products **is maintained throughout all stages of the supply chain** from the site of manufacturer to the pharmacy or person authorised or entitled to supply pharmaceutical products to the public.

藥品檢查合作計劃 (PIC/S) –

良好分銷規範(GDP)為**質量保證**的一部分，旨在確保藥劑製品自製造廠房起，至藥房或經授權或有權向公眾供應藥劑製品之人士，在**供應鏈的每個階段均能維持其質量**。

(Source 資料來源: PIC/S Guide to Good Distribution Practice for Medicinal Products)

Background 背景

World Health Organization ("WHO") –

That part of **quality assurance** that ensures that the **quality** of a medical product is maintained by means of adequate control of the numerous activities that occur **during the trade and distribution process**, as well as providing a tool to **secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated and/ or misbranded medical products**.

世界衛生組織 (WHO) –

品質保證的一部分，通過對**貿易和分銷過程中**發生的眾多活動進行適當管控，**以確保**醫療產品的**品質得以維持**，同時亦作為一種工具來**保護分銷系統，防止偽造、未經核准、非法進口、遭竊、不合格、摻假和/或標示不實的醫療產品流入**。

(Source 資料來源: WHO Good storage and distribution practices for medical products)

Background 背景

Why implement GDP? 為什麼推行良好分銷規範?

"The Chief Executive's 2023 Policy Address" announced that the Government will leverage the medical strengths of the Hong Kong Special Administrative Region with the long-term objective of establishing an authority, i.e. **the Hong Kong Centre for the Medical Products Regulation (CMPR)**, that registers drugs and medical devices under the "primary evaluation" approach.

《行政長官2023年施政報告》公布，政府會發揮香港特別行政區醫療優勢，長遠目標是建立「第一層審批」的藥物及醫療器械註冊機構（即**「香港藥物及醫療器械監督管理中心」**）。

Background 背景

Why implement GDP? 為什麼推行良好分銷規範?

This will help accelerate the clinical use of new drugs and medical devices, and foster the development of industries relating to the research and development and clinical trials of medical products, **developing Hong Kong into an international health and medical innovative hub**.

藉此加快新藥械臨床應用以提升醫療水平，並帶動建設藥械研發和臨床測試的產業發展，**發展香港成為國際醫療創新樞紐**。

Background 背景

In 2025, **the Pharmacy and Poisons Board of Hong Kong ("the Board")** has **reviewed** the **implementation of GDP** for pharmaceutical products in **Chinese Mainland** and **other overseas jurisdictions**.

(*The Board is a statutory body established under the Pharmacy and Poisons Ordinance to perform statutory functions under the Ordinance and its subsidiary legislation. The Drug Office of the Department of Health provides professional support to the Board.*)

於2025年，**香港藥劑業及毒藥管理局（「管理局」）**全面**檢視中國內地**及**其他海外管轄區**就**推行藥劑製品良好分銷規範的情況**。

(管理局是根據《藥劑業及毒藥條例》成立的法定機構，負責執行該條例及其附屬法例所訂明的法定職能。衞生署藥物辦公室為管理局提供專業支援。)

Background 背景

The **Board** also reviewed the **gap analysis** of the requirements stipulated in the current Code of Practice for Holder of Wholesale Dealer Licence ("**COP**") and the **PIC/S Guide to Good Distribution Practice**. To align with PIC/S GDP, it was necessary to strengthen regulatory control on the areas that are only partially covered / not covered in the current COP.

管理局亦審視了現行**《批發商牌照持有人執業守則》**與 **PIC/S Guide to Good Distribution Practice** 所載規定之間的**差距分析**。為與PIC/S GDP保持一致，有必要加強規管現行《批發商牌照持有人執業守則》中僅局部涵蓋或尚未涵蓋的範疇。

Background 背景

Why PIC/S GDP? 為什麼 PIC/S GDP?

Effective 1 January 2016, the **Board** became a **participating authority of the PIC/S**. In Hong Kong, **all manufacturers** of pharmaceutical products must fully meet the **PIC/S Good Manufacturing Practice (GMP)** standards before being granted a licence by the Board to manufacture pharmaceutical products. Accordingly, as a PIC/S participating authority, the Board will also apply the **PIC/S GDP standards to licensed manufacturers and licensed wholesale dealers**.

管理局由2016年1月1日起成為**藥品檢查合作計劃 (PIC/S) 會員機構**。在香港，所有**藥劑製品製造商**要全面符合**PIC/S的「生產質量管理規範」(GMP)** 標準，才可獲管理局發牌製造藥劑製品。故此，作為 PIC/S 會員機構，管理局也將對**持牌製造商和持牌批發商採用 PIC/S GDP的標準**。

Background 背景

In May 2025, the **Board** **endorsed** to **require licensed manufacturers** and **licensed wholesale dealers** to **implement GDP** in Hong Kong **by adopting the PIC/S Guide to Good Distribution Practice** through the imposition of additional licensing condition. This decision aims to further **improve the regulatory system for the distribution** of pharmaceutical products.

Also, it was recommended making corresponding amendments to the current Code of Practice for Holder of Wholesale Dealer Licence ("COP") to avoid overlapping content.

於2025年5月，**管理局**決定採納**「藥品檢查合作計劃」《良好分銷規範指引》(PIC/S Guide to Good Distribution Practice)**，並透過施加額外牌照條件**要求持牌製造商**及**持牌批發商**在香港**實施GDP**。此項決定旨在**進一步完善**藥劑製品**分銷環節的監管制度**。

亦建議相應修訂現行《批發商牌照持有人執業守則》(「《執業守則》」)，以避免內容重疊。

Background 背景

The **Board** also **endorsed** the followings for GDP implementation –

管理局亦**批准**以下良好分銷規範之實施事項 –

- **Establishment** of **GDP Task Force**
- **Preparation** of the **Guide to Good Distribution Practice for Pharmaceutical Products** and relevant **guidance document**, and **updates to** the current **Code of Practice for Holder of Wholesale Dealer Licence**
- **Implementation timeline** (last part of the presentation)

- 成立**GDP**工作小組
- 編製《藥劑製品良好分銷規範指引》及相關指引文件，並更新現行《批發商牌照持有人執業守則》
- 實施時間表（簡報的最後部分）

Background 背景

Same as COP, the requirement for **compliance with the GDP Guide** will **not apply to** the trade solely dealing in **non-medicinal poisons** (such as chemical reagents, hair-dyes and industrial chemicals) or solely dealing in **medical devices** containing poisons.

與《執業守則》相同，**遵守《良好分銷規範指引》**之要求將不適用於僅經營**非藥用毒藥**（例如化學試劑、染髮劑和工業化學品）或僅經營含毒藥**醫療儀器**之行業。

GDP TASK FORCE GDP工作小組

Establishment of GDP Task Force
GDP 工作小組的成立

PPBHK endorsed the establishment of GDP Task Force
香港藥劑業及毒藥管理局批准成立GDP工作小組

WDL Committee endorsed the establishment of GDP Task Force
藥劑業及毒藥（批發牌照）委員會批准成立GDP工作小組

The **1st meeting** of GDP Task Force
GDP工作小組**第一次會議**

The **2nd meeting** of GDP Task Force
GDP工作小組**第二次會議**

The **3rd meeting** of GDP Task Force
GDP工作小組**第三次會議**

PPBHK = Pharmacy and Poisons Board of Hong Kong
WDL Committee = Pharmacy and Poisons (Wholesale Licences) Committee

Composition of GDP Task Force
GDP 工作小組的成員

Composition of Membership includes representative(s) from:

成員包括來自以下機構／界別的代表：

- Hong Kong Association of the Pharmaceutical Industry 香港科研製藥聯會
- Hong Kong Logistics Association 香港物流協會
- Hong Kong Private Hospitals Association 香港私家醫院聯會
- Hospital Authority 醫院管理局
- Pharmaceutical Distributors Association of Hong Kong 香港醫藥經銷業協會
- Pharmaceutical Manufacturers Association 香港製藥商會
- Drug Office, Department of Health 衞生署藥物辦公室

Terms of Reference 職權範圍

(1) To assist the Department of Health ("DH") in the implementation of PIC/S GDP by **assisting the formulation** of the "Guide to Good Distribution Practice for Pharmaceutical Products" ("**GDP Guide**").

協助衞生署實施PIC/S良好分銷規範，透過**協助制訂**《藥劑製品良好分銷規範指引》（「**《良好分銷規範指引》**」）。

(2) To **identify areas** in the GDP Guide where **additional guidance are needed**, and **provide input on drafting** "Guidance for Industry: GDP Guide" ("**Guidance for Industry**").

識別《藥劑製品良好分銷規範指引》中需要**額外指引的範疇**，並就**草擬**《業界指引 -藥劑製品良好分銷規範指引》（「**《業界指引》**」）**提供意見**。

Terms of Reference 職權範圍

(3) To **provide inputs** on **updating** the Code of Practice for Holder of Wholesale Dealer Licence (**"COP"**) to facilitate implementation of GDP.

就**更新**《批發商牌照持有人執業守則》（「**《執業守則》**」）**提供意見**，以便良好分銷規範的推行。

(4) To **provide comments/feedback** for DH to review the **implementation** of the GDP Guide and **provide inputs on necessary updates** to relevant **Guidance for Industry** or **COP**.

就衞生署檢討《良好分銷規範指引》的**實施情況提供意見／反應**，就相關**《業界指引》**或**《執業守則》**的必要更新**提供建議**。

Key Outcomes 主要結果

- Members provided valuable and practical **comments** relevant to the **current local situation**.

  成員就現時**本地情況提供**了寶貴而實用的**意見**。

- Members **recognized the gap** analysis between the **GDP Guide and the current COP**. It was concluded that **additional guidance** was required for the following **five major areas** in developing the Guidance for Industry :

  成員確認了**《藥劑製品良好分銷規範指引》與現行《執業守則》**之間的差距分析。會上總結認為，在制定《業界指引》時，需就以下**五大範疇**提供**額外指引**：

Chapter 1	**Quality Management**	**第1章　質量管理**
Chapter 2	**Personnel**	**第2章　人員**
Chapter 7	**Outsourced Activities**	**第7章　外判工作**
Chapter 8	**Self-Inspections**	**第8章　自檢**
Chapter 9	**Transportation**	**第9章　運輸**

Key Outcomes 主要結果

- Members **reviewed and provided comments** on the **initial** draft documents of **GDP Guide**, **Guidance for Industry** and **COP**.

  成員**審閱**了以下**初稿**文件並**提供意見** —《良好分銷規範指引》、《業界指引》以及《執業守則》。

- The above draft documents was **subsequently revised and refined** based on the **comments from Members**.

  上述文件初稿**其後根據成員的意見作出修訂及優化**。

- Members **confirmed** the **current version** of **GDP Guide**, **Guidance for Industry** and **COP** for trade consultation.

  成員**確認**以**現行版本**的《良好分銷規範指引》、《業界指引》以及《執業守則》進行業界諮詢。

GDP DOCUMENTS　GDP文件

GDP Documents GDP文件

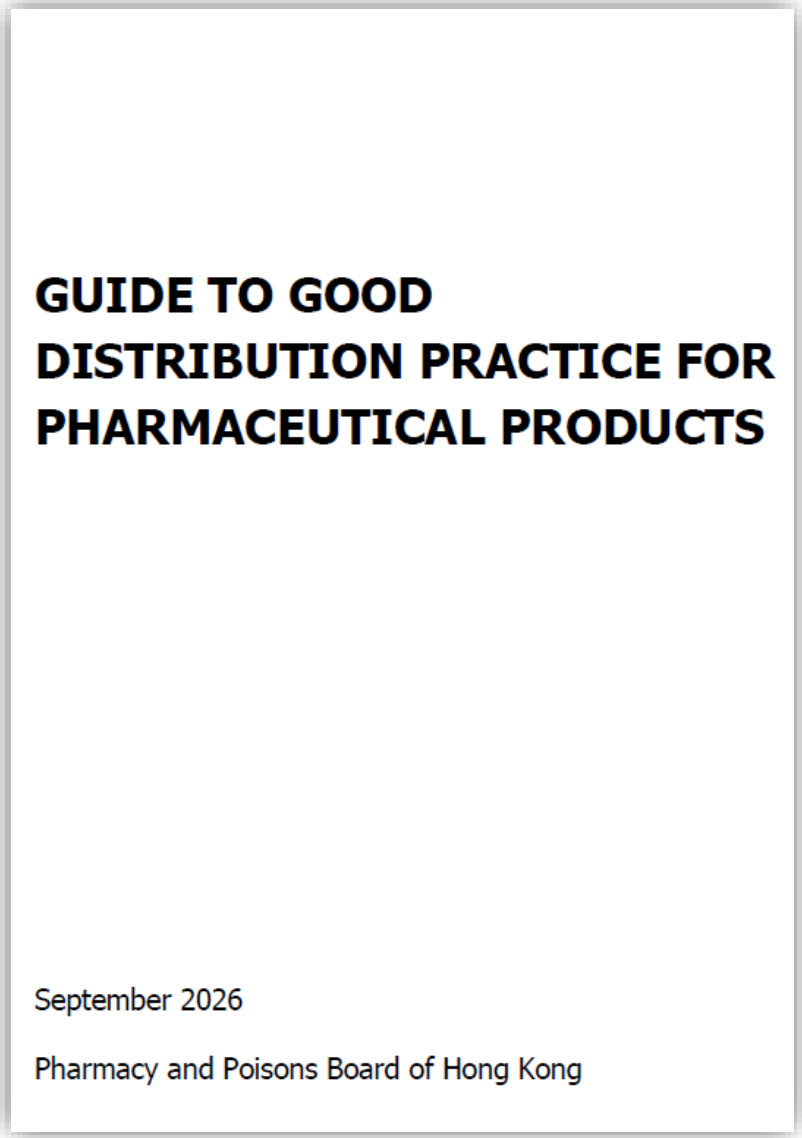
1. **Guide to Good Distribution Practice for Pharmaceutical Products ("GDP Guide")**

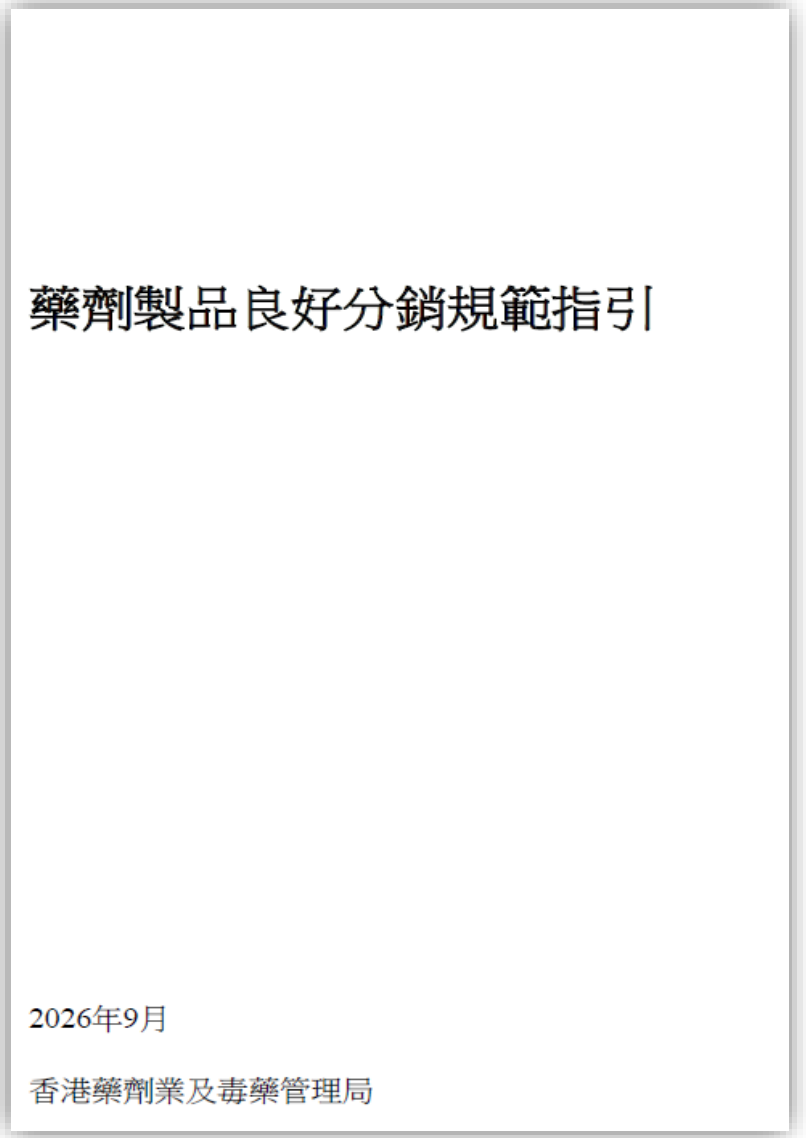
   《藥劑製品良好分銷規範指引》(「《良好分銷規範指引》;《GDP指引》」)

2. **Guidance for Industry: Guide to Good Distribution Practice for Pharmaceutical Products ("Guidance for Industry")**

   《業界指引:藥劑製品良好分銷規範指引》(「《業界指引》」)

GDP Guide 良好分銷規範指引





GDP Guide 良好分銷規範指引

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GDP Guide 良好分銷規範指引

The GDP Guide is divided into two parts – **Part I** and **Part II**.
《良好分銷規範指引》分為兩部分 — **第一部**及**第二部**。

Part I sets out the requirements for **pharmaceutical products**. **Part II** sets out the requirements specific to **active substances**.
第一部載列對**藥劑製品**的相關要求。**第二部**則就**原料藥**提出特定要求。

Each part provides **stand-alone guidance** on good distribution practice for pharmaceutical products and active substances respectively.
各部分分別就藥劑製品及原料藥的良好分銷規範提供**獨立指引**。

GDP Guide 良好分銷規範指引

The requirements are **based on PIC/S Guide to Good Distribution Practice for Medicinal Products (PE 011-1)** and **PIC/S Guidelines on the Principles of Good Distribution Practice of Active Substances for Medicinal Products for Human Use (PI 047-1)**.

相關要求是**根據 PIC/S Guide to Good Distribution Practice for Medicinal Products (PE 011-1)** and **PIC/S Guidelines on the Principles of Good Distribution Practice of Active Substances for Medicinal Products for Human Use (PI 047-1)**.

Mainly **editorial /textual amendments** to suit local situation:

主要為**編輯／文字上的修訂**，以配合本地情況：

- Introduction 引言
- Scope 範圍
- Legal terms and local regulatory requirements 法律用語及本地規管要求
- Glossary 辭彙

Outline of GDP Guide 良好分銷規範指引概述

Part I
第一部

Chapter 1 Quality Management
第1章 質量管理

Chapter 2 Personnel
第2章 人員

Chapter 3 Premises and Equipment
第3章 處所及設備

Chapter 4 Documentation
第4章 文件紀錄

Chapter 5 Operations
第5章 運作

Chapter 6 Complaints, Returns, Suspected Falsified Pharmaceutical Products And Pharmaceutical Product Recalls
第6章 投訴、退貨、懷疑偽冒藥劑製品及藥劑製品回收

Chapter 7 Outsourced Activities
第7章 外判工作

Chapter 8 Self-inspections
第8章 自檢

Chapter 9 Transportation
第9章 運輸

Outline of GDP Guide 良好分銷規範指引概述

Part II
第二部

Chapter 1 Scope
第1章 涵蓋範圍

Chapter 2 Quality System
第2章 質量系統

Chapter 3 Personnel
第3章 人員

Chapter 4 Documentation
第4章 文件紀錄

Chapter 5 Premises and Equipment
第5章 處所及設備

Chapter 6 Operations
第6章 運作

Chapter 7 Returns, Complaints and Recalls
第7章 退貨、投訴及回收

Chapter 8 Self-inspections
第8章 自檢

GDP Guide vs COP 良好分銷規範指引vs執業守則

Chapter 1 Quality Management 第1章 質量管理	**Chapter 2 Personnel** 第2章 人員	**Chapter 3 Premises and Equipment** 第3章 處所及設備
Chapter 4 Documentation 第4章 文件紀錄	**Chapter 5 Operations** 第5章 運作	**Chapter 6 Complaints, Returns, Suspected Falsified Pharmaceutical Products And Pharmaceutical Product Recalls** 第6章 投訴、退貨、懷疑偽冒藥劑製品及藥劑製品回收
Chapter 7 Outsourced Activities 第7章 外判工作	**Chapter 8 Self-inspections** 第8章 自檢	**Chapter 9 Transportation** 第9章 運輸

GDP Guide 良好分銷規範指引

Part I 第一部

Chapter 1 QUALITY MANAGEMENT
第1章 質量管理

- *"Wholesale distributors should **maintain a quality system** setting out responsibilities, processes and risk management principles in relation to their activities."「批發分銷商應**建立質量系統**，訂明與其業務活動相關的職責、流程及風險管理原則。」*

- Introduces the concept of **quality system** 介紹**質量系統**概念

- The **management of a WDL holder** is **responsible for the quality system**, which requires their leadership and active participation **批發商牌照持有人的管理層須對質量系統負責**，質量系統需要管理層的領導與積極參與。

GDP Guide 良好分銷規範指引

Chapter 2 PERSONNEL
第2章 人員

- "*The wholesale distributor must designate **personnel responsible for GDP compliance.** Relevant personnel should have **appropriate competence and experience** as well as **knowledge of and training in GDP**" 「批發分銷商必須指定**負責符合良好分銷規範的人員（即指定負責人）**。相關人員應具備**適當能力與經驗**，掌握**良好分銷規範知識並接受相關培訓**。」*

- Defines **responsibilities and requirements** **of Responsible Person** ("RP") who is responsible for GDP compliance of a WDL holder 界定**負責**批發商牌照持有人符合良好分銷規範之人士（**即指定負責人**）的**職責與要求**

- Defines the **training requirements** for **all relevant staff including the RP** 界定包括**指定負責人**在內的所有相關人員的**培訓要求**

GDP Guide 良好分銷規範指引

Chapter 3 PREMISES AND EQUIPMENT
第3章 處所及設備

- **Premises** should be designed or adapted to ensure that the required storage conditions are maintained 處所應經過設計或改造，以確保維持所需貯存條件

- **Equipment impacting on storage and distribution** of pharmaceutical products should be designed, located, maintained and cleaned to **suit its intended purpose** **影響**藥劑製品**貯存與分銷的設備**，其設計、配置、保養及清潔應**符合預期用途**

- The **repair, maintenance and calibration activities** for **key** equipment should be **recorded** **關鍵**設備的**維修、保養及校正**應**備存紀錄**

- **Key** equipment and key process(es) should be identified for **qualification and/or validation** 應識別**關鍵**設備與**關鍵**流程的**確認及／或驗證**

GDP Guide 良好分銷規範指引

Chapter 4 DOCUMENTATION
第4章 文件紀錄

- **Good documentation constitutes an essential part of the quality system** 完善的文件紀錄為質量系統的核心要素
- Written documentation should **prevent errors** and **permits the tracking** of relevant distribution operations 書面文件應**預防**口頭溝通的**錯誤**並能夠**追蹤**相關分銷運作
- Documentation **comprises all written procedures, instructions, contracts, records and data** 文件紀錄**涵蓋所有書面程序、指令、合約、紀錄及數據**
- Attention should be paid to the **approval, distribution, review and retention** of documentation 應當注重文件的**核准、分發、審閱及保存**程序

GDP Guide 良好分銷規範指引

Chapter 5 OPERATIONS
第5章 運作

- Includes **qualification of suppliers and customers**, **receipt** of pharmaceutical products, storage, **destruction** of obsolete goods, **picking**, **supply, and import and export** 包括**供應商與客戶的確認**、藥劑製品**收貨**、**貯存**、過期物品**銷毀**、**揀貨**、**供應以及進出口**

- All actions taken should ensure that the **identity** of the pharmaceutical product **is preserved** and that wholesale distribution is performed according to the information on the outer packaging 所有行動均應確保藥劑製品**正確無誤**，且批發分銷須依據外包裝資料進行

- Ensure that their **proposed suppliers or customers are authorised or entitled to conduct wholesale dealing activities** with them 應確保其**擬議供應商或客戶已獲授權或有權**與其**進行批發交易活動**

GDP Guide 良好分銷規範指引

Chapter 6 COMPLAINTS, RETURNS, SUSPECTED FALSIFIED PHARMACEUTICAL PRODUCTS AND PHARMACEUTICAL PRODUCT RECALLS

第6章 投訴、退貨、懷疑偽冒藥劑製品及藥劑製品回收

- All **complaints, returns, suspected falsified** pharmaceutical products and recalls should be handled carefully according to written procedures and **recorded** 所有**投訴、退貨、懷疑偽冒**藥劑製品及回收應按照書面程序謹慎處理並**備存紀錄**

- An assessment of returned pharmaceutical products should be performed by designated personnel before any approval for resale 退回的藥劑製品須經指定人員評估，其後方可核准重新銷售

GDP Guide 良好分銷規範指引

Chapter 7 OUTSOURCED ACTIVITIES
第7章 外判工作

- Defines the **roles and responsibilities** of the **Contract Giver** and the **Contract Acceptor**
  界定**合約委託方**與**合約受託方**的**角色與職責**

- The requirement of **written contract** specifying the duties of each party relating to the outsourced activity 簽訂**書面合約**以規範各方在外判工作中的義務

- Any **activity covered by the GDP Guide** that is outsourced should be **correctly defined, agreed and controlled** 凡屬**良好分銷規範指引涵蓋範圍**的外判工作，均應予以正確**界定、約定及監控**

GDP Guide 良好分銷規範指引

Chapter 8 SELF-INSPECTIONS
第8章 自檢

- Defines the requirement for a **self-Inspection program** 界定對**自檢計劃**的要求
- To **monitor implementation and compliance** with GDP principles and to **propose necessary corrective measures** 旨在**監察執行與遵循**良好分銷規範原則的狀況，並**提出必要的糾正措施**
- RP should ensure the self-inspections are **performed at appropriate regular intervals** 負責人應確保定期在**適當的相隔時間進行**自檢

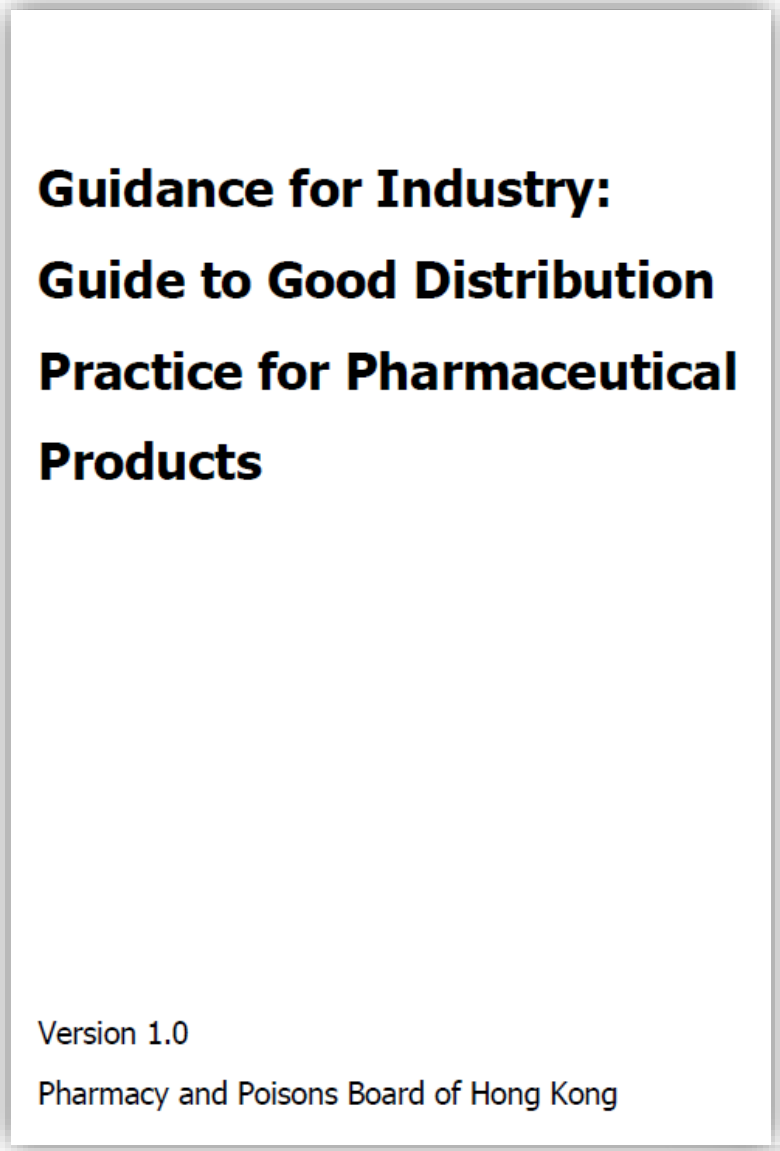
GDP Guide 良好分銷規範指引

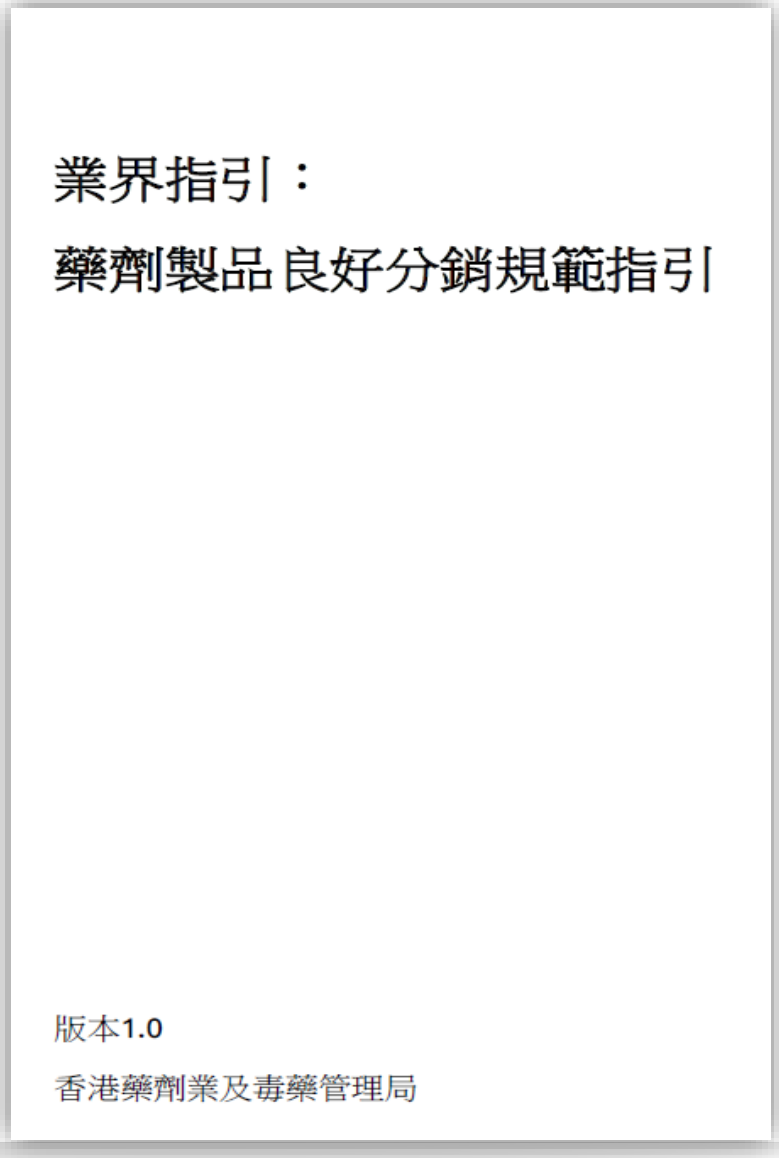
Chapter 9 TRANSPORTATION
第9章 運輸

- Defines the **responsibility of the WDL holder in protecting the supplied pharmaceutical products** against breakage, adulteration, theft as well as ensuring that temperature conditions are maintained within acceptable limits **during transport** 界定**批發商牌照持有人在運輸過程中保護所供應的藥劑製品的責任**，包括防止藥劑製品破損、摻雜、失竊，並確保溫度條件維持在可接受範圍內

- Regardless of the mode of transport, it should be **possible to demonstrate** that the pharmaceutical products have **not been exposed to conditions that may compromise their quality and integrity** 無論採用何種運輸方式，應**能證明**藥劑製品**未暴露於可能損害其質量與完整性的環境條件中**

Guidance for Industry 業界指引





Guidance for Industry 業界指引

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Guidance for Industry 業界指引

It is **administrative document** to provide additional information to facilitate the licensed wholesale dealers to comply with the GDP Guide.

此為一份**行政文件**，旨在提供補充說明以協助持牌批發商遵守《良好分銷規範指引》。

It should be **read in conjunction with the GDP Guide**.

須**與《良好分銷規範指引》一併閱讀**。

Additional information is provided on **specific clauses** of the GDP Guide. **Not to include the clauses** which are clearly specified in the GDP Guide as they are deemed to be **self-explanatory**.

針對《良好分銷規範指引》中的**特定條款**提供**補充說明**。**不包括**在《良好分銷規範指引》中已明確訂定且**內容自明的條款**。

Guidance for Industry 業界指引

It is developed based on other **international guidelines**, e.g. PIC/S, WHO.

依據其他**國際指引**制定，例如藥品檢查合作計劃、世界衛生組織。

Nevertheless, the wholesalers may develop specific ways to comply with the GDP Guide, provided that proper scientific justification and the principles of GDP have been taken into consideration.

儘管如此，批發商仍可制定具體方式以遵守《良好分銷規範指引》，惟須考慮適當的科學理據及良好分銷規範原則。

It is intended that this document will be **amended from time to time** to include additional guidance arising from **discussions with relevant stakeholders** and from on-site inspections by inspectors of the Drug Office.

擬將**不時修訂**，以納入**與相關持份者討論**以及藥物辦公室督察進行實地巡察所得之額外指引。

Guidance for Industry 業界指引

TOR of **GDP Task Force** –

To **identify areas** in the GDP Guide where **additional guidance** are needed, and **provide input on drafting Guidance for Industry**.

GDP工作小組的職權範圍 –

識別《良好分銷規範指引》中需要**額外指引的範疇**，並就**草擬《業界指引》提供意見**。

Certain sections are **revised/ devised** based on the **comments from the GDP Task Force** (some examples as follows).

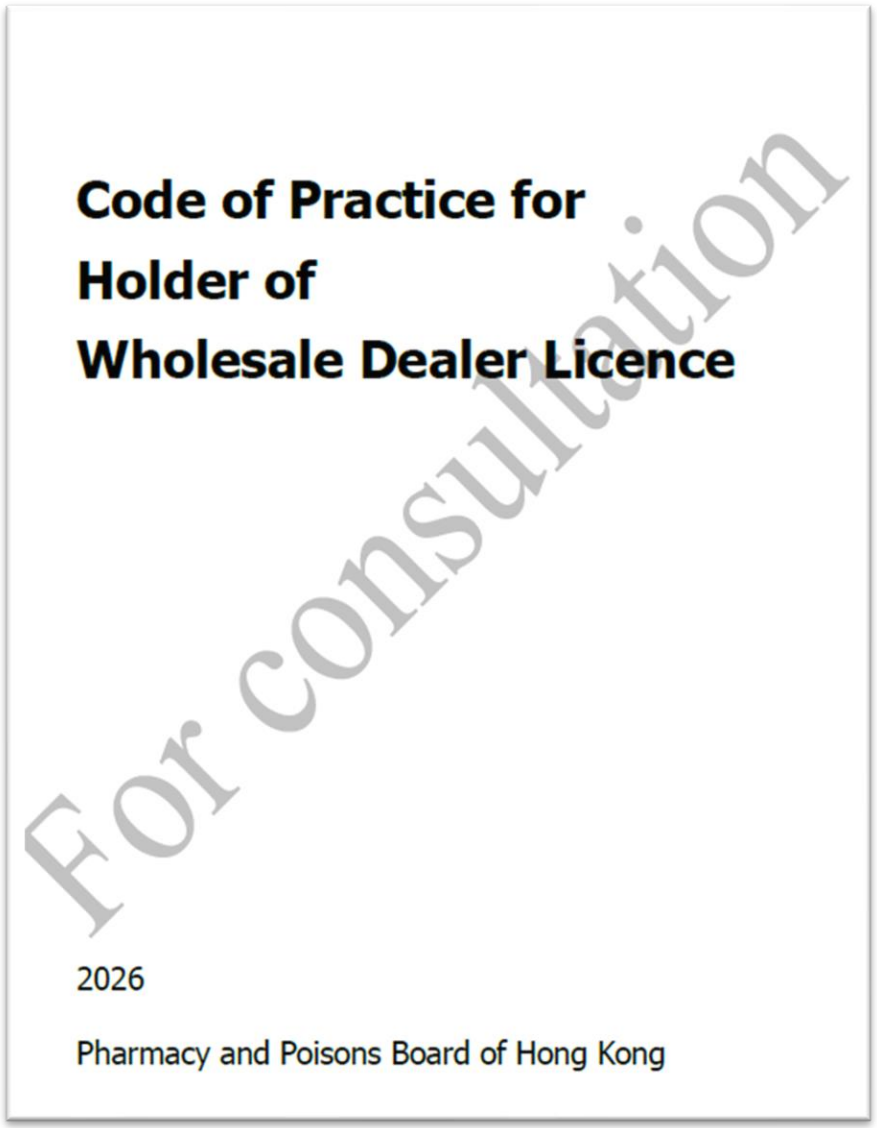
部分章節已按**GDP工作小組**的**意見作出修訂或擬定**（以下是一些例子）。

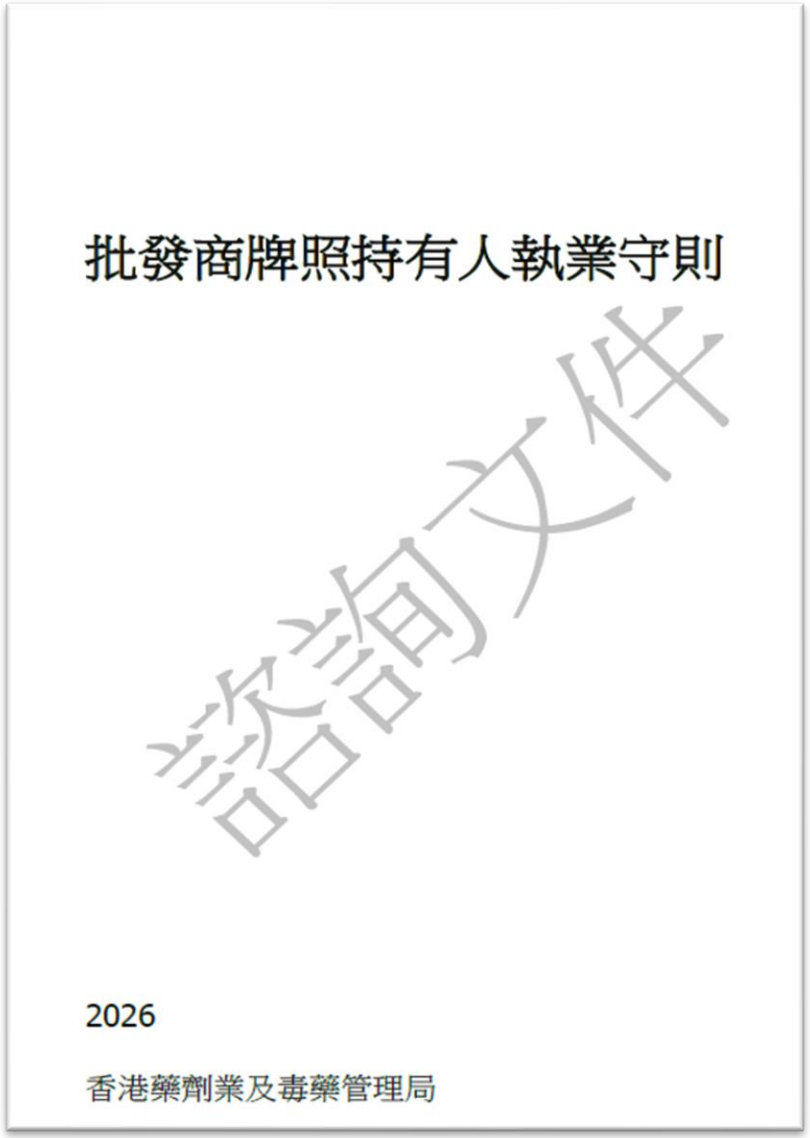
Guidance for Industry 業界指引

Clause no.	Requirements	要求
	Purpose and Scope	目的及涵蓋範圍
1.2.7v	Deviation – Temperature excursions	偏差 - 溫度偏差
3.3.2	Mapping studies	溫濕度分佈測繪
3.6.1	Qualification of equipment	設備確認
7.2.2	Audit	審查
8.2.2	External audits	外部審查
9.2.1	Continuous Monitoring Temperature during Transportation	持續監測運輸過程中的溫度
9.2.3	Vehicles and equipment for transportation	運輸車輛及設備
9.4.6	Use of cool packs	蓄冷劑的使用
9.4.7	Control of cool packs	蓄冷劑的管理

CODE OF PRACTICE FOR WDL
批發商牌照持有人執業守則

Code of Practice 執業守則





Code of Practice 執業守則

Revision is based on the **implementation of the GDP Guide**.

修訂是基於《良好分銷規範指引》的實施情況。

Remove certain requirements which are considered to be covered in the GDP Guide (in principles). Some details of the current requirements are supplemented by the Guidance for Industry.

刪除一些已為《良好分銷規範指引》所涵蓋之要求（原則上）。部分現行要求的細節則由《業界指引》補充。

Retain the legal requirements and other **non-GDP issues** (e.g. advanced therapy products, adverse drug reaction reporting, guidelines issued by the Board).

保留法律要求及其他**不屬於良好分銷規範範疇**之事項（例如先進療法製品、藥品不良反應呈報、管理局所發布之指引）。

Code of Practice 執業守則

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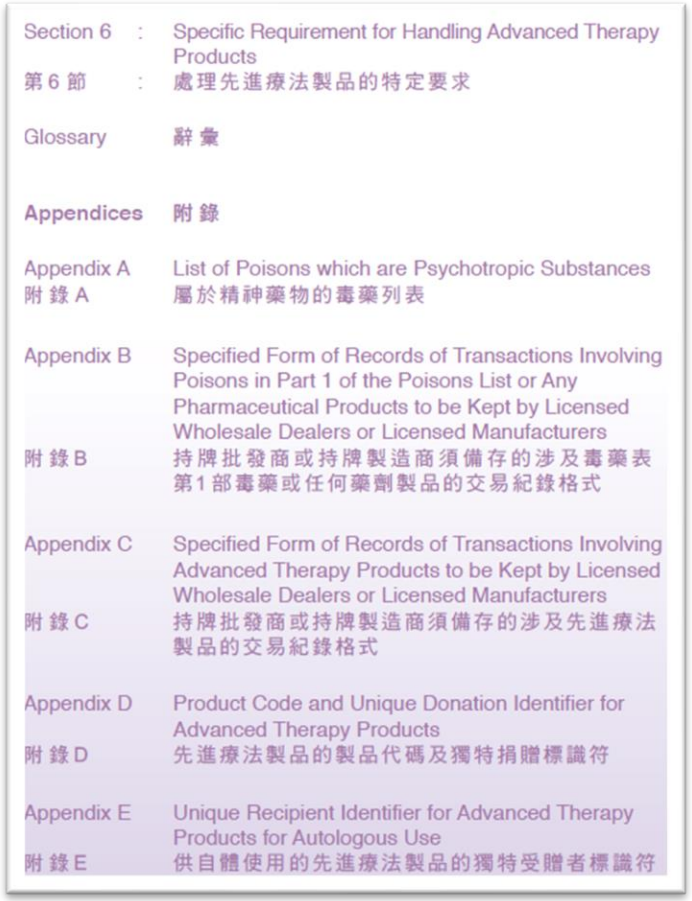

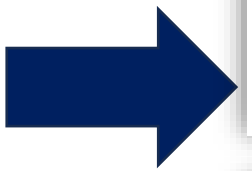

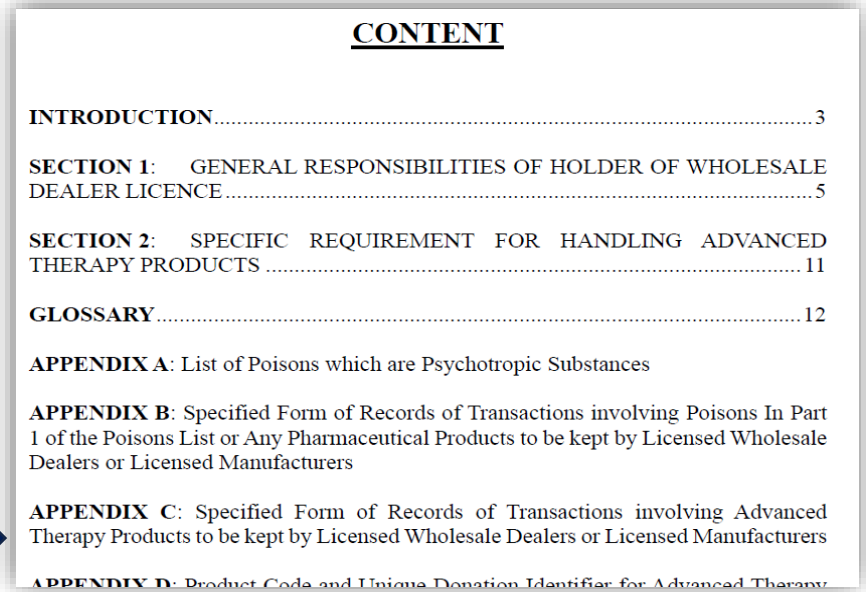

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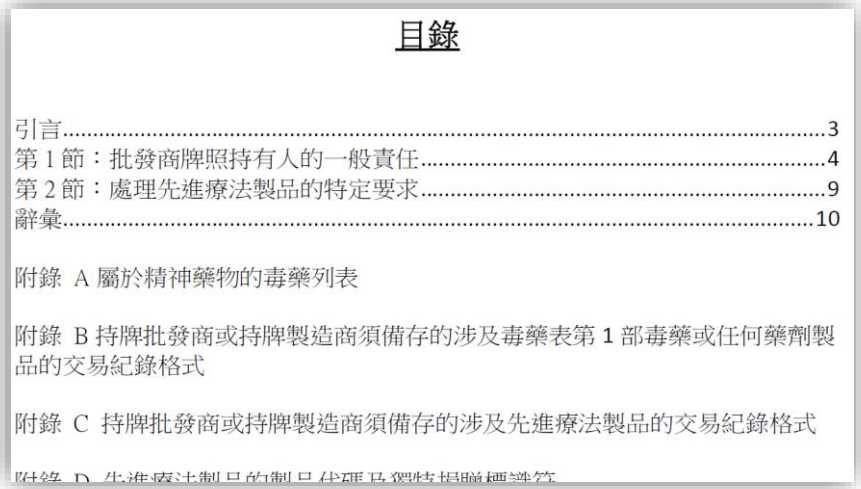

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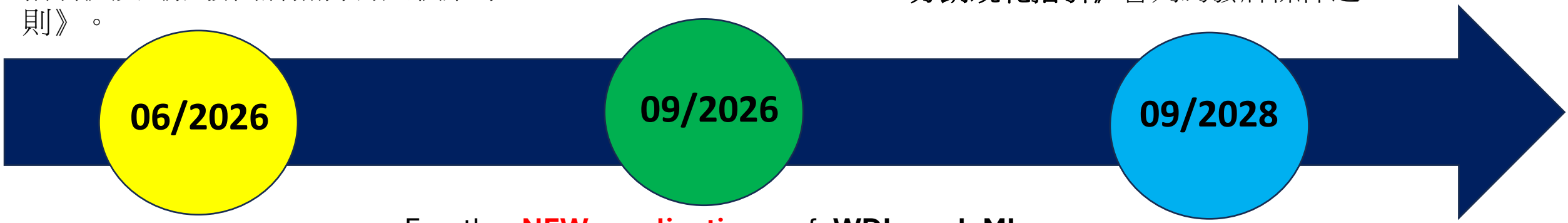
IMPLEMENTATION TIMELINE
實施時間表

Implementation Timeline 實施時間表

The Pharmacy and Poisons Board endorsed the finalized **GDP Guide**, the **Guidance for Industry** and the **COP for WDL**.
藥劑業及毒藥管理局正式通過最終修訂的《良好分銷規範指引》、《業界指引》及《批發商牌照持有人執業守則》。

The licensing conditions on **compliance with the GDP Guide** would be imposed for **EXISTING WDL Holders and ML Holders** for licences **renewed on or after 30/9/2028**.
現時批發商牌照及製造商牌照持有人於**2028年9月30日或以後續牌**時，**遵守《良好分銷規範指引》**會列為發牌條件之一。



For the **NEW applications** of **WDL and ML received on or after 30/9/2026**, **compliance with the GDP Guide** would be imposed as one of the licensing requirements.
於**2026年9月30日或之後所收到**的**批發商牌照及製造商牌照新申請**，必須符合**《良好分銷規範指引》**，作為其中的發牌要求。

WDL = Wholesale Dealer Licence
ML = Licence for Manufacturer

Thank You