西藥藥品優良製造規範

-藥品優良運銷指引

PIC/S：Guide to Good Distribution Practice for Medicinal Products

PE011-1 (1 June 2014)

衛生福利部

中華民國 104 年 3 月

序

藥品品質攸關國人身體健康，為維護民眾用藥安全及持續提升我國製藥產業之國際競爭力，衛生福利部食品藥物管理署將藥品運銷管理列為近年施政首要目標之一，以期建構健全完善藥品供應鏈體系。

今日，全球化趨勢與跨國專業分工使得藥品供應鏈更加複雜，為有效確保藥品品質,藥品管理政策應涵蓋藥品供應鏈。為保障藥品從出廠後至使用前之品質，世界各國衛生主管機關對於藥品品質的要求已從過去生產面向的「藥品優良製造規範」（Good Manufacturing Practice，GMP）延伸到運銷面向的「藥品優良運銷規範」（Good Distribution Practice，GDP）。

國際間目前已有許多組織及國家開始實施藥品優良運銷指引，包含世界衛生組織、歐盟、新加坡、馬來西亞、英國、德國、瑞士、美國與澳洲等，我國亦於102年10月檢送PIC/S GDP草案內容之中英對照予各藥業公協會轉知所屬會員參考。國際醫藥品稽查協約組織（Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme，PIC/S）於103年6月正式公布其藥品優良運銷指引(GDP)，此規範未來勢必成為國際GDP標準，因此藉由推動與國際同步之藥品優良運銷指引，落實藥品運銷品質管理，不僅可保障全體國人用藥安全，進一步更能提升我國藥品運銷品質並創造國際競爭力。

PIC/S組織所公布之藥品GDP規範分為前言、目的、範圍、條文內容及術語表，條文內容包含品質管理、人事、作業場所及設備、文件管理、作業、申訴、退回、疑似偽、禁藥及藥品回收、委外作業、自我查核、運輸，總計九章。其適用範圍為所有藥品批發運銷活動，包含所有藥品採購、儲存、供應、輸入及輸出等，其適用產品類型為人用藥品及類似產品。此規範具體說明藥品運銷活動應建構之硬體設施與應建置的文件系統，提供從事批發運銷活動業者明確之指引，進而強化藥品運銷管控,維護藥品品質與完整性。未來PIC/S組織更新GDP條文時，本署配合隨時更新西藥藥品優良製造規範-藥品優良運銷指引（以下簡稱本指引）。

衛生福利部食品藥物管理署

中華民國104年3月

目錄

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1. 本指引係採 PIC/S GDP（PE011-1)制訂，考量本國國情及現況，將部分條文酌修，以符合國內法令之規定，且本規範僅適用人用西藥藥品。
2. 本指引所指批發運銷商係進行藥事法中批發運銷相關活動之我國藥品販賣業者及藥品製造業者。

前言 INTRODUCTION	
本指引是以歐盟對於人用藥之「藥品優良運銷規範」指引為基礎(2013/C 343/01)。該指引已被 GDP 專家圈為 PIC/S 之目的採用，且本指引已刪除歐盟專用資料。 本規範已被 PIC/S 採用作為指引文件。各 PIC/S 會員主管機關應自行決定是否採用本指引作為具有法律約束力之標準。	This Guide is based on the EU Guidelines on Good Distribution Practice (GDP) of Medicinal Products for Human Use (2013/C 343/01). The EU Guidelines have been adapted by the Expert Circle on GDP for PIC/S purposes. However, the EU specific references have been deleted in this Guide. This Guide has been adopted by PIC/S as a guidance document. It is up to each PIC/S Participating Authority to decide whether it should become a legally-binding standard.
藥品的批發運銷是整合供應鏈管理中重要的活動。現今的藥品運銷網絡日益複雜且包含許多參與者。本指引制定適當的工具以協助批發運銷商進行其活動，並預防偽、禁藥流入合法供應鏈中。遵守本指引可確保運銷鏈的管控，進而維護藥品的品質與完整性。	The wholesale distribution of medicinal products is an important activity in integrated supply chain management. Today's distribution network for medicinal products is increasingly complex and involves many players. These guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products.
藥品批發運銷指的是藥品採購、儲存、供應、輸入或輸出的所有活動，但不包含供應藥品給大眾。這類活動是由製造商或其受託者、進口商、其他批發運銷商或由藥師及經授權供應藥品給大眾的人員執行。在某些 PIC/S 會員主管機關的國家，輸入可能被列入 GMP 的範圍內，且可能需要提供製造許可。	Wholesale distribution of medicinal products is all activities consisting of procuring, holding, supplying, importing or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public. In the territories of some PIC/S

	Participating Authorities importation may fall under GMP and a manufacturer's license may be required.
任何扮演批發運銷商角色者，應符合國內法令之要求。 持有藥品製造許可包含該許可所涵蓋之藥品運銷，因此，製造廠執行任何自家產品的運銷作業必須遵守 GDP。	Any person acting as a wholesale distributor has to hold a wholesale distribution licence in accordance with national legislation. Possession of a manufacturing licence includes authorisation to distribute the medicinal products covered by the authorisation. Manufacturers performing any distribution activities with their own products must therefore comply with GDP.
批發運銷的定義並非取決於運銷商是否於特定海關領域內建立或營運，例如在自由貿易區或自由倉庫。所有與批發運銷活動相關的責任(例如輸入、輸出、儲存或供應)也適用於這類運銷商。其他參與運銷藥品的業者也應遵守本指引的相關章節。 本指引所使用的術語表包含於附件一中。	The definition of wholesale distribution does not depend on whether that distributor is established or operating in specific customs areas, such as in free zones or in free warehouses. All obligations related to wholesale distribution activities (such as importing, exporting, holding or supplying) also apply to these distributors. Relevant sections of these guidelines should also be adhered to by other actors involved in the distribution of medicinal products. A glossary of some terms used in the Guide has been incorporated as Annex 1.
目的 PURPOSE	
確保維持藥品運銷過程中高標準的品質保證與完整性、促進藥品批發許可的一致及進一步消除藥品貿易障礙，而採用本指引。 國家衛生主管機關的行政措施應針對這些標準應用在實務上，且任何針對本指引的新或修正法規應至少符合其水準。這類標準也提供批發運銷商作為制訂符合其個別需求的具體規則之基礎。除了本指引說明之外，尚有其他可被接受的方法也能達到原則。本文件可作為稽查準備之指引，也可用於訓練之目的。	In order to ensure the maintaining of high standards of quality assurance and the integrity of the distribution processes of medicinal products, to promote uniformity in licensing of wholesaling of medicinal products and to further facilitate the removal of barriers to trade in medicinal products, the following Guide to Good Distribution Practice (GDP) for Medicinal Products has been adopted. Administrative measures of national health authorities should be directed towards the application of these standards in practice, and any new or amended national regulations for good distribution practice should at least meet their level. These standards are also intended to serve wholesale distributors as a basis for the

	elaboration of specific rules adapted to their individual needs. It is recognised that there are acceptable methods, other than those described in this Guide, which are capable of achieving the principles of the Guide. This document provides guidance for preparation for inspections and may be used for training purposes.
範圍 SCOPE	
本文所載之標準適用於人用藥品與類似產品。本指引也適用於研究用藥品(IMP)。 本文件在發行時反映出目前的技術水準。其目的不在於對技術創新或追求卓越上造成障礙，或限制新概念或新技術的發展，新概念或技術應經確效，並提供相當程度之品質保證與運銷流程的完整性，至少應等同於本指引之標準。	The standards set out herein apply to medicines and similar products intended for human use. It is recommended, however, that the same kind of attention be given to the distribution of veterinary medicinal products. This guideline can also be applicable for Investigational Medicinal Products (IMP). At the time of issue, this document reflected the current state of the art. It is not intended to be a barrier to technical innovation or the pursuit of excellence or to place any restraint upon the development of new concepts or new technologies, which have been validated and provide a level of Quality Assurance and integrity of the distribution processes at least equivalent to those set out in this Guide.

	中譯	原文
第 1 章 品質管理 (Chapter 1 Quality Management)		
1.1 原則 (Principle)		
	批發運銷商應訂定一套與其活動相關的職責、流程及風險管理原則的品質系統。	Wholesale distributors should maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.
	所有運銷活動在程序上應清楚規範，並且經過系統式審查，運銷流程的所有關鍵性步驟與重大變更都應證明其正當性並確效。	All distribution activities should be clearly defined in procedures and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated.
	品質系統是管理者的責任，且需要其領導能力及積極參與，以及員工的承諾予以支持。	The quality system is the responsibility of the organisation's management and requires their leadership and active participation and should be supported by staff commitment.
1.2 品質系統 (Quality System)		
1.2.1	品質系統應包含組織架構、程序、流程、資源及必要活動，以確保儲存及/或運輸時交付的產品維持其品質及完整性，並來自合法供應鏈。	The system for managing quality should encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the product delivered maintains its quality and integrity and remains within the legal supply chain during storage and/or transportation.
1.2.2	品質系統應充分文件化，並監測其有效性；所有與品質系統相關的活動應予以規範及記錄；應訂定品質手冊或類似文件。	The quality system should be fully documented and its effectiveness monitored. All quality system related activities should be defined and documented. A quality manual or equivalent documentation approach should be established
1.2.3	被指定之權責人員應由管理階層指派，其職權及職責應清楚明定，以確保品質系統的執行及維持。	Designated responsible person(s) should be appointed by the management, who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained.
1.2.4	運銷商的管理者應確保品質系統皆有勝任之人員及適當足夠的作	The management of the distributor should ensure that all parts of the quality

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	業場所、設備及設施等資源。	system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.
1.2.5	發展或修改品質系統時，應考量運銷商活動的規模、架構及複雜性。	The size, structure and complexity of distributor's activities should be taken into consideration when developing or modifying the quality system.
1.2.6	應具備變更管制系統，此系統應包含品質風險管理原則，且應依照風險比例有效的設置此系統。	A change control system should be in place. This system should incorporate quality risk management principles, and be proportionate and effective.
1.2.7	品質系統應確保：	The quality system should ensure that:
	i)藥品的採購、儲存、供應、輸入或輸出均符合本指引的要求；	i)medicinal products are procured, held, supplied, imported or exported in a way that is compliant with the requirements of GDP;
	ii)管理職責經清楚的明定；	ii)management responsibilities are clearly specified;
	iii)產品在適當的期間內交付給正確的接受者；	iii)products are delivered to the right recipients within a satisfactory time period;
	iv)於執行活動的同時進行記錄；	iv)records are made contemporaneously;
	v)偏差要予以文件化與調查；	v)deviations from established procedures are documented and investigated;
	vi) 依照品質風險管理原則，採取適當的矯正預防措施(CAPA)，矯正並預防偏差情況。	iv)appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.
1.3 委外作業管理 (Management of Outsourced Activities)		
	品質系統應擴大到任何關於藥品採購、儲存、供應、輸入或輸出之委外作業的管制及審查。此流程應納入品質風險管理並包含：	The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply, import or export of medicinal products. These processes should incorporate quality risk management and include:
	i)評估受託者執行活動之適任性與能力、藥品保存之完整性與安全性及文件維護，必要時檢查許可及市場狀態；	i)assessing the suitability and competence of the Contract Acceptor to carry out the activity, preserving the integrity and security of the medicinal

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		products, and requesting, preserving documentation, and checking authorisation or marketing status, if required;
	ii)規範參與品質相關活動者的職責及溝通流程。	ii)defining the responsibilities and communication processes for the quality-related activities of the parties involved;
	iii)定期監測及審查受託者的績效，並識別及執行任何必須改善之處。	iii) monitoring and review of the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.
1.4 管理階層檢討及監督 (Management Review and Monitoring)		
1.4.1	管理階層應依正式流程定期檢討品質系統，其檢討應包括：	The management should have a formal process for reviewing the quality system on a periodic basis. The review should include:
	i)達成品質系統目標的評量；	i)measurement of the achievement of quality system objectives;
	ii)評估可用來監測品質系統內流程有效性的績效指標，如申訴、回收、退回、偏差、矯正預防措施(CAPA)、流程變更；委外作業的回饋意見；自我評估流程，包括風險評估及稽核；外部評估，如主管機關的查核與調查結果及客戶的稽核。	ii)assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, recalls, returns, deviations, CAPA, changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments and audits; and external assessments such as inspections, findings and customer audits;
	iii)新法規、指引以及會影響品質管理系統的品質議題；	iii)emerging regulations, guidance and quality issues that can impact the quality management system;
	iv)可增進品質系統之改革；	iv)innovations that might enhance the quality system;
	v)商業環境及目標的變更。	v)changes in business environment and objectives.
1.4.2	每一項品質系統的檢討結果應即時記錄並有效地進行內部溝通。	The outcome of each management review of the quality system should be documented in a timely manner and effectively communicated internally.

	中譯	原文
1.5 品質風險管理 (Quality Risk Management)		
1.5.1	品質風險管理是可用以評估、管制、溝通及審查藥品品質風險之系統性流程。其適用方式可採主動性及回溯性兩種。	Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.
1.5.2	品質風險管理應確保品質風險評估是以科學知識、流程經驗及最終連結到病患保護為主。此流程的執行、形式及文件應與風險等級相當。 品質風險管理的流程及應用範例可參見 ICH(International Conference on Harmonisation)Q9 指引。	Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found in guideline Q9 of the International Conference on Harmonisation (ICH).
第 2 章 人事 (Chapter 2 Personnel)		
2.1 原則 (Principle)		
	藥品的正確運銷仰賴人員。為此，批發運銷商須配置足夠的勝任人員執行其所有負責之工作。工作人員應清楚瞭解其個別職責並作成紀錄。	The correct distribution of medicinal products relies upon people. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.
2.2 一般規定(General)		
2.2.1	參與所有階段的藥品批發運銷活動應具備足夠數量的勝任人員，所需人員數量視作業量及作業範圍而定。	There should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities of medicinal products. The number of personnel required will depend on the volume and scope of activities.
2.2.2	批發運銷商的組織圖需界定組織架構，並清楚標示所有人員的角色、職責以及相互關係。	The organisational structure of the wholesale distributor should be set out in an organisation chart. The role, responsibilities, and interrelationships of

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		all personnel should be clearly indicated.
2.2.3	關鍵人員的角色、職責及代理人制度之安排，應建立書面職務說明。	The role and responsibilities of employees working in key positions should be set out in written job descriptions, along with any arrangements for deputising.
2.3 職責之指派 (Designation of responsibilities)		
2.3.1	批發運銷商必須指定權責人員確保作業符合本指引。相關人員應具有適當的能力與經驗，以及瞭解本指引與接受有關本指引之相關訓練。	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.
2.3.2	批發運銷商應提供非營業時段之聯繫人員（如緊急事件、回收）。被指定之權責人員可指派職務代理人，但仍需擔負此責任。	Wholesale distributors should nominate personnel for out of hours contact (e.g. emergencies and/or recall). Designated responsible person(s) may delegate duties but not responsibilities.
2.3.3	被指定之權責人員之書面職務說明應規範與其職責相關決策的授權。批發運銷商應給予指定之權責人員完成其職務所需之權限、適當資源及職責。	Written job descriptions for designated responsible person(s) should define their authority to take decisions with regard to their responsibilities. The wholesale distributor should give the designated responsible person(s) the defined authority, adequate resources and responsibility needed to fulfil their duties.
2.3.4	被指定之權責人員應以確保批發運銷商遵守本指引且履行公共服務責任的方式執行其職責。	Designated responsible person(s) should carry out their duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.
2.3.5	被指定之權責人員的職責包括，但不侷限於：	The responsibilities of the designated responsible person(s) include but are not limited to:
	i)確保品質管理系統之執行及維持；	i) ensuring that a quality management system is implemented and maintained;
	ii)著重於被授權活動之管理及紀錄真實性與品質；	ii) focusing on the management of authorised activities and the accuracy and quality of records;
	iii)確保職前及持續訓練計畫之執行及維持；	iii) ensuring that initial and continuous training programmes are implemented

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		and maintained;
	iv)協調及立即執行任何藥品回收作業；	iv) coordinating and promptly performing any recall operations for medicinal products;
	v)確保有效處理客戶申訴；	v) ensuring that relevant customer complaints are dealt with effectively;
	vi)確保供應商及客戶經核准	vi) ensuring that suppliers and customers are approved;
	vii)核准所有可能影響符合本指引之轉委託作業	vii) approving any subcontracted activities which may impact on GDP;
	viii)確保事先安排計畫，在適當的定期間隔內進行自我查核，且應執行必要的矯正措施；	viii) ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
	ix)保存關於職務代理的適當紀錄；	ix) keeping appropriate records of any delegated duties;
	x)所有退回、拒用、回收、偽、禁藥的最終處理判定。	x) deciding on the final disposition of returned, rejected, recalled or falsified products;
	xi)核准退回品進入可銷售品庫存；	xi) approving any returns to saleable stock;
	xii)確保遵守國內法令對特定產品所附加的其他要求	xii) ensuring that any additional requirements imposed on certain products by national legislation are adhered to.
2.4 訓練 (Training)		
2.4.1	參與批發運銷活動的所有人員應接受本指引要求之訓練，在開始執行作業前應具有適當能力及經驗。	All personnel involved in wholesale distribution activities should be trained on the requirements of GDP. They should have the appropriate competence and experience prior to commencing their tasks.
2.4.2	人員應依照書面程序及訓練計畫，接受與其職務相關的職前及持續訓練。被指定之權責人員也應透過定期訓練維持其本指引之執行能力。	Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme. Designated responsible person(s) should also maintain their competence in GDP through regular training.
2.4.3	此外，訓練應包括產品識別以及避	In addition, training should include the

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	免偽、禁藥進入供應鏈。	supply chain.
2.4.4	需以嚴謹條件處理之產品，其負責人員應接受特定訓練。這類產品如：有危害性之產品、放射性物質、有特定濫用風險之產品(包含麻醉藥、治療精神異常用藥)及對溫度敏感的產品。	Personnel dealing with any products which require more stringent handling conditions should receive specific training. Examples of such products include hazardous products, radioactive materials, products presenting special risks of abuse (including narcotic and psychotropic substances), and temperature-sensitive products.
2.4.5	應保存所有訓練紀錄，且訓練的有效性應定期評估及文件化。	A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.
2.5 衛生 (Hygiene)		
	在執行作業時，應制定及遵守與人員衛生相關之程序，包括健康、衛生習慣與服裝。	Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.
第 3 章作業場所及設備 (Chapter 3 Premises and Equipment)		
3.1 原則 (Principle)		
	批發運銷商必須具備適當且足夠的作業場所、配備及設備，以確保能夠適當儲存及運銷藥品，此作業場所必須是潔淨、乾燥及維持在可接受的溫度範圍內。	Wholesale distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.
3.2 作業場所 (Premises)		
3.2.1	作業場所應設計或調適以確保維持所需的儲存條件。作業場所應具有適當安全性，結構要完善且有足夠的容量可安全儲存及處理藥品。儲存空間應提供適當的照明及通風以精確及安全地執行所有作業。	The premises should be designed or adapted to ensure that the required storage conditions are maintained. They should be suitably secure, structurally sound and of sufficient capacity to allow safe storage and handling of the medicinal products. Storage areas should be provided with adequate lighting and ventilation to enable all operations to be carried out accurately and safely.

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3.2.2	作業場所非直接由批發運銷商營運時，應具備書面委託合約。該合約委託之作業場所應符合國內法令之要求。	Where premises are not directly operated by the wholesale distributor, a written contract should be in place. The contracted premises should be covered by a separate wholesale distribution authorisation if required by national legislation.
3.2.3	藥品應儲存於具適當標示並嚴格管控進出人員之隔離區。任何替代實體隔離之方式，如以電腦化系統為主的電子隔離區域，應提供同等的安全並進行確效。	Medicinal products should be stored in segregated areas which are clearly marked and have access restricted to authorised personnel. Any system replacing physical segregation, such as electronic segregation based on a computerised system, should provide equivalent security and should be validated.
3.2.4	等待進一步決定處理或已由可銷售品庫存移除之藥品，例如疑似偽、禁藥及退回品，應實體或透過同等效力之電子系統予以隔離。應採用風險導向之方法評估實體隔離及專用區的儲存要求。至少偽、禁藥、過期藥品、回收藥品、拒用藥品及未授權國內上市的藥品必須要被實體隔離。 應清楚界定並適當管制此區域以確保這些產品與可銷售品庫存區分。	Products pending a decision as to their disposition or products that have been removed from saleable stock should be segregated either physically or through an equivalent electronic system. The requirement for physical segregation and storage in a dedicated area should be assessed using a risk based approach. At least, falsified medicinal products, expired products, recalled products, rejected products and medicinal products not authorised for the internal market must always be physically segregated. The appropriate degree of security should be applied in these areas to ensure that such items remain separate from saleable stock. These areas should be clearly identified.
3.2.5	應特別注意國內法令明定需特別處理說明之藥品儲存。此類產品(如麻醉藥及治療精神異常用藥)可能需要特殊儲存條件(以及特殊許可)。	Special attention should be paid to the storage of products with specific handling as specified in national legislation. Special storage conditions (and special authorisations) may be required for such products (e.g. narcotics and psychotropic substances).
3.2.6	放射性物質及其他危害性之藥品，以及具引起火災、爆炸等特殊	Radioactive materials and other hazardous products, as well as products

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	安全性風險的產品（如醫用氣體、可燃物及可燃性液體與固體），應儲存在一或多個符合國內法令規範，安全性更高且具備適當安全措施的專用區域。	presenting special safety risks of fire or explosion (e.g. medicinal gases, combustibles, flammable liquids and solids), should be stored in one or more dedicated areas subject to national legislation and appropriate safety and security measures.
3.2.7	收貨區及出貨區應保護產品免於受到天氣之影響。收貨區、出貨區及儲存區應適當的隔離。應有程序管制內銷及外銷產品。在收貨過程中檢查貨物之收貨區應予以指定並具適當配備。	Receiving and dispatch bays should protect products from prevailing weather conditions. There should be adequate separation between the receipt and dispatch and storage areas. Procedures should be in place to maintain control of inbound/outbound goods. Reception areas where deliveries are examined following receipt should be designated and suitably equipped.
3.2.8	應防止未經授權之人員進入管制作業場所的所有區域。預防措施通常包括監測入侵者警報系統及適當之入口管制。訪客應由經授權的人員陪同。	Unauthorised access to all areas of the authorised premises should be prevented. Prevention measures would usually include a monitored intruder alarm system and appropriate access control. Visitors should be accompanied by authorised personnel.
3.2.9	作業場所及儲存設施應保持乾淨且不得有垃圾與灰塵，具備清潔計畫、指令及紀錄，並作清潔以避免成為污染源。	Premises and storage facilities should be clean and free from litter and dust. Cleaning programmes, instructions and records should be in place. Cleaning should be conducted so as not to present a source of contamination.
3.2.10	作業場所的設計與配置應提供保護，以防止昆蟲或其他動物的入侵，且具備防蟲鼠的計畫，並維持適當的防蟲鼠紀錄。	Premises should be designed and equipped so as to afford protection against the entry of insects, rodents or other animals. A preventive pest control programme should be in place. Appropriate pest control records should be maintained.
3.2.11	員工的休息室、盥洗室及飲食區應與儲存區適當的隔離。應禁止在儲存區存放食物、飲料、香菸或個人使用的藥品。	Rest, wash and refreshment rooms for employees should be adequately separated from the storage areas. The presence of food, drink, smoking material or medicinal products for personal use should be prohibited in the

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		storage areas.
3.3.溫度及環境管制 (Temperature and Environment Control)		
3.3.1	應具備適當的設備及程序以確認藥品的儲存環境。需考量的環境因素包括作業場所的溫度、濕度、光線及清潔。	Suitable equipment and procedures should be in place to check the environment where medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.
3.3.2	儲存區應在代表性的條件下於開始使用前進行初步的溫度測繪評估。 溫度監測設備應依照測繪評估結果設置，以確保監測設備是位於歷經極端溫度波動的位置。溫度測繪評估應依風險評估於有重大改變時重複執行。若為數平方公尺之小型常溫作業場所，應執行潛在之風險評估(如冷或暖氣機)，並依照其評估結果放置溫度監測器。	An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise should be repeated for significant changes according to the results of a risk assessment exercise. For small premises of a few square meters which are at room temperature, an assessment of potential risks (e.g. heater/air-conditioner) should be conducted and temperature monitors placed accordingly.
3.4 設備 (Equipment)		
3.4.1	影響儲存及運銷藥品之所有設備應依照符合其預定目的的標準設計、設置、維護及清潔。操作具重要功能的關鍵設備，應規劃進行維護保養。	All equipment impacting on storage and distribution of medicinal products should be designed, located, maintained and cleaned to a standard which suits its intended purpose. Planned maintenance should be in place for key equipment vital to the functionality of the operation.
3.4.2	用於管制或監測藥品儲存環境之設備，應依風險與可靠性評估結果，在界定的時間間隔進行校正。	Equipment used to control or to monitor the environment where the medicinal products are stored should be calibrated at defined intervals based on a risk and reliability assessment.
3.4.3	設備的校正應可被追溯到國家或國際量測標準。設備應具備適當的	Calibration of equipment should be traceable to a national or international measurement standard. Appropriate

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	警報系統以在偏離預定儲存條件時發出警報，且設定適當地警報級別，並定期測試警報以確保功能正常運作。	alarm systems should be in place to provide alerts when there are excursions from predefined storage conditions. Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality.
3.4.4	設備的維修、維護及校正作業不得危害到藥品品質及完整性；在設備發生故障時，應有程序確保藥品維持其完整性。	Equipment repair, maintenance and calibration operations should be carried out in such a way that the quality and integrity of the medicinal products is not compromised. Procedures should be in place to ensure the integrity of medicinal products are maintained in the event of equipment failure.
3.4.5	應製作關鍵設備的維修、維護及校正作業紀錄，並保存結果。關鍵設備如冰庫、監測入侵者警報與入口管制系統、冷藏庫、溫濕度計或其他溫度與濕度記錄裝置、空氣處理裝置及供應鏈內使用的任何設備。	Adequate records of repair, maintenance and calibration activities for key equipment should be made and the results should be retained. Key equipment would include for example cold stores, monitored intruder alarm and access control systems, refrigerators, thermo hygrometers, or other temperature and humidity recording devices, air handling units and any equipment used in conjunction with the onward supply chain.
3.5 電腦化系統 (Computerised Systems)		
3.5.1	使用電腦化系統前，系統應顯示經適當的確效或確認，該系統能準確、持續且再現性地達到預期的結果。	Before a computerised system is brought into use, it should be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.
3.5.2	應可取得系統書面說明(適當時包括圖解)，此說明應不斷更新。文件應說明原則、目標、安全措施、系統範圍與主要功能(電腦化系統如何使用及與其他系統互動的方式)。	A written, detailed description of the system should be available (including diagrams where appropriate). This should be kept up to date. The document should describe principles, objectives, security measures, system scope and main features, how the computerised system is used and the way it interacts with other systems.

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3.5.3	僅有經授權的人員始得輸入或修改數據。	Data should only be entered into the computerised system or amended by persons authorised to do so.
3.5.4	數據應以物理或電子方法確保其不受意外或非授權的修改，儲存之數據應定期檢查其可存取性。 數據應定期備份，備份數據應依國內法令訂定保存時間，但至少在分開及安全的地點保存 5 年。	Data should be secured by physical or electronic means and protected against accidental or unauthorised modifications. Stored data should be checked periodically for accessibility. Data should be protected by backing up at regular intervals. Backup data should be retained for the period stated in national legislation but at least 5 years at a separate and secure location.
3.5.5	電腦系統失效或當機時遵循的程序應予以規範，應包括數據復原系統。	Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.
3.6 驗證及確效 (Qualification and Validation)		
3.6.1	批發運銷商應識別何種關鍵設備驗證、關鍵流程確效可確保其安裝及操作的正確性，驗證與確效作業(如儲存、揀貨與包裝流程及運輸)之範圍及程度應採文件化的風險評估方式。	Wholesale distributors should identify what key equipment qualification and/or key process validation is necessary to ensure correct installation and operation. The scope and extent of such qualification and/or validation activities (such as storage, pick and pack processes, transportation) should be determined using a documented risk assessment approach.
3.6.2	設備與流程在開始使用前及任何重大變更後(如維修或維護)應分別驗證或確效。	Equipment and processes should be respectively qualified and/or validated before commencing use and after any significant changes (e.g. repair or maintenance).
3.6.3	應準備確效與驗證報告，總結說明獲得的結果及評論任何觀測到的偏差；偏差應文件化並採取進一步行動以矯正偏差及避免重複發生，必要時應適用矯正預防措施(CAPA)。合格確效的證明及流程或設備的許可應由適當的人員製作及核准。	Validation and qualification reports should be prepared summarising the results obtained and commenting on any observed deviations. Deviations from established procedures should be documented and further actions decided to correct deviations and avoid their reoccurrence (corrective and preventive actions). The principles of CAPA should be applied where necessary. Evidence of

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		satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel
第 4 章文件(Chapter 4 Documentation)		
4.1 原則 (Principle)		
	優良文件是構成品質系統必要的部分，書面文件應避免來自口頭溝通的誤解，並容許藥品運銷相關作業的追蹤，進行每項作業時應記錄。	Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products. Records should be made at the time each operation is undertaken.
4.2 General(一般規定)		
4.2.1	文件包含以紙本或電子形式呈現的所有書面程序、指令、合約、紀錄及數據，文件應能立即取得/取回。	Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available/retrievable.
4.2.2	有關員工、申訴者或任何其他個人資料之處理，應依國內法令之規定存取。	With regard to the processing of personal data of employees, complainants or any other natural person, national legislation on the protection of individuals applies to the processing of personal data and to the free movement of such data.
4.2.3	關於批發運銷商活動範圍之文件應使員工充分地理解，並以員工可瞭解的語言書寫，書寫文件應使用明確的語言且應無錯誤。	Documentation should be sufficiently comprehensive with respect to the scope of the wholesale distributor’s activities and in a language understood by personnel. It should be written in clear, unambiguous language and be free from errors.
4.2.4	依規定，文件應由被指定之人員核准、簽章並註明日期。文件本身不得用手寫，但需要手寫填入數據時，應有足夠的空間供此類數據填入。	Documentation should be approved, signed and dated by designated persons, as required. It should not be handwritten; although, where it is necessary, sufficient space should be provided for such entries.
4.2.5	文件中所進行的任何變更應簽章	Any alteration made in the

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	並註明日期；該變更應允許讀取原來的資訊。適當時，更改理由應記錄之。	documentation should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.
4.2.6	文件應依國內法令所規定的期間保存，但至少 5 年。當個人資料不為運銷活動目的所需時，應予以刪除或匿名。	Documents should be retained for the period stated in national legislation but at least 5 years. Personal data should be deleted or anonymised as soon as their storage is no longer necessary for the purpose of distribution activities.
4.2.7	每位人員應可隨時取得與其執行作業相關之文件。	Each employee should have ready access to all necessary documentation for the tasks executed.
4.2.8	應特別留意使用有效並經核准的作業程序。文件應有明確的內容，其標題、性質及目的應清楚說明；文件應定期審查及更新，版本管制應納入作業程序內；文件經改版後，系統應有防止不慎使用先前版本的功能，被取代或廢棄的程序應從工作站移除及歸檔。	Attention should be paid to using valid and approved procedures. Documents should have unambiguous content; title, nature and purpose should be clearly stated. Documents should be reviewed regularly and kept up to date. Version control should be applied to procedures. After revision of a document a system should exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures should be removed from workstations and archived.
4.2.9	任何藥品接收、供應的交易紀錄需以發票、送貨單、電腦或任何其他形式保存。紀錄需至少包括下列資料：日期、藥品名稱，及接收與供應的數量，適當時應有供應商、客戶及受託者之名稱、地址，及批號、失效日期(依國內法令之規定)。適當時應有供應商、客戶與受託者之名稱與地址，及批號與失效日期(依國內法令之規定)。 記錄應與作業同時進行，且如為手寫，字跡應清楚、易讀且不得拭除。	Records must be kept either in the form of purchase/sales invoices, delivery slips, or on computer or any other form, for any transaction in medicinal products received or supplied. Records must include at least the following information: date; name of the medicinal product; quantity received, supplied; name and address of the supplier, customer, or consignee, as appropriate; and batch number, expiry date, as required by national legislation. Records are made contemporaneously and if handwritten, in clear, legible and indelible handwriting.

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第 5 章作業 (Chapter 5 Operations)		
5.1 原則 (Principle)		
	批發運銷商採取的所有作業應確保藥品識別之完整，以及藥品的批發運銷依照外包裝資料所提供的說明執行。批發運銷商應盡可能確保所有產品的來源，並採取所有可用的方法減少偽、禁藥進入合法供應鏈之風險。	All actions taken by wholesale distributors should ensure that the identity of the medicinal product is not lost and that the wholesale distribution of medicinal products is performed according to the information on the outer packaging. The wholesale distributor should use all means available to minimise the risk of falsified medicinal products entering the legal supply chain.
	批發運銷商之運銷之所有藥品必須取得中央衛生主管機關之許可。所有關鍵作業應於品質系統中適當文件化並充分描述。	All medicinal products distributed in the intended market by a wholesale distributor must be appropriately authorised by the national authorities. All key operations described below should be fully described in the quality system in appropriate documentation.
5.2 供應商之資格認可 (Qualification of Suppliers)		
5.2.1	批發運銷商必須從符合國內法令要求之供應者取得藥品。	Wholesale distributors must obtain their supplies of medicinal products only from persons who are themselves in possession of a wholesale distribution authorisation, or who are in possession of a manufacturing authorisation which covers the product in question.
5.2.2	從另一個批發運銷商取得藥品時，接收端必須確認供應的批發運銷商是否持有許可證，並遵守藥品優良運銷指引的原則與指引。	Where medicinal products are obtained from another wholesale distributor the receiving wholesale distributor must verify that the supplier complies with the principles and guidelines of good distribution practices and that they hold a licence.
5.2.3	在進行任何藥品採購之前，應對供應商進行適當的資格認可及核准。此作業應以程序管制，且其結果應文件化並使用風險導向之方法定期審閱。	Appropriate qualification and approval of suppliers should be performed prior to procurement of any medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked using a risk based approach.
5.2.4	批發運銷商在與新的供應商締結	When entering into a new contract with new suppliers the wholesale distributor

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	新合約時，應進行實質檢核(‘due diligence’ checks)以評估其供應藥品的適當性、能力及可靠性，需特別注意：	should carry out ‘due diligence’ checks in order to assess the suitability, competence and reliability of the other party. Attention should be paid to:
	i)供應商的聲譽或可靠性；	i) the reputation or reliability of the supplier;
	ii)供應的藥品是否可能為偽、禁藥；	ii) offers of medicinal products more likely to be falsified;
	iii)大量供應通常僅能限量取得的藥品；	iii) large offers of medicinal products which are generally only available in limited quantities;
	iv)供應商所經手產品之多樣性	iv) diversity of products handled by supplier;
	v)價格超出範圍。	v) and out-of-range prices.
5.3 客戶的認可 (Qualification of Customers)		
5.3.1	批發運銷商須確保其藥品只能供應給符合國內法令要求之對象。	Wholesale distributors must ensure they supply medicinal products only to persons who are themselves in possession of a wholesale distribution authorisation or who are authorised or entitled to supply medicinal products to the public or otherwise authorised to procure medicinal products from a distributor (for example medicinal products intended for clinical trials).
5.3.2	檢查及定期複查客戶持有藥品販賣之許可文件及其他相關證明文件(依據國內法令)。	Checks and periodic rechecks may include: requesting copies of customer's authorisations, verifying status on an authority website, requesting evidence of qualifications or entitlement according to national legislation.
5.3.3	有風險性之藥品交易時（如麻醉藥，治療精神異常用藥），批發運銷商應監測及調查任何異常情況；如有挪用或誤用藥品之異常銷售情形時，應予以調查，必要時，向衛生主管機關通報；應採取步驟，以確保履行其所肩負的任何公共服務責任。	Wholesale distributors should monitor their transactions and investigate any irregularity in the sales patterns of medicinal products at risk of diversion (e.g. narcotics, psychotropic substances). Unusual sales patterns that may constitute diversion or misuse of medicinal product should be investigated and reported to competent authorities where necessary. Steps should be taken to ensure fulfilment of any public service

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		obligation imposed upon them.
5.4 收貨 (Receipt of medicinal products)		
5.4.1	收貨之目的是確保抵達的貨物正確無誤、藥品來自核准的供應商，以及貨物在運送期間未明顯地受損。	The purpose of the receiving function is to ensure that the arriving consignment is correct, that the medicinal products originate from approved suppliers and that they have not been visibly damaged during transport.
5.4.2	藥品需要進行特殊的處理、儲存或安全措施時應優先處理，一旦進行適當的檢查後，應立即送至適當的儲存設施。	Medicinal products requiring special handling, storage or security measures should be prioritised and once appropriate checks have been conducted they should be immediately transferred to appropriate storage facilities.
5.4.3	藥品未得到書面授權可銷售前，該等批次不得移至可銷售品庫存。	Batches of medicinal products should not be transferred to saleable stock before assurance has been obtained in accordance with written procedures, that they are authorised for sale.
5.4.4	若懷疑為偽、禁藥品，應將該批次藥品隔離，並依國內法令之規定通報主管機關。	If a falsified product is suspected, the batch should be segregated and reported to competent authorities as required by national legislation.
5.5 儲存 (Storage)		
5.5.1	藥品與保健食品(必要時)應與其他可能改變藥品(或保健食品)本質的產品分開儲存，且不得受到光線、溫度、濕度及其他外部有害因素的影響；需要特定儲存條件之產品應特別注意。	Medicinal products and, if necessary, healthcare products should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention should be paid to products requiring specific storage conditions.
5.5.2	必要時，進廠藥品之容器在儲存前應予以清潔。對進廠貨物進行的任何行為（如煙燻），不得影響到藥品品質。	Incoming containers of medicinal products should be cleaned, if necessary, before storage. Any activities performed on the incoming goods (e.g. fumigation) should not impact on the quality of the medicinal products.
5.5.3	倉儲作業須確保維持適當的儲存條件且提供適當的庫存安全。	Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks.

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5.5.4	庫存應依照先到期先出貨原則運作，若有例外情形應予以記錄。	Stock should be rotated according to the first expiry, first out (FEFO) principle. Exceptions should be documented.
5.5.5	藥品應以防止溢漏、破損、污染及混雜的方式處理及儲存。藥品不得直接存放於地板上，除非該包裝具特定儲存設計(例如部分醫用氣體鋼瓶)。	Medicinal products should be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Medicinal products should not be stored directly on the floor unless the package is designed to allow such storage (such as for some medicinal gas cylinders).
5.5.6	接近有效期間或保存期限的藥品，應立即從可銷售品庫存移開。	Medicinal products that are nearing their expiry date/shelf life should be withdrawn immediately from saleable stock.
5.5.7	應依國內法規要求定期進行庫存盤點，異常情形應予以調查並文件化，必要時應通報主管機關。	Stock inventories should be performed regularly taking into account national legislation requirements. Stock irregularities should be investigated, documented and reported to the competent authorities when needed.
5.6 廢棄物銷毀 (Destruction of obsolete Goods)		
5.6.1	要銷毀的藥品應適當標示、分開儲存且依照書面程序處理。	Medicinal products intended for destruction should be appropriately identified, held separately and handled in accordance with a written procedure.
5.6.2	藥品銷毀應依照處置該類產品之國內或國際關於處理、運送、處置之要求。	Destruction of medicinal products should be in accordance with national or international requirements for handling, transport and disposal of such products.
5.6.3	所有銷燬藥品的紀錄應依所界定期限予以保存。	Records of all destroyed medicinal products should be retained for a defined period.
5.7 揀貨 (Picking)		
	應具備適當的管制方式以確保揀選出正確且仍有適當架儲期的產品。	Controls should be in place to ensure the correct product is picked. The product should have an appropriate remaining shelf life when it is picked.
5.8 供應(Supply)		
	所有供應附上之文件(如送貨單/包裝清單)須述明日期、藥品名稱與劑型、藥品批次號碼、失效日期(依	For all supplies, a document (e.g. delivery note/packing list) must be enclosed stating the date; name and

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	國內法令之規定)、供應數量、供應商名稱與地址、收貨人的姓名、送貨地址及適用的運送與儲存條件。紀錄應予以保存，以追蹤產品的實際流向。	pharmaceutical dosage form of the medicinal product, batch number ,expiry date, as required by national legislation; quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) and applicable transport and storage conditions. Records should be kept so that the actual location of the product can be known.
5.9 輸入與輸出 (Import and export)		
5.9.1	藥品輸入及輸出應依國內法令之規定及國際準則或標準執行。批發商應採取適當措施，以防止未授權之藥品及外銷用藥品流通於國內市場。	Import and export activities should be conducted in accordance with national legislation and with international guidelines or standards when appropriate. This is also the case if the wholesale distributor is holding medicinal product in a free zone. Wholesalers should take the appropriate measures in order to prevent medicinal products not authorised for the internal market and intended for export from reaching the internal market.
5.9.2	當批發運銷商從其他國家取得藥品時，必須確保其代理商經授權或依主管機關之規定可供應藥品。當批發運銷商供應其他國家藥品時，必須確保其代理商經授權或依主管機關之規定可取得藥品。	Where wholesale distributors obtain/supply medicinal products from/to other countries, they must ensure that entities are authorised or entitled to supply/receive medicinal products in accordance with the applicable legal and administrative provisions of the countries concerned.
第 6 章 申訴、退回、疑似偽、禁藥及藥品回收 (Chapter 6 Complaints, Returns, suspected falsified Medicinal Products and Medicinal Product Recalls)		
6.1 原則 (Principle)		
	所有申訴、退回、疑似偽、禁藥及回收品須記錄且依書面程序謹慎處理，紀錄應可供主管機關隨時取得。任何退回品在取得重新銷售核准前，應由指定人員執行評估。若要成功打擊偽、禁藥，需供應鏈內的所有成員使用一致的方式。	All complaints, returns, suspected falsified medicinal products and recalls must be recorded and handled carefully according to written procedures. Records should be made available to the competent authorities. An assessment of returned medicinal products should be performed by designated personnel before any approval for resale. A

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		consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified medicinal products.
6.2 申訴 (Complaints)		
6.2.1	申訴應記錄所有原始細節，應區分藥品品質及運銷相關的申訴；如發生關於藥品品質及疑似產品瑕疵之申訴，應立即通知製造商及/或上市許可持有人；任何產品運銷之申訴應詳細調查以確認申訴的來源或原因。	Complaints should be recorded with all the original details. A distinction should be made between complaints related to the quality of a medicinal product and those related to distribution. In the event of a complaint about the quality of a medicinal product and a potential product defect, the manufacturer and/or marketing authorisation holder should be informed without delay. Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint.
6.2.2	如發現或懷疑藥品有瑕疵，應考慮調查該藥品之其他批次。	If a defect relating to a medicinal product is discovered or suspected, consideration should be given to whether other batches of the product should also be investigated.
6.2.3	應指定人員負責處理申訴問題。	A person should be appointed to handle complaints.
6.2.4	必要時，申訴經調查及評估後，應採取適當的後續追蹤調查行動(包含 CAPA)，並通知主管機關。	If necessary, appropriate follow-up actions (including CAPA) should be taken after investigation and evaluation of the complaint, including where required notification to the national competent authorities.
6.3 退回品 (Returned Medicinal Products)		
6.3.1	退回品須依書面流程處理，此流程應將與產品有關的風險基礎、任何特殊儲存要求及藥品自原始出貨後所經歷的時間等納入考量。退回作業應依主管機關之規定及合約處理，且須維持退回品之紀錄/清單。	Returned products must be handled according to a written, risk based process taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched. Returns should be conducted in accordance with national legislation, and contractual arrangements between the parties. A record/ list of returned goods must be maintained.

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6.3.2	已離開運銷商作業場所之藥品，只有在確認符合以下所有情況，才能退回到可銷售品庫存：	Medicinal products which have left the premises of the distributor should only be returned to saleable stock if all of the following are confirmed:
	i)藥品的外包裝(secondary package)未開封、未受損、狀態良好、未過期且未曾被回收。	i) the medicinal products are in their unopened and undamaged secondary packaging and are in good condition; have not expired and have not been recalled;
	ii)由藥局退回之藥品，僅在經評估可接受的時間限制內，始可退回至可銷售品庫存。	ii) medicinal products returned from a customer not holding a wholesale distribution authorisation or from pharmacies authorised to supply medicinal products to the public should only be returned to saleable stock if they are returned within an acceptable time limit, for example 10 days;
	iii)經客戶證明藥品之運送、儲存及處理符合特定的儲存要求。	iii) it has been demonstrated by the customer that the medicinal products have been transported, stored and handled in compliance with the specific storage requirements;
	iv)藥品已由接受充分地訓練且經授權之勝任人員進行檢查及評估。運銷商有合理證據證明產品已供應至該客戶(如透過原始送貨單影本或相關發票號碼影本、藥品批次號碼、失效日期等，依國內法令之規定)，且無理由懷疑該藥品為偽、禁藥。	iv) they have been examined and assessed by a sufficiently trained and competent person authorised to do so; the distributor has reasonable evidence that the product was supplied to that customer (via copies of the original delivery note or by referencing invoice numbers/batch numbers, expiry date etc., as required by national legislation), and that there is no reason to believe that the product has been falsified.
6.3.3	需要特殊儲存條件(如低溫)之藥品，只有在文件證明產品於整個期間一直儲存在允許的儲存條件內，才能退回至可銷售品庫存。若有任何偏差發生，須在可證明產品完整性的條件下進行風險評估。其證明應涵蓋下列過程： (i)-運送至客戶； (ii)-產品之檢查；	Moreover, for medicinal products requiring specific temperature storage conditions such as low temperature, returns to saleable stock can only be made if there is documented evidence that the product has been stored under the authorised storage conditions throughout the entire time. If any deviation has occurred a risk assessment has to be performed, on which basis the

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	(iii)-運送包裝之拆封； (iv)-退回產品之包裝； (v)-收集產品並退回給運銷商； (vi)-運輸過程中的溫度紀錄； (vii)-退回運銷點的冷藏庫。	integrity of the product can be demonstrated. The evidence should cover: i) delivery to customer; ii) examination of the product; iii) opening of the transport packaging; iv) return of the product to the packaging; v) collection and return to the distributor; vi) record of temperature readings during transportation; vii) return to the distribution site refrigerator.
6.3.4	退回至可銷售品庫存之產品，其放置應使先到期先出(FEFO)之系統有效運作。	Products returned to saleable stock should be placed such that the 'first expired first out' (FEFO) system operates effectively.
6.3.5	遭竊後取回之產品不得回至可銷售品庫存及販賣給消費者。	Stolen products that have been recovered cannot be returned to saleable stock and sold to customers.
6.4 偽、禁藥(Falsified Medicinal Products)		
6.4.1	應立即停止疑似偽、禁藥的銷售及運銷。	The sale and distribution of a suspected falsified medicinal product should be suspended immediately.
6.4.2	批發運銷商識別出任何偽、禁藥或疑似偽、禁藥，必須立即通知主管機關及上市許可持有人，並依主管機關指示執行相關作業；應具備程序確認上述作業執行之有效性，並記錄所有原始細節及調查。	Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified and act on the instructions as specified by the competent authority. A procedure should be in place to this effect. It should be recorded with all the original details and investigated.
6.4.3	任何於供應鏈發現之偽、禁藥，應立即進行實體隔離，並存放於遠離其他藥品之專用區域，且應適當標示。所有相關活動應予以文件化並保留紀錄。	Any falsified medicinal products found in the supply chain should immediately be physically segregated and stored in a dedicated area away from all other medicinal products and be appropriately labelled. All relevant activities in relation to such products should be documented and records retained.

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6.4.4	確認為偽、禁藥時，應有正式處置決策，將該產品從市場下架，包括因應公共衛生、法規或法律需求所保留的任何必要樣本，以確保產品不會重新進入供應鏈。所有相關決策應適當予以記錄。	Upon confirmation as a falsified medicinal product, a formal decision should be taken on removal of such product from the market, ensuring that it does not re-enter the supply chain, including retention of any samples necessary for public health, regulatory, or legal needs and arrangements for its disposal. All related decisions should be appropriately documented.
6.5 藥品回收(Medicinal Product Recalls)		
6.5.1	應具備適當文件及程序以確保產品接收與運銷之追溯，以利產品回收。	There should be documentation and procedures in place to ensure traceability of products received and distributed, to facilitate product recall.
6.5.2	如發生產品回收之情形，應依緊急程度通知產品運銷的所有客戶及告知清楚的行動指令。	In the event of a product recall, all customers to whom the product has been distributed shall be informed with the appropriate degree of urgency and clear actionable instructions.
6.5.3	所有產品回收應告知主管機關，如產品已輸出，須依國內法令之規定通知國外的主管機關及/或監管機關回收該產品。	The national regulatory authority should be informed of all product recalls. If the product is exported, the overseas counterparts and/or regulatory authorities must be informed of the recall as required by national legislation.
6.5.4	應定期評估藥品回收作業安排之有效性(至少每年一次)。	The effectiveness of the arrangements for product recall should be evaluated regularly (at least annually).
6.5.5	回收作業在任何時候應能立即啟動。	Recall operations should be capable of being initiated promptly and at any time.
6.5.6	運銷商必須遵守回收訊息的指令，必要時，該回收訊息應經主管機關核准。	The distributor must follow the instructions of a recall message, which should be approved, if required, by the competent authorities.
6.5.7	執行任何回收作業時應即時記錄，並將紀錄立即提供給主管機關。	Any recall operation should be recorded at the time it is carried out. Records should be made readily available to the competent authorities.
6.5.8	運銷紀錄應使回收權責人員易於取得，且應包含關於運銷商及直接銷售客戶的充分資訊(連同地址、	The distribution records should be readily accessible to the person(s) responsible for the recall, and should

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	上下班時間的電話與傳真號碼、送交的批次號碼(依主管機關規定)及數量)，包含輸出產品及藥品樣品在內(依國內法令之規定)。	contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batch numbers as required by national legislation and quantities delivered), including those for exported products and medicinal product samples (if permitted by national legislation).
6.5.9	回收作業之進度應予記錄並提出最終報告，包括回收藥品之數量調和。	The progress of the recall process should be recorded for a final report including reconciliation of the recalled product.
第 7 章委外作業 (Chapter 7 Outsourced Activities)		
7.1 原則 (Principle)		
	任何本指引所涵蓋之委外作業應清楚界定、同意且管制，以避免發生可能影響產品完整性之誤解。委託者與受託者之間須有書面合約，合約中清楚訂定雙方責任歸屬。	Any activity covered by the GDP Guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party.
7.2 委託者 (Contract Giver)		
7.2.1	委託者負責將作業外包。	The Contract Giver is responsible for the activities contracted out.
7.2.2	委託者負責評估受託者確實履行要求之工作能力，確保本指引所闡述之藥品優良運銷指引的原則與指引受到遵循。委外作業開始前及有變更時，應進行受託者之稽核，稽核頻率應基於委外作業之風險予以規範，委託者應可隨時進行稽核。	The Contract Giver is responsible for assessing the competence of the Contract Acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. An audit of the Contract Acceptor should be performed before commencement of, and whenever there has been a change to, the outsourced activities. The requirement for audit and frequency should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.
7.2.3	委託者應提供受託者所有必要的	The Contract Giver should provide the

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	資訊，以使其依照特定之產品要求及任何其他相關要求，正確履行約定的作業。	Contract Acceptor with all the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.
7.3 受託者 (Contract Acceptor)		
7.3.1	受託者應負責 GDP 涵蓋範圍及委託者委派之活動。	The Contract Acceptor is responsible for the activities covered by GDP and delegated by the Contract Giver.
7.3.2	受託者應有適當的作業場所與設備、程序、知識與經驗及勝任人員，以執行委託者所託付的工作。	The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the Contract Giver.
7.3.3	受託者未經委託者事先評估、核准該等安排及稽核第三方(由委託者或受託者執行)前，不得將契約所委託的任何工作轉託給第三方。受託者及任何第三方間所作的安排，應確保批發運銷提供之資料是依照委託者及受託者原約定的方式。	The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party by the Contract Giver or the Contract Acceptor. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.
7.3.4	受託者應避免對受託處理之產品品質可能造成不良影響的任何活動。	The Contract Acceptor should refrain from any activity which may adversely affect the quality of the product(s) handled for the Contract Giver.
7.3.5	受託者必須依照合約要求，向委託者提交任何可能影響產品品質之資訊。	The Contract Acceptor must forward any information that can influence the quality of the product(s) to the Contract Giver in accordance with the requirement of the contract.
第 8 章 自我查核 (Chapter 8 Self-Inspections)		
8.1 原則 (Principle)		
	為監測 GDP 原則之執行與符合性，及提出必要的矯正措施，應執行自我查核。	Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to

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		propose necessary corrective measures.
8.2 自我查核 (Self-Inspections)		
8.2.1	應在界定的時間範圍內執行自我查核計畫，包含 GDP 各方面之法規、指引及程序的符合性。自我查核在限定範圍內可切割為數個個別的自我查核主題。	A self-inspection programme should be implemented covering all aspects of GDP and compliance with the regulations, guidelines and procedures within a defined time frame. Self-inspections may be divided into several individual self- inspections of limited scope.
8.2.2	自我查核應由公司指定內部的勝任人員，以公正且詳細的方式執行。獨立的外部專家稽核也可能有幫助，但不得以此取代自我查核。	Self-inspections should be conducted in an impartial and detailed way by designated competent company personnel. Audits by independent external experts may also be useful but may not be used as a substitute for self-inspection.
8.2.3	所有自我查核應予記錄，報告應包含在查核期間所執行之所有觀察，報告影本應提供給管理者及其他相關人員；若發現異常及缺失應確定其原因，且矯正預防措施(CAPA)應文件化及追蹤。	All self-inspections should be recorded. Reports should contain all the observations made during the inspection. A copy of the report should be provided to the management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their cause should be determined and the corrective and preventive actions (CAPA) should be documented and followed up.
第 9 章 運輸 (Chapter 9 Transportation)		
9.1 原則 (Principle)		
9.1.1	批發運銷商的職責，是在供應藥品時防止藥品破損、摻假、竊盜，及確保在運送時維持在可接受的溫度條件下。	It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration, theft, and to ensure that temperature conditions are maintained within acceptable limits during transport.
9.1.2	在任何運送模式下，都應能夠證明藥品不會暴露在可能危害藥品品質及完整性的狀況，且應基於風險考量規劃運輸路線。	Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.

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9.2 運輸 (Transportation)		
9.2.1	藥品在運輸過程所需的儲存條件，應維持在外包裝及相關包裝資訊所描述之界定範圍。	The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the outer packaging and/or relevant packaging information.
9.2.2	若在運輸時發生偏差，如溫度偏離或產品毀損，應通報運銷商及受影響藥品之收貨者，且應有調查及處理溫度偏離情況的程序。	If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported to the distributor and recipient of the affected medicinal products. A procedure should also be in place for investigating and handling temperature excursions.
9.2.3	批發運銷商的職責，是確保用於運銷、儲存或處理藥品的車輛與設備適合其預定用途，且裝備適當，以防止產品暴露在可能影響其品質及包裝完整性的情況。	It is the responsibility of the wholesale distributor to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity.
9.2.4	所有參與運銷流程之車輛及設備，應備有操作及維護的書面程序，包括清潔及安全注意事項。	There should be written procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.
9.2.5	溫度管制需求應依運送路線的風險評估決定。運送時，在車輛及裝存箱櫃內用於監測溫度的設備，應定期進行維護及校正。	Risk assessment of delivery routes should be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles and/or containers, should be maintained and calibrated at regular intervals.
9.2.6	運送藥品時，應盡可能使用專用的車輛與設備；使用非專用的車輛與設備時，應有適當的程序以確保不會危及藥品品質及完整性。	Dedicated vehicles and equipment should be used, where possible, when handling medicinal products. Where non-dedicated vehicles and equipment are used procedures should be in place to ensure that the quality and integrity of the medicinal product will not be

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		compromised.
9.2.7	貨物應送至送貨單上所標示的地址，且應交給收貨者或其作業場所，藥品不得留在任何替代的作業場所。	Deliveries should be made to the address stated on the delivery note and into the care or the premises of the consignee. Medicinal products should not be left on alternative premises.
9.2.8	在正常營業時間外之緊急運送，應指定特定人員且有書面程序。	For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available.
9.2.9	運輸若由第三方執行時，合約應包含第七章之要求，批發運銷商應告知並確保運輸者運輸相關之所有條件。當運輸過程中有上、下貨或經轉運站時，應特別注意其儲存設施之溫度監測、清潔及安全性。	Where transportation is performed by a third party, the contract in place should encompass the requirements of Chapter 7. Transportation providers should be made aware by the wholesale distributor of the relevant transport conditions applicable to the consignment. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.
9.2.10	產品於運送路程中，應有措施縮短產品進入下一階段運輸前的暫存時間。	Provision should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route
9.3 裝存箱櫃、包裝及標示 (Containers, packaging and labelling)		
9.3.1	藥品應在對品質不會產生不良作用及適當保護其免受外在影響(如污染)之裝存箱櫃中運送。	Medicinal products should be transported in containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.
9.3.2	選擇裝存箱櫃及包裝時，應考量藥品儲存與運送的要求、藥品數量所需的空間、預期外部極端溫度、儲存在海關過境之最長時間、包裝的驗證狀態及運輸容器的確效狀態。	Selection of a container and packaging should be based on the storage and transportation requirements of the medicinal products; the space required for the amount of medicines; the anticipated external temperature extremes; the estimated maximum time for transportation including transit storage at customs; the qualification

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		status of the packaging and the validation status of the shipping containers.
9.3.3	裝存箱櫃應標示處理與儲存要求及其他注意事項的充足資訊，以確保藥品在任何時候都經過妥善處理及保護。裝存箱櫃應能夠識別其內容物及來源。	Containers should bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. The containers should enable identification of the contents of the containers and the source.
9.4 需要管制條件的產品 (Products requiring controlled Conditions)		
9.4.1	運送需特殊管制的藥品，如麻醉藥或治療精神異常用藥，批發運銷商應依照國內法令之要求，維持安全及可靠的供應鏈；應有附加的管制系統規範這些藥品之運送，並有計畫書來處理發生的任何竊盜事件。	In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances, the wholesale distributor should maintain a safe and secure supply chain for these products in accordance with requirements laid down in national legislation. There should be additional control systems in place for delivery of these products. There should be a protocol to address the occurrence of any theft.
9.4.2	應以安全、專用及可靠的裝存箱櫃與車輛運送高活性及放射性的藥品，相關安全措施應遵守國際協議及國內法令之規定。	Medicinal products comprising highly active and radioactive materials should be transported in safe, dedicated and secure containers and vehicles. The relevant safety measures should be in accordance with international agreements and national legislation.
9.4.3	對於溫度敏感的產品，應使用經驗證的設備(例如保溫包裝、溫控裝存箱櫃或溫控車)，以確保產品在製造商、批發運銷商及客戶間運送時，維持在正確的運輸條件。	For temperature-sensitive products, qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and customer.
9.4.4	溫控車在運送時所使用的溫度監測設備應定期進行維護及校正，並於代表性條件下執行溫度測繪，且	If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular

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	應考量季節變化(必要時)。	intervals. Temperature mapping under representative conditions should be carried out and should take into account seasonal variations, if applicable.
9.4.5	如客戶要求時，應提供相關資料，以證明產品維持在溫度儲存條件內。	If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions.
9.4.6	在隔熱箱使用保冷劑時，須放在不會與產品直接接觸之處，員工必須接受組裝隔熱箱(季節性配置)及重複使用保冷劑相關程序之訓練。	If cool packs are used in insulated boxes, they need to be located such that the product does not come in direct contact with the cool pack. Staff must be trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool packs.
9.4.7	應有系統可管制保冷劑的重複使用，確保不會誤用到未完全冷卻的保冷劑。冷凍保冷劑及冷藏保冷劑應有適當的實體隔離。	There should be a system in place to control the reuse of cool packs to ensure that incompletely cooled packs are not used in error. There should be adequate physical segregation between frozen and chilled ice packs.
9.4.8	應有書面程序說明溫度敏感產品之運送流程及季節性溫度變化的管制。	The process for delivery of sensitive products and control of seasonal temperature variations should be described in a written procedure.

術語表

用詞	中譯	原文
Competent Authority 主管機關	對於在其管轄地區的藥品批發運銷具有法律上授予職權、資格或權力的管轄機關。	Organisation that has the legally delegated or invested authority, capacity or power over wholesaling of medicinal products in the jurisdiction in which it is located.
Contract Acceptor 受託者	執行委託者委託之 GDP 涵蓋範圍活動的公司	The company who is contracted to conduct an activity covered by GDP by the contract giver.
Contract Giver 委託者	將 GDP 涵蓋範圍之任何活動委託給另一個合法機構的公司。	The company who is contracting out any activity covered by GDP to another legal entity.
Due diligence 實質檢核	這是用於多概念之術語，包含在簽署合約前對企業或人員進行的調查，或確認其符合特定標準。	This is a term used for a number of concepts, involving either an investigation of a business or persons prior to signing a contract, or an act with a certain standard of care.
Export 輸出	允許貨物離開國家海關領域或經濟區域。	Allow goods to leave the customs territory of the country or economic area.
Falsified (counterfeit) medicinal product 偽/禁(仿冒)藥	歐洲經濟區內： 任何具有下列不實陳述之藥品： a) 藥品的識別，包括其包裝及標示、名稱或關於任何成分的組成，包括賦形劑及這些成分的效力； b) 其來源，包括其製造商、製造國家、其原產國或販賣許可持有者；或 c) 其紀錄，包括與運銷途徑相關的紀錄與文件。 來源：2013/C 343/01	<u>Within the EEA:</u> “Any medicinal product with a false representation of: a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or c) its history, including the records and documents relating to the distribution channels used.” <u>Source: 2013/C 343/01</u>

	歐洲經濟區外： 任何藥品其蓄意地、不實地貼錯有關藥品識別及/或來源之標籤。 仿冒可同時適用於原廠藥與學名藥。仿冒品可能包括其產品含正確或錯誤之成份、不含有效成分、具有不足(不足量)之活性成分或偽造包裝。 來源：WHO Technical Report	Outside the EEA: Any medicinal product "which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of) active ingredient(s) or with fake packaging." Source: WHO Technical Report Series, No. 957, 2010
Free zones and free warehouses 自由貿易區與自由倉庫	依據國家海關之法規，自由貿易區與自由倉庫是國家海關領域或經濟區域或位於該領域之設施的一部分且與其他部分分開。	Free zones and free warehouses are parts of the customs territory of the country or economic area or premises situated in that territory and separated from the rest of it in accordance with national customs regulations.
Good Distribution Practice (GDP) 藥品優良運銷指引	GDP 是品質保證的一部分，確保藥品品質在供應鏈上所有階段皆被維持，包含從製造廠到藥局或經授權供應藥品給大眾之人員。	GDP is that part of quality assurance which ensures that the quality of medicinal 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 medicinal products to the public.
Holding 儲存	儲存藥品。	Storing medicinal products.
Import 輸入	允許貨物進入海關領域或經濟區域。	Allow goods to enter the customs territory of the country or economic area.
Manufacturing Licence 藥品製造許可	國家主管機關所核發之可製造(與運銷)藥品的書面授權許可。	A written authorisation from the national regulatory authority to manufacture (& distribute) those medicinal products covered under the licence.

Procuring 採購	從製造商、進口商或其他批發運銷商取得、獲得、或購買藥品。	Obtaining, acquiring, purchasing or buying medicinal products from manufacturers, importers or other wholesale distributors.
Public Service Obligations 公共服務責任	執照持有者/許可證持有者對於已在其管轄區上市且在職責範圍內的藥品應確保適當並持續供應，以涵蓋管轄區內病患之需求。	The authorisation/licence holder shall, in respect of a medicinal product that has actually been placed on the market in its jurisdiction and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product so that the needs of patients in its jurisdiction in respect of such medicinal product are covered.
Qualification 驗證	證明任何設備的運轉正常且確實能達到預期結果的行為。 確效一詞有時會廣義包含驗證的概念。	Action of proving that any equipment works correctly and actually leads to the expected results. The word validation is sometimes widened to incorporate the concept of qualification.
Quality Risk Management 品質風險管理	在產品生命週期間針對藥品品質風險之評估、管制、溝通及審查的系統化流程。	A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product life cycle.
Quality System 品質系統	執行品質政策及確保符合品質目標之系統各方面的總稱。(ICH，Q9)。	The sum of all aspects of a system that implements quality policy and ensures that quality objectives are met. (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Q9)
Supplying 供應	所有提供、銷售、捐贈藥品至批發商、藥師、經授權供應藥品給大眾之人員的活動。	All activities of providing, selling, donating medicinal products to wholesalers, pharmacists, or persons authorised or entitled to supply medicinal products to the public.

Suspected falsified (counterfeit) medicinal product 疑似偽/禁(仿冒)藥	任何疑似具有下列不實陳述之藥品： a) 藥品的識別，包括其包裝及標示、名稱或關於任何成分的組成，包括賦形劑及這些成分的效力； b) 其來源，包括其製造商、製造國家、其原產國或販賣許可持有者；或 c) 其紀錄，包括與運銷途徑相關的紀錄與文件。	Any medicinal product suspected to have a false representation of: a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or c) its history, including the records and documents relating to the distribution channels used.
Temperature 溫度	冷凍：低於 -15 ℃ 冷藏：+2 到+8 ℃ 低溫：+8 到+ 15 ℃ 室溫：+15 到+ 25 ℃ 環境溫度：非冷藏藥品所需的儲存溫度；通常於產品上標示為「儲存於 25 ℃ 以下」或「儲存於 30 ℃ 以下」。	Deep freeze : Below -15 ℃ In a refrigerator : +2 to +8 ℃ Cold or Cool: +8 to + 15 ℃ Room Temperature: +15 to + 25 ℃ Ambient: The required storage temperature of non refrigerated medicinal product; usually stated on the product as ‘store below 25 °C’ or ‘store below 30 °C’.
Transport 運送	在兩個地點之間移動藥品，其存放未超過不當的時間。	Moving medicinal products between two locations without storing them for unjustified periods of time.
Validation 確效	證明任何程序、流程、設備、材料、活動或系統確實能達到預期結果的行為(也可參見驗證)。	Action of proving that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also Qualification).
Wholesale distribution 批發運銷	藥品的批發運銷包含採購、儲存、供應、輸入或輸出藥品之所有活動，但不包含供應藥品給大眾。	Wholesale distribution of medicinal products is all activities consisting of procuring, holding, supplying, importing or exporting medicinal products, apart from supplying medicinal products to the public.
Wholesale distributor 批發運銷商	進行批發運銷活動的操作者。	Operator who conducts wholesale distribution activities.