國際醫藥品稽查協約組織
藥品優良運銷規範
(草案)

PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS
PE 011 (Draft 1, 20 August 2013)

目錄

(Table of Contents)

	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.
	所有運銷活動應經清楚規範，並且經過系統式審查，運銷流程的所有關鍵性步驟和重大變更都應證明其正當性並經確效。	All distribution activities should be clearly defined 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	管理品質系統應包含組織架構、程序、流程與資源及必要之活動，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出自合法供應鏈。	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，並監督其有效性。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	被指定之負責人員應由管理部門指派，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所有的品質系統，皆有稱職人員及適當足	The management of the distributor should ensure that all parts of the

	夠的作業場所、設備及設施等資源。	quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.
1.2.5	開發或修改品質系統時，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、存放、供應、輸入或輸出均符合藥品優良運銷規範的要求；	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)已建立程序的偏差要予以文件化與調查；	v)deviations from established procedures are documented and investigated;
	vi)採取適當的矯正預防措施(CAPA)，以依照品質風險管理原則矯正並防止偏差情況。	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、存放、供應、輸入或輸出之委外作業的管制及審查。此流程應包含品質風險管理並包括：	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的適合性及能力，必要時檢查授權狀態；	i)assessing the suitability and competence of the Contract Acceptor to carry out the activity and checking

		authorisation status, if required;
	ii)規範參與者品質相關活動的職責及溝通流程。	ii)defining the responsibilities and communication processes for the quality-related activities of the parties involved;
	iii)監測及審查受託者的績效，以及定期確認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 管理部門審查及監督 (Management Review and Monitoring)		
1.4.1	管理者應依正式流程定期審查品質系統。其應包括：	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、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, 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	每一項品質系統的審查結果應及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.
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式流程。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、程序經驗及最終連結到病患保護為主。此程序的執行、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 指導方針。	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稱職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 一般人員(General)		
2.2.1	應具備足夠數量的稱職人員參與所有階段的藥品批發運銷活動，所需人員數量視作業範圍及作業量而定。	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出組織架構，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 all personnel should be clearly indicated.
2.2.3	居關鍵位置員工職務之角色與職責，以及其代理人制度之安排，應建立書面工作說明。	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 指定之負責人員(Designation of responsibilities)		
2.3.1	批發運銷商必須指定符合藥品優良運銷規範之負責人員。相關人員應具有適當的能力與經驗以及瞭解藥品優良運銷規範與接受藥品優良運銷規範的訓練。	The wholesale distributor must designate personnel responsible for GDP compliance. Relevent 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（如緊急事件和/或回收）。被指定之負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. emergiencies and/or recall). Designated responsible person(s) may delegate duties but not responsibilities.
2.3.3	被指定之負責人員的書面職務說明應規範其作出與其職責相關決策的授權。批發運銷商應清楚地授予被指定之負責人員履行其義務的權限、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	被指定之負責人員應以確保批發運銷商遵守藥品優良運銷規範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	被指定之負責人員的職責包括，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)著重於授權活動管理及紀錄之準確度與品質；	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 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)確保有效處理相關的客戶申訴；	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)核准所有可能影響藥品優良運銷規範之轉委託作業	vii) approving any subcontracted activities which may impact on GDP;
	viii)確保在事先安排之計畫後，適當的定期間隔內進行自我查核，且應具備必要的矯正措施；	viii) ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;
	ix)保存關於代理職務的適當紀錄；	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)核准所有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加諸的其他要求	xii) ensuring that any additional requirements imposed on certain products by national law 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藥品優良運銷規範要求之訓練，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書面訓練計畫，接受與其職務相關的職前及持續訓練。被指定之負責人員也應透過定期訓練維持其藥品優良運銷規範執行能力。	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方面以及避免偽/禁藥進入供應鏈。	In addition, training should include aspects of product identification and avoidance of falsified medicines entering the supply chain.
2.4.4	需以更嚴謹條件處理之產品有關	Personnel dealing with any products

	人員，應接受特定訓練。這類產品例如：有危險之產品、放射性材料、有特定濫用風險之產品(包含麻醉藥、治療精神異常用藥)以及對溫度敏感的產品。	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	應保存所有訓練之紀錄，且該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，其應包括健康、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、安裝配備及設備，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限制範圍內。	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 to enable all operations to be carried out accurately and safely.
3.2.2	作業場所非直接由批發運銷商營運時，應具備委託合約，該受委	Where premises are not directly operated by the wholesale distributor, a contract should be in place. The

	託合約之作業場所應具有藥品販賣之藥商許可執照(或依主管機關之要求)。	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，應提供同等的安全及確效。	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和專用區的儲存要求。至少偽/禁藥、過期藥品、回收藥品、拒用藥品及未授權國內市場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	應特別注意國內法規明定具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(以及特殊授權)。	Special attention should be paid to the storage of products with specific handling instructions as specified in national law. 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險之藥品，以及引起火災、爆炸等特殊安全性風險的產品（如氣體、可燃物、可燃性液體和固體），應儲存在一或多個符合國內法規規範，安	Radioactive materials and other hazardous products, as well as products presenting special safety risks of fire or explosion (e.g. medicinal gases, combustibles, flammable liquids and

	全性更高且具備安全措施的專用區域。	solids), should be stored in one or more dedicated areas subject to local 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氣候之影響。收貨區、出貨區及儲存區應適當的隔離。應有程序管制國內和國外產品。在收貨時檢查貨物之收貨區應予以指定並裝備。	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授權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。訪客應由廠內人員陪同。	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.
3.2.9	作業場所及儲存設施應保持乾淨且不可有垃圾與灰塵。應具備清潔計畫、說明及紀錄。應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	作業場所的設計及設備應防止昆蟲、老鼠或其他動物進入。應具備防蟲鼠的計畫。	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.
3.2.11	員工的休息室、盥洗室及餐飲室應與儲存區隔離。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 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。要考量到的環境因素包括作業場所的溫度、光	Suitable equipment and procedures should be in place to check the environment where medicinal products

	線、濕度及清潔。	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試驗。 溫度監測設備應依照測繪試驗結果設置，以確保監測設備是位於歷經極端溫度波動的位置。溫度測繪試驗應依風險評估或當設施或溫度監測設備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，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. heaters) 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、設置及維護。操作重要功能性的關鍵設備，應進行規劃性的維護保養。	All equipment impacting on storage and distribution of medicinal products should be designed, located and maintained 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。應具備適當的警報系統以在偏離預定儲存條件時發出警報。應設定適當地警報級別，並定期測試警報以確保功能的運作正常。	Calibration of equipment should be traceable to a national or international measurement standard. Appropriate 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、維護以及校正作業不可危害到藥品的完整性。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 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	應製作關鍵設備的適當維修、維護以及校正活動紀錄，並保存結果。關鍵設備包括如冰庫、監測入侵者警報及入口管制系統、冷藏庫、溫濕度計或其他溫度以及濕度紀錄裝置、空氣處理裝置以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證明，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	應可取得系統書面細節說明(適當時包括圖解)，此說明應更新。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.
3.5.3	僅有經授權的人員始得輸入或修改資料/數據。	Data should only be entered into the computerised system or amended by persons authorised to do so.
3.5.4	資料/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。	Data should be secured by physical or electronic means and protected against

	儲存之資料/數據應定期檢查其可存取性。 資料/數據應定期備份。備份資料/數據應依國內法規訂定保存時間，但在分開及安全的地點至少 5 年。	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守的程序應予以規範。其應包括資料/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	批發運銷商應確認何種關鍵設備驗證及/或關鍵流程確效是必須的，以確保其安裝及操作的正確性。該驗證及/或確效作業(例如儲存、揀貨及包裝流程)之範圍及程度應以文件化的風險評估方式測定。	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) should be determined using a documented risk assessment approach.
3.6.2	設備與流程在開始使用前以及有重大變更(如：維修及維護)應分別驗證及/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，總結說明取得的結果及評論任何觀測到的偏差。已建立程序的偏差應文件化並採取進一步行動矯正偏差及避免其重複發生(矯正預防措施)。必要時應適用矯正預防措施(CAPA)。合格確效證明以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 satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel
第 4 章文件管理 (Chapter 4 Documentation)		

4.1 原則 (Principle)		
	優良文件為品質系統之重要的一環。書面文件應避免來自口頭溝通的誤解，並且容許藥品運銷相關作業的追蹤。進行每項作業時應作記錄。	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程序、指令、合約、紀錄及資料/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、申訴者或其他個人資料/數據之處理，應依主管機關之規定存取。	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	文件關於批發運銷商活動範圍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	必要時，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修改應簽章並註明日期；該更改應允許讀取原來的資訊。適當時，更改理由應記錄之。	Any alteration made in the 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，但至少五年。當個人資料/	Documents should be retained for the period stated in national legislation but

	數據不為運銷活動目的所需時應予以刪除或匿名。	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。文件應定期審查並不斷更新。版本管制應納入程序內。文件經修訂後，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	應以販售發票、送貨單、電腦或任何其他形式保存藥品接收、供應的交易紀錄。紀錄必需至少包括下列資料：日期、藥品名稱，以及接收、供應的數量，適當時應有供應商、客戶、受託者名稱、地址及批次號碼(如需要)。	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 (if required).
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.
	批發運銷商之所有藥品必須取得衛生主管機關核准的上市許可。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 供應商之認可 (Qualification of Suppliers)		
5.2.1	批發運銷商必須從持有藥品販賣之藥商許可執照的人員，或持有藥品製造之藥商許可執照的人員取得供應藥品。	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遵守藥品優良運銷規範的原則與指導方針及其具有授權。	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 an authorisation.
5.2.3	在進行任何藥品採購之前，應對供應商進行適當的認可及核准。此作業應以程序管制，且其結果應文件化並使用風險導向的方法定期審閱。	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新合約時，為評估其他當事人供應藥品的適當性、能力及可靠性應進行實質檢核(‘due diligence’ checks)。特別需要注意的是：	When entering into a new contract with new suppliers the wholesale distributor 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)提供更有可能是偽/禁藥的藥品；	ii) offers of medicinal products more likely to be falsified;
	iii)大量提供通常僅予限量使用的藥品；	iii) large offers of medicinal products which are generally only available in limited quantities;

	iv)價格超出範圍。	iv) and out-of-range prices.
5.3 客戶的認可 (Qualification of Customers)		
5.3.1	批發運銷商必須確保其只能供應藥品給持有藥品販賣之藥商許可執照的批發運銷商或者是被授權可從運銷商取得藥品（例如臨床試驗用藥）。	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的藥品販賣之藥商許可執照文件及其他相關證明文件。	Checks and periodic rechecks may include: requesting copies of customer's authorisations according to national law, 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。若有異常挪用或誤用風險的藥品時，應予以調查，必要時，向衛生主管機關通報，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 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，以及貨物在運輸期間未明顯地受損。	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儲存或安全措施時應優先處理，並進行適當的檢查後，應立即送至適當的儲存設施。	Medicinal products requiring special 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	在未得到書面授權確保可被銷售時，該批次藥品不可被移到可銷售品庫存。	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.
5.5 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，且不可受到光線、溫度、濕度及其他外部等有害因素的影響。應特別注意需要特定儲存條件之產品。	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），不可影響到藥品品質。	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存貨安全。。	Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks.
5.5.4	存貨應依照先到期先出貨原則進行運作，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。藥品不可直接存放於地板上。除非該包裝以可直接儲存之方式設計(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	接近失效日期/架儲期的藥品，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及文件化。	Stock inventories should be performed regularly taking into account national legislation requirements. Stock irregularities should be investigated and documented.
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、分開存放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	藥品的銷毀應依照關於處置該類產品的國內或國際關於持有、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	所有銷毀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的產品。揀選的產品應有適當的架儲期。	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，皆須附上足以述明日期之文件(送貨單/包裝清單)、藥品的名稱及劑型，藥品批次號碼(必要時)、供應數量、供應商名稱及地址、收貨人的姓名、送貨地址(假如實際儲存作業場所不同時)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。	For all supplies, a document (e.g. delivery note/packing list) must be enclosed stating the date; name and pharmaceutical dosage form of the medicinal product, batch number (if required); 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主管機關之規定執行。 批發商應採取適當措施，以防止未授權之藥品流通於國內市場及輸出。	Import and export activities should be conducted in accordance with national legislation. 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/向其他國家獲得/供應藥品時，必須確保其代理商為合法且依主管機關之規定被授權可供應/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、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。紀錄應供主管機關隨時可取得。退回品在取得重新銷售許可前應執行評估。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 before any approval for resale. A 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。與藥品品質及運銷相關的申訴應作出區分。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起源或原因。	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	應指定人員負責處理申訴問題。	A person should be appointed to handle complaints.
6.2.3	必要時，調查及評估申訴後，應採取適當的後續追蹤調查行動(包含 CAPA)。包含必須通知主管機關。	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	退回品應依書面流程處理，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。	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 law, if relevant, and contractual arrangements between the parties.
6.3.2	已離開運銷商作業場所之藥品只有在確認所有以下情況，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) 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)從未持有藥品販賣之藥商許可執照的客戶或從藥局退回的藥品，僅可在接受的時間限制內(例如十天)，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)經客戶證明藥品是依照其特定儲存要求運送、儲存及處理。	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)藥品已由受充分地訓練且經授權之稱職人員進行檢查及評估。	iv) they have been examined and assessed by a sufficiently trained and competent person authorised to do so;

	v)運銷商有合理證據證明：產品已供應至該客戶(透過原始送貨單影本或相關發票號碼影本/藥品批次號碼等)，並無足夠理由懷疑該藥品為偽/禁藥。	v) 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, etc.), and that there is no reason to believe that the product has been falsified.
6.3.3	需要特殊溫度儲存條件之藥品(如低溫)只有在有足夠文件證明產品在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，在可證明產品完整性的條件下進行風險評估。 其證據應涵蓋： (i) -運送至客戶 (ii)-檢查產品 (iii) -拆封運輸包裝 (iv) -將退回之產品包裝 (v)-收集產品並退回給運銷商 (vi) -退回運銷點的冷藏庫	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 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. return to the distribution site refrigerator.
6.3.4	退回至可銷售品庫存之產品，其放置應依先到期先出(FEFO)之系統，以有效運作。	Products returned to saleable stock should be placed such that the 'first expired first out' (FEFO) system operates effectively.
6.3.5	曾遭竊後取回之產品不可歸回至可銷售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	批發運銷商識別是偽/禁藥或疑似偽/禁藥，必須立即通知主管機關，並依主管機關指示執行相關作業，必要時，通知上市許可持	Wholesale distributors must immediately inform the competent authority and the marketing authorisation holder of any medicinal

	有人，應具備程序確認上述作業執行之有效性。應記錄所有原始細節及調查。	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疑似偽/禁藥應立即進行實體隔離並存放於遠離其他藥品之專門區域。所有相關活動應予以文件化及保持紀錄。	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. All relevant activities in relation to such products should be documented and records retained.
6.5 藥品回收(Medicinal Product Recalls)		
6.5.1	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).
6.5.2	回收作業應能立即且在任何時候啟動。	Recall operations should be capable of being initiated promptly and at any time.
6.5.3	運銷商必須遵守回收訊息的指示，必要時，該回收訊息，應經由主管機關核准。	The distributor must follow the instructions of a recall message, which should be approved, if required, by the competent authorities.
6.5.4	執行任何回收作業時應予以記錄。紀錄應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.
6.5.5	運銷紀錄應使負責回收人員易於取得，且應包含關於運銷商和直銷客戶的充分資訊(連同地址、上、下班時間的電話/傳真號碼、送交的批次和數量)，包含輸出產品及藥品樣品在內(依主管機關之規定)。	The distribution records should be readily accessible to the person(s) responsible for the recall, and should 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).
6.5.6	回收流程之進度應予記錄並提出	The progress of the recall process

	最終報告，包括回收藥品之數量調和。	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)		
	所有藥品優良運銷規範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，合約中清楚制定雙方責任歸屬。	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的能力，確保本指引所闡述之藥品優良運銷規範的原則與指導方針受到遵循。委外作業開始之前及每當委外作業有變更時應進行受託者之稽核。稽核頻率應基於委外作業本質之風險予以規範。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資訊，以使其依照特定產品要求及任何其他相關要求，正確履行約定的作業。	The Contract Giver should provide the 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	受託者應有適當的作業場所與設備、程序、知識與經驗及稱職人	The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience,

	員，以執行委託者所託付的工作。	and competent personnel to carry out the work ordered by the Contract Giver.
7.3.2	受託者未經委託者事先評估、同意該等安排及稽核第三方(由委託者或受託者執行)，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原委託者及受託者約定的方式。	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.
7.3.3	受託者應避免對委託者委託處理之產品品質可能會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.
7.3.4	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)		
	為監測執行與遵守藥品優良運銷規範原則，應執行自我查核，並就必要的矯正措施提出建議。	Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to 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實施自我查核計畫，包含藥品優良運銷規範各方面與遵守法規、指引及程序。自我查核在限定範圍內可切割為數個各別的自我查核主題。	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公司內部的稱職人員，以公正且詳細的方式執行。獨立的外部專家稽核也	Self-inspections should be conducted in an impartial and detailed way by designated competent company personnel. Audits by independent

	可能有幫助，但不可以此取代自我查核。	external experts may also be useful but may not be used as a substitute for self-inspection.
8.2.3	所有自我查核應予以記錄。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。若發現違反規定及/或缺失應確定其原因，且矯正預防措施(CAPA)應予以文件化及追蹤。	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，維持藥品品質，防止破損、摻假、竊盜以及確保在運送時維持在可接受的溫度限制條件下。	It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration and 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，都應能夠被證明藥品不會暴露在可能危害到藥品品質及完整性的狀況。應基於風險基礎考量規劃運輸路線。	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.
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和/或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。應有程序調查及處理溫度偏離的情況。	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	批發運銷商應確保用於運銷、儲存或處理藥品的車輛及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	應依各路線的風險評估決定溫度管制需求。運送時，在車輛及/或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	處理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。	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 of the medicinal product will not be compromised.
9.2.7	貨物應送至送貨單上所標示的地址，且應交到收貨者的手上或其作業場所。藥品不可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	如在正常營業時間外之緊急運送，應指定特定人員且應有書面程序。	For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available.
9.2.9	若運輸轉委託給第三方，則合約應包含第七章之要求。此外，批發運銷商應告知運輸者所有運送相關條件。當運輸過程中有上/下	Where transportation is performed by a third party, the contract in place should encompass the requirements of Chapter 7. Transportation providers should be

	貨或經轉運站時，應特別注意溫度監測、清潔以及轉運間儲存設施之安全性。	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	產品於運送過程中，應有預備措施以縮短產品在等待進入下一階段運輸時的暫存時間。	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汙染等外在影響之裝存箱櫃中運送。	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，應依照藥品儲存及運輸的要求、藥品數量所需的空間、預期外部極端溫度以及儲存在海關過境和經驗證的包裝及確效的運輸容器。	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 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受保護。	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.
9.4 需要控管條件的產品 (Products requiring controlled Conditions)		
9.4.1	運送需要特殊條件的藥品，如管制藥品或治療精神異常用藥，批發運銷商應依照主管機關之規定，維持安全及可靠的供應鏈。應有附加的管制系統規範運送這	In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances, the wholesale distributor should maintain a safe and

	些藥品。應有一計畫書來處理發生的竊盜事件。	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及車輛運送高活性及放射性物質的藥品。相關安全措施應遵守國際協議及國內主管機關之規定。	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。應執行代表性條件下的溫度測繪，且考量到季節變化(必要時)。	If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular 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，以證明產品運送時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	在隔熱箱使用冷卻包時，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)及重複使用冷卻包程序之訓練。	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	應有系統可管制重複使用冷卻包，確保不會誤用到不完整的冷卻包。冷凍冷卻包及冷藏冷卻包應有實體隔離。	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.