PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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AIDE - MEMOIRE

INSPECTION OF GOOD DISTRIBUTION PRACTICE (GDP) FOR MEDICINAL PRODUCTS IN THE SUPPLY CHAIN

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1. DOCUMENT HISTORY

Adoption by Committee	20 January 2023
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2. INTRODUCTION

2.1 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. A wholesale distributor is an operator who conducts wholesale distribution activities

2.2 Compliance with Good Distribution Practice (GDP) by manufacturers and wholesale distributors is a key element in ensuring the quality and safety of medicinal products in the supply chain. All obligations related to wholesale distribution activities (such as importing, exporting, holding, or supplying) also apply to these distributors

2.3 Possession of a manufacturing licence may include authorisation to distribute the medicinal products covered by the authorisation. Manufacturers performing any distribution activities should therefore comply with GDP.

2.4 Inspections of sites involved in wholesale distribution of medicinal products should be thorough and conducted when the site is operating under normal conditions. PIC/S has developed this Aide Memoire, which can be considered a good tool for enhancing the understanding and performance of inspectors.

2.5 The Aide-Memoire is a voluntary guidance document for GDP inspectors, who inspect in accordance with the PIC/S GDP Guide. The PIC/S GDP Guide is legally non-binding unless it has been declared a legal standard in the jurisdiction of a Participating Authority.

3. PURPOSE

3.1 The purpose of this document is to provide guidance for GDP inspectors to assist in training and preparing for inspections.

3.2 The Aide Memoire was drafted with the aim of facilitating effective planning and conducting of GDP inspections at any authorized entity in the supply chain. The Aide-Memoire should enhance the efficiency of the GDP inspection and evaluation process.

4. SCOPE

4.1 This document applies to any entity, who holds a wholesale distribution licence in accordance with national legislation, or a manufacturing licence which includes authorisation to distribute the medicinal products covered by the authorisation. This document describes the different aspects, which may be evaluated during a GDP inspection of finished product.

4.2 At the time of issue, this document reflects current practices. It is not intended to be a barrier to technical innovation or the pursuit of excellence.

4.3 This Aide Memoire refers to the following Guidelines:

a) PICS Guide to Good Distribution Practice for medicinal products (PE 011-1), as well as
b) PIC/S Guide to GMP for medicinal products (PE 009-16 (Part I)), in which it is stated that one of the basic requirements of GMP is that the distribution of the products minimises any risk to their quality and takes account of good distribution practice.

5. AIDE-MEMOIRE

5.1 The Aide-Memoire consists of 10 tables containing general subjects and items to be investigated during the GDP inspection of manufacturers and wholesale distributors. Some important questions and relevant references to the PIC/S documentation are also included.

6. REVISION HISTORY

Date	Version Number	Reasons for revision

1.	GENERAL			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Type of Activity	• Procurement • Holding/Storage • Supply • Export • Contracted operation	Is content of Licence / application accurate?	
	Medicinal Products Handled	Any medicines the company may handle in line with national legislative definition. Common examples may include: Prescription only **(POM)** • Without prescription (for sale through pharmacies only) sales without prescription are to those authorized in accordance with national law (e.g. pharmacies, hospitals, other wholesalers, etc. **(P)** • General Sales List/Over the Counter **(GSL)** • Controlled Drugs according to National Law • Products requiring low temperature storage conditions • Medicinal Gases • Products unlicensed in country (unauthorised) • Other	Is content of Licence / application accurate?	
	Review of previous inspection issues		Have deficiencies from previous inspection been appropriately addressed in line with corrective/preventative	

			actions (CAPAs) outlined in company's response to previous inspection findings?	
	Review of key changes since previous inspection		Changes to operations that may affect the risk profile of the organisation e.g. premises, equipment, computerised systems, sub-contracted activities, key personnel, products handled Were changes managed in accordance with appropriate change control procedures?	
2.	**QUALITY MANAGEMENT**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Quality System	Change control	• Appropriate procedure available? • Log of change requests raised in period since last inspection. • Classification in accordance with quality risk management principles? • Were the changes notified to and approved by the relevant authorities if it was required?	PIC/S GDP 1.2.6
		Deviation management	• Is an appropriate procedure defining deviation management available? Is a record of deviations raised in period since last inspection? • Classification in accordance with quality risk management principles and appropriately documented. • Have appropriate CAPAs been taken to correct and prevent deviations?	PIC/S GDP 1.2.7

	Management of Outsourced Activities	The wholesaler should define what activities are part of GDP and thus need to be managed if outsourced.	• Are any GDP-related activities outsourced? • Have the principles of quality risk management been incorporated? • How does the company initially approve a service provider? • Is there a system for monitoring and review of the performance of contract acceptors?	PIC/S GDP 1.3, 7.1
	Management Review and Monitoring		• Appropriate procedure available? • Is the outcome of review documented and communicated internally?	PIC/S GDP 1.4
	Quality Risk Management		• Appropriate procedure available? • Have the principles been incorporated into the company's management of change, deviations, complaints, outsourced activities? • Which processes identify risk to the quality of the product?	PIC/S GDP 1.5
3.	**PERSONNEL**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	General	Organisation chart	• Is organisation chart available? • Is the number of persons involved in wholesaling operation adequate or appropriate for the GDP operations?	PIC/S GDP 1.2.1, 2.2.2 1.2.4
		Job Descriptions	• Are Job Descriptions available for key personnel?	2.2.3
	Designation of Responsibilities	Designated Responsible Person(s)	• Does the job description reflect the key responsibilities?	2.3.5
	Training	GDP Training	• Have relevant personnel received initial and continuous GDP training?	PIC/S GDP 2.4.1, 2.4.2, 2.4.3, 2.4.4, 2.4.5

			• Are training records available? • Are assessments conducted and documented? • Is there a programme for regular periodic training in GDP? • Does the training programme include aspects related to falsified medicinal products? • Is specific training provided related to temperature-sensitive products and controlled drugs?	
		Training in written procedures (SOPs)	• Have personnel received training in SOPs relevant to their role? • Are assessments conducted and documented? • Is training provided in updated revisions to SOPs? • Is specific training provided pertaining to medicines handled, e.g. related to temperature-sensitive, hazardous, radioactive products and controlled drugs?	PIC/S GDP 2.4.2
	Hygiene		• Is there an appropriate procedure in place covering health, hygiene, and clothing requirements?	PIC/S GDP 2.5
4.	**Premises and Equipment**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Premises		• Is there adequate lighting and ventilation in the storage areas?	PIC/S GDP 3.2.1,
			• Is access to storage areas appropriately restricted to authorised personnel?	3.2.3, 3.2.8
		Segregation	• Are rejected products, returned products,	3.2.4

			expired products, and recalled products physically segregated? • Do procedures require falsified medicinal products to be physically segregated? • Are products not authorised for the approved market physically segregated, even in cold storage areas? • Are these areas clearly identified and demarcated? • Are controlled drugs stored in accordance with national legislation? • Are radioactive materials and other hazardous products stored in accordance with national legislation? • Are the procedures and controls for management of inbound and outbound goods appropriate? • Are radioactive materials and other hazardous products, as well as products presenting special safety risk of fire or explosion, stored in accordance with national legislation? • Are receiving and dispatch bays protect products from prevailing weather conditions? • Is there sufficient space/capacity to allow safe storage and handling of products? • Are the storage areas appropriately maintained?	3.2.5 3.2.6 3.2.7
		Cleaning and pest control	• Are there cleaning procedures and records available? • Is there a pest control programme in place? • Are pest control records available?	3.2.9 3.2.10

			• Are the rest, wash and refreshment areas appropriately segregated from the storage areas?	3.2.11
	Temperature and Environment Control		• Are the environmental conditions monitored and are such records available? • Has temperature mapping been conducted for the storage areas? • Where required by local legislation, is humidity monitored and equipment appropriately verified? • Were any hot spots or cold spots identified? • Are these locations routinely monitored? • Is there an appropriate procedure in place for handling/management of temperature excursions outside of predefined temperature limit extremes, and according to the written procedure?	PIC/S GDP 3.3.1, 3.3.2
		Fridge / Cold store	• Have the temperature monitoring devices been calibrated within the intended operating range? • Is the continuous temperature monitoring data available? • Are temperature alarms installed and tested regularly to ensure adequate functionality? • Is there an appropriate procedure for handling temperature excursions? • Is there a back-up system in the event of fridge/cold room failure? • Has temperature mapping been conducted for fridge/cold store? • Are the temperature monitoring devices positioned in the appropriate locations to	PIC/S GDP 3.4.2. 3.4.3 5.5.1 5.5.3 3.4.3 3.4.3 3.4.4 3.3.2 3.3.2

			monitor the storage condition?	
	Equipment		• Is there a programme/schedule in place for planned maintenance? • Are maintenance records available? • Is there a programme/schedule in place for calibration? • Are the calibrations traceable to national/international standards? • Are records of calibration available? • Are alarm/alert systems in place to highlight temperature excursions? • Are appropriate mechanisms or alarms in place to identify other deviations, where appropriate (e.g. automated equipment such as picking automation, A-frames etc.) and how are these calibrated? • Is there such a system in place which can ensure integrity of product in the event of equipment failure?	PIC/S GDP 3.4.1, 3.4.3, 3.4.5
	Computerised Systems		• Is there a list of computerised systems available? • Are systems validated or tested? • Is user access restricted by role? • Is the computer system auditable? • Are detailed descriptions of the systems including diagrams available? • Are appropriate security controls in place to prevent unauthorised access?	PIC/S GDP 3.5.1, 3.5.2, 3.5.4, 3.5.5

			• Is access to stored data checked on a periodic basis? • Are appropriate back-up procedures in place? • Is there an appropriate procedure for power loss and disaster recovery of data?	
	Qualification and Validation		• Has the company identified which equipment is required to be qualified and which processes to be validated? • Have principles of quality risk management been used to determine extent of qualification and validation required? • Are the risk assessments available? • Are the qualification/validation reports available? • Have deviations been recorded and addressed? • Have the qualification/validation reports been completed and approved prior to use of the equipment? • Are there criteria and appropriate procedures established for requalification and revalidation?	PIC/S GDP 3.6.1, 3.6.3
5.	**Documentation**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	General	Procedures	• Is there an index of procedures available? • Are procedures approved and dated by relevant personnel? • Is version control in place? • Are the correct and current procedures	PIC/S GDP 4.2.4, 4.2.6, 4.2.7, 4.2.8

			available in the work areas? • Are procedures reviewed periodically?	
		Records	• Are appropriate controls in place for the process of updating documents? • Are invoices available for purchases and sales? • Are delivery slips/orders available? • Are records stored in a manner to ensure they are protected from loss or damage? • Do the records demonstrate full traceability of goods, from purchase, transportation, receipt, and onward sale? • Are archived documentation appropriately stored and accessible? • Are records made in clear, legible, and indelible manner? • Are customs documentation available, where applicable?	PIC/S GDP 4.2.9
6.	**Operations**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Qualification of Suppliers		• Is there a list of approved suppliers available? • Is there an appropriate procedure for supplier qualification/approval? • Have checks of suppliers been done to verify the authority of suppliers to supply the classifications of medicinal products received? • Have 'due diligence' checks been conducted? • Are periodic checks conducted using the principles of quality risk management?	PIC/S GDP 5.2.1, 5.2.2, 5.2.3, 5.2.4

			• Are records of the above checks available? • How do you ensure that the supplies of medicinal products are obtained only from persons/organisations who are in possession of a valid wholesale distribution authorisation or manufacturing authorisation?	
	Qualification of Customers		• Is there a list of qualified customers available? • Is there an appropriate procedure for customer qualification and approval including requirements for the opening of a new account? • Have checks been done to verify the authority of customers to receive the classifications of medicinal products supplied? • Provide the records. • Are periodic checks conducted using the principles of quality risk management? • Are records of the qualification of each customer available? • For products at risk of diversion, is there a monitoring system for all sales? • Is there an appropriate procedure for investigating irregularities in sales patterns? • How do you ensure that medicinal products are only supplied to persons/organisations who are in possession of a valid distribution authorisation or who are authorised or entitled to supply to the public?	PIC/S GDP 5.3.1, 5.3.2, 5.3.3

	Receipt of Medicinal Products		• Is there an appropriate procedure in place for goods receipt to include checking against a purchase order? • Assess records. Questions may include: • Are records of the receipt of goods available? • Are records of the temperature conditions during transportation available? • Are records of routine stock checks and any subsequent investigations available? • Are there checks to ensure goods have been authorised for sale? • Do procedures for receipt of goods require the person checking the goods to consider whether the goods may be falsified? • For products with special storage requirements, are checks conducted at receipt to ensure correct storage conditions have been maintained during transportation? • Is there an appropriate procedure for handling non-conforming product at receipt?	PIC/S GDP 5.4.1, 4.4.2, 5.4.3
	Storage		• Is stock rotated in accordance with First Expiry First Out (FEFO) principle? • Is there a system in place to ensure products expired or nearing expiry date are removed from saleable stock? • Are provisions in place to ensure products are not stored directly on the floor? Are stock inventories checked periodically and appropriate investigation	PIC/S GDP 5.5.1, 5.5.4, 5.5.5, 5.5.6, 5.5.7

	Security		of irregularities conducted? • Are stock records available? • Are appropriate procedures in place for handling products with special storage conditions? • Are medicines segregated or protected from harmful substances? • Is access to the premises and storage area appropriately controlled? • Does the company employ security measures, e.g. alarm systems, CCTV, locker searches, persons searches? Are alarms linked to personnel, security, police? • Does the company vet personnel within sensitive areas, e.g. controlled drug storage areas? • Does the company require any additional security measures relating to the nature of their business, to protect medicines and public health? E.g. controlled substances, vaccine handling etc.	
	Destruction of Expired and/or Obsolete Goods		• Is there an appropriate procedure for handling material for destruction? • Is a storage area for expired and/ or obsolete goods available and is it appropriately segregated and labelled? • Are records available for products which have been destroyed?	PIC/S GDP 5.5.1, 5.5.4, 5.5.5, 5.5.6, 5.5.7 PIC/S GDP 5.6.1, 5.6.2, 5.6.3

	Picking		• Are controls in place to ensure correct product is picked? • Is there a check to ensure sufficient shelf life remaining?	PIC/S GDP 5.7
	Supply		• Have delivery notes, packing lists been provided with products supplied? • Are supply records available?	PIC/S GDP 5.8
	Import and Export		• Are appropriate procedures in place for import and export activities?	PIC/S GDP 5.9
7.	**Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Complaints	Differ between product quality defects and handling/distribution complaints.	• Is there an appropriate procedure for handling complaints and who is responsible? • How are complaints recorded and investigated? • Show me the log of complaints. • How are complaints received by the organisation and how are they handled upon receipt? • What mechanisms are in place to distinguish service and quality complaints? • What mechanisms are in place to protect against falsified medicinal products when assessing complaints? • How are complaints escalated, in case of a product quality defect? • How is an investigation of a complaint closed?	PIC/S GDP 6.2

	Returned Medical Products	This pertains to the assessment of goods returned from a customer and their potential return to saleable stock.	• From whom does the company accept returns? • Is there any access restriction for the returns area? • Does the company have an appropriate procedure for handling returns? • Is this procedure risk based? • How does the company perform assessment of returned products? • Show me the returns log. • Who are responsible in different stages of the returns process? • How does the company handle returns of products requiring specific storage conditions? • How is FEFO maintained?	PIC/S GDP 6.3
	Falsified Medicinal Products	Products at higher risk of falsification Review of Wholesale-to-Wholesale Transactions	• Show me appropriate procedures that cover vigilance against falsified medicinal products. • How does the company assess risk to medicines handled by the company where the risk of falsification is higher? • How was this list compiled? • Review of paper/documentation audit trail for purchase of high-risk products from other wholesalers. • Review of product ownership in relation to movement. • Review of dispatch documents vs. receiving documents. • Provide purchase discounts since last inspection. • Cross check of a sample of purchase orders for these products against	PIC/S GDP 6.4

			seller's wholesale authorisation.	
		Falsified products in returns Intelligence Gathering	• What procedures are in place to identify potentially falsified medicinal products when receiving goods returned from customers? • Has the company received unsolicited offers of products at cheaper prices? • Has the company received deliveries through unusual means, e.g. unmarked vans? • How does the company report suspicious approaches concerning purchase of medicinal product to competent authority?	
	Medicinal Product Recall	Recall can be impacted by the level of traceability required nationally. Are recalls done per batch or per delivery? Consider the final fate of recalled product and reconciliation.	• Provide the appropriate procedure for handling recalls. • Are there records of recalls that have been received and assessed/undertaken by the wholesaler? • How do you ensure recalls can be actioned in a timely manner at any time, e.g. able to be actioned at any time day or night? • How does the company communicate recalls to the customer? • Are the roles and responsibilities for staff clearly defined? Explain how the company liaises with the competent authority/marketing authorisation holder before any recall action undertaken. • Is there a clear and effective process for the identification and traceability of products subject to recall?	PIC/S GDP 6.5

			• How does the company handle, and segregate recalled product in the warehouse? • Explain arrangements for return of recalled medicinal product to MA holder/or destruction. • Is a final report of the recall activity (including reconciliation and destruction) recorded? • How and how often does the company challenge the recall procedure? • How does the company check for active product recalls? From where is information regarding recalls received?	
8.	**Outsourced Activities**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Outsourced activities	See also Management of Outsourced activities above. Ensure that responsibilities are clear in contracts. Especially for activities in the interface between contract giver and acceptor and between different contract acceptors.	• Are quality agreements in place and are these being followed for all related activities? • Review current contracts with service providers and assess relevant detail to business model and activities described. • Are audits allowed in contract? • Show me your audit schedule. • How does the company ensure that no work is handed off to a third party without their knowledge? • Is there a process to manage the quality of products or services? Are there records available? Are there records and examples of cases where the quality of product or service was in question?	PIC/S Guide to GMP for medicinal products (PE 009-16 (Part I)) PIC/S GDP 7.1 7.2.2 7.2.2 7.3.3 7.3.5

9.	**Self-Inspections**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Self-inspection	The scope and outcome of self-inspection differ from that of audits performed by customers or corporate head office or inspections by authorities. Depending on the policy of an agency you may request to see the self-inspection reports.	• Provide your appropriate procedure for self-inspection. • Provide your self-inspection plan. • Are self-inspections performed in accordance with local procedures, and as scheduled? • How are auditors selected? • How are personnel trained to perform self-inspections? • How does the company ensure that the auditor is independent from the area being inspected? • What is the process for the timely rectification of any issues identified? • How are CAPAs verified as being effective?	PIC/S GDP 8.1 8.2.1 8.2.2 8.2.3
10.	**Transportation**			
	Area of operation/ items	**Notes**	**Crucial questions << show me >>**	**Supporting documents**
	Responsibility		• Does the company outsource transportation services or does the company transport in company owned vehicles? • Are vehicles cleaned and fit for purpose? • Provide temperature monitoring data for selected shipments. • Explain the organisations approach for planning transportation. • Are drivers trained in GDP, do they have	PIC/S GDP 9.1.1 9.1.2, 9.2.5, 9.2.10 2.4.1, 2.4.2

			access to relevant written procedures?	
	Storage conditions during transportation	At all times it should be clear who is responsible for the product being transported. If the responsibility differs from ownership, this must be clearly defined, e.g. in an agreement.	• How are storage conditions ensured during transportation? • What happens if storage conditions are not maintained during transportation? • Explain how storage conditions are maintained during temporary storage in hubs or reloading during transportation. • What kind of additional control systems does the company have in place for delivery of these products? • Are there protocols or policies in place to address the occurrence of theft? • Are narcotics or other products at high risk for theft appropriately handled? • Are highly toxic or radioactive products appropriately handled? • Are temperature sensitive products appropriately handled?	9.2.1, 9.2.2 9.2.9
	Vehicles and equipment		• Who owns the vehicles used? • How is equipment maintained and calibrated? • How are the necessary storage conditions achieved within the vehicles? • Has appropriate temperature mapping of each vehicle's-controlled storage area been performed?	9.2.3, 9.2.4, 9.2.5 9.4.4
	Containers, Packaging and Labelling		• Explain how packaging is chosen for transportation of medicines? • How are cool packs handled and packed?	9.3.1, 9.3.2, 9.4.6, 9.4.7

			• What information is part of transport labelling? • Has each packaging configuration been appropriately qualified? • Are all packages correctly labelled with all relevant information, e.g. identity, source, handling, temperature, and storage conditions? • Have temperature-controlled containers or thermal packaging been fully qualified?	9.3.3
	Products Requiring Controlled Conditions		• Are narcotics or other products at high risk for theft handled? • Are highly toxic or radioactive products handled? • Are temperature-sensitive products handled? • Are appropriate procedures available for handling high risk narcotics, highly toxic or radioactive products • Are procedures available for handling temperature-sensitive products?	9.4.1 9.4.2 9.4.3 9.4.8