PIC/S GDP と医薬品の適正流通（GDP）ガイドラインの対比

PIC/S GDP vs Japanese GDP Guideline

（Tentative : Translated by Japanese GDP guideline preparation working team, Health Labour Science Research in June 2019）

PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS (June 2014)	JAPANESE GUIDELINE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS (June 2019 Tentative)
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INTRODUCTION	INTRODUCTION

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.	
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.	The wholesale distribution of medicinal products to pharmacy and medical institution after market release of medicinal products is an important activity consisting of procuring, holding and supplying, etc. in integrated supply chain management. Today's distribution network for medicinal products is increasingly complex and involves many players. This Good Distribution Practice (GDP) (hereinafter referred to as "Guideline") lays down appropriate tools to assist wholesale distributors and marketing authorization holders (hereinafter referred to as "wholesale distributors etc.") in conducting their activities, and compliance with this Guideline will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products. This Guideline also lays down the appropriate tools to prevent falsified medicines from entering the legal supply chain.

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 licence may be required.	
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.	
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.	A glossary of some terms used in this Guideline has been incorporated as Glossary.
PURPOSE	PURPOSE
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.	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 all activities of wholesale distributors etc. of medicinal products and to further facilitate the removal of barriers to trade in medicinal products, this Guideline 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.	This Guideline is also intended to serve wholesale distributors etc. 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 Guideline, which are capable of achieving the principles of this Guideline.
SCOPE	SCOPE
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	This Guideline applies to all activities consisting of procuring, holding and supplying medicinal products to pharmacy and medical institution after market release of medicinal products.

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.	
CHAPTER 1 — QUALITY MANAGEMENT	CHAPTER 1 — QUALITY MANAGEMENT
1.1. PRINCIPLE	1.1. PRINCIPLE
Wholesale distributors should maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. 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. 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.	Wholesale distributors etc. should maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. Wholesale distributors etc. should clearly define all distribution activities in procedures and systematically review them. All critical steps of distribution processes and significant changes should be justified and where relevant validated. Management of wholesale distributors etc. has the responsibility of quality system and is required to have their leadership and active participation, and should be supported by staff commitment.
1.2. QUALITY SYSTEM	1.2. QUALITY SYSTEM
1.2.1 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	1.2.1 The system for managing quality for wholesale distributor etc. should encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the

maintains its quality and integrity and remains within the legal supply chain during storage and/or transportation.	product delivered maintains its quality and integrity and remains within the legal supply chain during storage and/or transportation.
1.2.2 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.	1.2.2 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 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.	1.2.3 The management of wholesale distributor etc. should appoint designated responsible person(s) who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained.
1.2.4 The management of the distributor should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.	1.2.4 The management of wholesale distributors etc. should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.
1.2.5 The size, structure and complexity of distributor's activities should be taken into consideration when developing or modifying the quality system.	1.2.5 The size, structure and complexity of activities of wholesale distributor etc. should be taken into consideration when developing or modifying the quality system.
1.2.6 A change control system should be in place. This system should incorporate quality risk management principles, and be proportionate and effective.	1.2.6 A change control system should be in place. This system should incorporate quality risk management principles, and be proportionate and effective.
1.2.7 The quality system should ensure that: i. medicinal products are procured, held, supplied, imported or exported in a way that	1.2.7 The quality system should ensure that: i. medicinal products are procured, held and supplied in a way that is compliant with the

is compliant with the requirements of GDP; ii. management responsibilities are clearly specified; iii. products are delivered to the right recipients within a satisfactory time period; iv. records are made contemporaneously; v. deviations from established procedures are documented and investigated; vi. 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.	requirements of this Guideline; ii. management responsibilities are clearly specified; iii. products are delivered to the right recipients within a satisfactory time period; iv. records are made contemporaneously; v. deviations from established procedures are documented and investigated; vi. appropriate corrective and preventive actions (hereinafter referred to as "CAPA") are taken to correct deviations and prevent them in line with the principles of quality risk management.
1.3. MANAGEMENT OF OUTSOURCED ACTIVITIES	1.3. MANAGEMENT OF OUTSOURCED ACTIVITIES
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.assessing the suitability and competence of the Contract Acceptor to carry out the activity, preserving the integrity and security of the medicinal products, and requesting, preserving documentation, and checking authorisation or marketing status, if required; ii. defining the responsibilities and communication processes for the quality-related activities of the parties involved; iii. monitoring and review of the	The quality system for wholesale distributors etc. should extend to the control and review of any outsourced activities related to the procurement, holding and supply, of medicinal products. These processes should incorporate quality risk management and include: i. assessing the suitability and competence of the Contract Acceptor to carry out the activity, preserving the integrity and security of the medicinal products, and requesting, preserving documentation, and checking authorisation or marketing status, if required; ii. defining the responsibilities, communication processes and so on, and their responsible person(s) for the quality-related activities of the parties involved; iii. monitoring and review of the

performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.	performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.
1.4. MANAGEMENT REVIEW AND MONITORING	1.4. MANAGEMENT REVIEW AND MONITORING
1.4.1 The management should have a formal process for reviewing the quality system on a periodic basis. The review should include: i. measurement of the achievement of quality system objectives; 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. emerging regulations, guidance and quality issues that can impact the quality management system; iv. innovations that might enhance the quality system; v. changes in business environment and objectives.	1.4.1 The management of wholesale distributors etc. should have a formal process for reviewing the quality system on a periodic basis. The review should include: i. measurement of the achievement of quality system objectives; ii. assessment of key performance indicators (KPI) 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 self-inspections; and external assessments such as regulatory inspections and customer audits including their findings; iii. emerging regulations, guidance and quality issues that can impact the quality management system; iv. innovations that might enhance the quality system; v. changes in business environment and objectives.
1.4.2 The outcome of each management review of the quality system should be documented in a timely manner and effectively communicated internally.	1.4.2 The outcome of each management review of the quality system should be documented in a timely manner and effectively communicated internally.

1.5. QUALITY RISK MANAGEMENT	1.5. QUALITY RISK MANAGEMENT
1.5.1 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.	1.5.1 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 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).	1.5.2 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.
CHAPTER 2 — PERSONNEL	CHAPTER 2 — PERSONNEL
2.1. PRINCIPLE	2.1. PRINCIPLE
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.	The correct distribution of medicinal products relies upon people. For this reason, there must be sufficient number of competent personnel to carry out all the tasks for which the wholesale distributors etc. is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.
2.2. GENERAL	2.2. GENERAL
2.2.1 There should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities of medicinal products.	2.2.1 There should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities consisting of procuring, holding and

The number of personnel required will depend on the volume and scope of activities.	supplying medicinal products. The number of personnel required will depend on the volume and scope of activities.
2.2.2 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.	2.2.2 The wholesale distributors etc. should set out the organisational structure in an organisation chart, and clearly indicate the role, responsibilities and interrelationships of all personnel.
2.2.3 The role and responsibilities of employees working in key positions should be set out in written job descriptions, along with any arrangements for deputising.	2.2.3 The wholesale distributors etc. should designate responsible persons working in key positions and set out their role and responsibilities in written job descriptions. The same should apply to deputies for such responsible persons.
2.3.DESIGNATION OF RESPONSIBILITIES	2.3.DESIGNATION OF RESPONSIBILITIES
2.3.1 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.	2.3.1 The wholesale distributors etc. must designate personnel responsible for compliance with this Gudeline. Relevant personnel should have appropriate competence and experience as well as knowledge of and training in this Guideline.
2.3.2 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.	2.3.2 Wholesale distributors etc. should build a system for out of hours contact (e.g. emergencies and/or recall).
2.3.3 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	2.3.3 Written job descriptions for responsible person(s) should define their authority to take decisions with regard to their responsibilities. Wholesale distributors etc. should give the designated responsible person(s) the defined authority, adequate resources and

responsibility needed to fulfil their duties.	responsibility needed to fulfil their duties.
2.3.4 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.	2.3.4 Designated responsible person(s) should carry out their duties for this Guideline as appropriate.
2.3.5 The responsibilities of the designated responsible person(s) include but are not limited to: i. ensuring that a quality management system is implemented and maintained; ii. focusing on the management of authorised activities and the accuracy and quality of records; iii. ensuring that initial and continuous training programmes are implemented and maintained; iv. coordinating and promptly performing any recall operations for medicinal products; v. ensuring that relevant customer complaints are dealt with effectively; vi. ensuring that suppliers and customers are approved; vii. approving any subcontracted activities which may impact on GDP; viii. ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place; ix. keeping appropriate records of any	2.3.5 The responsibilities of the designated responsible person(s) include but are not limited to: i. ensuring that a quality management system is implemented and maintained; ii. focusing on the management of authorised activities and ensuring the accuracy and quality of records; iii. ensuring that initial and continuous training programmes are implemented and maintained for all personnel who are involved in the activities in this Guideline; iv. coordinating and promptly performing any recall operations for medicinal products for the recall implemented by marketing authorization holder; v. ensuring that relevant customer complaints are dealt with effectively; vi. ensuring that suppliers and customers hold legally required licences etc. for drug selling business and so on. ; vii. confirm any subcontracted activities which may impact on this Guideline; viii. ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place; ix. keeping appropriate records of any

delegated duties; x. deciding on the final disposition of returned, rejected, recalled or falsified products; xi. approving any returns to saleable stock; xii. ensuring that any additional requirements imposed on certain products by national legislation are adhered to.	delegated duties; x. deciding on the final disposition of returned, rejected, recalled or falsified products; xi. approving any returns to saleable stock; xii. ensuring that any additional requirements imposed on certain products by national legislation are adhered to.
2.4. Training	2.4. TRAINING
2.4.1 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.	2.4.1 All personnel involved in wholesale distribution activities consisting of procuring, holding and supplying medicinal products should be trained on the requirements of this Guideline. They should have the appropriate competence and experience prior to commencing their tasks.
2.4.2 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.	2.4.2 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 this Guideline through regular training. Management of wholesale distributors etc. should also receive training for this Guideline.
2.4.3 In addition, training should include aspects of product identification and avoidance of falsified medicines entering the supply chain.	2.4.3 In addition, training should include aspects of product identification and avoidance of falsified medicines entering the supply chain.
2.4.4 Personnel dealing with any products which require more stringent handling conditions should receive specific training.	2.4.4 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.	Examples of such products include poisonous and deleterious drugs, radioactive materials, products presenting special risks of abuse (including narcotics, raw material for stimulants and psychotropic drugs), and temperature-sensitive products (e.g. refrigerated product).
2.4.5 A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.	2.4.5 A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.
2.5. HYGIENE	2.5. HYGIENE
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.	Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health and hygiene, and clothing as necessary.
CHAPTER 3 — PREMISES AND EQUIPMENT	CHAPTER 3 — PREMISES AND EQUIPMENT
3.1. PRINCIPLE	3.1. PRINCIPLE
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.	Wholesale distributors etc. must comply with Regulations for Buildings and Facilities for Pharmacies, etc., and 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. PREMISES	3.2. PREMISES
3.2.1 The premises should be designed or adapted to ensure that the required storage conditions are maintained.	3.2.1 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.	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.
3.2.2 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.	3.2.2 Where premises are not directly operated by the wholesale distributor, a written contract should be in place.
3.2.3 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.	3.2.3 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 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	3.2.4 Products pending a decision as to their disposition 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, rejected products, falsified medicinal products and recalled products must always be physically segregated.

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.	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 Special attention should be paid to the storage of products with specific handling instructions as specified in national legislation. Special storage conditions (and special authorisations) may be required for such products (e.g. narcotics and psychotropic substances).	3.2.5 The storage of products with specific handling instructions (e.g. narcotics and psychotropic substances) should be in accordance with related laws and regulations.
3.2.6 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 solids), should be stored in one or more dedicated areas subject to national legislation and appropriate safety and security measures.	3.2.6 Radioactive materials, and poisonous and deleterious drugs as well as products presenting special safety risks of fire or explosion (e.g. medicinal gases, combustibles, flammable liquids and solids) should be appropriately stored in accordance with related national legislation and appropriate safety and security measures.
3.2.7 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.	3.2.7 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 Unauthorised access to all areas of the authorised premises should be prevented.	3.2.8 Authorised personnel to access storage areas should be designated and access to the

Prevention measures would usually include a monitored intruder alarm system and appropriate access control. Visitors should be accompanied by authorised personnel.	areas should be limited to them, and a procedure for access should be documented. The same procedure is desirable to be applied to access to other areas than the storage areas. Prevention measures for unauthorized access would usually include a monitored intruder alarm system and appropriate access control. Visitors should be accompanied by authorised personnel.
3.2.9 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.	3.2.9 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 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.	3.2.10 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 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.	3.2.11 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. TEMPERATURE AND ENVIRONMENT CONTROL	3.3. TEMPERATURE AND ENVIRONMENT CONTROL
3.3.1 Suitable equipment and procedures should be in place to check the environment	3.3.1 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.	where medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.
3.3.2 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.	3.3.2 An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment (e.g. data logger) should be located at appropriate position(s) according to the results of the mapping exercise. 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. EQUIPMENT	3.4. EQUIPMENT
3.4.1 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.	3.4.1 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.
3.4.2 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.	3.4.2 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.

	Calibration of equipment should be traceable to a national and international measurement standard.
3.4.3 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.	3.4.3 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 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.	3.4.4 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 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.	3.4.5 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, thermometers, or other temperature recording devices, air handling units and any equipment used in conjunction with the onward supply chain.
3.5. COMPUTERISED SYSTEMS	3.5. COMPUTERISED SYSTEMS
3.5.1 Before a computerised system is	3.5.1 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.	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 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.	3.5.2 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 Data should only be entered into the computerised system or amended by persons authorised to do so.	3.5.3 Data should only be entered into the computerised system or amended by persons authorised to do so.
3.5.4 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.	3.5.4 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 at a separate and secure location.
3.5.5 Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.	3.5.5 Procedures to be followed if the system fails or breaks down should be defined. This should include systems for the restoration of data.
	3.5.6 Guideline on Management of Computerized Systems for Marketing Authorization Holders and Manufacturers of

	Drugs and Quasi-drugs (PFSB/CND (Yakushoku-kanma) Notification No. 1021-11 October 21, 2010) issued by Ministry of Health, Labour and Welfare should be referred to.
3.6. QUALIFICATION AND VALIDATION	3.6. QUALIFICATION AND VALIDATION
3.6.1 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.	3.6.1 Wholesale distributors etc. 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 according to risk.
3.6.2 Equipment and processes should be respectively qualified and/or validated before commencing use and after any significant changes (e.g. repair or maintenance).	3.6.2 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 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.	3.6.3 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 should be decided to CAPA. Evidence of satisfactory validation and acceptance of a process or piece of equipment should be produced and approved by appropriate personnel.

CHAPTER 4 — DOCUMENTATION	CHAPTER 4 — DOCUMENTATION
4.1. PRINCIPLE	4.1. PRINCIPLE
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.	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	4.2. GENERAL
4.2.1 Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available/retrievable.	4.2.1 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 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.	4.2.2 With regard to the processing of personal data of employees, complainants or any other natural person, related laws such as the Act on Protection of the Personal Information are applied to the processing of personal data .
4.2.3 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.	4.2.3 Documentation should be sufficiently comprehensive with respect to the scope of the activities of wholesale distributors etc. and in a language understood by personnel.
4.2.4 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	4.2.4 Documentation should be approved, signed and dated by designated persons, as required.

be provided for such entries.	
4.2.5 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.	4.2.5 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 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.	4.2.6 Documents should be retained for the period stated in national legislation.
4.2.7 Each employee should have ready access to all necessary documentation for the tasks executed.	4.2.7 Each employee should have ready access to all necessary documentation for the tasks executed.
4.2.8 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.	4.2.8 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 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.	4.2.9 Any transactions such as purchase or receipt and selling or transfer of medicinal products must be recorded. The records must be kept in the form of document as a general rule for a period required by national legislation and they should be kept in the form of purchase/sales invoices or delivery slips. Alternatively, they can be kept in the form on computer or any other form provided that such forms are able to provide easy retrieval of the records as required. Any handwritten records should be clear, legible and indelible. Records must include at least the following information: ① name of medicinal product; ② lot number (manufacturing number or code for medicinal product without lot configulation); ③ expiry date; ④ quantity; ⑤ date of purchase or receipt and selling or transfer; ⑥ name of recipient or his/her organisation, address or location of recipient, telephone number and other contact details of customer etc.; ⑦ presented information to confirm the items in the item ; ⑧ documents showing that natural person who trades medicinal product has an employment relationship with customer etc. or is designated for the trade by customer etc.
CHAPTER 5 — OPERATIONS	CHAPTER 5 — OPERATIONS
5.1. PRINCIPLE	5.1. PRINCIPLE
All actions taken by wholesale distributors	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. 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.	etc. should ensure that the identity of the medicinal product is not lost and that the wholesale distribution consisting of procuring, holding and supplying medicinal products is performed according to the information on the outer packaging (handling instructions etc.). The wholesale distributors etc. should use all means available to minimise the risk of falsified medicinal products entering the legal supply chain. All key operations described below should be fully described in the quality system in appropriate documentation.
5.2. QUALIFICATION OF SUPPLIERS	5.2. QUALIFICATION OF SUPPLIERS
5.2.1 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.	5.2.1 Wholesale distributors etc. 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 marketing authorisation which covers the product in question.
5.2.2 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.	5.2.2 Where medicinal products are obtained from another wholesale distributors etc. the receiving wholesale distributors etc. must verify that the supplier complies with the principles and guidelines of good distribution practices and that they hold a licence for drug selling business etc.
5.2.3 Appropriate qualification and approval of suppliers should be performed prior to	5.2.3 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.	procurement of any medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked according to risk.
5.2.4 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. the reputation or reliability of the supplier; ii. offers of medicinal products more likely to be falsified; iii. large offers of medicinal products which are generally only available in limited quantities; iv. diversity of products handled by supplier; v. and out-of-range prices.	5.2.4 When entering into a new contract with new suppliers, the wholesale distributors etc. should carry out 'qualification' checks. Attention should be paid to: i. the reputation or reliability of the supplier; ii. offers of medicinal products more likely to be falsified; iii. large offers of medicinal products which are generally only available in limited quantities; iv. diversity of products handled by supplier (e.g. stability/bias of supply, instability in variety of products); v. and out-of-range prices (big discount etc.).
5.3. Qualification of customers	5.3. QUALIFICATION OF CUSTOMERS
5.3.1 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).	5.3.1 Wholesale distributors, etc. must ensure the customers are founder of pharmacy, marketing authorization holder of medicinal products or drug seller, or founder of hospital, clinic and medical care facility for rearing animal, or other persons who are authorised or entitled by Ordinance of the Ministry of Health, Labour and Welfare.
5.3.2 Checks and periodic rechecks may include: requesting copies of customer's authorisations, verifying status on an	5.3.2 Checks and periodic rechecks may include: requesting copies of customer's authorisations, evidence of qualifications or

authority website, requesting evidence of qualifications or entitlement according to national legislation.	entitlement according to national legislation.
5.3.3 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.	5.3.3 Unusual sales patterns that may constitute diversion or misuse of medicinal product should be investigated and reported to competent authorities where necessary.
5.4. RECEIPT OF MEDICINAL PRODUCTS	5.4. RECEIPT OF MEDICINAL PRODUCTS
5.4.1 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.	5.4.1 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 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.	5.4.2 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.
5.5. STORAGE	5.5. STORAGE
5.5.1 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,	5.5.1 Medicinal products should be stored separately from other products to protect their quality. Furthermore, they 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.	moisture and other external factors. Particular attention should be paid to products requiring specific storage conditions.
5.5.2 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.	5.5.2 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 Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks.	5.5.3 Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks.
5.5.4 Stock should be rotated according to the first expiry, first out (FEFO) principle. Exceptions should be documented.	5.5.4 Stock should be rotated according to the first expiry, first out (FEFO) principle as well as the first in, first out (FIFO) principle as appropriate. Exceptions should be documented.
5.5.5 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).	5.5.5 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 Medicinal products that are nearing their expiry date/shelf life should be withdrawn immediately from saleable stock.	5.5.6 Medicinal products that are nearing their expiry date/shelf life should be withdrawn immediately from saleable stock.
5.5.7 Stock inventories should be performed regularly taking into account national legislation requirements. Stock irregularities should be	5.5.7 Stock inventories should be performed regularly. Stock irregularities should be

investigated,documented and reported to the competent authorities when needed.	investigated,documented and reported to the competent authorities when needed.
5.6. DESTRUCTION OF OBSOLETE GOODS	5.6. DESTRUCTION OF OBSOLETE GOODS
5.6.1 Medicinal products intended for destruction should be appropriately identified, held separately and handled in accordance with a written procedure.	5.6.1 Medicinal products intended for destruction should be appropriately identified, held separately and handled in accordance with a written procedure.
5.6.2 Destruction of medicinal products should be in accordance with national or international requirements for handling, transport and disposal of such products.	5.6.2 Destruction of medicinal products must be in accordance with related laws and regulations.
5.6.3 Records of all destroyed medicinal products should be retained for a defined period.	5.6.3 Records of all destroyed medicinal products should be retained for a defined period.
5.7. PICKING	5.7. PICKING
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.	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. SUPPLY	5.8. SUPPLY
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, 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.	For all supplies, a document (e.g. delivery note/packing list) must be enclosed or provided by alternative method to customer etc. stating name, pharmaceutical dosage form, lot number (manufacturing number or code for medicinal products without lot configuration), expiry date, transport conditions, storage conditions; quantity; date of purchase or receipt and selling or transfer; name of recipient or his/her organization, address or location of recipient, telephone number and other contact details of customer etc. Their records

	should be kept. When the actual location to deliver is different from the address etc. of consignee, information of the delivered location should also be written.
5.9. IMPORT AND EXPORT	
5.9.1 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 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.	
CHAPTER 6 — COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS	CHAPTER 6 — COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS
6.1. PRINCIPLE	6.1. PRINCIPLE
All complaints, returns, suspected falsified medicinal products and recalls must be recorded and handled carefully according to written procedures.	Wholesale distributors etc. should cooperate with marketing authorization holder for complaints, returns, suspected falsified medicinal products and recalls.

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 consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified medicinal products.	All their activities should be recorded according to written procedures and the 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 only if quality of returned medicinal product is ensured for its entire storage by the consignee. 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. COMPLAINTS AND QUALITY INFORMATION	6.2. COMPLAINTS AND QUALITY INFORMATION
6.2.1 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.	6.2.1 Complaints should be recorded with all the original details. A distinction should be made between complaints (quality information) related to the quality of a medicinal product and complaints related to distribution. In the event of a quality information of a medicinal product and a potential product defect, the 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 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.	6.2.2 If a quality defect related 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 A person should be appointed to handle complaints.	6.2.3 A person should be appointed to handle complaints.
6.2.4 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.	6.2.4 If necessary, appropriate follow-up actions (including CAPA) should be taken after investigation and evaluation of the complaint, including where required information to the competent authorities.
6.3. RETURNED MEDICINAL PRODUCTS	6.3. RETURNED MEDICINAL PRODUCTS
6.3.1 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.	6.3.1 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 negotiation. Contractual arrangements between the parties should be made and documented in advance. A record/ list of returned goods must be maintained.
6.3.2 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. 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. 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	6.3.2 Medicinal products which have been retrned by the customer should only be returned to saleable stock if all of the following are confirmed: 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. they are returned within an acceptable time limit (e.g. 10 days);

returned within an acceptable time limit, for example 10 days; 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. they have been examined and assessed by a sufficiently trained and competent person authorised to do so; 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, expiry date etc., as required by national legislation), and that there is no reason to believe that the product has been falsified.	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. they have been examined and assessed by a sufficiently trained and competent person v. the wholesale distributors etc. has reasonable evidence that the product was supplied to the customer (via copies of the original delivery note, by lot number of referencing invoice number, or manufacturing number, etc.), and that there is no reason to believe that the product has been falsified.
6.3.3 Moreover, for medicinal products requiring specific temperature storage conditions, 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;	6.3.3 Medicinal products requiring specific temperature storage conditions cannot be essentially returned to saleable stock. However, this shall not apply if there is documented evidence that the product has been stored under the authorised storage conditions throughout the entire time.

vi. record of temperature readings during transportation; vii. return to the distribution site refrigerator.	
6.3.4 Products returned to saleable stock should be placed such that the 'first expired first out' (FEFO) system operates effectively.	6.3.4 Products returned to saleable stock should be placed such thatFEFO/FIFO system operates effectively.
6.3.5 Stolen products that have been recovered cannot be returned to saleable stock and sold to customers.	6.3.5 Stolen products that have been recovered cannot be returned to saleable stock and sold to customers.
6.4. FALSIFIED MEDICINAL PRODUCTS	6.4. FALSIFIED MEDICINAL PRODUCTS
6.4.1 The sale and distribution of a suspected falsified medicinal product should be suspended immediately.	6.4.1 The sale and distribution of a suspected falsified medicinal product should be suspended immediately.
6.4.2 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.	6.4.2 The wholesale distributors etc. must immediately inform the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified and send the products to them. The marketing authorisation holder examine their authenticity by visual examination etc. with the retention sample. When they are examined as highly probable to be falsified products, the corresponding lot should be segregated and immediately report it to the competent authority and discuss for any further actions. Any relevant persons and organizations must follow the instructions (including recall) determined by discussion between the competent authority and the marketing authorisation holder. A procedure should be in place to the above effect.

It should be recorded with all the original details and investigated.	It should be recorded with all the original details and investigated.
6.4.3 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.	6.4.3 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.
6.4.4 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.	6.4.4 Upon confirmation as a falsified medicinal product, any causes of introduction to the supply chain should be identified and any preventive measures for its recurrence should be taken as required., All related activities including holding of the relevant products at the marketing authorization holder should be appropriately documented and retained.
6.5. MEDICINAL PRODUCT RECALLS	6.5. MEDICINAL PRODUCT RECALLS
6.5.1 There should be documentation and procedures in place to ensure traceability of products received and distributed, to facilitate product recall.	6.5.1 There should be documentation and procedures in place to ensure traceability of products received and distributed, to facilitate product recall.
6.5.2 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.	6.5.2 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 The national regulatory authority should be informed of all product recalls.	6.5.3 The marketing authorization holder should inform all product recalls to the

If the product is exported, the overseas counterparts and/or regulatory authorities must be informed of the recall as required by national legislation.	competent authorities.
6.5.4 The effectiveness of the arrangements for product recall should be evaluated regularly (at least annually).	6.5.4 The effectiveness of the procedures for product recall should be evaluated where necessary.
6.5.5 Recall operations should be capable of being initiated promptly and at any time.	6.5.5 Recall operations should be capable of being initiated promptly and at any time.
6.5.6 The distributor must follow the instructions of a recall message, which should be approved, if required, by the competent authorities.	6.5.6 The wholesale distributors etc. should cope with a recall request.
6.5.7 Any recall operation should be recorded at the time it is carried out. Records should be made readily available to the competent authorities.	6.5.7 Any recall operation should be recorded at the time it is carried out.
6.5.8 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).	6.5.8 The distribution records should be readily accessible to the person(s) responsible for the recall, and should contain sufficient information on wholesale distributors etc. and directly supplied customers (with addresses, phone/fax numbers inside and outside working hours, email address, and as required by national legislation, name, lot number or manufacturing number, etc., expiry date, quantities delivered, etc. of medicinal product).
6.5.9 The progress of the recall process should be recorded for a final report including reconciliation of the recalled product.	6.5.9 The progress of the recall process should be recorded for a final report including reconciliation of the recalled product.
CHAPTER 7 — OUTSOURCED ACTIVITIES	CHAPTER 7 — OUTSOURCED ACTIVITIES

7.1. PRINCIPLE	7.1. PRINCIPLE
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.	Any activity covered by this Guideline 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. CONTRACT GIVER	7.2. CONTRACT GIVER
7.2.1 The Contract Giver is responsible for the activities contracted out.	7.2.1 The Contract Giver is responsible for the activities contracted out.
7.2.2 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.	7.2.2 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 this Guideline is followed. 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 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.	7.2.3 The Contract Giver should provide the Contract Acceptor with the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.

7.3. CONTRACT ACCEPTOR	7.3. CONTRACT ACCEPTOR
7.3.1 The Contract Acceptor is responsible for the activities covered by GDP and delegated by the Contract Giver.	7.3.1 The Contract Acceptor is responsible for the activities covered by this Guideline and delegated by the Contract Giver.
7.3.2 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.	7.3.2 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 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 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 about procuring, holding and supplying medicinal products (quality information required to conduct the activities contracted.) is made available in the same way as between the original Contract Giver and Contract Acceptor.
7.3.4 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 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 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.	7.3.5 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.
CHAPTER 8 — SELF-INSPECTIONS	CHAPTER 8 — SELF-INSPECTIONS

8.1. PRINCIPLE	8.1. PRINCIPLE
Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.	Self-inspections should be conducted in order to monitor implementation of and compliance with the principles of this Guideline and to propose necessary corrective measures.
8.2. SELF-INSPECTIONS	8.2. SELF-INSPECTIONS
8.2.1 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.	8.2.1 A self-inspection programme should be implemented covering all aspects of this Guideline and related procedures within a defined time frame. Self-inspections may be divided into several individual self-inspections of limited scope.
8.2.2 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.	8.2.2 Self-inspections should be regularly conducted by designated competent personnel.
8.2.3 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.	8.2.3 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 andCAPA should be documented and followed up in accordance with written procedures.
CHAPTER 9 — TRANSPORTATION	CHAPTER 9 — TRANSPORTATION
9.1. PRINCIPLE	9.1. PRINCIPLE
9.1.1 It is the responsibility of the supplying	9.1.1 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.	wholesale distributors etc. to protect medicinal products against breakage, adulteration, theft and to ensure that temperature conditions are maintained within acceptable limits during transport.
9.1.2 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	9.1.2 Regardless of the mode of transport, it should be demonstrated according to risk that the medicines have not been exposed to conditions that may compromise their integrity.
9.2. TRANSPORTATION	9.2. TRANSPORTATION
9.2.1 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.	9.2.1 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 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.	9.2.2 If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported to wholesale distributors etc. in accordance with written procedures. A procedure should also be in place for investigating and handling temperature excursions.
9.2.3 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.	9.2.3 Vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use. They should be appropriately equipped to prevent exposure of the products to conditions that could affect quality of the products and their packaging.
9.2.4 There should be written procedures in place for the operation and maintenance of	9.2.4 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.	all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.
9.2.5 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.	9.2.5 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 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 compromised.	9.2.6 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 compromised.
9.2.7 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.	9.2.7 Deliveries should not be made to any other addresses/premises than those stated on the delivery note.
9.2.8 For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available.	9.2.8 For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available.
9.2.9 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	9.2.9 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 distributors etc. 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.	unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any storage facilities.
9.2.10 Provision should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route.	9.2.10 Provision should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route.
9.3. CONTAINERS, PACKAGING AND LABELLING	9.3. SHIPPING CONTAINERS, PACKAGING AND LABELLING
9.3.1 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.	9.3.1 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 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.	9.3.2 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; the validation status of packaging and shipping containers.
9.3.3 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.	9.3.3 Shipping 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 shipping containers should enable identification of the contents of the containers and the source.

9.4. PRODUCTS REQUIRING SPECIAL CONDITIONS	9.4. PRODUCTS REQUIRING SPECIAL CONDITIONS
9.4.1 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.	9.4.1 In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances, the wholesale distributors etc. 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, missing, etc.
9.4.2 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.	9.4.2 Medicinal products comprising highly active and radioactive materials should be transported in accordance with related laws and regulations.
9.4.3 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.	9.4.3 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 wholesale distributors etc. and customer.
9.4.4 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	9.4.4 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.	conditions should be carried out and should take into account seasonal variations, if applicable.
9.4.5 If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions.	9.4.5 If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions.
9.4.6 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.	9.4.6 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 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.	9.4.7 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 The process for delivery of sensitive products and control of seasonal temperature variations should be described in a written procedure.	9.4.8 The process for delivery of sensitive products and control of seasonal temperature variations should be described in a written procedure.