GUIDANCE ON THE REQUIREMENT TO IMPORT, HANDLE, STORE AND DISTRIBUTE COVID-19 VACCINES IN MALAYSIA

1.0 INTRODUCTION

This guidance lays down the appropriate principles for those involved in the supply chain of COVID-19 vaccines in conducting their activities while ensuring the maintenance of high standards of quality assurance and integrity of the distribution processes. All parties involved, including but not limited to manufacturers, importers and wholesalers of COVID-19 vaccines are required to adopt proper distribution and store management procedures appropriate for the activities to ensure the product quality and efficacy is preserved and safe to be administered to the Malaysian population. These procedures should include the management of personnel, premises, facilities, transportation and adequate documentary procedures that preserve the safety and quality of the product.

2.0 GLOSSARY OF TERMS

Good Distribution Practice (GDP)	The measures that need to be considered in the storage, transportation and distribution of any product such that the nature and quality intended is preserved when it reaches the consumer.
Cold Chain	The process used to maintain optimal conditions during the transport, storage, and handling of cold chain products, from the point of manufacturer to the point of use
Qualification	Documented testing that demonstrates, with a high degree of assurance, that an equipment/facility will meet its predetermined acceptance criteria
Validation	Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.

3.0 PURPOSE

The purpose of this document is to provide guidance on the requirement to import, handle, store and distribute COVID-19 vaccines in Malaysia to ensure quality, safety & efficacy of the products are preserved until the point of vaccination.

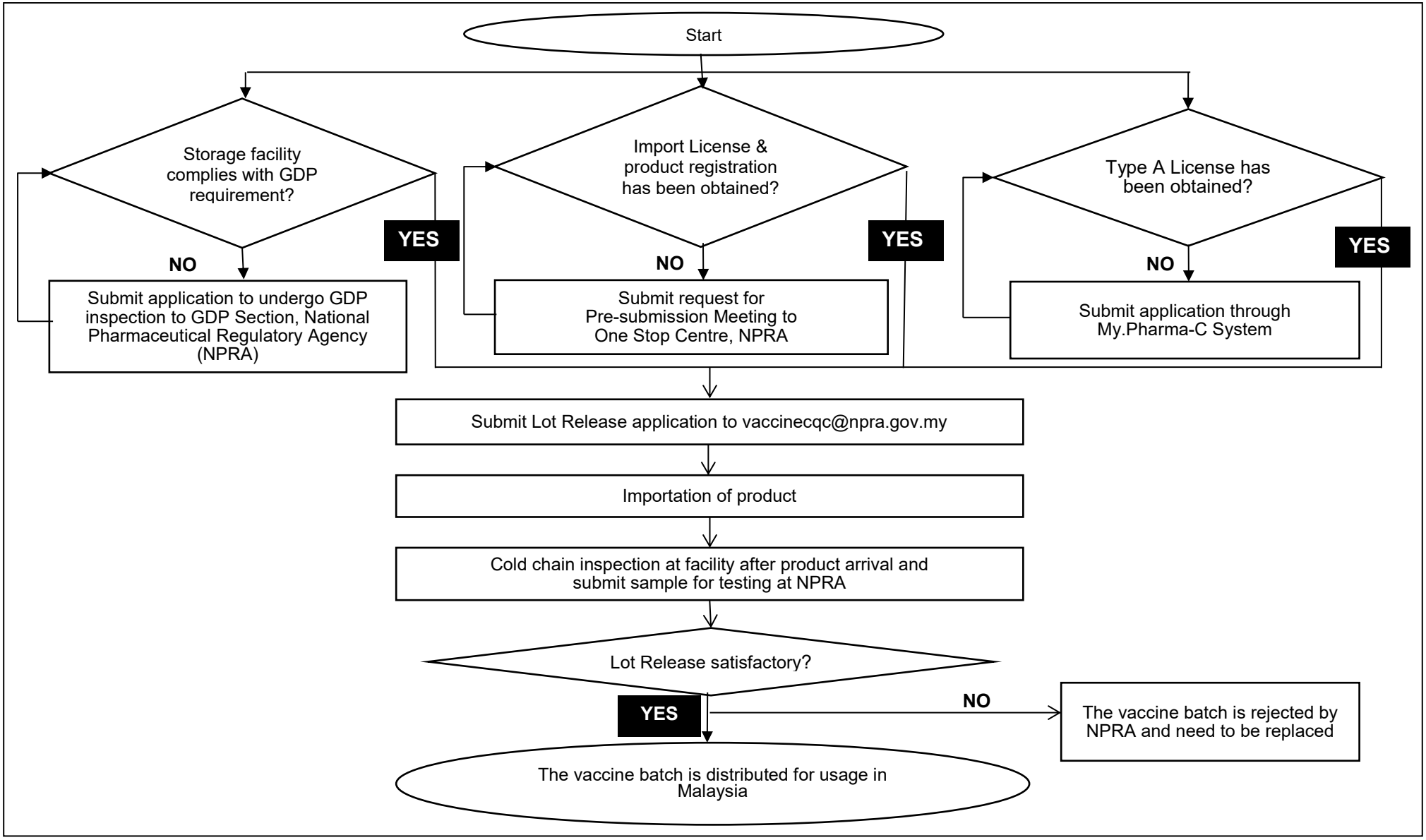
4.0 SCOPE & RESPONSIBILITIES

4.1 This guidance is applicable to all organisations and individuals involved in any aspect of the storage and distribution of COVID-19 vaccines including but not limited to the following:

- **Manufacturers** of active pharmaceutical ingredients, products and manufacturers involved in packaging/repackaging operations.
- **Importers and exporters.**
- **Wholesale distributors and distribution organisations** involved in road, rail, sea and/or air services.
- **Third-party logistics providers and freight forwarders**.
- Pharmacies including but not limited to retail, compounding and hospital.
- Health care professionals storing products prior to dispensing or administering to patients.

4.2 COVID-19 vaccine is regulated under the Poisons Act 1952 and its Regulations and Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984. Therefore, this guidance also requires that COVID-19 vaccines are imported, sale, supply, stored, distributed and transported in accordance with the requirements of the respective Acts and Regulations.

5.0 PROCESS FLOW FOR IMPORTATION OF COVID-19 VACCINE BY LICENCE HOLDER



6.0 STANDARD OPERATING PROCEDURES FOR MANAGING THE DISTRIBUTION OF COVID-19 VACCINES

	STANDARD/REQUIREMENTS	REFERENCE
6.1	**PRINCIPLE**	
6.1.1	Pre-Requirement: • Registered pharmacist with Type A licence issued under the Poisons Act 1952 (wholesale and retail or wholesale only) • Import Licence for registered vaccine issued under the Control of Drugs and Cosmetics Regulations 1984 • Distribution, storage and handling of vaccines shall follow Guideline on Good Distribution Practice (Third Edition, 2018)	• **Poisons Act 1952 and its Regulations** • **Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984** • **Guideline on Good Distribution Practice (Third Edition, 2018)**
6.1.2	A quality system setting out responsibilities, processes and risk management principles in relation to the activities of importation, exportation, procurement, storage, transportation and distribution of products should be maintained. All relevant activities should be clearly defined in procedures and systemically reviewed. All critical steps of the 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 personnel commitment.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 1: Quality System** Principle
6.1.3	There must be sufficient competent personnel to carry out all the assigned tasks. Individual responsibilities should be clearly understood by the personnel and be recorded.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 2: Personnel** Principle
6.1.4	Premises and equipment must be suitable and adequate as to ensure proper loading, unloading and storage, protection from contamination and distribution of products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises & Equipment** Principle

	STANDARD/REQUIREMENTS	REFERENCE
6.1.5	All actions taken should ensure that the identity of the products is not lost and the distribution of products is performed according to the information on the outer packaging. The risk of substandard and falsified products entering the legal supply chain should be eliminated/ minimised. All supplies of products must only be purchased from approved suppliers or companies that are authorised by the authorities. Where products are obtained from another wholesaler, the receiving wholesaler must verify that the supplier complies with the principles and guidelines of good distribution practices and that they hold a valid licence issued by the authority. All products purchased from suppliers and distributed in the intended market by company must be appropriately authorised by the authority. All key operations should be fully described in the quality system in appropriate documentation.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 4: Stock Handling & Stock Control** Principle
6.1.6	It is the responsibility of all **manufacturers, importers and wholesalers** of products to protect their products against breakage, adulteration, theft and to ensure that temperature conditions are maintained within acceptable limits during transport. Regardless of the mode of transport, it should be possible to demonstrate that the products have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 5: Transportation** Principle
6.1.7	All complaints must be recorded and handled carefully according to written procedures. Records should be made available to competent authority. An assessment of returned products should be performed by designated personnel before any approval for resale.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 6: Products/Cosmetics Complaint** Principle
6.1.8	The Control of Drugs and Cosmetics Regulations 1984, requires every licensed **manufacturer, importer and wholesaler** to have a procedure (Product Recall Procedure), which sets out in a step-wise manner the various actions to be taken to ensure the prompt recall of defective products. Such procedures should be reviewed regularly and updated.	**Control of Drugs and Cosmetics Regulations 1984** • **Regulation 25: Distribution Records** **Guideline on Good Distribution Practice (Third Edition, 2018)**

	STANDARD/REQUIREMENTS	REFERENCE
		• **Chapter 7: Products/Cosmetics Recall** Principle
6.1.9	Any substandard and falsified products found in the distribution network should be physically segregated from other products to avoid any confusion. They should be clearly labelled. All relevant activities in relation to such products should be documented and records retained. The sale and distribution of suspected substandard and falsified products should be suspended immediately. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against substandard and falsified products.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 8: Substandard and Falsified Products/Cosmetics** Principle
6.1.10	Any activities performed, referenced in the GDP guideline and delegated to another party should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the products. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly established the duties of each party.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 5: Transportation** Para 5.16-5.17 • **Chapter 9: Outsourced Activities** Principle
6.1.11	The quality system should include self-inspections. These should be conducted in order to monitor implementation and compliance with the principles of GDP and to trigger necessary corrective and preventive measures.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 10: Self-Inspection** Principle
6.1.12	Policies and procedures should be in place to ensure: • All records are kept in accordance with legislative requirements. • All records are maintained in accordance with the general requirements of this guideline and other relevant guideline by the national regulatory authority. • Prevent errors from verbal communication and permits the tracking of relevant operations during the receipt, storage and distribution of products.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 11: Management of Documentation & Records** Principle

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
6.2	**GENERAL**		
6.2.1	Policies and procedures should be available to ensure that the activities of receipt, storage and distribution are done without compromising on the safety, identity, strength, purity and quality of **time and temperature sensitive products (TTSP)** according to the manufacturer's recommended conditions as per the approved product's label by the authority as well as the product stability data.	• Written procedures on the handling of time and temperature sensitive products should be available to ensure that the quality, efficacy and safety of the products are not compromised. • All policies and procedures should be made aware to all personnel concerned. • All policies and procedures should be available in writing and situated in accessible area for easy reference by the personnel.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP**) Principle
6.3	**PERSONNEL**		
6.3.1	List of products including the cold chain storage temperature specifications should be provided for **reference to personnel** who handle the receipt of TTSP. • Regular and appropriate training should be provided for all personnel (including drivers) involved in the handling of TTSP to ensure the quality of TTSP are maintained. The training should	• List of all time and temperature sensitive products and its storage requirement should be available for reference to all warehouse personnel who handle the receipt of products. • Training schedule, continuous training and assessment to ensure personnel are equipped with specific knowledge and skills to handle time and temperature sensitive products should be provided. Training record and	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 1 & 2

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
	also cover on applicable pharmaceutical legislations and regulations. • SOPs and safety issues and response to emergencies. Training records and effectiveness checks on training provided should be available upon request.	effectiveness checks on training should be recorded and available upon request.	
6.4	**IMPORTATION (POINT OF ENTRY)**		
6.4.1	**Monitoring and controlling the importation** of pharmaceutical products including vaccines to ensure compliance with the requirement of the Poisons Act 1952 and Sale of Drugs Act 1952 and its Regulations.	• The importer must appoint forwarding agent/ customs agent to act on his behalf on matters relating to declaration and clearance of goods or entry under the Customs Act 1967. • The importer must submit exportation documents receive from the exporting party to the forwarding agent/ customs agent for import declaration purpose. • Documents required for declaration and clearance at the entry point include Type A Licence, Import Licence and other documents such as invoice, packing list, bill of lading/ airway bill. • The forwarding agent/ customs agent must submit the import document (K1 form) and other documents to	• **Poisons Act 1952 and its Regulations** • **Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984** • **Guideline on Good Distribution Practice (Third Edition, 2018)** • ***Panduan Pengimportan Barang-Barang Kawalan Bahagian Penguatkuasaan Farmasi (BPF) Kementerian Kesihatan Malaysia (KKM) Melalui Pintu Masuk Utama Kastam*. This reference can be download at www.pharmacy.gov.my**

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
		Pharmacy Enforcement Officer at the entry point. • The importer must ensure vaccines are store and handle based on Guideline on Good Distribution Practice and product specific requirement at the entry point.	
6.5	**FACILITIES AND EQUIPMENTS**		
6.5.1	**Net storage capacity of the storage facilities** should be sufficient to accommodate peak TTSP stock levels under correct temperature conditions and in a manner which enables efficient and correct stock management operations to take place.	Storage facilities should be of sufficient capacity to avoid the risks associated with overstocking and to ensure that good warehousing practices can be adopted. (First In-First Out (FIFO) or First Expired-First Out (FEFO). Overstocking makes FIFO or FEFO handling difficult or impossible and hinders accurate physical stock counts.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises & Equipment** • **Chapter 4: Stock Handling & Stock Control** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 3
6.5.2	TTSP **storage facilities should be qualified** prior to prevail that it is capable of storing the product in accordance with the specifications given situation. Qualification and validation records must be kept and TTSP storage facilities must be able to operate at all time in accordance to the qualifying conditions.	• Storage facilities should be qualified to ensure that labelled TTSP temperatures can be maintained during long-term storage and that the facility can be demonstrated to the authority and other interested parties that due diligence has been observed. • Storage facilities should be able to operate as per validated condition.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 4

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
		• Qualification documents of the storage facilities should be readily available upon request.	
6.5.3	**Household-style unit refrigerators and freezers** are only acceptable if they have been independently tested and found to comply with the temperature control requirements of a recognized standard for pharmaceutical refrigerators or freezers.	Household-style unit refrigerators and freezers should be purpose-designed for the storage of time and temperature sensitive products.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 5
6.5.4	Controlled or **hazardous TTSP** should be stored in dedicated, separated and securely locked facilities/areas that comply fully with all legislative and regulatory requirements.	To protect this category of products against theft and misuse and to safeguard personnel in the event of an accident involving hazardous substances.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 6
6.5.5	**Cold room, freezer room, refrigerator and freezer must be fitted with an alarm system** to alert personnel if any occurrence of temperature beyond specifications. Action and warning limits should be established. Periodic testing program on the alarm system should be established to ensure the alarm system is functioning.	• Alarm systems should include visual and audible alarms. • Alarm systems should be able to alert personnel during emergencies (including after working hours).	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 7

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
6.5.6	**Alternative power systems** should be established to ensure temperature remained and the temperature/ humidity detector will continue functioning in the event of power failure. **Periodic testing program on alternative power systems should be established** to ensure that it works. Alternative plan to provide alternative areas where storage temperature equivalent should be provided if no alternative power systems can be provided.	• Company should provide back-up power supply (e.g. uninterrupted power supply (UPS) system). • Company to develop and maintain a contingency plan in the event of power failure or any other unforeseen situation that may cause products to be at risk.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 1: Quality System** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 8
6.5.7	**Calibration and temperature monitoring functions** of all equipment, including alarms and other related equipment, **must be inspected at least annually.**	No clarifying remarks.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises and Equipment** Para 3.19 – 3.27 • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 9
6.5.8	**Periodic maintenance program** for all temperature controlled rooms, cold rooms, freezer rooms, refrigerators and freezers must be established and implemented.	• Company should provide validation reports for temperature mapping of the facilities. • Location of temperature logger should be identified.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises and Equipment** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 10

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
6.5.9	**Maximum and minimum temperature and humidity (if needed)** for all temperature controlled rooms, cold rooms, freezer rooms, refrigerators and freezers must be **monitored and recorded continuously using temperature and humidity monitoring devices.**	• Temperature and humidity (if needed) monitoring should be recorded to ensure that products are stored according to their temperature specifications. • Continuous recording devices are preferable as thermometers provide only limited and discontinuous temperature information.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises and Equipment** Para 3.16 -3.17 • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 13
6.5.10	Suitability of locations for placing temperature sensors in all temperature controlled rooms, cold rooms, freezer rooms, refrigerators and freezers used for storage of **TTSP should be subjected to temperature mapping study.** Mapping studies should be conducted in accordance with written procedures and storage conditions determined before operation.	• **Validation reports for temperature mapping** of storage facilities should be available. • **Location of temperature logger** should be identified.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises and Equipment** Para 3.18 • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 14
6.6	**STOCK RECEIVING AND HANDLING**		
6.6.1	**Verification upon receipt of products** should be done to ensure there are no signs of tampering and non-conformance (such as deviation of temperature profile from the manufacturer's recommendation as	Verification of products upon receipt should be conducted by personnel to ensure no signs of tampering to container systems used for delivery of products as well as other nonconformity such as deviation of temperature profile from the	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 4: Stock Handling and Stock Control** Para 4.1 – 4.5

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
	per the approved product's label by the authority, physical damage to products, packaging materials, etc.).	manufacturer's recommendation as per the approved product's label; physical damage to the products, packaging materials, label defects, etc.	• **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 11
6.6.2	All TTSP (e.g. rejected, quarantined) must be **stored under the storage conditions stated on the label** other than the product which will be disposed off. If the storage temperature is found to have deviated from the storage specifications, manufacturer for the products should be contacted to confirm the suitability of the use of products and the decision recorded.	No clarifying remarks.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 12
6.6.3	**Container systems** used for delivery of TTSP should be **fully qualified** to show that it is 'fit for purpose' and capable of maintaining the temperature profile defined for each product during transportation/ distribution, can minimize product degradation due to temperature sensitivity and can meet the product stability profile requirements stated by the pharmaceutical manufacturer.	• To ensure that products can safely be transported within the temperature profile defined for each product and that compliance should be able to be demonstrated to authority and other interested parties. • **Qualification and validation reports for container systems** used in delivery of products should be available.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 3: Premises and Equipment** Para 3.24 • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 15

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
	Documented evidence of such assurance and compliance should be demonstrated.		
6.6.4	**Packaging operations** for TTSP should be verified in accordance with written procedures. Packaging for TTSP should be mapped and continuously monitored.	• The packaging operations should be verified by a second person to ensure that the packaging operations are carried out in accordance with written procedures. • Packaging for products should be mapped and continuously monitored **by temperature indicator / calibrated temperature monitoring device.**	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 16
6.6.5	There should be a system in place to control the **reuse of temperature protection components** (e.g. ice/water blankets, water/gel packs, phase change materials, insulated packaging, etc.) to ensure that incomplete components are not used in error.	There should be procedure and associated records in place if cool packs are to be reused, in order to prevent the use of incompletely cooled packs, expired cool packs as well as physical segregation between frozen and cool packs.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 17
6.6.6	Necessary **precaution steps** should be implemented when using **dry ice** during transportation in order to **avoid a direct contact with the product** and consequently caused coagulation of products and personnel.	No clarifying remarks.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 18

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
6.6.7	TTSP should be **clearly labelled** and identifiable from other products in the same delivery. In cases where TTSP are to be air freighted, the package(s) should be labelled according to the International Air Transport Association (IATA) regulations.	To ensure that products are correctly and safely handled at all points in the supply chain.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 19
6.6.8	Procedures must be implemented to handle the **returned products** and also the products that have been stored under out of the specified storage condition during the reception, storage and distribution of products.	No clarifying remarks.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 4: Stock Handling and Stock Control** Para 4.13 – 4.21 • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 20
6.7	**TRANSPORTATION**		
6.7.1	TTSP should be **transported under validated conditions** to ensure that the relevant temperature range is maintained according to the directions on the label of the products. In addition, simulation studies can be conducted to validate the delivery conditions, taking into account the possibility of the worst situation.	• Any temperature excursions outside of the labeled storage conditions, for brief period, may be acceptable provided stability data and scientific/technical justification is available to ensure that product quality is not affected. • To ensure that products can safely be transported within the temperature profile defined for each product and	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 5: Transportation** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 21

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
		that compliance should be able to be demonstrated to authority and other interested parties. • **Validation reports** for transportation should be available. • Temperature monitoring devices or indicators should be used when appropriate (based on validation study done).	
6.7.2	**Refrigerated vehicles or containers** to transport TTSP should be mapped and continuously monitored.	Transportation of TTSP should be continuously monitored by calibrated temperature monitoring device.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 5: Transportation** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 22
6.7.3	**Delivery route** planning for TTSP should be created to prevent the risk of exposure to the products beyond the control of the ambient temperature. TTSP should be clearly identified from other items in the same distribution activities.	No clarifying remarks.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 5: Transportation** • **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 23
6.7.4	**Products labelled "Keep Frozen"** should be transported in such a manner to ensure that it remains frozen.	No clarifying remarks.	**Guideline on Good Distribution Practice (Third Edition, 2018)** • **Chapter 5: Transportation**

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
			• **Annex I: Management of Time and Temperature Sensitive Products (TTSP)** Clause 24
6.8	**LOT RELEASE REQUIREMENT**		
6.8.1	Refer to TRANSPORTATION (6.7)	Additional requirement: • Manufacturers shall include **WHO Prequalified Temperature Monitoring Devices** for transportation and shipping of their products	**WHO Guidelines on the International Packaging and Shipping of Vaccines, December 2005 (WHO/IVB/05.23).**
6.8.2	Submission of Lot Release application	Importer shall submit Lot Release application to: vaccinecqc@npra.gov.my together with the following document: • Batch Release Certificate from National Regulatory Authority of country of origin for the vaccine batch • Manufacture's summary protocol for the batch (lot summary protocol) • Packing list • Air Waybill	
6.8.3	Arrangement for cold chain inspection	**Vaccine other than Pfizer:** • Once the arrival date has been confirm, importer shall arrange for inspection through: vaccinecqc@npra.gov.my • Warehouse to download temperature data logger and prepare Vaccine Arrival Report (Part 1)	

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
		Vaccine from Pfizer: • Once the arrival date has been confirm, Pfizer shall arrange for inspection through: vaccinecqc@npra.gov.my • Pfizer to download temperature data logger at point of vaccine delivery	
6.8.4	Sample submission for testing in NPRA laboratory	**Vaccine other than Pfizer:** • Importer to arrange for sample submission to NPRA laboratory **Vaccine from Pfizer:** • Pfizer to arrange for sample submission to NPRA laboratory	
6.8.5	Non-conformance in Lot Release requirements	If Lot Release requirement is not fulfil, it is the responsibility of the following: a) To quarantine the vaccine batch • **Vaccine other than Pfizer:** Importer • **Vaccine from Pfizer:** Pfizer b) To replace the vaccine batch: • **Vaccine other than Pfizer:** Subject to agreement • **Vaccine from Pfizer:** Pfizer	

	STANDARD/REQUIREMENTS	EXPLANATION	REFERENCE
REFERENCES			
1	**Poisons Act 1952 and its Regulations**		
2	**Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984**		
3	**Guideline on Good Distribution Practice (Third Edition, 2018)**		
4	**Supplementary Notes on Annex 1: Management of Time and Temperature Sensitive Products (TTSP) of Guideline on Good Distribution Practice**		
5	**WHO Guidelines on the International Packaging and Shipping of Vaccines, December 2005 (WHO/IVB/05.23)**		
6	**Panduan Pengimportan Barang-Barang Kawalan Bahagian Penguatkuasaan Farmasi (BPF) Kementerian Kesihatan Malaysia (KKM) Melalui Pintu Masuk Utama Kastam**		

7.0 DOCUMENTATION

DISTRIBUTION LEVEL	PROCESS	RESPONSIBILITY	GUIDELINES / REFERENCE	DOCUMENTS REQUIREMENT
IMPORTER	• Submission of Lot Release Application via email notification • Appoint forwarding agents	Importer	• Poisons Act 1952 **Control of Drugs and Cosmetics Regulations 1984**	• Type A Licence • Import Licence for registered vaccine • Invoice • Bill of lading (port)/ airway bill (plane) • K1 Declaration • Packing & Shipping Validation Document

DISTRIBUTION LEVEL	PROCESS	RESPONSIBILITY	GUIDELINES / REFERENCE	DOCUMENTS REQUIREMENT
				• Lot Summary Protocol/Batch Release Certificate • Packing list WHO Prequalified Data Logger
TEMPORARY STORAGE AT ENTRY POINT	Declaration and clearance of product at the entry point	• Importer Freight forwarding agent	• Customs Act 1967 • Poisons Act 1952 • **Control of Drugs and Cosmetics Regulations 1984** *Panduan Pengimportan Barang-Barang Kawalan Bahagian Penguatkuasaan Farmasi (BPF) Kementerian Kesihatan Malaysia (KKM) Melalui Pintu Masuk Utama Kastam*	• Import document (K1 form) • Type A Licence • Import Licence for registered vaccine • Other documents such as invoice, packing list, bill of lading/ airway bill
WAREHOUSE	**Vaccine other than Pfizer:** • Warehouse to inform NPRA team on shipment arrival and arrange for cold chain inspection • NPRA team conduct cold chain inspection Warehouse to download temperature data logger and prepare Vaccine Arrival Report (Part 1)	• Warehouse NPRA	**Guideline on Good Distribution Practice (Third Edition, 2018)**	• Vaccine Arrival Report (Part 1) • Batch Release Certificate
	Vaccine from Pfizer:			

DISTRIBUTION LEVEL	PROCESS	RESPONSIBILITY	GUIDELINES / REFERENCE	DOCUMENTS REQUIREMENT
	Not applicable	Not applicable	Not applicable	Not applicable
HEALTH/ VACCINATION CENTER	**Vaccine other than Pfizer:** Not applicable	Not applicable	Not applicable	Not applicable
	Vaccine from Pfizer: • Pfizer to inform NPRA team on shipment arrival and arrange for cold chain inspection • NPRA team conduct cold chain inspection • Pfizer to download temperature data logger • NPRA team to assess temperature record	• Pfizer NPRA	**Guideline on Good Distribution Practice (Third Edition, 2018)**	• Vaccine Arrival Report (Part 1) • Batch Release Certificate