Ministry of Health Malaysia

GUIDELINE FOR THE MANAGEMENT OF MEDICINE DONATIONS

MINISTRY OF HEALTH MALAYSIA

PHARMACEUTICAL SERVICES PROGRAMME

First printed: 2024

e ISBN 978-967-2854-55-5

ACKNOWLEDGEMENT

The Pharmaceutical Services Programme of the Ministry of Health would like to express appreciation to the following contributors for their support and contribution throughout the preparation of this guideline:

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Association of Private Hospitals of Malaysia (APHM)
Disease Control Division, Ministry of Health Malaysia
Global Peace Mission Malaysia
Health Service Division, Ministry of Defence
Malaysia Medical Relief Society (MERCY Malaysia)
Malaysian Organisation of Pharmaceutical Industries (MOPI)
National Security Council, Prime Minister's Department
Hospital Canselor Tuanku Muhriz (UKM), Malaysia
Pharmaceutical Association of Malaysia (PhAMA)
Procurement and Privatization Division, Ministry of Health Malaysia
Royal Malaysian Customs Department
University Malaya Medical Centre (UMMC), Malaysia

ABBREVIATION

APHM	Association of Private Hospitals of Malaysia
CPRC	Crisis Preparedness Response Centre
DCA	Drug Control Authority
DG	Director General
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
IEHK	Interagency Emergency Health Kit
INN	International Non-proprietary Name
MOFA	Ministry of Foreign Affairs, Malaysia
MERCY	Malaysia Medical Relief Society
MNMP	Malaysian National Medicines Policy
MOH	Ministry of Health
MOPI	Malaysian Organisation of Pharmaceutical Industries
NEML	National Essential Medicines List
NGO	Non-Governmental Organisation
NPRA	National Pharmaceutical Regulatory Agency
NSC	National Security Council
PhAMA	Pharmaceutical Association of Malaysia
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PSP	Pharmaceutical Services Programme
WHO	World Health Organisation

GLOSSARY

- **Dangerous drug** ~ Any drugs or substance which is for the time being comprised in the First Schedule of Dangerous Drugs Act 1952, Malaysia (Annex 1).

- **Development Aid** ~ This is the international transfer of public funds in the form of loans or grants, either directly from one government to another (bilateral aid), or indirectly through non-governmental organizations or a multilateral agency (multilateral aid) such as the World Bank or WHO.

- **Drug Control Authority** ~ Drug Control Authority is the executive body established under the Control of Drugs and Cosmetics Regulations 1984.The main task of this Authority is to ensure the safety, quality and efficacy of medicinal products and safety and quality of traditional medicines, health supplements and cosmetics that are marketed in Malaysia.

- **Emergency** ~ A situation that poses an immediate risk to health, life, property or environment. A "state of emergency" demands to "be declared" or imposed by an authority such as the National Security Council of Malaysia.

- **Good Distribution Practice** ~ Good Distribution Practice is defined as the measures that need to be considered in the storage, transportation and distribution of any registered product / notified cosmetic and its related materials such that the nature and quality intended is preserved when it reaches the consumer.

- **Interagency Emergency Health Kit** ~ Interagency Emergency Health Kit is a kit designed to meet the needs of a displaced population without medical facilities, or a population with disrupted medical facilities in the immediate aftermath of a natural disaster or during an emergency.

- **International Non-proprietary Names** ~ International Non-proprietary Names identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A non-proprietary name is also known as a generic name. (Guidelines on the Use of International Non-proprietary Names (INN) For Pharmaceutical Substance, WHO/PHARM S/NOM 1570).

- **Medicine Donations** ~ Form of gift given by physical or legal persons, typically for charitable purposes and/or to benefit a cause in both emergency and non-emergency situations. It also may consist of emergency, relief or humanitarian aid items. Foreign mobile field hospitals/clinics require clearance by the MOH Malaysia. The medicine supply that is part of foreign mobile field hospitals / clinics is not in the scope of these guidelines.

- **National Essential Medicines List** ~ National Essential Medicines List comprises of essential medicines which satisfy the priority health care needs of the population; thus, should be easily available in adequate quantities and in suitable dosage forms. The NEML consists of list of medicines needed for primary, secondary and tertiary health care treatment.

- **Non-Governmental Organisation** ~ Non-governmental organisation is a legally constituted non-profit organisation created by natural or legal persons that operates independently from any government and a term usually used by governments to refer to entities that have no government status.

- **Psychotropic substance** ~ Any of the substances specified in the Third Schedule of Poisons Act 1952, Malaysia (Annex 2).

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1.0 INTRODUCTION

The guideline for the management of medicine donations has been developed by the Working Group of the Technical Committee of Drug Availability under the umbrella of the Malaysian National Medicines Policy (MNMP). The core principles of this guideline are adapted from the World Health Organization (WHO) Guidelines for Medicine Donations (Revised 2010).

The aim of this guideline is to improve the quality of medicine donations, and to facilitate donation procedures. It is intended to serve as a basis for national utilization in dealing with medicine donations. There are legitimate differences between the different scenarios of medicine donations. Therefore, basic rules for an appropriate donation have to be followed.

The importation and supply of medicines donated by foreign or local parties to private agency or any entity in Malaysia, including the Malaysian Government, must be done in compliance with the laws in force, namely the Sale of Drugs Act 1952 and its regulations, the Poisons Act 1952 and its regulations and the Dangerous Drugs Act 1952 and its regulations.

2.0 CORE PRINCIPLES

Guideline for the Management of Medicine Donations is based on four core principles, as stated by the WHO Guidelines for Medicine Donations, namely:

1. Donations of medicines should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited medicine donations are to be discouraged.

2. Donations of medicines should be made with full respect for the wishes and authority of the recipient, and in conformity with existing government health policies and administrative arrangements of the recipient country.

3. There should be no double standards in quality. If the quality of a medicine is unacceptable in the donor country, it is also unacceptable as a donation.

4. There should be effective coordination and collaboration between the donor and the recipient. Donations should be based on an expressed need and should not be sent unannounced.

Core principles for a donation

(i) Maximum benefit to the recipient
(ii) Respect for wishes and authority of the recipient
(iii) No double standards in quality
(iv) Effective communication between donor and recipient

3.0 SCOPE

This document shall be used specifically for all MOH health facilities involved in local and foreign medicine donations. Nonetheless, other stakeholders may use this document as a reference for matters related to medicine donations.

4.0 MANAGEMENT OF MEDICINE DONATIONS WITHIN MALAYSIA (LOCAL MEDICINE DONATIONS)

Medicine donations within Malaysia comprises of **donations from private agency or entity to government and donations from government to private agency**. All donated medicine within Malaysia shall comply with the existing laws, regulations and guidelines **as follows:**

(a) Poisons Act 1952 and its Regulations
(b) Dangerous Drugs Act 1952 and its Regulations
(c) Sale of Drugs Act 1952 and its Regulations
(d) Pekeliling Perkhidmatan Sumber Manusia (MyPPSM) Ceraian UP 7.2.5 – Pengurusan Penerimaan atau Pemberian Hadiah, Keraian dan Tajaan dalam Perkhidmatan Awam
(e) Tatacara Pengurusan Stor Kerajaan (TPS) (2018)
(f) Pelan Pengurusan Krisis dan Bencana Peringkat Kementerian Kesihatan Malaysia (2015)
(g) Garis Panduan Pengurusan Farmasi Logistik Kementerian Kesihatan Malaysia (2020)
(h) Pelan Pengurusan Krisis dan Bencana bagi Perkhidmatan Farmasi (2016)
(i) Garis Panduan Permohonan Kelulusan Penerimaan Hadiah Bukan Tunai untuk Kegunaan Jabatan di Kementerian Kesihatan Malaysia (2023)

This guideline should be read in conjunction with the existing laws and regulations together with other relevant legislations where applicable.

4.1 Selection of Medicines

4.1.1 All medicine donations should be based on an expressed need, should be relevant to the disease pattern in Malaysia and quantities should be agreed upon by both donor and recipient. Medicines should not be sent to recipient without prior consent.

4.1.2 All donated medicines must be registered under the Control of Drugs and Cosmetics Regulations 1984 made under the Sale of Drugs Act 1952. Donated medicines which are to be used in MOH health facility should be listed in the Ministry of Health Malaysia Drug Formulary or its equivalent or be included in the national standard treatment guidelines, unless exceptions apply.

4.2 Quality Assurance and Shelf-Life

4.2.1 All donated medicines should be obtained from a quality-ensured source and have a remaining shelf-life of at least one year upon receiving. An exception may be made for direct donations to specific health institution or non-governmental organizations, provided that the responsible professionals at the recipient acknowledges the shelf-life and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases, it is important that the date of receiving and the expiry dates of the medicines be informed to the recipient well in advance.

4.2.2 Returned medicines to a pharmacy or elsewhere, or medicines given to health professionals should not be donated.

4.3 Presentation, Packing and Labelling

4.3.1 All donation of medicines should be packed in accordance with international shipping and Control of Drugs and Cosmetics Regulations 1984 requirements (applicable to medicine donations from Peninsular Malaysia to East Malaysia and vice versa).

4.3.2 All medicines should be labelled as a minimum in English language. The label on each container should contain at least the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, country of manufacture, quantity in the container, storage conditions and expiry date.

4.3.3 Medicines should not be mixed with other supplies (such as food) in the same box.

4.3.4 Recipients should be informed about the status of donations of medicines, whether they being considered, prepared or underway.

4.3.5 Transport, warehousing, port clearance and appropriate storage and handling costs should be paid by the donor agency unless specifically agreed otherwise with the recipient in advance. If the donation is to a government agency but require a cost to be borne by government, the agency should ensure adequate funds are available. The donor should bear the costs of transport or disposal of donations.

4.4 Administrative Procedure for Receiving Local Medicine Donations at MOH and MOH Health Facility

4.4.1 Donations where the intended recipient is a government agency should strictly follow the Public Service Circulars and the guidelines as follows;

(i) Pekeliling Perkhidmatan Sumber Manusia (MyPPSM) Ceraian UP 7.2.5 – Pengurusan Penerimaan atau Pemberian Hadiah, Keraian dan Tajaan dalam Perkhidmatan Awam

(ii) Tatacara Pengurusan Stor Kerajaan (TPS) (2018)

(iii) Garis Panduan Pengurusan Farmasi Logistik Kementerian Kesihatan Malaysia (2020)

(iv) Garis Panduan Permohonan Kelulusan Penerimaan Hadiah Bukan Tunai untuk Kegunaan Jabatan di Kementerian Kesihatan Malaysia (2023)

(v) Garis Panduan Pengurusan Produk Rangkaian Sejuk di Fasiliti Kementerian Kesihatan Malaysia (2019) (applicable for cold chain items such as vaccine)

4.4.2 Donation of psychotropic substances and dangerous drug within Malaysia needs to fulfil the requirements under the Poisons Act 1952, Poisons (Psychotropic Substances) Regulations 1989 and Dangerous Drugs Act 1952.

4.4.3 Possible exemptions, such as donation of unregistered products in emergency situation must apply under specific circumstances by special permission / special provision from the Minister of Health Malaysia.

4.4.4 These procedures should be read in conjunction with the current laws and regulations together with other relevant legislations where applicable.

4.4.5 In non-emergency situations, local standard procedures governing donations should apply. The donor should first seek advice from the MOH Malaysia for the appropriate channel in obtaining approval for donation.

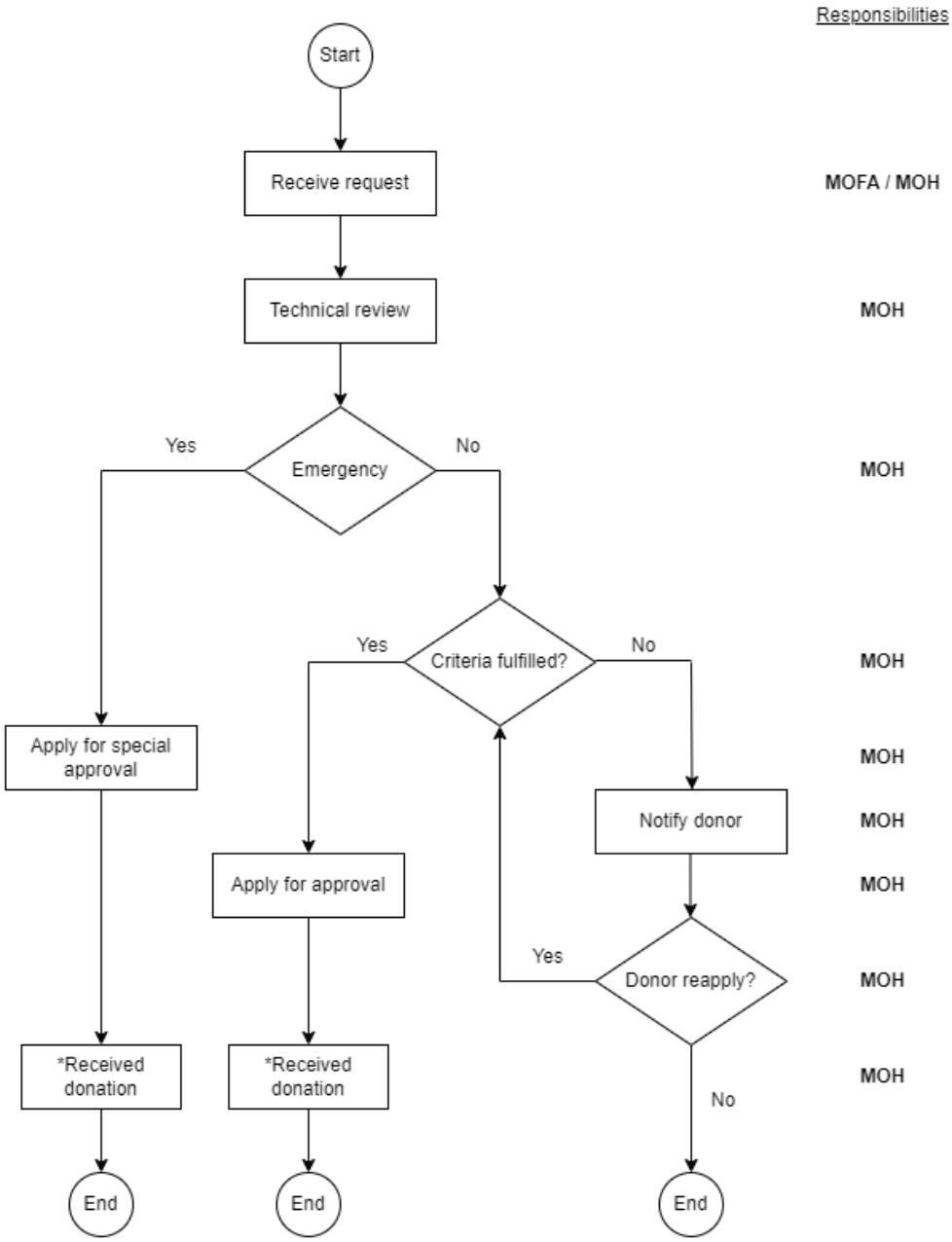
4.4.6 Donations where the intended recipient is a government affiliated entity, should strictly follow the guidelines stipulated in the Public Service Circulars as follows:

(i) Pekeliling Perkhidmatan Sumber Manusia (MyPPSM) Ceraian UP 7.2.5 – Pengurusan Penerimaan atau Pemberian Hadiah, Keraian dan Tajaan dalam Perkhidmatan Awam

4.4.7 Donations where the intended recipient is a private institution or NGO; should adhere to the general rules for the management of medicine donations in Chapter 4 or Chapter 6 of this guideline, followed by any specific medicine donations policy or procedures of the recipient.

4.4.8 Procedures for receiving medicine donations are summarized diagrammatically as per **Figure 1.**

Figure 1: Flow Chart for receiving Medicine Donations



*Receiving of any biological products and vaccines is in line with the Lot Release requirements enforced by NPRA

5.0 MANAGEMENT OF MEDICINE DONATIONS BY MALAYSIA

Medicine donations to be exported from Malaysia to other countries or international agencies shall comply with the existing laws, regulations and guidelines as follows:

(a) Poisons Act 1952 and its Regulations
(b) Dangerous Drugs Act 1952 and its Regulations
(c) Sale of Drugs Act 1952 and its Regulations
(d) Customs Act 1967
(e) Single Convention on Narcotic Drugs 1961
(f) Convention on Psychotropic Substances 1971
(g) United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988
(h) Garis Panduan Pengurusan Produk Rangkaian Sejuk di Fasiliti Kementerian Kesihatan Malaysia 2019

5.1 Selection of Medicines

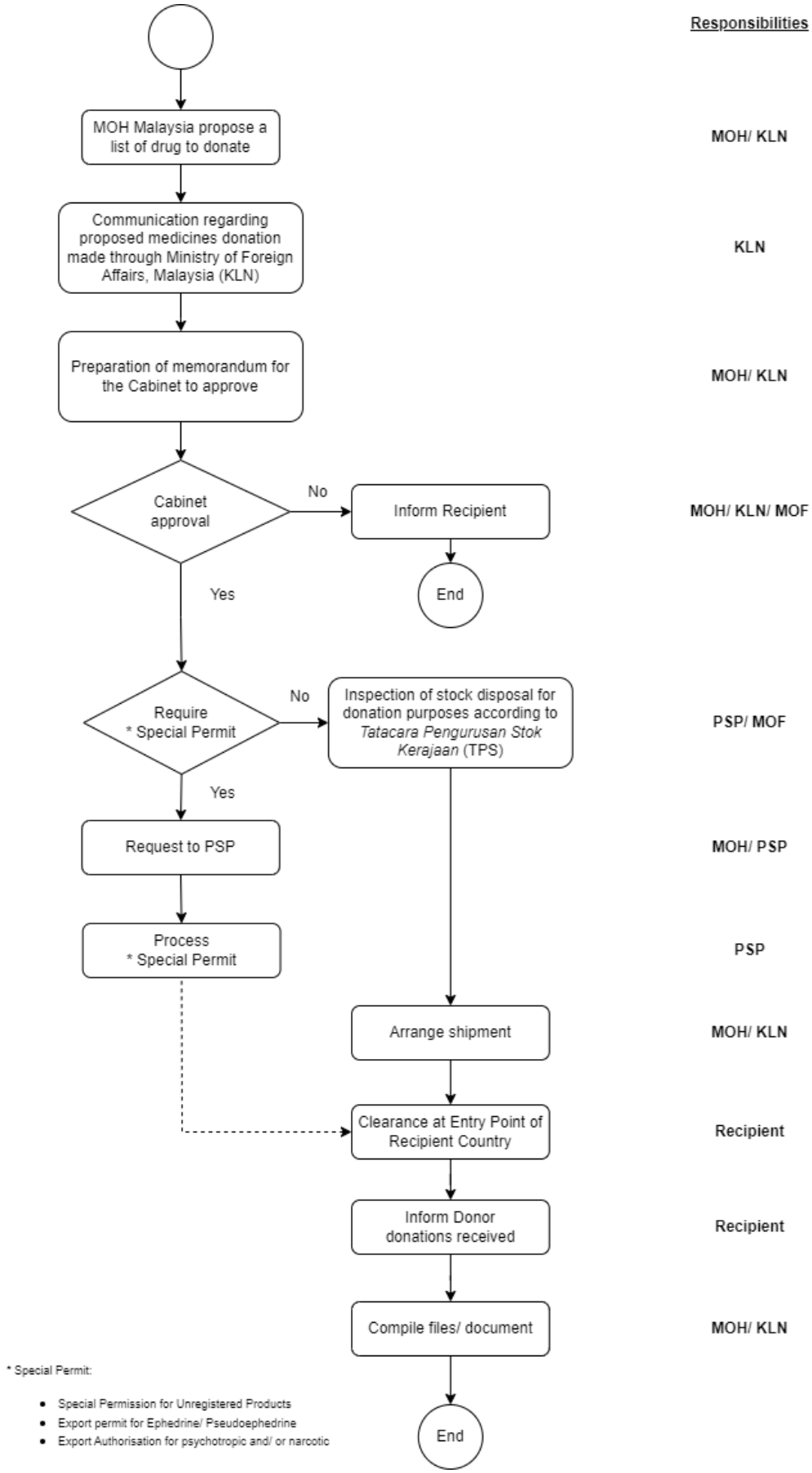
5.1.1 All medicine donations should be based on an expressed need, and quantities should be agreed upon by both Malaysia and the recipient. Medicines should not be sent to the recipients without prior consent.

5.1.2 The presentation, strength and formulation of donated medicines should be fulfilling the requirement of the recipient.

5.1.3 Cabinet approval via MOFA must be obtained for all donations.

5.1.4 Procedures for donating medicine are summarized diagrammatically as **Figure 2**.

Figure 2: Flow Chart for Medicine Donations by Malaysia



5.2 Quality Assurance

5.2.1 All donated medicines should be obtained from a quality-ensured source and comply with the requirement of the recipient's regulatory authority.

5.2.2 Medicines must be registered with the DCA of Malaysia prior to donation.

5.2.3 Medicines that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals should not be donated.

5.2.4 Vaccine or plasma product that failed to comply to Lot Release requirements shall not be donated.

5.3 Presentation, Packing and Labelling

5.3.1 All donated medicines should comply with the requirement of Control of Drugs and Cosmetics Regulations 1984 and the recipient's regulatory authority.

5.3.2 All medicines should be labelled in a language that is easily understood by health professionals in the recipient country. The label on each container should contain at least the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, country of manufacture, quantity in the container, storage conditions and expiry date.

5.3.3 Donated medicines should be presented in pack sizes that are suitable for the recipients and appropriate to the setting in which they will be distributed or dispensed.

5.3.4 All donated medicines should be packed in accordance with international shipping requirements, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. Medicines should not be mixed with other supplies in the same box.

5.4 Information and Management

5.4.1 Recipients should be provided with information for medicine donations, including:

(i) Type and quantities of donated medicines
(ii) International Non-proprietary Name (INN) or generic name
(iii) Strength dosage form
(iv) Manufacturer
(v) Expiry date
(vi) Reference to earlier correspondence (for example, the letter of consent by the recipient)
(vii) The expected date of arrival and port of entry
(viii) The identity and contact address of the donor
(ix) Certificate of Analysis (COA) for every batch of medicines donated
(x) Manufacturer's Good Manufacturing Practice (GMP) documents
(xi) Lot Release Certificate issued by NPRA (applicable for vaccine or plasma product only)

5.4.2 The declared value of donated medicines should be based upon actual/ available market price of the medicines in Malaysia.

5.4.3 The international and local transport, warehousing, port clearance and customs, storage, handling and disposal or reverse logistics of expired donated products costs; should be agreed upon by both parties.

5.4.4 Donation of psychotropic substances and dangerous drug exported to other countries requires an Export Authorisations as outlined under the Poisons Act 1952, Poisons (Psychotropic Substances) Regulations 1989, and Dangerous Drugs Act 1952 as well as international conventions i.e. Single Convention on Narcotic Drugs 1961; Convention on Psychotropic Substances 1971]. Whereas an Export Licence under the Customs Act 1967 is needed for the exportation of product containing ephedrine / pseudoephedrine.

5.5 Possible Exemptions

5.5.1 Possible exemptions must be applied under specific circumstances by special permission (for unregistered product)

6.0 MANAGEMENT OF MEDICINE DONATIONS FROM OTHER COUNTRIES TO MALAYSIA

All donated medicine imported into Malaysia from other countries or international agencies shall comply with the existing laws, regulations and guidelines as follows:

(a) Poisons Act 1952 and its Regulations
(b) Dangerous Drugs Act 1952 and its Regulations
(c) Sale of Drugs Act 1952 and its Regulations
(d) Customs Act 1967
(e) Single Convention on Narcotic Drugs 1961
(f) Convention on Psychotropic Substances 1971
(g) United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988
(h) Guideline for Good Distribution Practice 2018
(i) Guidance Document for Biologicals Lot Release in Malaysia 2019 (applicable for importation of vaccines / plasma products only)

6.1 Selection of Medicines

6.1.1 All medicine donations should be based on an expressed need, relevant to the disease pattern in Malaysia and with agreed quantities between donor and recipient in Malaysia. Medicines should not be sent to the recipients without prior consent.

6.1.2 All donated medicines should be registered with DCA. Possible exceptions may be granted based on circumstances with sudden outbreaks of uncommon or newly emerging diseases with the approval from relevant authorities.

6.1.3 Donated medicines which are to be used in MOH health facility should be listed in the Ministry of Health Malaysia Drug Formulary or its equivalent or be included in the national standard treatment guidelines, unless exceptions apply.

6.1.4 The presentation, strength and formulation of donated medicines should, as much as possible, be similar to the medicines commonly used in Malaysia.

6.1.5 Cabinet approval via MOFA must be obtained for all donations.

6.1.6 Possible exemptions, such as International Emergency Medical Team (iEMT) with donation of unregistered products in emergency situation must apply under specific circumstances by special permission / special provision from the Minister of Health Malaysia.

6.1.7 Procedures for receiving medicine donations are summarized diagrammatically as **Figure 3** and **Figure 4**.

6.2 Possible Exceptions

6.2.1 An exception on the listing within the Ministry of Health Malaysia Drug Formulary can be made when the medicine is needed in circumstances with sudden outbreaks of uncommon or newly emerging diseases.

6.2.2 In acute emergencies, requirement for registration may not be practical. Special permission may be sought directly from the MOH Malaysia for the importation of these unregistered products.

6.2.3 An exception on the remaining shelf-life may be made when the responsible professionals at the receiving end (private health institutions or non-governmental organizations) acknowledges that he / she is aware of the shelf-life; and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases, it is important that the date of receiving and the expiry dates of the medicines be informed to the recipient well in advance.

Figure 3: Flow Chart for Receiving Medicine Donations from Other Countries (Government)

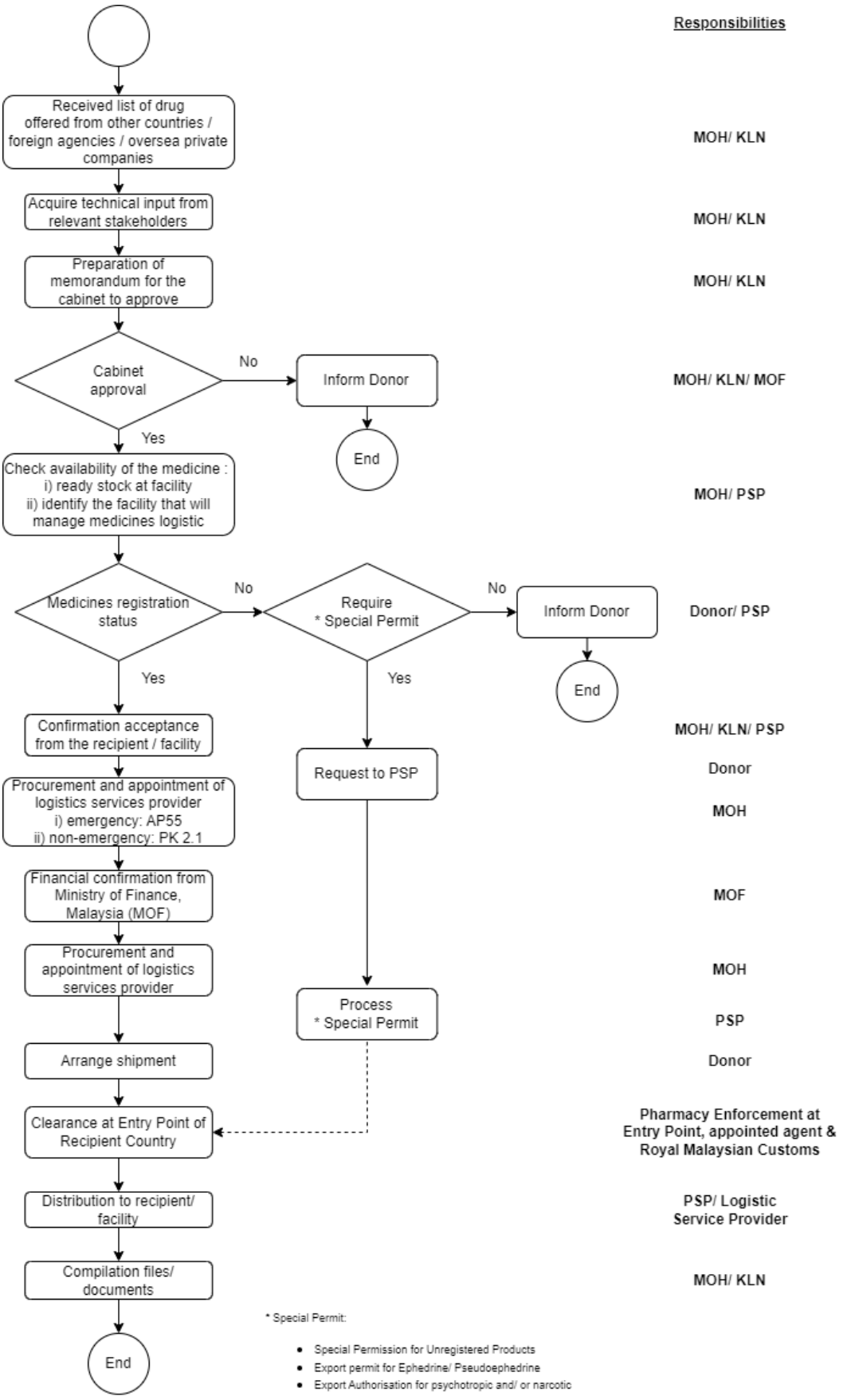
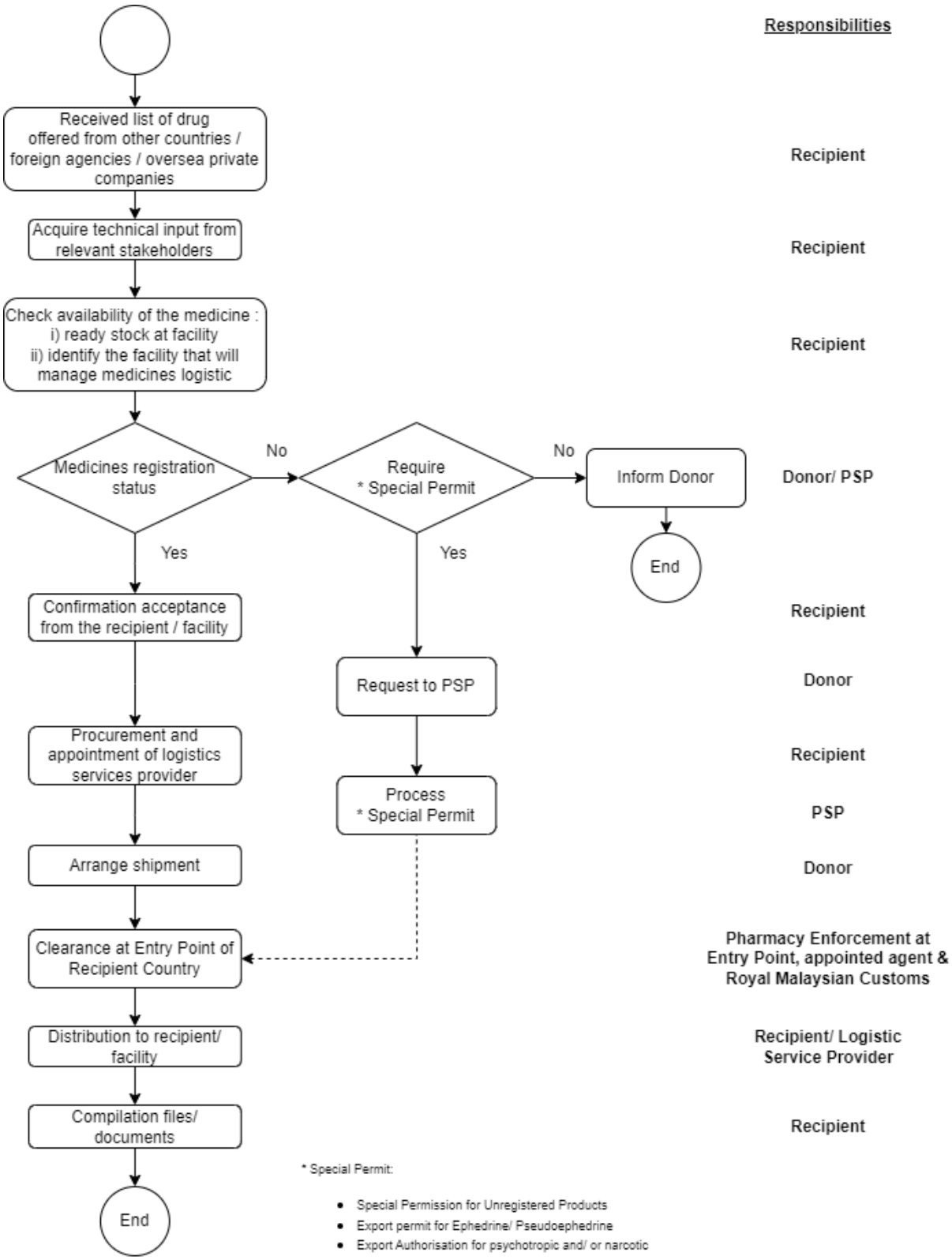


Figure 4: Flow Chart for Receiving Medicine Donations from Other Countries (Private Agency or Entity)



6.3 Quality Assurance and Shelf-Life

6.3.1 All donated medicines should be obtained from a quality-ensured source and comply with quality standards in both donor country and Malaysia. Medicines must be registered with the DCA of Malaysia or obtain special permission, prior to entry. Prior consultation with the recipient is advised before shipment.

If the above document is unavailable, evidence of certification on either of the following may be used for permission of importation:

(a) Pharmaceutical Inspection Cooperation Scheme member countries (PIC/S) / WHO Good Manufacturing Practice standards;
(b) WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

6.3.2 Medicines that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals; should not be donated.

6.3.3 All donated medicines upon arrival in Malaysia; should have a remaining shelf-life of at least one year for non-emergency and emergency donations.

6.4 Presentation, Packing and Labelling

6.4.1 All medicines should be labelled in English and / or Malay language. The label on each individual container should at least consist of the International Non-proprietary Name (INN) or generic name, country of origin, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions, expiry date and route of administration for injections. The package insert should also be made available in English and / or Malay language.

6.4.2 Donated medicines should be presented in pack sizes that are suitable for the recipients and appropriate to the setting in which they will be distributed or dispensed.

6.4.3 All donated medicines should be packed in accordance with international shipping requirements, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. Medicines should not be mixed with other supplies in the same carton.

6.5 Information and Management

6.5.1 Recipients should be provided with information medicine donations, including the type and quantities of donated medicines including their International Non-proprietary Name (INN) or generic name, strength, dosage form, manufacturer and expiry date; reference to earlier correspondence (for example, the letter of consent by the recipient); the expected date of arrival and port of entry; and the identity and contact address of the donor.

6.5.2 The declared value of a medicine donation should be based upon the wholesale price of its generic equivalent in Malaysia, or, if such information is not available, on the wholesale world-market price for its generic equivalent.

6.5.3 Costs of international and local transport, warehousing, port clearance and (customs) storage, handling and disposal or reverse logistics of expired donated products should be paid for by the donor agency, unless specifically agreed upon in advanced by the two parties.

6.5.4 Donation of psychotropic substances and dangerous drug which is imported from other countries requires an Import Authorisations as outlined under the Poisons Act 1952, Poisons (Psychotropic Substances) Regulations 1989, and Dangerous Drugs Act 1952 as well as international conventions i.e. Single Convention on Narcotic Drugs 1961; Convention on Psychotropic Substances 1971]. Whereas an Import Licence under the Customs Act 1967 is needed for the importation of product containing ephedrine / pseudoephedrine.

6.5.5 Possible exemptions may apply under specific circumstances by special permission from the competent authority for unregistered product.

7.0 MANAGEMENT OF DONATED MEDICINES

7.1 Clearance of Donated Medicines

7.1.1 It is recognized that medicine donations mostly occur in time of crisis and dire need. The procedures outlined will assist in expediting the clearance of these supplies without compromising the public safety and security of the nation. To ensure rapid customs clearance, medicine donations should be pre-planned with all the necessary requirements for customs clearance prior to shipment.

7.1.2 The following documents should be made available:

(a) Relevant licence / authorisation for import / export of the intended medicine shipment. These include special permits pertaining to the shipment of:

(i) medicines containing psychotropic substances (Authorisation to Import / Export Psychotropic Substances)
(ii) medicines containing dangerous drug (Authorisation to Import / Export Dangerous Drugs)
(iii) product containing ephedrine/ pseudoephedrine (licence to import/ export ephedrine/ pseudoephedrine)
(iv) unregistered product (Exemption letter by the MOH Malaysia)

(b) Bill of lading / airway bill
(c) Import invoice
(d) Packing list
(e) Relevant custom clearance forms (Declaration of Goods Imported / Declaration of Goods Exported)

7.1.3 Inadequate documentation will hinder the smooth processing for all donated medicines. Under the guidelines, the Royal Malaysian Customs and Health Ministry Officials managing medicine donations will assist in allowing fast entry for useful donations, while rejecting donations which are deemed inappropriate.

7.2 Logistic Management of Donated Medicines

7.2.1 On arrival the medicines should be inspected and their receipt confirmed to the donor agency. They should then be stored and distributed in accordance with the requirements principles of Good Distribution Practice (GDP), and under the responsibility of adequately trained professionals. For shipment that involved vaccine or plasma products, the products shall subjected for lot release activities before the batch can be released. The donated medicines should not be diverted for export, commercial sale or into illicit channels.

7.2.2 The guideline recognises that communication can be disrupted during crisis and disasters; therefore, the recipient should ensure security of information pertaining to donated medicines. All parties involved in the handling of donated medicines including distribution, updated record of inventory should be maintained for tracking purposes. Disposal of damaged or expired stock should follow the current practice of disposal.

7.3 Action Required from Donor / Recipient Agencies

7.3.1 Donors should always respect the four core principles for medicine donations, embodied by the Malaysian Guideline of the Management of Medicine Donations. This implies donors should adhere to the requirements in the guideline when responding to the priority needs indicated by the recipients. Unannounced donations should be avoided.

7.3.2 In most circumstances, the Pharmaceutical Services Programme of the MOH Malaysia shall act as the focal point in discussion with the recipient authorities.

This role includes the determination of the storage, logistics and distribution of donated medicines. Other matters pertaining to the needs and priorities; remains with the special committee headed by the Director General of Health in disaster situations.

7.3.3 In principle, there should be bi-directional communications between the donor and recipient to assist the coordinating body for proper processing of all donations, from the point of expressed needs to the final reception of donations. For the purposes of this guideline, the following information elements should be made available to all parties involved:

(a) Donor related information

(i) The identity of the donor agency and recipient, and their respective designated contact person
(ii) The INN name, dosage form, quantities, batch number, expiry dates, and any special storage conditions of donated medicines
(iii) The expected shipment date, port of entry and expected arrival date of the donated medicine
(iv) Batch Release Certificate issued by country or origin or reference countries (e.g.: UK, USA, France, Sweden, Australia, Canada, Japan, Switzerland) (applicable only to importation of vaccine or plasma products)

(b) Recipient related information

(i) The expressed need of the recipient, which includes name and quantity of medicines required
(ii) The successful delivery of donated medicines to the recipient
(iii) Occurrences of theft, damage or loss of donated medicine
(iv) The existence of adverse reaction cases related to usage of donated medicines
(v) The need for additional supply

7.3.4 It is strongly advised that both donor and recipient should take all necessary measures to avoid inappropriate medicine donations. The recipient should ensure there are written statements documenting mutual agreement of the type, quantity, and quality of the donated medicines intended for shipment. The recipient has the right to reject any consignment or part thereof not previously agreed as implied by the previous statement. If the donated medicines are registered in Malaysia, the recipient has the right to reject the consignment.

7.3.5 The Royal Malaysian Customs reserve the rights to take the appropriate actions necessary within its authority to deal with inappropriate medicine donations when it involves customs clearance. In the case where the consignment of donated medicines is refused for clearance, current international conventions of dealing with unwanted or unclaimed goods of the respective port of entry authority shall be applicable.

7.3.6 Management of donated medicines shall comply with the Sale of Drugs Act 1952, Poisons Act 1952, and Dangerous Drugs Act 1952 and other relevant legislations where applicable. Exemptions may apply under specific circumstances by special permission from the competent authority.

7.3.7 Recipient is responsible to report the occurrences of any adverse reactions suspected following the administration of the donated medicines as well as safety issue(s) arises either locally or internationally to the National Pharmaceutical Regulatory Agency (NPRA). Recipient should be aware on the available local reporting guideline including reporting time-frame and detail documentation for the report and investigation (if required).

7.3.8 The recipient shall notify NPRA of any product quality-related issues of which the recipient is aware of, with complete investigation report in accordance with the Drug Registration Guidance Document (DRGD) by NPRA.

For any inquiries please email to **pharmacy@moh.gov.my**

ANNEX 1: MEDICINE DONATION DETAILS FORM

MEDICINE DONATION DETAILS FORM

Donor Information

Donor Agency : _____ Telephone No. : _____

Address : _____ Fax No. : _____

_____ E-mail : _____

Contact Person/s : _____

Recipient Information

Port of entry : _____ Telephone No. : _____

Recipient Agency : _____ Fax No. : _____

Address : _____ E-mail : _____

_____

List of Medicines Offered / Accepted

No.	Generic Name (INN) *(Please specify strength & dosage form)*	Trade Name	Batch No.	Reg. No	Manufacturer & Country of Origin	Pack Size	Qtty	Exp. Date	Expected Time of Arrival	Accepted By

** Please declare additional supporting document (if any)*

Prepared by : Checked by : Approved by :

_____ _____ _____

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