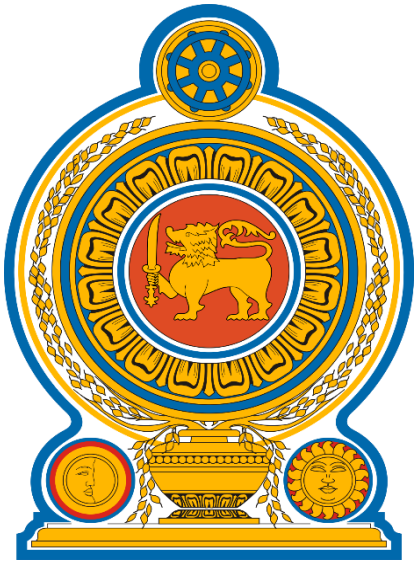

GUIDELINE FOR THE MANAGEMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS

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NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

GUIDELINE FOR THE MANAGEMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS

CONTENTS

1. PURPOSE

This document provides guidance to suppliers of Investigational Medicinal Products (IMPs), sponsors, clinical research organizations (CROs), investigators and other relevant members of the research team on the regulatory requirements relating to the local manufacture or import, supply and storage of IMPs. Suppliers include importers, local manufacturers, wholesalers, sponsors and any other persons who supply IMPs.

To facilitate the conduct of clinical trials, especially multi-center clinical trials it is necessary to have a common understanding of the definition of an investigational medicinal product.

This guideline also lays down principles for management of the IMP and intends to help understand IMP related Good Clinical Practices (GCP) requirements that should be followed by relevant stakeholders in the handling of IMPs. By adhering to this guideline, it is expected that the supply chain relating to IMP is safeguarded without compromising the quality of the relevant products. This would help to protect the trial participants without placing them under undue risks. Also, prevention of any unauthorized use of these products is anticipated. In another aspect, commitment to this guideline will influence the trial integrity since unsatisfactory manufacturing, handling, and storage could lead to inconsistency of the IMP and thereby affecting accuracy of clinical trial data.

The guideline compliments Clinical Trial Regulations 52 to 60, which specify the responsibilities relevant to IMP. This guideline also specifies the responsibilities of the investigators, manufacturers, importers and suppliers with relevant to IMP.

2. OBJECTIVES OF THE GUIDELINE

The key objectives of this guideline include the following:

(a) To facilitate access to IMPs required in clinical research

(b) To advocate imported or locally-manufactured IMPs to have adequate quality

(c) To monitor the supply of imported or locally-manufactured IMPs and restrict their use only to trial participants recruited in the authorized relevant clinical trials.

(d) To reinforce traceability and accountability of IMPs through record-keeping

(e) To provide guidance on appropriate IMP labelling

(f) To advocate reporting of suspected unexpected serious adverse reactions (SUSARs), or medical device adverse events related to the use of IMPs

(g) To ensure GDP and GSP in handling of IMPs

(h) To provide guidance on disposal/re-export of unused IMPs after the trial ends

(i) All previous applicable to Non-investigational medicinal products (NIMPs)

3. SCOPE

This guideline applies to importers, local manufacturers and other suppliers of IMPs which are intended for the use in clinical trials regulated by NMRA as stipulated in the Clinical Trials Regulations. The document describes requirements to be fulfilled for the manufacture or importation of IMPs and provides a guidance

on acceptable or allowable quantities of an IMP for a clinical trial. The document also gives a guidance to sponsors, CROs, investigators and other site staff on the management of IMPs including reception, preparation, dispensing, storage, handling and disposal of any unused quantities.

This guideline should be read in conjunction with both the National Medicines Regulations and the Clinical Trials Regulations and related ones. Accordingly, Investigational Medicinal Product (IMP) may be a medicine, a medical device, or a borderline product. The IMP may be or may not be a registered product in Sri Lanka. There is also to consider other Medicinal products used in clinical trials, may be supplied to subjects participating in a trial and used in accordance with the protocol.

4. PROCEDURE

4.1 Information on IMPs

The use of a novel IMP may be an added risk to the participants in comparison to patients treated with marketed products, and therefore added assurance is required with respect to safety, quality and efficacy. When planning a trial, the sponsor should ensure that sufficient safety and efficacy data on the IMP from non-clinical studies and/or clinical trials are available to support or human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

The sponsor should update the investigator's Brochure as significant new information becomes available. For IMPs with marketing authorization, the Summary of Product Characteristics (SmPC) shall be submitted.

For novel medical devices used as test products in clinical trials, device technical file (device master file) should be submitted.

A copy of valid Good Manufacturing Practices (GMP) certificate issued by the National Regulatory Authority of the country of origin should be submitted with the application along with certificates of analysis for the IMP.

If a reference product, i.e. an active comparator or a placebo is used in the clinical trial, GMP certificate of the relevant manufacturer (if different from the test product manufacturer) should also be submitted.

4.2 Approval for the Importation or Manufacture of IMP

To facilitate access to IMP for a clinical trial, product registration and licensing processes which are applicable for marketing authorization and relevant distribution procedures are exempted. This is on the condition that the importers or manufacturers who intent to supply IMP to a clinical trial should obtain prior approval from the NMRA and such IMP is used only in the specific trial.

The sponsor, the CRO, the Site Management Organization (SMO) or the holder of the letter of authorization may apply for the approvals for the importation or manufacture of an IMP on behalf of the importer or the local manufacturer.

Responsibilities of the manufacturer and the sponsor should be appropriately defined and agreed in a written contract. The sponsor should ensure that the IMPs are manufactured in accordance with applicable GMP and labelled according to regulatory requirements. Control of the IMP should remain under the sponsor until completion of the batch certification by the Qualified Person (QP) and the

regulatory release by the sponsor. Both these steps should be recorded and retained in the clinical trial master file held by, or on behalf of, the sponsor.

The sponsor should verify that all required documents are obtained (e.g. letter of authorization from NMRA, ethics approval), decoding arrangements if applicable are in place, and any other regulatory requirements are complied with before IMPs are shipped and supplied to the clinical trial sites. The sponsor should have standard operating procedures (SOPs) in place that describe the IMP release process.

The sponsor should determine, inform and document, for the investigational medicinal product(s), acceptable storage temperatures, storage conditions (e.g. protection from light) and storage times. Should inform all involved parties (e.g. monitors, investigators, pharmacists, storage managers) of these determinations.

The principles of good distribution practices (GDP)- GL-013 and good storage practices (GSP)- GL-015 should be adhered to throughout the supply chain.

4.2.1. Importation of IMPs

Importers of IMPs should obtain a sample import license from NMRA for the importation of an IMP unless it is a registered product in Sri Lanka. Part IV of the National Medicines Regulations No. 2145/1 of 14.10.2019 stipulates the conditions for import of medicines for clinical trials. An application should be made to NMRA for the importation of each consignment of a particular product in the form specified in Schedule XI of the regulations.

If the IMP falls into the category of controlled substances, i.e. narcotic, psychotropic or precursor, relevant import authorization for the consignment should also be obtained prior to import.

Shipping of the IMPs should be conducted according to instructions given by, or on behalf of, the sponsor in the shipping order. Applicable elements of guidelines on Good Distribution Practices (GDP) (GL-013) should be adhered to while ensuring quality of the product. Temperature and Humidity control and monitoring of the storage conditions are necessary unless IMP does not require special storage conditions and, these records should be maintained. Any deviations from the specified conditions during the shipment should be formally investigated.

IMP should be stored under authorized personnel and access should be controlled to the authorized personnel only

The investigational medicinal product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

4.2.2. Local manufacture of IMPs.

Similarly, the local manufacturers should obtain the approval of the Authority prior to local manufacture of an unregistered medicine required for a clinical trial as stipulated in Part II, regulation 31 (2).

The manufacture of IMP for use in clinical trials should follow principles and guidelines of GMP as set out in WHO GMP guidelines. The manufacturing or assembly of the IMP should be carried out at a premise approved and GMP certified by NMRA. Release of the IMP should be certified by a Qualified Person (QP).

If the IMP is an already registered product and used in its authorized form, no further QP certification is required. If the registered product is reassembled, relabelled or manipulated by the manufacturer, a further QP certificate will be required.

All manufactures who produce or assemble IMPs should follow 'Supplementary Guidelines for the Manufacture of Investigational Pharmaceutical Products for Clinical Trials in Humans' published by WHO.

Records of manufacture of locally-manufactured IMPs

A manufacturer of any IMP must keep all records of the manufacture, assembly and testing of the material for the following duration, whichever is longer:

- One year after the expiry date of the IMP
- 5 years after the date of manufacture, assembly and testing

4.2.3. Assembly or repackaging of IMP performed at clinical trial centres

Assembly of IMP may be performed outside of a GMP-certified facility provided that assembly is related to packaging and labelling and not to manufacture of the product from starting material. However, the basic principles and guidelines of GMP should be adhered to.

For an example, it may be necessary to repack the original bulk product of the IMP or placebo into individual containers and to label to ensure the identity of the IMP or placebo is not disclosed. The site approval of NMRA is not required for the hospital or the medical centre at which repacking is done. The exemption applies only if the product is to be used exclusively in a trial being conducted in that hospital or medical centre.

The repackaging process should be performed and witnessed by delegated and trained study staff and the process should be documented and signed off. For a blinded study, handling of bulk IMP and repackaging should be carried out by unblinded staff and handed over to blinded staff for dispensing. A dummy batch number may be used in the repacked label in order to prevent the disclosure of identity of the product and records kept with unblinded staff.

4.3 Labelling of Investigational Medicinal Product (IMP)

The labelling must ensure protection of the trial subject, enable identification of the product and trial, and assist proper use of the product. If applicable, the IMP should be coded and labelled in a manner that protects the blinding.

The following minimum information should be included on the IMP label, in English and also comply with all applicable regulatory requirements:

- The name of the sponsor
- A clinical trial reference code.
- The designation, reference number or other identification mark of the IMP
- The name and address of the manufacturer
- The production batch number
- The date of manufacture and the date of expiry, in the month and year format (i.e. MM/YYYY)
- The storage conditions appropriate for the IMP
- A statement "For clinical trial use only"

Minimum requirements for size constrained labels

- The designation, reference number or other identification mark of the IMP

- Batch number
- Expiry date
- The storage conditions appropriate for the IMP

Labelling for IMPs with marketing authorization in Sri Lanka

- The labelling guidelines for marketed products apply
- When used in a clinical trial, the product should be labelled "For clinical trial use only". This labelling serves to differentiate from the same product being used in non-clinical setting.

Dispensing labels

- Study code and identity of the IMP
- Study participant identification
- Batch number (a dummy batch number may be used for blinded studies)
- Date of Expiry
- The statement "For clinical trial use only"

Re-labelling for extension of expiry date

- Prior approval from NMRA should be obtained for the extension of shelf life, with supporting stability data
- Supporting document for the extension of shelf-life should be available in the study file
- The original expiry date should not be obscured, instead a line should be drawn across the date, initialled and dated. The new expiry date should be adhered next to the original date.
- The re-labelling process should be witnessed and documented by the delegated study staff.

4.4 Allowable quantities of the Investigational Medicinal Product (IMP)

The quantity of IMP which is going to be used in a clinical trial must not exceed the quantity required by the total number of study participants on the relevant treatment. To facilitate calculation of the allowable quantity, the applicant should provide the following information in the clinical trial application and the trial protocol.

- Posology of the IMP, i.e. dose, frequency and duration of the treatment
- Total dose a trial participant can receive.
- Total planned number of trial participants and number for each arm.

Where prior calculation of the exact dosing of the IMP for a particular study participant cannot be derived for a trial (e.g.: the dose of the IMP is calculated according to the body weight), the maximum allowable quantity of the IMP shall be calculated approximately taking into consideration a parameter such as maximum possible weight of a participant.

However, NMRA may request for further data such as demographic data and dose calculated for randomized participants when an application is made to import the IMP.

There may be occasions where the number of study participants need to be extended or dosing need to be changed during the cause of the study. There may be situations where the consignments need to be replaced due to issues such as storage mishaps. In circumstances where a supply of quantity of IMP that exceed the allowable quantity is required, prior approval of the NMRA should be obtained with necessary justifications.

4.5 Supplying and handling of IMPs

The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of IMPs for the trial and documentation thereof. The procedures should address safe receipt, handling, storage, dispensing, retrieval of unused products from trial participants, and disposal of any unused IMPs.

The following IMP related activities have implications on GCP:

1. Storage

All the investigational products should be stored in a manner that can be identified easily. If the product cannot be identified, the product shall not be used in the trial.

- IMPs should be kept under lock and key ideally in a locked cupboard or a secured area with controlled access.
- IMPs should have dedicated storage space to that of general medicinal products used in the hospital. Ideally, each trial should have dedicated storage space.
- Appropriate storage conditions should be maintained throughout the supply chain.
- Temperature monitoring devices (if applicable) should be immediately checked on arrival of IMP (e.g. shipment)
- Regular monitoring and recording of storage temperatures should be conducted. Any temperature excursions should be promptly reported.
- Backup power supply/alarm system to notify breakdown of power supply should be in place.
- For remote storage of IMPs, Standard Operating Procedures (SOPs) should be available.

2. Accountability

In the management of IMP, every dose of used or unused study medication should be accounted for.

- Movement of the IMP should be traceable throughout the supply chain
- Content of shipment for quantity and quality should be checked.
- Dispensing should be carried out in accordance with the study protocol
- Accurate and real time recording should be done in accountability logs. Stock counts must tally.

3. Documentation

A study file related to each individual trial should be set up and maintained. The following documents related to IMP management should be readily available for inspection

- Standard Operating Procedures (SOPs) that reflect current practices relevant to IMPs
- Written instructions for handling and storage of IMPs
- Accurate and clear accountability logs
- Transfer/Transportation logs
- Shipping documents
- Certificates of analysis
- Temperature logs
- Thermometer calibration/re-calibration certificates
- Preventive maintenance reports for refrigerators and freezers
- Re-packaging/re-labelling reports

- Delegation logs to document roles, responsibilities and signatures
- Training records pertaining to persons handling the IMP (e.g. Pharmacists training log)
- Destruction records and certificates of destruction
- IMP return forms
- Relevant correspondences

4.6 Disposal of unused IMPs

Any unused stocks of IMP (including expired or those which can no longer be used for research) should be disposed of in order to prevent them of being abused. Such consignments shall be either destructed or exported back to the sponsor* with the approval of the NMRA.

- The sponsor is responsible for ensuring that any unused or returned IMP is disposed within 6 months of the conclusion or termination of the clinical research.
- Policy on disposal and if applicable, procedure for destruction should be in place.
- IMPs should not be destroyed without the prior written approval of the sponsor.
- All destruction operations should be properly recorded and accounted for. Accountability logs should be updated accordingly. Certificates of destruction should be maintained.
- Alternatively, if the sponsor deems that any unused IMP is fit to be put to some other use other than in clinical research (e.g., for laboratory research or channeled to normal clinical practice), the sponsor must obtain permission from NMRA before using the material for that purpose.
- The sponsor should keep detailed records of destruction, export or the purpose for which the IMP has been used.

All stakeholders should adhere to the following regulations and guidelines:

- Disposal of Therapeutic Goods, Part XIV of the National Medicines Regulations No. 2145/1 of 14th October 2019
- Guideline on Safe Disposal of Expired and Unwanted Pharmaceuticals, GL-003

Records of disposal of unused IMPs

The following should be included:

- the official name, proprietary name (i.e., brand name) or other description of the IMP
- the identification number of the IMP (e.g., the control number, lot number, batch number or serial number in a medical device)
- details of the disposal, export or putting to some other use, including
- the date on which the IMP was disposed, exported or put to some other use,
- the quantity of IMP disposed, exported or put to some other use, and
- the name and address of the person responsible for the disposal, export or putting to some other use of the IMP

The records relevant to disposal of IMP should be available at trial site for inspection. The records of disposal must be kept at least for the following periods:

- for 2 years after informing NMRA of discontinuation of a clinical trial;
- for 2 years after cancellation of letter of authorization;
- for 10 years after the completion of a clinical trial (i.e., after “Last-Patient-Last-Visit); or
- any other period as NMRA may direct.

4.7 Non-investigational medicinal products (NIMPs) used in a clinical trial

Medicinal products used in the context of a clinical trial and not falling within the definition of an IMP are non-investigational medicinal products (NIMPs). They include:

- Concomitant medications required for co-morbidities
- Rescue medications and challenge agents
- Medications required for background treatment or standard of care
- Diagnostics
- Medical devices

The clinical trial application has allocated specific space to declare such auxiliary medication required for clinical trial participants. Also, a separate list of medical devices that is required in the conduct of clinical trial needs to be furnished with the application. As per NMRA interpretations, in vitro diagnostics are categorized as medical devices.

It is recommended that NIMPs with marketing authorization in Sri Lanka are used. Applications for sample licenses may be furnished to import consignments of NIMPs which are not available in Sri Lanka.

5. RESPONSIBILITIES AND OBLIGATIONS RELEVANT TO IMP MANAGEMENT

5.1 Responsibilities and obligations of the sponsor

The sponsor is responsible for supplying the investigator(s)/institution(s) with the IMPs. The sponsor should not supply an investigator or institution with the IMP until all required documentation are obtained.

The sponsor should:

- Ensure timely delivery of IMPs to the investigators
- Maintain records that document shipment, receipt, disposition, return and destruction of IMPs
- Take steps to ensure that the IMPs are stable over the period of use
- Report suspected unexpected serious adverse drug reaction (SUSARs) to NMRA, relevant ERC and other relevant site investigators
- Maintain sufficient quantities of IMPs used in the trial as reference samples and maintain records of batch analyses and characteristics. To the extent stability permits, samples should be retained until the analyses trial data are completed.
- Maintain a system for retrieving IMPs and documenting this retrieval
- Maintain a system for the disposal of unused IMPs and for documentation of this disposal

5.2 Responsibilities and obligations of the investigator

Responsibility for accountability of IMPs at the trial site rests with the principal investigator (PI). The PI may assign some or all of his duties related to the IMP accountability at the trial site to an appropriate pharmacist or another appropriate individual who is under the supervision of the PI.

The investigator should:

- Maintain records that document adequately that the study participants were provided with the doses specified by the protocol and reconcile all IMP received from the sponsor.
- Ensure that all IMP labels adhered to requirements specified in applicable regulations and guidelines

- Ensure that IMPs are used only in accordance with the approved protocol.
- Ensure that each study participant is explained with the correct use of the IMP, and that each participant is following the instructions properly.
- Report suspected unexpected serious adverse drug reaction (SUSARs) to the sponsor, NMRA, and the relevant ERC.

5.3 Responsibilities and obligations of those involved in supply chain

Parties involved in the IMP supply chain i.e. importers, local manufacturers, wholesalers, sponsors, investigators and other relevant members in the research team have a responsibility to ensure supply chain integrity and prevent the inadvertent or deliberate release of the IMP into the market or for use other than in the particular clinical trial.

Proper recordkeeping would enable proper evaluation of the accountability and traceability of the IMP. The following should be adhered to by relevant stakeholders:

- Ensure the IMP is of the correct identity and conforms with the applicable standards of strength, quality and purity of material
- Ensure compliance with labelling requirements
- Maintain records of the supply and receipt of the product to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or disposal of unused products.
- Store IMP as specified by the sponsor, labeled instructions, and in accordance with applicable regulatory requirements.
- Report suspected unexpected serious adverse drug reaction (SUSARs) to relevant parties.
- Ensure IMP supply/use only for clinical research purpose
- Ensure disposal/export of IMP within 6 months after research completion/ termination

Records of Receipt & Supply of IMP

Any person who supplies or receive IMP is required to keep records of receipt and/or supply, as applicable. The keeping of such records is important to enable proper accountability and traceability of the IMP.

The records of receipt and supply need not follow any specific format. However, they should include the following elements:-

- the official name, proprietary name (i.e., brand name) or other description of the IMP
- the identification number of the IMP (e.g., control number, lot number or batch number)
- the date of manufacture and the date of expiry of the IMP
- details of each receipt or supply, including the date on which the IMP was received or supplied, the quantity of IMP received or supplied, and the name and address of the person from whom the IMP was received, or to whom the IMP was supplied.

The records must be kept up-to-date at all times, and be available for inspection by NMRA upon request.

Medical devices (MDs)

For medical devices used in a clinical trial as an IMP or a NIMP, the following should be adhered to in addition to requirements listed under 5.3 above.

- Ensure that the MD complies with the National Medicines Regulatory Authority (Medical Devices) Regulations
- Ensure Compliance with ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

- Report MD defects and adverse effects to NMRA
- Maintain records of complaints and notify NMRA of MD recalls
- Notify NMRA of any field safety corrective actions (FSCAs)

6. ABBREVIATIONS

CRO – Clinical Research Organization
ERC – Ethics Review Committee
GCP – Good Clinical Practices
GDP – Good Distribution Practices
GMP – Good Manufacturing Practices
GSP – Good Storage Practices
IMP – Investigational Medicinal Product
MD – Medical Device
NIMP – Non-investigational Medicinal Product
NMRA – National Medicines Regulatory Authority
PI – Principal Investigator
QP – Qualified Person
SMO – Site Management Organization
SmPC – Summary of Product Characteristics
SOP – Standard Operating Procedure
SUSAR – Suspected Unexpected Serious Adverse Reaction

7. DEFINITIONS

Batch Number
A distinctive combination of number and/or letters which specifically identifies a batch

Bulk Product
A product which has completed all processing stages up to, but not including, final packaging

Investigational Medicinal Product
A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator's Brochure
A collection of data for the investigator consisting of all the relevant information on the investigational medicinal product(s), including chemical and pharmaceutical data and toxicological, pharmacokinetic and pharmacodynamic data obtained from studies in animals as well as in humans, and the results of earlier clinical trials. There should be adequate data to justify the nature, scale and duration of the proposed trial and to evaluate the potential safety and need for special precautions. If new data are generated, the investigator's brochure must be updated.

Manufacture
All operations of purchase of material, production, quality control, release, storage, distribution of medicinal products and related controls

Non-investigational Medicinal Product
A NIMP is a medicinal product which is not classified as an IMP in a trial, but may be administered to study participants during the trial. Examples include concomitant or rescue medications used for preventive, diagnostic or therapeutic reasons or medication given to ensure that adequate medical care is provided for the trial participant during the trial.

Packaging
All operations including filling in a container and labelling, which a bulk product has to undergo in order to become a finished product. (NB: Sterile filling into primary container is not regarded as part of packaging process, but considered as part of manufacturing)

Placebo
An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.

Principal Investigator (PI)
A doctor or dentist, as the case may be, having specialized in the area of study and specified in an approval as the person responsible for the conduct and supervision of a clinical trial

Protocol
A document that states the background, rationale and objectives of the trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the investigator, the institution involved and the sponsor. It can also function as a contract.

Qualified Person
A person by his education, exceptional knowledge and experience competent and authorized to release each batch of a drug product either commercial or investigational which implies that the concerned batch is in compliant with GMP and marketing authorization requirements.

Sponsor
An individual, a company, an institution or an organization which takes responsibility for the initiation, management and/or financing of a clinical trial. When an investigator initiates and takes full responsibility for a trial, the investigator then also assumes the role of the sponsor.

Study Participant
An individual who participates in a clinical trial, either as a recipient of the investigational medicinal product under investigation or as a control. The individual may be a healthy person who volunteers to participate in a trial, a person with a condition unrelated to the use of the investigational medicinal product, a person (usually a patient) whose condition is relevant to the use of the investigational medicinal product.

Starting Material
Any substance used in the production of a medicinal product, but excluding packaging material

8. RELATED LEGISLATIONS

1. National Medicine Regulatory Authority Act No. 05 of 2015
2. National Medicine (Clinical Trials) Regulations 2145/2, 14th October 2019
3. National Medicines Regulations 2145/1, 14th October 2019
4. Poison, Opium and Dangerous Drugs Ordinance No. 43 of 1935
5. Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act No. 01 of 2008, 25th January 2008
6. The Establishment of Precursor Control Authority Regulation 1653/7, 5th October 2010

9. REFERENCES

1. Clinical Trials Guidance- Clinical Research Materials 02 May 2017 GN-CTB-2-001C-001, Health Sciences Authority, Singapore
2. Singapore Guidelines for Good Clinical Practices, Ministry of Health, Singapore, 1 October 1999
3. Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use in accordance with Good Clinical Practice and Good Manufacturing Practice, EMA/202679/2018, European Medicines Agency, 26 April 2018
4. Description of the medicines for human use (clinical trials) regulations 2004, MHRA, United Kingdom
5. Good Manufacturing Practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans', WHO Technical Report Series , No. 863, 1996, Annex 7
6. ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

10. FEEDBACK

Staff and customers may provide feedback about this document by emailing pathmaperuma.a@nmra.gov.lk

	NAME	SIGNATURE
Prepared by		
Reviewed By		
Recommended By		
Approved by		

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