HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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CLINICAL TRIALS GUIDANCE

LABELLING OF INVESTIGATIONAL AND AUXILIARY PRODUCTS IN CLINICAL TRIALS

GN-CT-07 Rev. No. 006

This guidance also applies to the labelling of Therapeutic Products, Cell, Tissue and Gene Therapy Products and Medicinal Products used in clinical research.

HSA
Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

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SUMMARY OF KEY AMENDMENTS

- Administrative changes due to HSA re-organisation

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1. INTRODUCTION

1.1. Purpose

The document serves to provide guidance to the industry on the following:

(a) Labelling elements and requirements for Therapeutic Products[1], Cell, Tissue and Gene Therapy Products (CTGTPs)[1] and Medicinal Products[2] used in clinical research, including clinical trials requiring a Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate;

(b) Handling situations where labelling elements are omitted;

(c) Handling situations where there are space constraints; and

(d) Handling situations where re-labelling is required.

1.2. Background

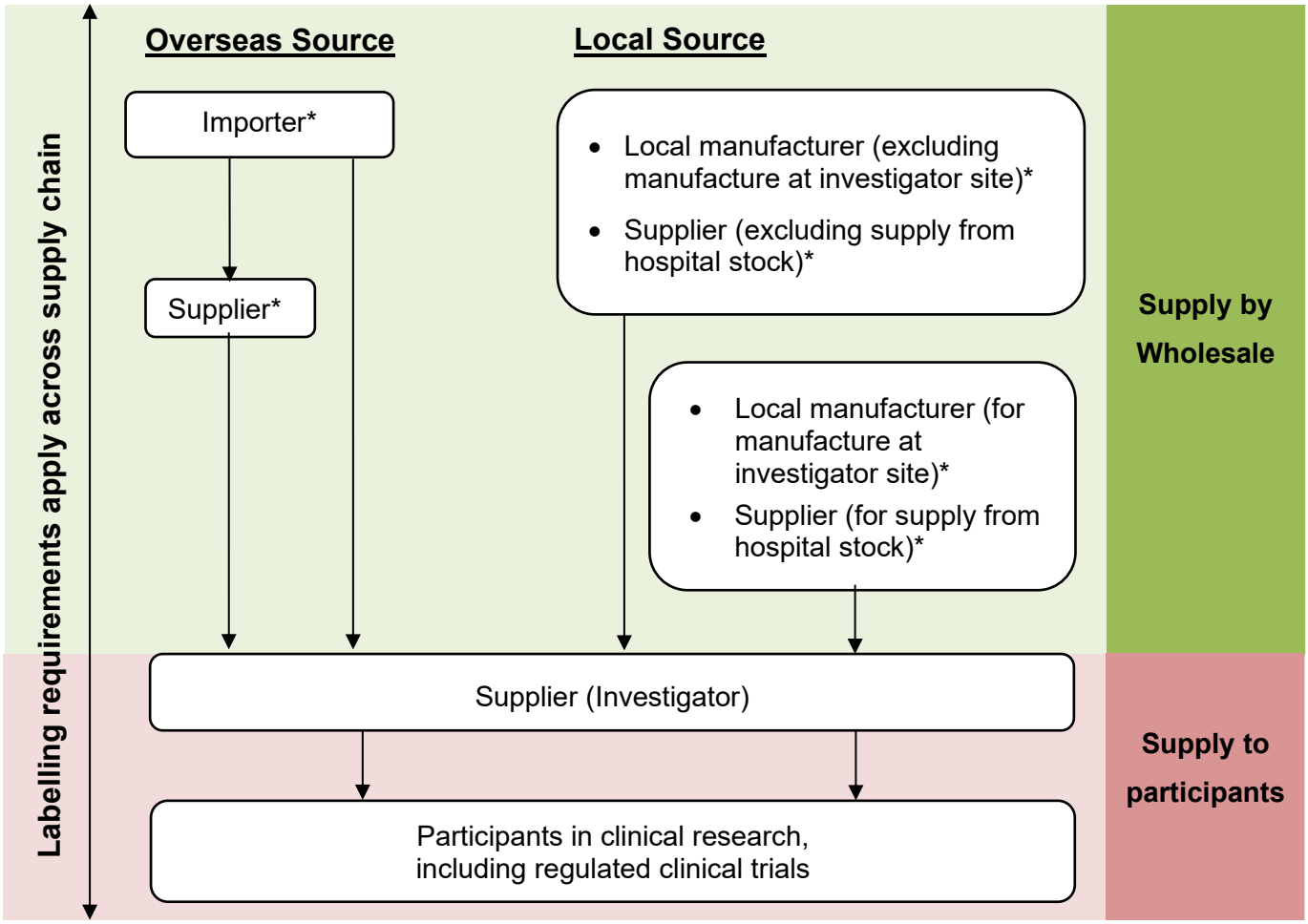
Product labelling is an important aspect in the use of Therapeutic Products, CTGTPs and Medicinal Products in clinical research.

Appropriate labelling ensures the protection of trial/research participants through the identification of the product and trial, the proper use and storage of the product and the enabling of product tracking from manufacture, import, and supply, to its return and destruction. Therefore, appropriate labelling should be applied across the entire product supply chain (Figure 1). In other words, all persons (e.g., manufacturers, importers, suppliers including sponsors and investigators) who supply investigational products and auxiliary products for the purpose of a clinical research have the responsibility to ensure that the product labels comply with the applicable regulations.

[1] Therapeutic Product and CTGTP are defined in the First Schedule of the Health Products Act.

[2] Medicinal Product is defined in the Medicines Act.

Figure 1. Product supply chain



Applicable regulations for labelling requirements

(a) Regulated clinical trials

(i) Supply at wholesale level

- Health Products (Clinical Research Materials) Regulations
- Medicines (Medicinal Products as Clinical Research Materials) Regulations

(ii) Supply to trial participants

- Health Products (Clinical Trials) Regulations
- Medicines (Clinical Trials) Regulations

(b) Other clinical research

(i) Supply at wholesale level and supply to research participants

- Health Products (Clinical Research Materials) Regulations
- Medicines (Medicinal Products as Clinical Research Materials) Regulations

With the globalisation of clinical trials, clinical trials are now often conducted across multiple regions of the world. In order to facilitate multi-regional clinical trials, HSA has aligned the labelling elements in the regulations with internationally harmonised product labelling requirements.

Furthermore, innovative approaches and technology have been implemented to manage the tracking and accountability of investigational products and auxiliary products used in clinical trials. For example, computerised technologies like interactive response technology (IRT) have been used to manage randomisation, investigational product accountability at investigator sites, dose titration, emergency unblinding and expiry date updating for clinical trials. A proportionate approach has thus been included in the regulations to allow for alternative approaches to the labelling requirements, provided the principles of labelling are not compromised.

1.3. Scope

This guidance applies to Therapeutic Products, CTGTPs and Medicinal Products manufactured, imported or supplied for use in accordance with the research protocol, for the following types of clinical research conducted in Singapore:

(a) Clinical trials regulated under the Health Products (Clinical Trials) Regulations and Medicines (Clinical Trials) Regulations (referred to in this guidance as "regulated clinical trials")
   (i) Clinical trials of Therapeutic Products and Class 2 CTGTPs[3] that are subject to the requirements for a Clinical Trials Authorisation (CTA) or Clinical Trials Notification (CTN)

[3] Class 1 and Class 2 CTGTP are defined in the Health Products (Cell, Tissue and Gene Therapy Products) Regulations.

- Class 1 CTGTP means a CTGTP that —
  (a) is the result of only minimal manipulation of human cell or tissue;
  (b) is intended for homologous use;
  (c) is not combined or used with a therapeutic product or a medical device; and
  (d) is assigned by HSA as a Class 1 CTGTP due to a lower health risk to a user of the product.

(ii) Clinical trials of Medicinal Products that are subject to the requirements for a Clinical Trial Certificate (CTC)

(b) Other clinical research involving the use of Therapeutic Products, CTGTPs or Medicinal Products

These include, but are not limited to, the following:

(i) Observational trials (Refer to the *Guidance on Determination of Whether a Clinical Trial Requires a Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or a Clinical Trial Certificate (CTC)* for further details)

(ii) Clinical studies that involve Therapeutic Products, CTGTPs or Medicinal Products, which are not the subject of investigation in these studies

Any reference to 'clinical trial' in this guidance from Section 2 onwards is also a reference to 'clinical research'.

2. DEFINITIONS

2.1. Investigational Product

An "investigational product" is defined as a Therapeutic Product / CTGTP / Medicinal Product / placebo that is to be tested or used as a reference in a clinical trial.

2.2. Auxiliary Product

An "auxiliary product" is defined as a Therapeutic Product / CTGTP / Medicinal Product used for the needs of a clinical trial as described in the protocol, but not as an investigational product.

2.3. Registered Product

A Registered Product refers to a product that is registered in Singapore (i.e., locally registered product), i.e., it has the same strength, composition, formulation, route

- Class 2 CTGTP means a CTGTP other than a Class 1 CTGTP.

of administration and is manufactured by the same manufacturer as the locally registered product.

Table 1 provides examples of investigational products and auxiliary products that are subject to labelling requirements outlined in this guidance.

Table 1. Examples of investigational products and auxiliary products

Purpose of Use	Type of Product
Test	Investigational Product
Reference (e.g., active comparator or placebo)	Investigational Product
Background treatment or standard of care required by the trial protocol, which is administered for the study indication and relevant to the design of the trial	Auxiliary Product
Challenge agents	Auxiliary Product
Unregistered rescue medications	Auxiliary Product

Note: The following products will not be subject to the labelling requirements outlined in this guidance, since they are typically used in accordance with standard of care:

- Locally registered Therapeutic Products / Medicinal Products used as pre-medications
- Locally registered rescue medications
- Locally registered products used for managing adverse events
- Locally registered concomitant medications for co-morbidities

3. LABELLING ELEMENTS FOR INVESTIGATIONAL PRODUCTS AND AUXILIARY PRODUCTS USED IN CLINICAL TRIAL

All persons who supply investigational products and auxiliary products for the purpose of a clinical trial (e.g. manufacturers, importers, suppliers including sponsors and investigators) must ensure that the products are appropriately labelled to meet the following principles:

(a) to ensure protection of the trial participant and product tracking;
(b) to enable identification of the product and the clinical trial;
(c) to facilitate proper use and storage of the product;
(d) to ensure the reliability and robustness of data generated in the clinical trial[4].

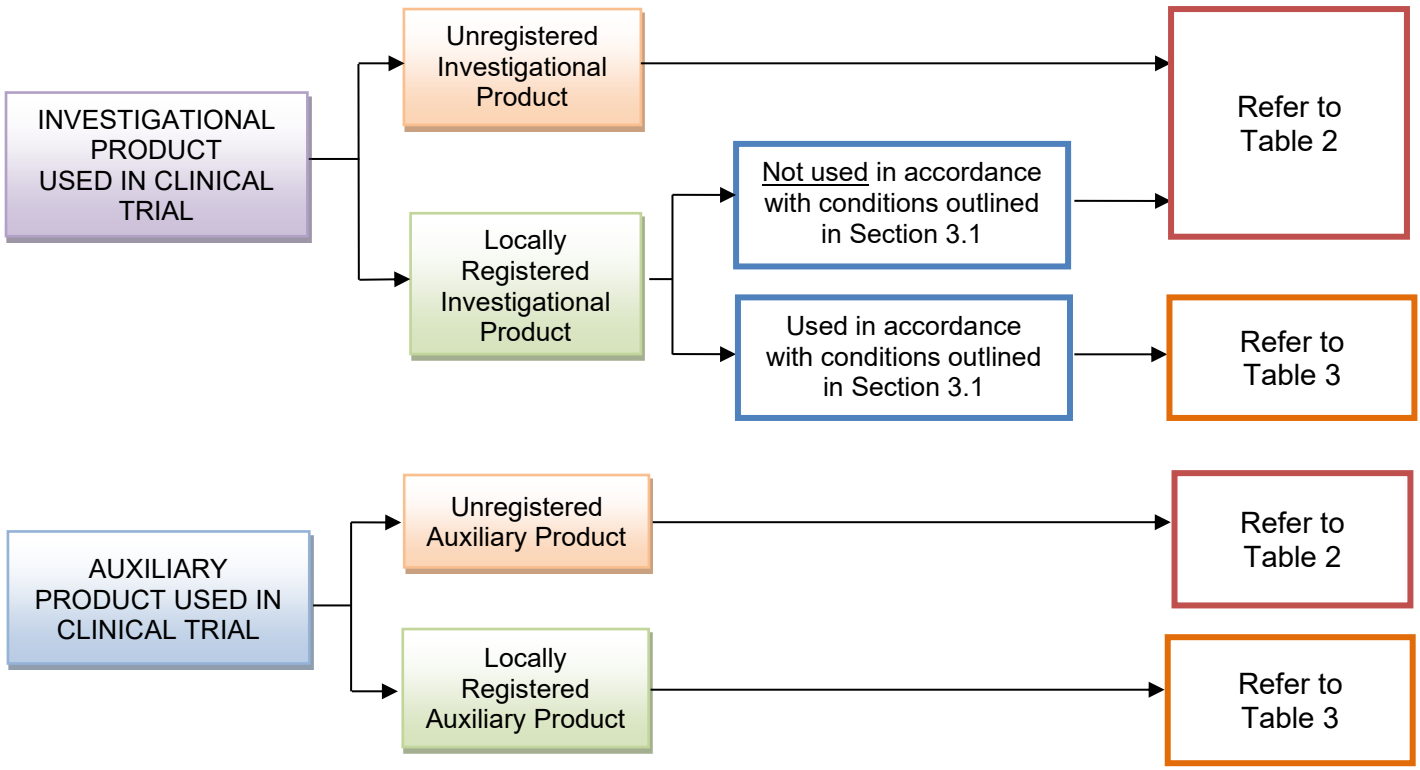
All information on the label of an investigational product or auxiliary product must be in English, and must be clearly legible and unambiguous.

All required labelling elements should be included on the labels of the primary packaging and secondary packaging of the investigational product and auxiliary product throughout the product supply chain (Figure 1). Refer to Section 4 of this guidance for handling situations where labelling elements may be omitted.

All persons (manufacturers, importers, suppliers including sponsors and investigators) who supply investigational products and auxiliary products for the purpose of a clinical trial should consider the local registration or approval status of the products and how the products are being used in the trial when determining the labelling elements (Figure 2).

[4] Not applicable to supply by wholesale

Figure 2. Determining product labelling requirements



3.1 Conditions in relation to Registered Investigational Products

All of the following conditions must be fulfilled:

(a) is not used in the clinical trial in a blinded fashion; and

(b) is not re-packaged[5] for use in the trial; and

(c) is used in accordance with the terms of its product registration/ licence.

[5] Re-packaging refers to removing the product from the container in which it is originally supplied by its manufacturer and (a) placing it in a different container; or (b) changing the outer packaging or other packaging in which the container is further enclosed.

The reference made to 're-packaged for use in the trial' for registered investigational products may apply to any of the following scenarios:

- For blinded clinical trials where the registered investigational product would have to be placed in a different container, or have the outer packaging or other packaging changed in order for the test and reference to be identical; or
- Transferring the registered investigational product from a bulk container to another container (e.g. box, Ziploc bag / bottle / cup etc.)

3.2. The labelling elements in Table 2 apply to:

(i) **Unregistered** Investigational Products and Auxiliary Products

(ii) **Registered** Investigational Products which are:

(a) used in the clinical trial in a blinded fashion; and/or

(b) re-packaged for use in the trial; and/or

(c) not used in accordance with the terms of its product registration/ licence.

Table 2. Labelling elements for unregistered investigational and auxiliary products and registered investigational products which do not fulfil all three conditions in Section 3.1

	Labelling Element	Wholesale Supply	Supply to Participant
(a)	the words "For clinical trial use only" or similar wordings;	✗	✓
(b)	a clinical trial reference code allowing identification of the trial, investigator site, investigator and sponsor;	✗	✓*
(c)	the trial participant identification code or treatment number and, where relevant, visit number;	✗	✓*
(d)	the name, address and telephone number of the main contact[6] for (i) information on the product; (ii) information on the trial; and (iii) emergency unblinding	✗	✓*
(e)	<u>in the case of a Therapeutic Product or Medicinal Product:</u> the name of the substance used in the product and its strength or potency, as well as, in the case of blinded trials, the name of the comparator or placebo; or <u>in the case of a Class 2 CTGTP,</u> the name of the CTGTP and a description, expressed qualitatively and quantitatively, of any active substance in the CTGTP, as well as, in the case of blinded trials, the name of the comparator or placebo;	✓	✓
(f)	the pharmaceutical form, route of administration and quantity of dosage units of the product;	✓*	✓*
(g)	the directions for use of the product (which may be a reference to a leaflet or other explanatory document intended for use by the participant or person administering the product);	✗	✓*
(h)	the batch or code number identifying the contents and packaging operation of the product;	✓*	✓*

[6] The main contact could either be the Principal Investigator (PI) or the sponsor who is able to provide information on (i) to (iii).

	Labelling Element	Wholesale Supply	Supply to Participant
(i)	the period of use (which may be an expiry date or a re-test date) in month and year format and in a manner that avoids any confusion as to which is the month and which is the year;	✓*	✓*
(j)	the storage conditions;	✓	✓
(k)	in the case of an autologous Class 2 CTGTP, the unique patient identifier and the words “for autologous use only” or similar wordings;	✓	✓
(l)	in the case of a Class 2 CTGTP, the list of excipients, including preservative systems (where applicable);	✓	✓
(m)	in the case of a Class 2 CTGTP, any warning that is necessary;	✓	✓
(n)	in the case of a Class 2 CTGTP, any precaution relating to the disposal of unused CTGTP or any waste derived from the CTGTP (where appropriate), and any available collection system for the unused product or waste.	✓	✓

** Element(s) need not appear on the label if it is available by any other means, so long as the principles of labelling are complied with and reasons for omission are set out in the **Reasons for Labelling Omissions Form (Appendix B)**. See Section 4 and Table 4 of this guidance for handling situations where labelling elements are omitted.*

3.3. The labelling elements in Table 3 apply to:

(i) **Registered** Investigational Products which are:

(a) not used in the clinical trial in a blinded fashion; and

(b) not re-packaged for use in the trial; and

(c) used in accordance with the terms of its product registration/ licence.

(ii) **Registered** Auxiliary Products

Table 3. Labelling elements for registered investigational products which fulfil all three conditions in Section 3.1, and registered auxiliary products

	Labelling Element	Wholesale Supply	Supply to Participant	
			Investigational Product	Auxiliary product
(a)	the words “For clinical trial use only” or similar wordings;	✗	✓*	✗
(b)	a clinical trial reference code allowing identification of the trial, investigator site, investigator and sponsor;	✗	✓*	✗
(c)	the name of the person to whom the product is to be administered or the trial participant identification code;	✗	✓	✓
(d)	the name, address and any identification number or logo of the licensed healthcare institution, licensed retail pharmacy, or investigator site where the product is supplied or dispensed;	✗	✓*	✓*
(e)	the name of the product, being the proprietary name or the appropriate non- proprietary name of the active ingredient in the product;	✓	✓	✓
(f)	in the case of a Therapeutic Product or Medicinal Product, where the appropriate non-proprietary name is included on the label of the product, the appropriate quantitative particulars of any active ingredient of the product; or in the case of a Class 2 CTGTP, the name of the CTGTP and a description, expressed qualitatively and quantitatively, of any active substance in the CTGTP;	✓	✓	✓
(g)	the directions for use of the product;	✗	✓*	✓*
(h)	an appropriate control number, such as a serial number, batch number or lot number;	✓	✓	✓
(i)	the expiry date of the product;	✓	✓	✓
(j)	the date that the product is dispensed;	✗	✓*	✓*

	Labelling Element	Wholesale Supply	Supply to Participant	
			Investigational Product	Auxiliary product
(k)	where the product is registered/ approved, the registration number/ product licence number assigned to the product by the Authority.	✓	✓*	✓*
(l)	the storage conditions;	✓	✓	✓
(m)	in the case of an autologous Class 2 CTGTP, the unique patient identifier and the words "for autologous use only" or similar wordings;	✓	✓	✓
(n)	in the case of a Class 2 CTGTP, the list of excipients, including preservative systems (where applicable);	✓	✓	✓
(o)	in the case of a Class 2 CTGTP, any warning that is necessary;	✓	✓	✓
(p)	in the case of a Class 2 CTGTP, any precaution relating to the disposal of unused CTGTP or any waste derived from the CTGTP (where appropriate), and any available collection system for the unused product or waste.	✓	✓	✓

** Element(s) need not appear on the label if it is available by any other means, so long as the principles of labelling are complied with and reasons for omission are set out in the **Reasons for Labelling Omissions Form (Appendix B)**. See Section 4 and Table 4 of this guidance for handling situations where labelling elements are omitted.*

4. HANDLING SITUATIONS WHERE LABELLING ELEMENTS ARE OMITTED

This section applies only to labelling elements in Tables 2 and 3 that have been marked with an asterisk.

All required labelling elements should be on the labels of the primary and secondary packaging of the investigational product and auxiliary product throughout the product supply chain (Figure 1).

However, there may be situations where certain labelling elements may be omitted from the product label. Examples of these situations may include use of computerised systems to track the batch number and expiry date of the product, or availability of alternative documentation to replace the missing labelling element etc. Refer to Appendix A for examples of situations where omission of labelling elements may be considered acceptable.

Therefore, certain labelling elements (i.e. marked with an asterisk in Table 2 and Table 3) may be omitted from the product label if they are available by any other means, so long as:

(i) The principles of labelling are complied with; and

(ii) The reasons for omission are set out in the Reasons for Labelling Omissions Form (Appendix B) and submitted to HSA. (NB: Submission to HSA is, however, not required for scenario outlined in Section 4.1. of this guidance.)

4.1. Scenario where the Reasons for Labelling Omissions Form is not required to be submitted to HSA

With effect from 4 December 2017, the omission of labelling element(s) in the following scenario will not require the submission of the Reasons for Labelling Omissions Form to HSA. The supplier may proceed to supply the products, so long as the principles of labelling are complied with and the other required labelling elements are present on the label.

A. Omission of Name, Address and Telephone Number of the Main Contact, provided that the following conditions are met:

- If the product is brought home by the participant, who is given such information in an alternative documentation (e.g. participant card, informed consent form, pamphlet, leaflet, diary card etc.) to be kept in his/ her possession, and the product label contains the name of sponsor/ product owner.
- If the product is administered at site, there are measures in place to ensure that the investigator site staff is contactable during product administration, and the product label contains the name of sponsor/ product owner.

The submission of the Reasons for Labelling Omissions Form to HSA is, however, still required for all other scenarios not specified in Section 4.1, or for the omissions of any other labelling element(s).

4.2. Notification Process

For regulated clinical trials, the local sponsor of the clinical trial should notify HSA of any omission of applicable labelling elements from the product label and the reasons for omission using the Reasons for Labelling Omissions Form. This information should be submitted either with the new CTA, CTN or CTC application, or via email to HSA_CT@hsa.gov.sg.

For other clinical research, the importer/ manufacturer/ sponsor should notify HSA of any omission of applicable labelling elements from the product label and the reasons for omission using the Reasons for Labelling Omissions Form. This information should be submitted via email to HSA_CT@hsa.gov.sg.

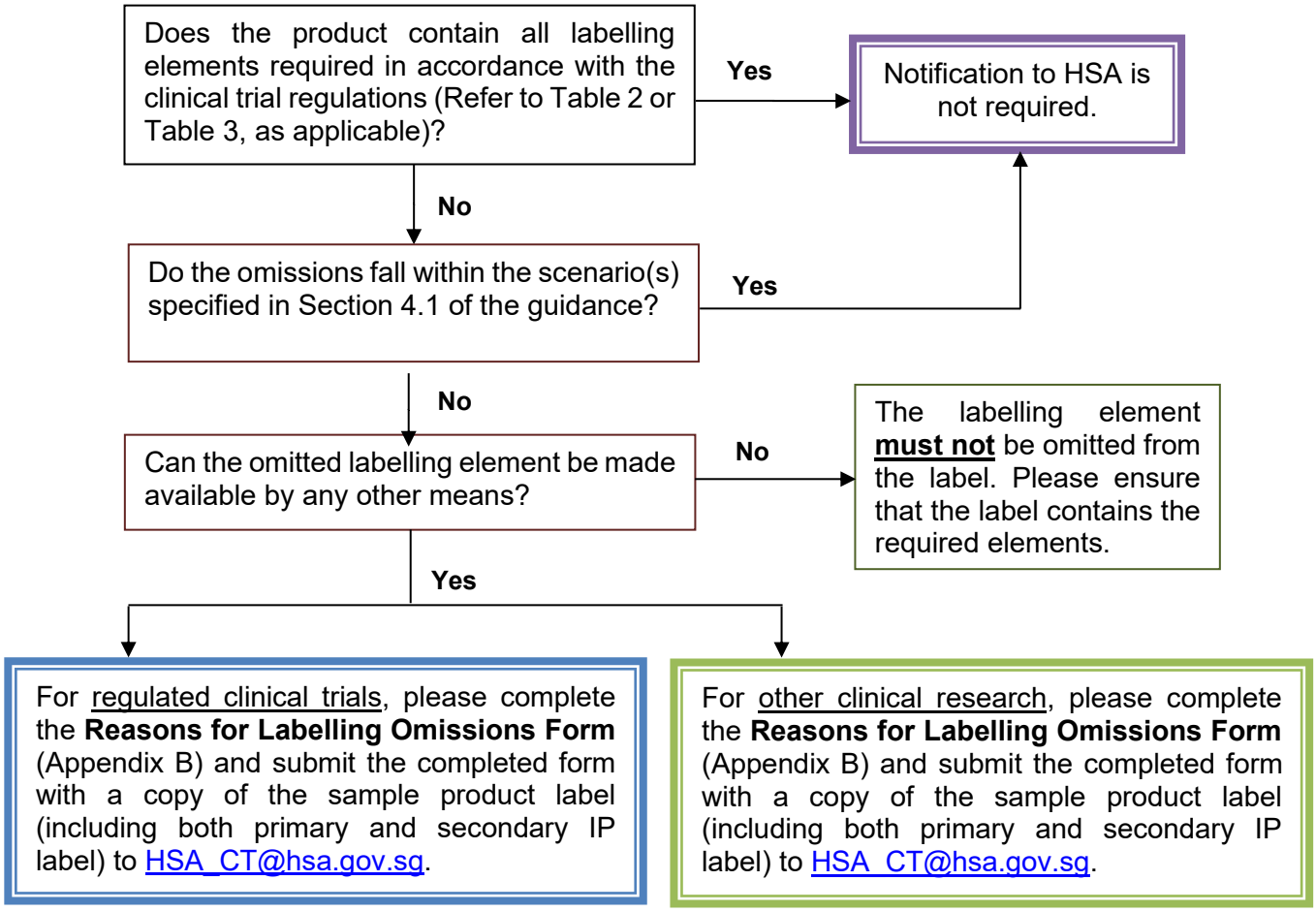
The Reasons for Labelling Omissions Form may be downloaded from the HSA website. A copy of the sample product label (including both primary and secondary IP labels) should be submitted together with the Reasons for Labelling Omissions Form.

HSA will review the reasons for omissions (in the Reasons for Labelling Omissions Form) and communicate the outcome of our review as to whether the omissions are acceptable. The submitter should not supply the products until the omissions have been acknowledged by HSA.

A copy of the Reasons for Labelling Omissions Form, the corresponding acknowledgement by HSA, and all relevant correspondences should be filed in the Trial Master File and Investigator Site Files.

Figure 3 is applicable to labelling elements that have been marked with an asterisk in Tables 2 and 3 of this guidance:

Figure 3. Notification process in situations where labelling element(s) is/are omitted



HSA will review the reasons for omissions (in the Reason for Labelling Omissions Form) and communicate the outcome of review to the submitter. **The submitter should not supply the products until the omissions have been acknowledged by HSA.**

5. HANDLING SITUATIONS WHERE THERE ARE SPACE CONSTRAINTS

All required labelling elements should be on the labels of the primary and secondary packaging of the investigational product and auxiliary product throughout the product supply chain (Figure 1).

However, there may be situations where all required labelling elements cannot be included in the primary packaging due to space constraints (e.g., blister strips, vials, ampoules, eye drop bottles etc.). In such situations, some labelling element(s) may be omitted from the primary packaging if all of the following conditions are met:

(i) The omitted labelling element is present on the secondary packaging†;
(ii) The primary and secondary packaging remain together until use;
(iii) The primary packaging contains the name of the substance used in the product and its strength or potency, as well as, in the case of blinded trials, the name of the comparator or placebo; and
(iv) The principles of labelling have been complied with.

† *In the event that the labelling element is omitted from the* ***secondary packaging****, a Reasons for Labelling Omissions Form (See Appendix B) should be submitted to HSA for the omission of the element on the secondary packaging.*

6. HANDLING SITUATIONS WHERE RE-LABELLING IS REQUIRED

6.1. Scenarios where re-labelling may be required

There may be situations where re-labelling is required due to the following scenarios:

(i) Extension of product expiry date

It is the sponsor's responsibility to ensure that the investigational product or auxiliary product is stable over the period of use and stored as specified by the manufacturer. In some instances, re-labelling may be carried out if the expiry date of the investigational product or auxiliary product has been extended.

It is not necessary for the local sponsor to submit retesting and re-labelling information of the product to HSA, unless requested. Investigator site staff involved in the clinical trial should be informed of the new re-test date or shelf life of the product(s). Supporting documents for extension of shelf life and records of re-labelling should be kept in both the Trial Master File and Investigator Site Files, where applicable, and available at all times for inspection.

(ii) Compliance with regulatory requirements for labelling

All required labelling elements should be included on the labels of the primary and secondary packaging of the investigational product and auxiliary product throughout the product supply chain (Figure 1). In some instances, re-labelling may be carried out to include the missing required labelling elements upon receipt of the product at the depot or local investigator site.

(iii) Change of sponsor’s name / address / telephone number

In situations where there is a change of the name, address, and telephone number of the main contact for information on the product, trial and for emergency unblinding, please notify HSA of the change, highlighting the following details:

a) Required change(s) on the IP label;
b) Estimated date when the IP re-labelling will be completed;

The current batches of the products may be used at the investigator sites whilst waiting for the new product labels to be ready. Notwithstanding this, it would be recommended for the sponsor to provide a memo about the impending changes to the IP label to the investigator site for reference and filing.

Once the new product labels are available for use, please ensure that the re-labelling process is performed in accordance with section 6.2.

6.2. Re-labelling process

If it becomes necessary to re-label the product,

(i) The operation should be performed by appropriately trained staff in accordance with Good Manufacturing Practice (GMP) principles and applicable standard operating procedures, and should be checked by a second person.;

(ii) This re-labelling operation may be performed at the investigator site by or under the supervision of a delegated and qualified investigator site staff (e.g., Pharmacist or Clinical Research Coordinator). Where this is not possible, it may be performed by the Monitor(s), who should be appropriately trained;

(iii) An additional label should be affixed onto the product without obscuring the labelling elements on the product label. In the situation of extension of product expiry date, this additional label should state the new expiry date and repeat the batch number and clinical trial reference code. It may be superimposed on the old expiry date, but for quality control reasons, not on the original batch number;

(iv) There should be line clearance from start to end, such that one type of product is re-labelled at a time;

(v) There should be label reconciliation, and any discrepancies investigated and accounted for before release; and

(vi) The re-labelling process should be properly documented.

Please note that it is not necessary for the above re-labelling process to be followed when affixing auxiliary labels / cautionary labels onto the product label during dispensing.

7. FREQUENTLY ASKED QUESTIONS (FAQ)

7.1. How should the IP/AP be labelled prior to delivery to the local investigator site?

The supply of the IP/AP to the local investigator site would be regarded as wholesale supply. The IP/AP supplied to the local investigator site must be labelled in accordance with labelling requirements for wholesale supply, as stipulated in Tables 2 and 3 of this guidance. It would be the responsibility of the sponsor, importer and supplier (if applicable) to ensure that the IP/AP is labelled in accordance with the applicable regulations.

7.2. Do the labelling requirements apply to locally registered Therapeutic Products and CTGTP and locally licensed medicinal products used in clinical trials?

Yes, the labelling requirements apply to locally registered therapeutic products and CTGTP and locally licensed medicinal products used in clinical trials. Refer to Sections 3.1, 3.2 and 3.3 of this guidance for further details.

7.3. If the investigational product (IP) or auxiliary product (AP) is to be administered to the participant at the investigator site via a syringe, infusion bag or plastic cup (e.g., for oral formulations), would the syringe, infusion bag or plastic cup be required to be labelled in accordance with the applicable regulations?

If the IP/AP is required to be administered to the participant at the investigator site through a syringe, infusion bag or plastic cup, the following labelling requirements will apply*:

- **Syringe or plastic cup** for immediate administration to the participant at the investigator site: The syringe or plastic cup should be labelled in accordance with clinical practice.
- **Infusion bag** for immediate administration to the participant at the investigator site: The infusion bag should be labelled in accordance with clinical practice and with the words ‘For Clinical Trial Use Only’. For

registered AP, the infusion bag should be labelled in accordance with clinical practice.

- **Syringe or infusion bag** for delayed administration to the participant at the investigator site: The syringe or infusion bag should be labelled in accordance with clinical practice and with the words 'For Clinical Trial Use Only'. For registered AP, the syringe or infusion bag should be labelled in accordance with clinical practice.

*NB: These recommendations do not apply to IP/AP that is brought home by the participant. In such a case, the labelling requirements for supply to participant, as stipulated in Tables 2 and 3 of this guidance must be complied with.

Additionally, there should be measures in place to ensure that the principles of labelling are complied with:

(i) to ensure protection of the subject and product tracking;
(ii) to enable identification of the product and the clinical trial;
(iii) to facilitate proper use and storage of the product;
(iv) to ensure the reliability and robustness of data generated in the clinical trial.

7.4. If the locally registered product is sourced from the hospital pharmacy, should it be labelled in accordance with the labelling requirements for wholesale supply prior to dispensing to the trial participant?

If the locally registered product is sourced from the hospital pharmacy, it does not need to be labelled in accordance with the labelling requirements for wholesale supply, as stipulated in Tables 2 and 3 of this guidance. It should be labelled in accordance with the labelling requirements for supply to participant at the point of dispensing. This will enable unused locally registered products to be returned to the hospital pharmacy stock.

7.5. What are the considerations for pooling the supply of investigational products or auxiliary products between several clinical trials in Singapore?

The sponsor should provide details of their IP pooling strategy to HSA and seek approval to proceed.

As the clinical trial reference code may be omitted from the IP label if the reasons for omission are justified, the sponsor may submit a Reasons for Labelling Omissions Form to HSA to omit the clinical trial reference code from the IP label. The sponsor should provide the reason(s) for omitting the clinical trial reference code from the IP label and describe how the clinical trial reference code will be traceable to other available IP documentation (e.g. IP shipping documentation).

8. REFERENCES

(i) Health Products Act

(ii) Medicines Act

(iii) Health Products (Clinical Trials) Regulations

(iv) Medicines (Clinical Trials) Regulations

(v) Health Products (Cells, Tissue and Gene Therapy Products) Regulations

(vi) Health Products (Clinical Research Materials) Regulations

(vii) Medicines (Medicinal Products as Clinical Research Materials) Regulations

(viii) ICH E6 (R3) Good Clinical Practice (GCP) Guideline

(ix) Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme (PIC/S) Annex 13 (dated 25 Aug 2023)

9. APPENDICES

9.1. Appendix A – Situations where omission of labelling elements may be considered acceptable

Labelling elements marked with an asterisk in Tables 2 and 3 of this guidance may be omitted if the reasons for omission are justified. Table 4 illustrates some situations where the omission of labelling elements may be considered acceptable.

This is not an exhaustive list.

Please note that unless specified in Section 4.1 of this guidance, it is still required to notify HSA of the omissions and reasons via the Reasons for Labelling Omissions Form, even if the examples in Table 4 apply to your situation.

Table 4. Examples of scenarios where labelling elements need not be present on the product label and can be provided by other means

Ref	Labelling Element	Situation where element can be provided by other means
(b)	a clinical trial reference code allowing identification of the trial, investigator site, investigator and sponsor;	• If the clinical trial reference code is documented or made available such that the participant or any person handling or administering the product is able to identify the trial, investigator site, investigator and sponsor, and the product is clearly distinguishable or physically segregated from any other products not intended for the purposes of the clinical trial to enable trial product accountability.
(c)	the trial participant identification code or treatment number and, where relevant, visit number;	• If the product is administered **immediately** at the investigator site, e.g., in early phase trial where the dispensing and administration of product takes place in a controlled unit and the whole process is witnessed and documented. The documentation (e.g., Investigational Product Dispensing Log) should include information that allows the batch of the administered product to be traced to the trial participant identification code or treatment number and, where relevant, visit number.

Ref	Labelling Element	Situation where element can be provided by other means
(d)	the name, address and telephone number of the main contact* for — (i) information on the product; (ii) information on the trial; and (iii) emergency unblinding; ** The main contact could either be the Principal Investigator (PI) or the sponsor who is able to provide information on (i) to (iii).*	• If the product is brought home by the participant, the participant is given a card/ leaflet with such information to be kept in his/ her possession; **and** the product label contains the name of sponsor/ product owner.* • If the product is administered at the investigator site, there are measures in place to ensure that the investigator site staff is contactable during administration; **and** the product label contains the name of sponsor/ product owner.* ** The submission of the Reasons for Labelling Omissions Form to HSA is not required in such scenario.*

(f)	the pharmaceutical form, route of administration and quantity of dosage units of the product;	• If the product is administered at the investigator site **and** reference is made to a leaflet or other explanatory document, intended for the participant or person administering the product, stating the pharmaceutical form, route of administration and quantity of dosage units of the product)
		
		• The omission would **not** be allowed in situations where there is potential for administration errors, e.g.:
		  • If product requires complex administration (e.g. Intrathecal injection)
		  • If the trial involves administration of more than one product via different routes within close intervals (e.g., oncology trial which involves the administration of one product via intravenous route and another product via intrathecal route at the same trial visit)

(g)	the directions for use of the product (which may be a reference to a leaflet or other explanatory document intended for use by the participant or person administering the product);	• If reference may be made to a leaflet or other explanatory document intended for the participant or person administering the product

Ref	Labelling Element	Situation where element can be provided by other means
(h)	the batch or code number identifying the contents and packaging operation of the product;	• If information can be managed adequately via validated computerised systems e.g., Interactive Response Technology (IRT).
(i)	the period of use (which may be an expiry date or a re-test date) in month and year format and in a manner that avoids any confusion as to which is the month and which is the year;	• If information can be managed adequately via validated computerised systems e.g., Interactive Response Technology (IRT), provided that the product is administered at the investigator site and no additional product is retained by the participant.

9.2. Appendix B – Reasons for Labelling Omissions Form

In situations where labelling elements are omitted from the product label used in a clinical research (including clinical trials requiring a Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC)), please complete this form for submission to HSA.

Please note the following:

1. Please use one form for each protocol.
2. Please submit a copy of the sample product label (including both primary and secondary labels) together with the Reasons for Labelling Omissions Form to HSA.

A. GENERAL INFORMATION

HSA File Reference Number / Clinical Trial Application Number, if applicable	
Protocol Title	
Protocol Ref.	
Local Sponsor	

B. OMISSION DETAILS

Product Name		
Strength		
Dosage Form		
Primary packaging *(e.g., blister strip, vial, ampoule etc.)*		
Secondary packaging *(e.g., carton, box etc.)*		
Type of product		☐ Investigational Product ☐ Auxiliary Product
Is the product a locally registered product in Singapore?		☐ Yes ☐ No
Labelling element(s) to be omitted *(Please list only one labelling element in each row)*	**Where will the labelling element be omitted from?**	**Reason(s) for omission and where this labelling element will be alternatively present**
	☐ Primary packaging ☐ Secondary packaging	
	☐ Primary packaging ☐ Secondary packaging	

Product Name		
Strength		
Dosage Form		
Primary packaging *(e.g., blister strip, vial, ampoule etc.)*		
Secondary packaging *(e.g., carton, box etc.)*		
Type of product		☐ Investigational Product ☐ Auxiliary Product
Is the product a locally registered product in Singapore?		☐ Yes ☐ No
Labelling element(s) to be omitted *(Please list only one labelling element in each row)*	**Where will the labelling element be omitted from?**	**Reason(s) for omission and where this labelling element will be alternatively present**
	☐ Primary packaging ☐ Secondary packaging	
	☐ Primary packaging ☐ Secondary packaging	

C. SUBMITTER'S DETAILS

Name	
Job Title	
Organisation	
Email address	
Telephone	
Signature	
Date	

For clinical trials requiring CTA, CTN or CTC, please submit the completed form with a copy of the sample product label (including both primary and secondary IP label) via email to HSA_CT@hsa.gov.sg.

For other clinical research, please submit the completed form with a copy of the sample product label (including both primary and secondary IP label) via email to HSA_CT@hsa.gov.sg.

HEALTH SCIENCES AUTHORITY

Applied Sciences Group
Blood Services Group
Enforcement Group
Integrated Health Regulation Group

www.hsa.gov.sg

CONTACT INFORMATION:

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Integrated Health Regulation Group

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HSA
Health Sciences Authority