This guidance also applies to the labelling of Therapeutic Products and Medicinal Products used in clinical research.
**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

- Revision History and Table of Contents: Administrative changes
- Section 1.2: Removed transitional grace period for compliance with revised labelling requirements
- Section 3.2: Clarified the labelling requirements for primary packaging
- Section 4 and Table 4 on labelling requirements for primary packaging: Removed; contents had been incorporated into Section 3.2
- Section 4.1 (previously Section 5): Added section on scenarios where the submission of the Reasons for Labelling Omissions Form to HSA is not required
- Section 4.2 (previously Section 5): Clarified that email submission of the Reasons for Labelling Omissions Form is permissible for regulated clinical trials
- Section 4, Figure 3 (previously Section 5): Clarified that submission of the Reasons for Labelling Omissions Form to HSA is not required, to be in line with Section 4.1
- Section 6.1 (previously Section 7): Clarified labelling requirements for registered auxiliary products
- Section 8.1, Table 4, (d) (previously Section 9.1): Clarified that submission of the Reasons for Labelling Omissions Form to HSA is not required, to be in line with Section 4.1
- Section 8.2 (previously Section 9.2): Amended the Reasons for Labelling Omissions Form to allow for multiple product entries from the same protocol
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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 and Medicinal Products used in clinical research, including clinical trials regulated by the Health Sciences Authority (HSA);
(b) Handling situations where labelling elements are omitted; and
(c) Handling situations where re-labelling is required.

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

Appropriate labelling ensures the protection of subjects through the identification of the product and trial, the proper use and storage of the product and the enabling of product traceability from manufacture, import, 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.
Applicable regulations for labelling requirements

**Regulated clinical trials**
- Supply at wholesale level
  - Health Products (Therapeutic Products as Clinical Research Materials) Regulations
  - Medicines (Medicinal Products as Clinical Research Materials) Regulations
- Supply to subjects
  - Health Products (Clinical Trials) Regulations
  - Medicines (Clinical Trials) Regulations

**Clinical research not regulated by HSA**
- Supply at wholesale level and supply to subjects
  - Health Products (Therapeutic Products as 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 traceability and accountability of investigational products and auxiliary products used in clinical trials. For example, computerised technologies like interactive voice response systems (IVRS) or interactive web response systems (IWRS) have been used to manage randomisation, investigational product accountability at trial sites, dose titration, emergency unblinding and expiry date updating for clinical trials. A measured degree of flexibility 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 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) Regulated Clinical Trials

(i) Clinical trials on Therapeutic Products that are subject to the requirements for a Clinical Trials Authorisation (CTA) or Clinical Trials Notification (CTN)

(ii) Clinical trials on Medicinal Products (e.g. Cell, Tissue and Gene Therapy Products; or Complementary Health Products) that are subject to the requirements for a Clinical Trial Certificate (CTC)

(b) Other clinical research not regulated by HSA, involving the use of Therapeutic Products or Medicinal Products

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

(i) Observational trials (Refer to the Guidance on Whether a Clinical Trial Requires a CTA, CTN or CTC for further details)

(ii) Clinical studies that involve Therapeutic Products 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/ Medicinal Product or a 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/ Medicinal Product used for the needs of a clinical trial as described in the protocol, but not as an investigational product.

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

<table>
<thead>
<tr>
<th>Purpose of Use</th>
<th>Type of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Investigational Product</td>
</tr>
<tr>
<td>Reference (e.g., active comparator or placebo)</td>
<td>Investigational Product</td>
</tr>
<tr>
<td>Background treatment or standard of care required by the research protocol, which is administered for the study indication and relevant to the design of the study</td>
<td>Auxiliary Product</td>
</tr>
<tr>
<td>Challenge agents</td>
<td>Auxiliary Product</td>
</tr>
<tr>
<td>Unregistered rescue medications</td>
<td>Auxiliary Product</td>
</tr>
</tbody>
</table>

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 Product/ Medicinal Product used as pre-medications
- Locally registered rescue medications
- Locally registered treatment for trial-related adverse events
- Locally registered concomitant medication 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 subject and traceability;
(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 trial¹.

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

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).

¹ Not applicable to supply by wholesale
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** for use in the trial; and
(c) is used in accordance with the terms of its product registration/ licence.

** Please refer to Section 6.2 to understand how is ‘re-packaging’ defined in this context.
3.2. The labelling requirements in Table 2 apply to:

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

(ii) **Registered** Investigational Products which **do not** fulfil all the conditions in section 3.1, i.e. the product:

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

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

(c) is 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 the three conditions

<table>
<thead>
<tr>
<th>Labelling Element</th>
<th>Wholesale Supply</th>
<th>Supply to Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) the words “For clinical trial use only” or similar wordings;</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>(b) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor;</td>
<td>X</td>
<td>✓*</td>
</tr>
<tr>
<td>(c) the trial subject identification number or treatment number and, where relevant, visit number;</td>
<td>X</td>
<td>✓*</td>
</tr>
<tr>
<td>(d) the name, address and telephone number of the main contact for —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(i) information on the product;</td>
<td>X</td>
<td>✓*</td>
</tr>
<tr>
<td>(ii) information on the trial; and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(iii) emergency unblinding;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) 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;</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>(f) the pharmaceutical form, route of administration and quantity of dosage units of the product;</td>
<td>✓*</td>
<td>✓*</td>
</tr>
<tr>
<td>(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 subject or person administering the product);</td>
<td>X</td>
<td>✓*</td>
</tr>
<tr>
<td>(h) the batch or code number identifying the contents and packaging operation of the product;</td>
<td>✓*</td>
<td>✓*</td>
</tr>
<tr>
<td>(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.</td>
<td>✓*</td>
<td>✓*</td>
</tr>
<tr>
<td>(j) the storage conditions.</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

* 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 of this guidance for handling situations where labelling elements are omitted.
All required labelling elements should be on the labels of the primary and secondary packaging of the investigational product and auxiliary product.

However, there may be situations where it is not possible to include all the required labelling elements on the primary packaging. For example:

- Primary packaging takes the form of blister packs or small units, on which all required labelling elements cannot be included on the primary packaging.

In such instances, an exception to including all the required labelling elements on the primary packaging may apply if all of the following conditions are met:

- The omitted labelling element is present on the secondary packaging†; and
- The primary and secondary packaging remain together until use; and
- 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
- The principles of labelling have been complied with.

Please also note that it is not necessary to submit the Reasons for Labelling Omissions Form for the omission of the labelling element on the primary packaging in such instances.

† In the event that the labelling element is omitted on the secondary packaging, a Reasons for Labelling Omissions Form should be submitted to HSA for the omission of the labelling element on the secondary packaging. Please refer to Section 4 of this guidance for further details.
3.3. The labelling elements in Table 3 apply to:

(i) **Registered** Investigational Products which fulfil **all** of the following conditions in section 3.1, i.e. the product

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

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

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

(ii) **Registered** Auxiliary Products

<table>
<thead>
<tr>
<th>Table 3. Labelling elements for registered investigational product which fulfils the three conditions, and registered auxiliary product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Labelling Element</strong></td>
</tr>
<tr>
<td>----------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>(a) the words “For clinical trial use only” or similar wordings;</td>
</tr>
<tr>
<td>(b) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor;</td>
</tr>
<tr>
<td>(c) the name of the person to whom the product is to be administered or the trial subject identification number;</td>
</tr>
<tr>
<td>(d) the name, address and any identification number or logo of the licensed healthcare institution, licensed retail pharmacy, or trial site where the product is supplied or dispensed;</td>
</tr>
<tr>
<td>(e) the name of the product, being the appropriate non-proprietary name and the proprietary designation;</td>
</tr>
<tr>
<td>(f) 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;</td>
</tr>
<tr>
<td>(g) the directions for use of the product;</td>
</tr>
<tr>
<td>(h) an appropriate control number, such as a serial number, batch number or lot number;</td>
</tr>
<tr>
<td>(i) the expiry date of the product;</td>
</tr>
<tr>
<td>(j) the date that the product is dispensed;</td>
</tr>
<tr>
<td>(k) where the product is registered/ approved, the registration number/ product licence number assigned to the product by the Authority.</td>
</tr>
</tbody>
</table>
4. HANDLING SITUATIONS WHERE LABELLING ELEMENTS ARE OMITTED

The labelling requirements in this section apply to:
(i) **Unregistered** Investigational Products and Auxiliary Products
(ii) **Registered** Investigational Products which **do not** fulfil all the conditions in section 3.1, i.e. the product:
   (a) is used in the clinical trial in a blinded fashion; or
   (b) is re-packaged for use in the trial; or
   (c) is not used in accordance with the terms of its product registration/licence.

There may be situations where omission of certain labelling elements from the product label may be acceptable in clinical trials. For example, the batch number and expiry date may be omitted from the product label in a blinded clinical trial, where the traceability and safe use of the product is instead managed through the use of a centralised electronic system. Refer to Appendix A for examples of situations where omission of labelling elements may be considered acceptable.

Therefore, certain labelling elements (marked with an asterisk in Table 2) may be omitted from the product label if they are 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) and submitted to HSA. Submission to HSA is, however, not required for scenarios outlined in Section 4.1. of this guidance.
4.1. Scenarios where the Reasons for Labelling Omissions Form is not required to be submitted to HSA

With effect from 4 December 2017, the omissions of labelling element(s) in these scenarios 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 labelling element(s) on primary packaging, provided that the following conditions are met (Refer to Section 3.2.):
   - the omitted labelling element is present on the secondary packaging†, and
   - the primary and secondary packaging remains together until use, and
   - 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.

† In the event that the labelling element is omitted on the secondary packaging, a Reasons for Labelling Omissions Form should be submitted to HSA for the omission of the element on the secondary packaging.

B. Omission of Name, Address or Telephone of Main Contact, provided that the following conditions are met:
   - If the product is brought home by the subject, the subject 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 site, there is measure in place to ensure that the site study team 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, however, still required for all other scenarios not specified in this section, or for the omissions of any other labelling element(s). Refer to Section 4.2. for the notification process.
4.2. Notification Process

For regulated clinical trials, the local sponsor of the clinical trial should notify HSA of omission of any 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 clinical research that is not a clinical trial regulated by HSA, the importer/manufacturer/sponsor should notify HSA of omission of any 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.

It is not necessary to include the sample label, unless specifically requested by HSA. HSA will review the reasons for omissions (in the “Reasons for Labelling Omissions” Form) and communicate the outcome of our review on 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” and the corresponding acknowledgement by HSA should be filed in the sponsor and investigator files.
Figure 3 is applicable to:

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

(ii) **Registered** Investigational Products which **do not** fulfil all the three conditions in Section 3.1, i.e. the product:

(a) is used in the clinical trial in a blinded fashion;
(b) is re-packaged for use in the trial;
(c) is not used in accordance with the terms of its product registration/licence.

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

Does the product contain all labelling elements required in accordance to the clinical trial regulations (Table 2)?

- **Yes**
  - Notification to HSA is not required.

- **No**
  
  Does the omissions fall within the scenarios specified in Section 4.1 of the guidance?

  - **Yes**
    
    The labelling element **must not** be omitted from the label. Please ensure that the label contains the required elements.

  - **No**

  Can the omitted labelling element be made available by any other means?

    - **Yes**
      
      For regulated clinical trials, please complete the **Reasons for Labelling Omissions Form** (Appendix B) and submit with the new CTA, CTN or CTC application, or via email to **HSA_CT@hsa.gov.sg**.

    - **No**

For clinical research that is not a clinical trial regulated by HSA, please complete the **Reasons for Labelling Omissions Form** (Appendix B) and submit via email to **HSA_CT@hsa.gov.sg**.

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 RE-LABELLING IS REQUIRED

It is the sponsor's responsibility to ensure that the investigational product or auxiliary products 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 expiration date of the investigational products or auxiliary products has been extended.

Supporting documents for such an extension of shelf-life should be available in the study files. It is not necessary for the local sponsor to submit retesting and re-labelling information of the product to HSA, unless requested. Site staff involved in the clinical trial should be informed of the new re-test date or shelf life of the product(s). These records should be kept in both the sponsor and investigator files, and available at all times for inspection.

If it becomes necessary to change the use-by date, an additional label should be affixed to the product. This additional label should state the new use-by date and repeat the batch number. It may be superimposed on the old use-by date, but for quality control reasons, not on the original batch number. This operation should be performed at an appropriately authorised manufacturing site. However, when justified, it may be performed at the trial site by or under the supervision of the study pharmacist, or other qualified study team member. Where this is not possible, it may be performed by the clinical trial monitor(s) who should be appropriately trained. The operation should be performed in accordance with Good Manufacturing Practice (GMP) principles, standard operating procedures and under contract, if applicable, and should be checked by a second person. This additional labelling should be properly documented in both the trial documentation and in the batch records.
6. FREQUENTLY ASKED QUESTIONS (FAQ) ON LABELLING

6.1. If the investigational product (IP) or auxiliary product (AP) is to be administered to the subject at the trial 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 subject at the trial site through a syringe, infusion bag or plastic cup, the following labelling requirements will apply*:

- **Syringe or plastic cup** for immediate administration to the subject at the trial site: The syringe or plastic cup should be labelled in accordance with clinical practice.

- **Infusion bag** for immediate administration to the subject at the trial site: The infusion bag should be labelled in accordance with clinical practice and 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 subject at the trial site: The syringe or infusion bag should be labelled in accordance with clinical practice and 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 subject.

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

(a) to ensure protection of the subject and traceability;
(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.
6.2. With reference to the condition (b) listed in Section 3.1 [i.e. (b) is not re-packaged for use in the trial], how is ‘re-packaging’ defined in this context?

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.)
7. REFERENCES

(i) Health Products (Clinical Trials) Regulations
(ii) Medicines (Clinical Trials) Regulations
(iii) Health Products (Therapeutic Products as Clinical Research Materials) Regulations
(iv) Medicines (Medicinal Products as Clinical Research Materials) Regulations
(v) European Union (EU) Clinical Trials Regulation (CTR) EU No 536/2014
(vi) Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme (PIC/S) Annex 13 (dated 1 Jan 2017)
8. APPENDICES

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

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

<table>
<thead>
<tr>
<th>Labelling Element</th>
<th>Situation where element can be provided by other means</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) the words “For clinical trial use only” or similar wordings;</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(b) a clinical trial reference code allowing identification of the trial, site, investigator and sponsor;</td>
<td>If the clinical trial reference code is documented or made available such that the subject or any person handling or administering the product is able to identify the trial, site, investigator and sponsor for the product, and the product is clearly distinguishable or physically segregated from any other therapeutic or medicinal products not intended for the purposes of the clinical trial to enable trial product accountability.</td>
</tr>
<tr>
<td>(c) the trial subject identification number or treatment number and, where relevant, visit number;</td>
<td>If the product is administered immediately at 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 Logs, Study Forms etc.) should include information that allows the batch of the administered product to be traced to the trial subject identification number or treatment number and, where relevant, visit number.</td>
</tr>
<tr>
<td>Labelling Element</td>
<td>Situation where element can be provided by other means</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(d) the name, address and telephone number of the main contact for —</td>
<td>If the product is brought home by the subject, the subject is given a card/ leaflet with such information to be kept in his/ her possession; <strong>and</strong> the product label contains the name of sponsor/ product owner.*</td>
</tr>
<tr>
<td>(i) information on the product;</td>
<td>If the product is administered at site, there is measure in place to ensure that the site study team is contactable during administration; <strong>and</strong> the product label contains the name of sponsor/ product owner.*</td>
</tr>
<tr>
<td>(ii) information on the trial;</td>
<td>* The submission of the Reasons for Labelling Omissions Form to HSA is not required in such scenario.</td>
</tr>
<tr>
<td>(iii) emergency unblinding;</td>
<td></td>
</tr>
<tr>
<td>(e) the name of the substance used in the product and its strength or potency,</td>
<td><strong>Not applicable</strong></td>
</tr>
<tr>
<td>as well as, in the case of blinded trials, the name of the comparator or placebo;</td>
<td></td>
</tr>
<tr>
<td>(f) the pharmaceutical form, route of administration and quantity of dosage</td>
<td>If the product is administered at site <strong>and</strong> reference is made to a leaflet or other explanatory document, intended for the subject or person administering the product, stating the pharmaceutical form, route of administration and quantity of dosage units of the product</td>
</tr>
<tr>
<td>units of the product;</td>
<td>The omission would <strong>not</strong> be allowed in situations where there is potential for administration errors, e.g.,:</td>
</tr>
<tr>
<td></td>
<td>• If product requires complex administration (e.g. Intrathecal injection)</td>
</tr>
<tr>
<td></td>
<td>• If 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 study visit)</td>
</tr>
<tr>
<td>(g) the directions for use of the product (which may be a reference to a leaflet</td>
<td>If reference may be made to a leaflet or other explanatory document intended for the subject or person administering the product</td>
</tr>
<tr>
<td>Labelling Element</td>
<td>Situation where element can be provided by other means</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(h) the batch or code number identifying the contents and packaging operation of</td>
<td>If information can be managed adequately via validated electronic systems e.g., Interactive Voice/ Web Response System (IVRS/ IWRS)</td>
</tr>
<tr>
<td>the product;</td>
<td></td>
</tr>
<tr>
<td>(i) the period of use (which may be an expiry date or a re-test date) in month</td>
<td>If information can be managed adequately via validated electronic systems e.g., Interactive Voice/ Web Response System (IVRS/ IWRS), provided that the product is administered at site, and no additional product is retained by the subject</td>
</tr>
<tr>
<td>and year format and in a manner that avoids any confusion as to which is the</td>
<td></td>
</tr>
<tr>
<td>month and which is the year.</td>
<td>Please refer to the EMEA Reflection Paper on the use of IVRS Technologies in Clinical Trials, for additional considerations.</td>
</tr>
<tr>
<td>(j) the storage conditions.</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
8.2. Appendix B – Reasons for Labelling Omissions Form

In situations where labelling elements are omitted from the product label used in a clinical research (including regulated clinical trial), please complete this form for submission to HSA.

**General Information**

| Protocol Title: | | | |
|-----------------|-----------------|-----------------|
| | | |

<table>
<thead>
<tr>
<th>Protocol Number:</th>
<th>Local Sponsor:</th>
</tr>
</thead>
<tbody>
<tr>
<td>____________________</td>
<td>____________________</td>
</tr>
</tbody>
</table>

*(please use one form for each protocol)*

**Details of Omission(s)**

<table>
<thead>
<tr>
<th>Product Name:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>____________________</td>
<td>____________________</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Labelling element(s) to be omitted</th>
<th>Reasons for omission(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Please list only an element in each row</em></td>
<td></td>
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<td></td>
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<table>
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<tr>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Submitter’s Details

Name: ________________________________  Job Title: ________________________________

Organisation: ________________________________________________________________

Email Address: __________________________  Telephone: ____________________________

Signature: ______________________________  Date: ________________________________

For regulated clinical trial, please submit the completed form with the new CTA, CTN or CTC application, or via email to HSA_CT@hsa.gov.sg.

For clinical research that is not a clinical trial regulated by HSA, please submit the completed form via email to HSA_CT@hsa.gov.sg.
CONTACT INFORMATION:
Clinical Trials Branch
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03, Helios
Singapore 138667
Tel: 6866 3446
Fax: 6478 9034
Email: HSA_CT@hsa.gov.sg
Website: www.hsa.gov.sg