## Appendix B – Reasons for Labelling Omissions Form

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 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.  **Please note the following:**   1. Please use one form for each protocol. 2. Please submit a copy of the sample product label together with the Reasons for Labelling Omissions Form to HSA. 3. **GENERAL INFORMATION**  |  |  | | --- | --- | | **Protocol Title** |  | | **Protocol Ref.** |  | | **Local Sponsor** |  |  1. **DETAILS OF OMISSION**  |  |  | | --- | --- | | **Product Name** |  | | **Strength** |  | | **Dosage Form**  (e.g. tablet, capsule, solution, suspension etc.) |  | | **Type of packaging**  (e.g. blister strip, vial, syringe, infusion bag etc.) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | |  |  | | --- | --- | | **Labelling element(s) to be omitted**  *(Please list only one labelling element in each row)* | **Reasons for omission(s)** | |  |  | |  |  |      |  |  | | --- | --- | | **Product Name** |  | | **Strength** |  | | **Dosage Form**  *(e.g. tablet, capsule, solution, suspension etc.)* |  | | **Type of packaging**  *(e.g. blister strip, vial, syringe, infusion bag etc.)* |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | |  |  | | --- | --- | | **Labelling element(s) to be omitted**  *(Please list only one labelling element in each row)* | **Reasons for omission(s)** | |  |  | |  |  |  1. **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](mailto: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](mailto:HSA_CT@hsa.gov.sg). |