**Checklist on Documentary Requirements for Voluntary Notification of CHP**

* This checklist should be used to ensure the submission of a complete dataset for product notification.
  + Documents 1 to 8 must be submitted for the dataset to be considered as complete
* Scanned copies of the original documents in colour should be submitted and hard copies of original documents are not required. However, HSA reserves the right to request for the original or certified true copy of submitted documents if there is any doubt that a submitted scanned document is not an accurate reflection of the original document.
* If the product name and brand name are different from the document(s) submitted, please submit a [product linkage form](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/linkage.pdf).
* HSA may also request for additional documents, other than those listed below, in the verification of the notification submission.
* **The file names of the required documents must be in English, and include the document number e.g., “3. Certificate of Analysis” instead of “certificate”.**

**Product name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

| **Document number** | **Documents** | **Points to note** | **Submitted (Y/N)** |
| --- | --- | --- | --- |
| Mandatory Documents | | | |
| 1 | Copy of the submitted form | * This refers to the attachment received in the acknowledgement email following the submission of the notification form |  |
| 2 | Manufacturer's Licence/Certification | * The manufacturer’s licence should be issued by the regulatory authority responsible for the product type in the country of manufacture. * Good Manufacturing Practice (GMP) certification should be issued by the regulatory authorities that adopted acceptable manufacturing standards. * Third party certification, such as GMP certification, Food Safety Management certification, should be issued by certification bodies that are accredited by the Singapore Accreditation Council (SAC) or other accreditation bodies listed under the SAC’s Mutual Recognition Agreement (MRA). * If the licence/certificate issued has no validity period indicated, the issue date should be within 3 years from the date of submission. |  |
| 3 | Description of manufacturing process | * Description of manufacturing process is a structured sequence of steps and processes used to manufacture raw materials into finished products. It can be presented as a flowchart or description of the process. |  |
| 4 | Finished product specifications | * The finished product specifications are a set of tests and limits that are applied to the product in order to ensure that every batch is of satisfactory and consistent quality throughout its shelf life. The product specifications should include the parameters that are likely to affect the safety and quality of the product such as parameters relating to the dosage forms, acceptance limits for batch release of the finished products. |  |
| 5 | Certificate of Analysis (including appropriate test parameters, their specification and references) | * The Certificate of Analysis should contain the relevant product testing parameters and results, as stated in the [Guidelines for Physical Test Parameters based on Dosage Forms of Health](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/tmhs_parameters_guidelines.pdf) Supplements and Traditional Medicines. * For example, products in the form of tablets are required to have the following test parameters in the Certificate of Analysis:  1. Disintegration or Dissolution 2. Hardness or Friability 3. Filling variation or Uniformity of dosage units  * The testing method and set specifications for each test parameter should be stated in the Certificate of Analysis and in accordance to established international pharmacopoeias or determined by the manufacturer/product owner with justification. |  |
| 6 | Laboratory test report for toxic heavy metal and microbial limits (including method reference) | The test report should minimally contain the following information:   1. Date of report 2. Brand name (if applicable) and product name 3. Batch number 4. Name of substance(s) tested 5. Reference(s) to the relevant specifications and testing procedures 6. Test result(s), including limit(s) of detection\* 7. Name and signature of analyst   \*For test results reported as not detected or “ND”, such as the test results for toxic heavy metals, the limit of detection must be stated on the test report |  |
| 7 | Final artwork or product label (including the location of batch number and expiry date) for all pack size(s) available | * The product label should contain the information required for each product label type and leaflet, as stated in the [Guidelines for Labelling Standards of Health](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/tmhs_labelling_guidelines.pdf) Supplements and Traditional Medicines. * If the batch number and expiry date of the product are printed on the packaging directly instead of the product label, the location of these information should be provided. * If the distributor is the same as the importer, the distributor information may be printed in place of the importer information. |  |
| 8 | Checklist on documentary requirements for voluntary notification of CHP |  |  |
| To be submitted, if applicable | | | |
| 9 | Package leaflet |  |  |
| 10 | Laboratory test report for adulterants screening | The test report should minimally contain the following information:   1. Date of report 2. Brand name (if applicable) and product name 3. Batch number 4. Name of substance(s) tested 5. Reference(s) to the relevant specifications and testing procedures 6. Test result(s), including limit(s) of detection\* 7. Name and signature of analyst   \*For test results reported as not detected or “ND”, such as the test results for toxic heavy metals, the limit of detection must be stated on the test report  The following types of product would require a laboratory test report for adulterants screening:   * weight loss * pain relief * male vitality enhancement.   Manufacturers of oral liquid products should ensure that they have conducted testing to establish that the level of DEG and EG for the following starting materials meet the required limits. These limits should be included into either the starting material specification or the finished product specification:   * Glycerin (also known as glycerol) * Propylene glycol * Sorbitol solution   Please refer to the [Guidelines for Testing Requirements of HS](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/tmhs_testing_guidelines.pdf) and TM for more information. |  |
| 11 | Laboratory test report for diethylene glycol (DEG) and ethylene glycol (EG) in starting material |  |
| 12 | Laboratory test report for DEG and EG in finished product |  |
| 13 | [TSE undertaking form](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/tse_form.pdf) | A TSE undertaking form is required if the product contains ruminant-derived materials e.g. bovine gelatin capsule.  The undertaking form should be completed and signed by the company representative. |  |
| 14 | [Undertaking Form for Website Address or QR Code on Packaging Materials](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/tmhs_website_undertaking.pdf) | An undertaking form is required if the product label contains any website address or QR code.  The undertaking form should be completed and signed by the company representative. |  |
| 15 | [Product linkage form](https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/linkage.pdf) | The product linkage form should be completed and signed by the company representative. |  |