HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

JANUARY 2025

VOLUNTARY NOTIFICATION SYSTEM FOR HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES – GUIDELINES ON THE NOTIFICATION PROCESS AND REQUIREMENTS

GL-CHPB-1-004 Rev. No. 004

The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at www.hsa.gov.sg.

HSA Health Sciences Authority

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1. Introduction

1.1 These guidelines outline the information for companies to voluntarily notify their health supplements (HS), traditional medicines (TM), medicated oils, balms (MOB) and medicated plasters under the Voluntary Notification System in Singapore. The information provided in these guidelines is not meant to supersede or replace any legislation. Other national legislative controls may be applicable, where relevant. HSA reserves the right, at our discretion, to refuse the notification of products that have non-compliance records or are under investigation by HSA.

Scope

1.2 These guidelines describe the procedures and requirements for the voluntary notification of a HS, TM, MOB and medicated plaster. More information on the definitions of the products can be found at:

- Regulatory overview of HS: https://www.hsa.gov.sg/health-supplements/overview
- Regulatory overview of TM: https://www.hsa.gov.sg/traditional-medicines/overview
- Regulatory overview of MOB and medicated plasters: https://www.hsa.gov.sg/medicated-oils-and-balms

1.3 In notifying a product, companies should ensure that the submission requirements specified in these guidelines are duly fulfilled. HSA may also request for additional information to supplement the specified submission requirements if deemed necessary to support the safety and quality of the product. Information on the submission requirements can be found in the following sections of these guidelines.

1.4 Companies are advised to check HSA's website for the latest version of these guidelines and other related guidelines.

Voluntary notification of HS, TM, MOB and medicated plaster

A notified product is specific with respect to its:

- Product name and brand name (if any);
- Product formulation (i.e., ingredient(s) and quantitative amount(s));
- Dosage form (i.e., physical presentation); and
- Indication(s) and dosing regimen.

2. Company Responsibilities

2.1 The locally registered company submitting the product notification may authorise officers or permanent employees, all of whom are referred to as the "company representative", to submit the product for voluntary notification in Singapore.

2.2 The company, in making a submission for the notification of the product, must ensure that all information contained in the submission is truthful and not misleading.

The company must inform HSA of any emerging information that may affect the safety or quality of the product to which the submission relates as soon as the company becomes aware of such information.

2.3 The company is responsible for submitting the notification and the supporting documents, including but not limited to the required documents, to complete the submission and respond to HSA's queries.

2.4 In notifying the product, the company is responsible for ensuring the safety and quality of the product through its life cycle. The list of declaration and undertaking can be found in Appendix 3.

3. Notification Process

3.1 A local company seeking to supply a HS, TM, MOB or medicated plaster in Singapore may voluntarily notify HSA on the product and receive HSA's written acceptance of the notification. The notification process involves a series of steps, as shown in Figure 1:

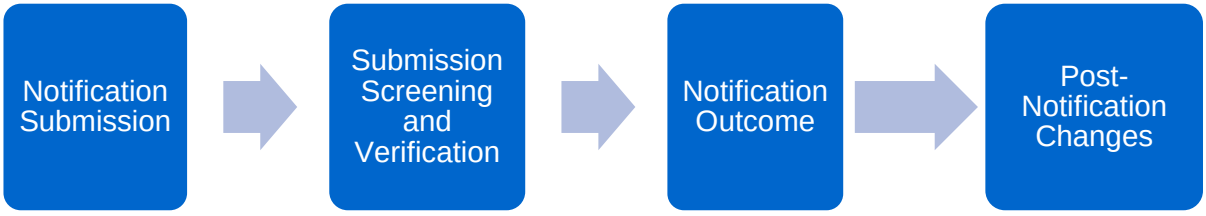


Figure 1: Notification process

4. Notification Submission

4.1 The notification submission comprises two key steps –

(i) online submission of the notification form via FormSG and
(ii) submission of the required documents via email.

Submission of FormSG notification form

4.2 All submissions of the FormSG Notification Form must be made online with mandatory log-in via Corppass. For more information on Corppass, refer to the following weblink: https://www.corppass.gov.sg

4.3 Please refer to Appendix 1 Guidelines on FormSG Notification Form Submission for details on the submission process.

Submission of the required documents via email

4.4 Following submission of the FormSG Notification Form, the company will receive an acknowledgement of the submission and a copy of the FormSG Notification Form as an attachment to the email. The email will also contain a Response ID.

4.5 To complete the notification submission, the following documents must be submitted as attachments in an email to HSA_TMHS@hsa.gov.sg within 2 working days of submitting the FormSG Notification Form. Otherwise, the submission will be invalid and closed without further notice. The product name and the Response ID should be included in the email subject. 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".

Processing of notification submission starts when all the required documents are received by HSA.

Required documents:

1. Copy of the submitted form
2. Manufacturer's Licence/Certification
3. Description of manufacturing process
4. Finished product specifications
5. Certificate of Analysis (including appropriate test parameters, their specifications and references)
6. Final artwork or product label (including the location of batch number and expiry date)
7. Product leaflet (if any)
8. Laboratory test report for toxic heavy metal and microbial limits (including method reference)*
9. Laboratory test report for adulterants screening (depending on type of product)*
10. Laboratory test report for diethylene glycol (DEG) and ethylene glycol (EG) in starting material (if applicable)*
11. Laboratory test report for DEG and EG in finished product (if applicable)*
12. Transmissible Spongiform Encephalopathy (TSE) undertaking form (if applicable)
13. Undertaking Form for Website Address or QR Code on Packaging Materials (if applicable)
14. Product linkage form (if applicable)
15. Checklist** on documentary requirements for voluntary notification of CHP (Appendix 2)

*Please refer to the Guidelines for Testing Requirements of HS and TM for more information.

****Each submission must be accompanied by a checklist duly completed by the company**. Submission checklist is provided in Appendix 2 to ensure submission of the complete dataset.

Submission requirements

4.6 All documents must be submitted in softcopies. Scanned copies of the original documents in colour should be submitted and hardcopies of original documents are not required. However, HSA reserves the right to request for the submission of the original or certified true copy of the submitted document. Please refer to 4.10 for more information on certifying non-original documents if the original documents cannot be provided.

4.7 The acceptable file format includes: JPEG, JPG, PDF, PNG, ZIP, DOC, HTML, TXT, PPT, RTF, XLS, XML, TIFF.

4.8 Companies must ensure that HSA has access to the content of the files. For protected files, password(s) must be provided. Files containing the below scripts will not be accepted due to cybersecurity reasons:

S/N	Script Type	Extension
1	VB Script	*.vbs, *.vbe, *.vb
2	VBA	*.vba
3	JS Script	*.js, *.jse
4	Windows Script File	*.wsf, *.ws
5	Windows Script Component	*.wsc, *.wsh
6	Powershell	*.ps1, *.ps1xml, *.ps2, *.ps2xml, *.psc1, *.psc2
7	Monad (legacy Powershell)	*.msh, *.msh1, *.msh2, *mshxml, *.msh1xml, *.msh2xml
8	Windows Shell	*.com
9	Batch	*.bat, *.cmd
10	Python	*.py, *.pyo, *.pcy, *.pyw, *.pys
11	Perl	*.pl, *.pls, *.p
12	Shortcut	*.lnk

Language and translation

4.9 All documents submitted in support of a notification submission to HSA must be in English. For documents in other languages, a certified translation or a verified translation may be acceptable.

Certifying non-original documents

4.10 If the softcopy of the official document submitted to HSA is not a scan of the original document, the document must be certified prior to submission. A certified true copy certifies that the photocopy presented is a true and accurate copy of the original document. Acceptable certification of documents to support the submission to HSA can be done by the Company Director or Company Secretary as registered with Accounting and Corporate Regulatory Authority (ACRA) or above, or by an independent authority such as a lawyer, notary public, Commissioner for Oaths/Declarations/Affidavits, Justice of Peace, the original issuer of the document or

Embassy/Consulate. A notarised and authenticated copy is the same as a certified true copy.

5 Submission Screening and Verification

5.1 Following a submission made via FormSG and the receipt of the required documents by HSA, the information provided will be screened to ensure the completeness of the documents. **The date of receipt of all the required documents will be taken as the submission date and the start of the screening timeline.**

5.2 For notification forms submitted without all the required documents, the submission will be considered invalid and closed without further notice.

5.3 If deficiencies are identified in the submitted documents, a query stating the deficiencies i.e., Input Request, in the form of an email, will be issued to the company.

5.4 In situations where the company is unable to provide a complete response by the due date, the company should inform HSA as soon as possible after receiving HSA's Input Request. The notification submission will be closed without further notice if the company fails to observe the specified response deadline.

5.5 If the company fails to address the deficiencies raised, the submission will not be accepted. An email will be sent to the company to inform that the submission will be closed. If the product is subsequently re-submitted for voluntary notification, it will be processed as a new submission.

6 Notification Outcome

6.1 Following the verification by HSA, companies will be informed of one of the following outcomes:

- **Notified** – the submission satisfies the notification requirements for safety and quality;
- **Rejected** – when the response provided by the company fails to address the Input Requests from HSA and the submission cannot satisfy the notification requirements.

The notification outcomes are final decisions issued by HSA.

6.2 Upon a ‘notified’ decision, the product will be added to the list of notified products, which will be published on the HSA website. This publication should not be misconstrued as an endorsement of the product by HSA.

6.3 Companies must comply with the notification conditions and the post-notification commitments. The declaration and undertaking, which include post notification commitments, can be viewed at Appendix 3.

7 Notification Submission Timeline

7.1 HSA will endeavour to provide a notification outcome within 60 working days, excluding stop-clock time. Companies should ensure that the information required is complete before submission. Incomplete submission and untimely responses to queries will cause unnecessary delays to the notification process and thus, will have a negative impact on the target processing timelines.

7.2 Stop-clock time refers to the time taken by companies to respond to any Input Request from HSA. Stop-clocks can occur during the screening and verification stages of the submission. The stop-clock starts when HSA requests for clarification of additional information with regard to a product notification submission. The stop-clock period ends when HSA receives a complete and satisfactory response to the query.

8 Post-Notification Process

Post-Notification Amendments

8.1 Companies are responsible for ensuring the product's quality and safety throughout its life cycle. Companies are required to inform HSA of any changes in their notified product at least 1 month prior to the supply of the product in the market. Details on the types of amendments and respective requirements can be found in Appendix 4.

8.2 HSA only accepts online submission of the amendment notification via FormSG. Details on the form can be found in Appendix 4.

Post-Notification Cancellation

8.3 Companies are required to inform HSA of the intent to cancel the product(s) notification. HSA only accepts online submission of the cancellation notification via FormSG.

8.4 The product will be removed from the list of notified products on the HSA website within 5 working days from the receipt of the duly completed form.

Appendix 1 - Guidelines on FormSG Submission

This appendix describes the processes and the information necessary for submitting a voluntary notification via FormSG. A checklist of the necessary information can be found in Section 3 of this appendix.

1 Submitting a new product notification

HSA only accepts submissions via FormSG.

NOTE: Companies must have Corppass to submit a voluntary notification via FormSG. For more information on Corppass, please refer to the following weblink:

https://www.corppass.gov.sg

2 Sections of a FormSG notification form

2.1 Section A: Company Particulars

Each submission for a voluntary notification is company-specific. The company named in this section must be based and registered in Singapore. The company bears full responsibility for ensuring that all available and relevant information is submitted in support of a submission.

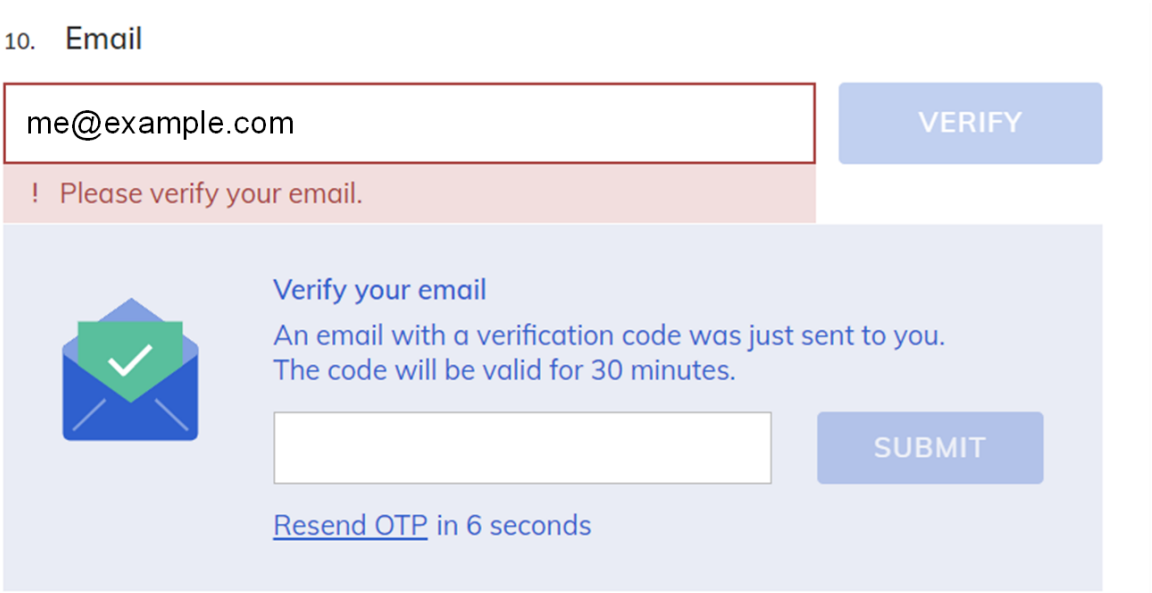
In this section, input the company's name, address and local telephone. If there is a direct local telephone number, input it into this section to facilitate timely communications between HSA and the company.

2.2 Section B: Company Representative's Particulars

The company may authorise officers, permanent employees, all of whom are referred to as the "company representative", to submit the voluntary notification in Singapore.

In this section, input the particulars of the company representative – salutation, name and designation.

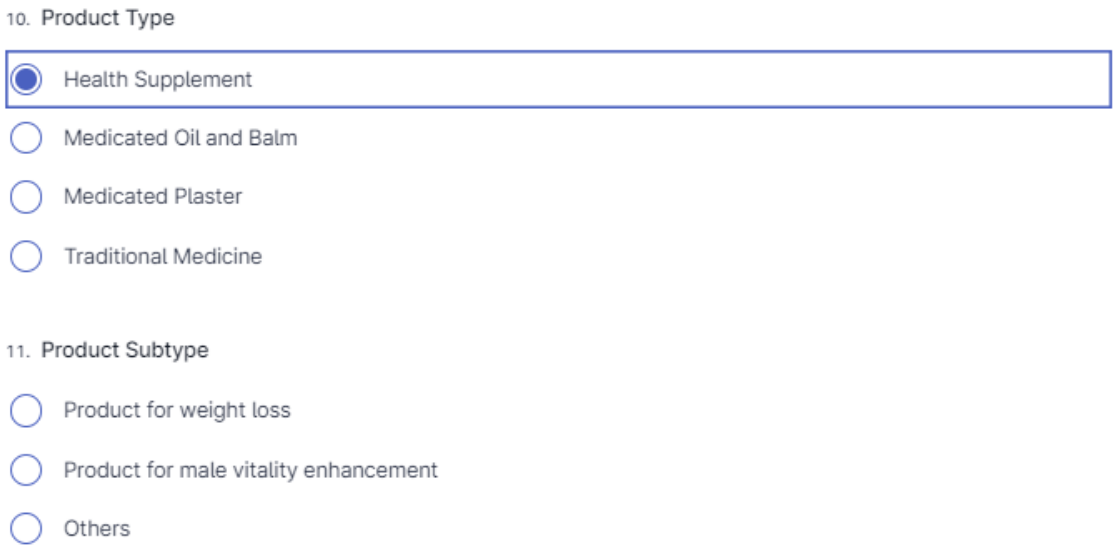
Please enter and verify the company representative's email address using a one-time password (OTP). This is to ensure that the email address is valid and correct to ensure no communication delays between HSA and the company representative.

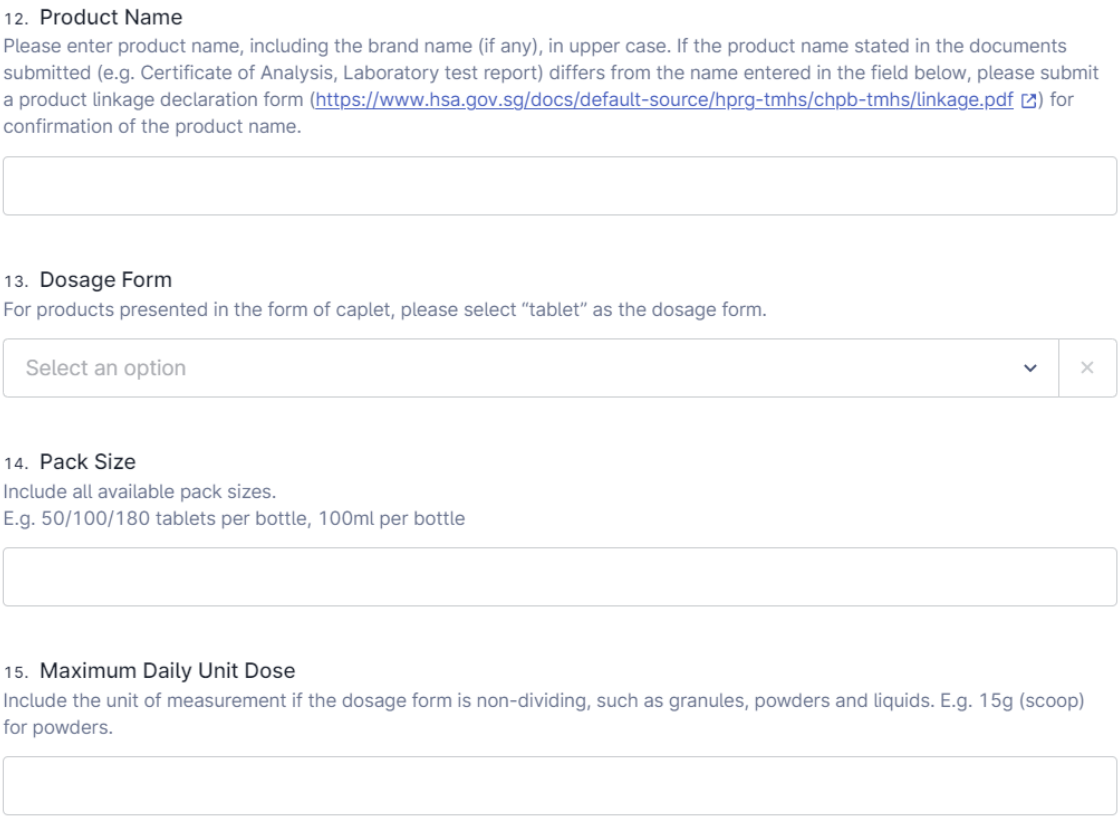


During the process of the notification submission, company representatives are advised to inform HSA immediately via HSA_TMHS@hsa.gov.sg if there are any changes to the particulars of the company representative, especially to the contact details.

2.3 Section C: General Product Details

In this section, enter specific details of the product, such as the product type, product subtype, product name and dosage form. A screenshot of the FormSG section C for HS is shown below as an example:





a) Product Type

All HS, TM, MOB and medicated plasters are eligible for voluntary notification. Companies can refer to the HSA website for more information on these product types and their respective regulatory controls.

b) Product Subtype

For the purpose of the application form, product subtype refers to the category of the product based on its intended use. A laboratory test report for adulterants screening must be submitted for the following product subtypes:

- weight loss
- pain relief
- male vitality enhancement.

c) Product Name

Product name is the name that is shown on the product labelling*. The product name includes the brand name of the product, where applicable. For example, if ABC is the brand of a Vitamin D Tablet, the product name field should state "ABC Vitamin D Tablet."

*the term ‘product labels’ or ‘product labelling’ refers to the inner label, outer carton and/or package leaflet of the product. More information on product labelling can be found here.

d) Dosage Form

Dosage form is defined as the physical form of a dose of a product which is intended for oral or topical administration e.g. tablet, capsule, ointment.

For a description of each dosage form, please refer to Guidelines for Physical Test Parameters based on Dosage Forms of Health Supplements and Traditional Medicines.

For products presented in the form of caplet, please select “tablet” as the dosage form.

e) Pack Size

Pack size refers to the amount of the product in a pack or container. This can be presented in absolute quantity (for solid dosage form) e.g. 30 capsules/container, or net content (for liquid, powder, or semi-solid dosage forms), e.g. 500ml/bottle.

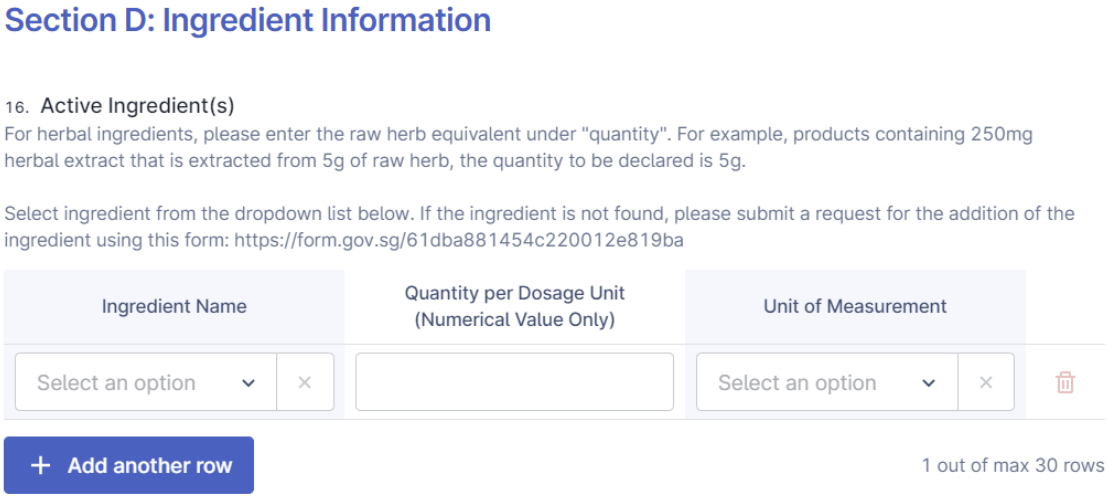
All available pack sizes for the same product should be listed in the form. e.g. 50/100/180 tablets per bottle.

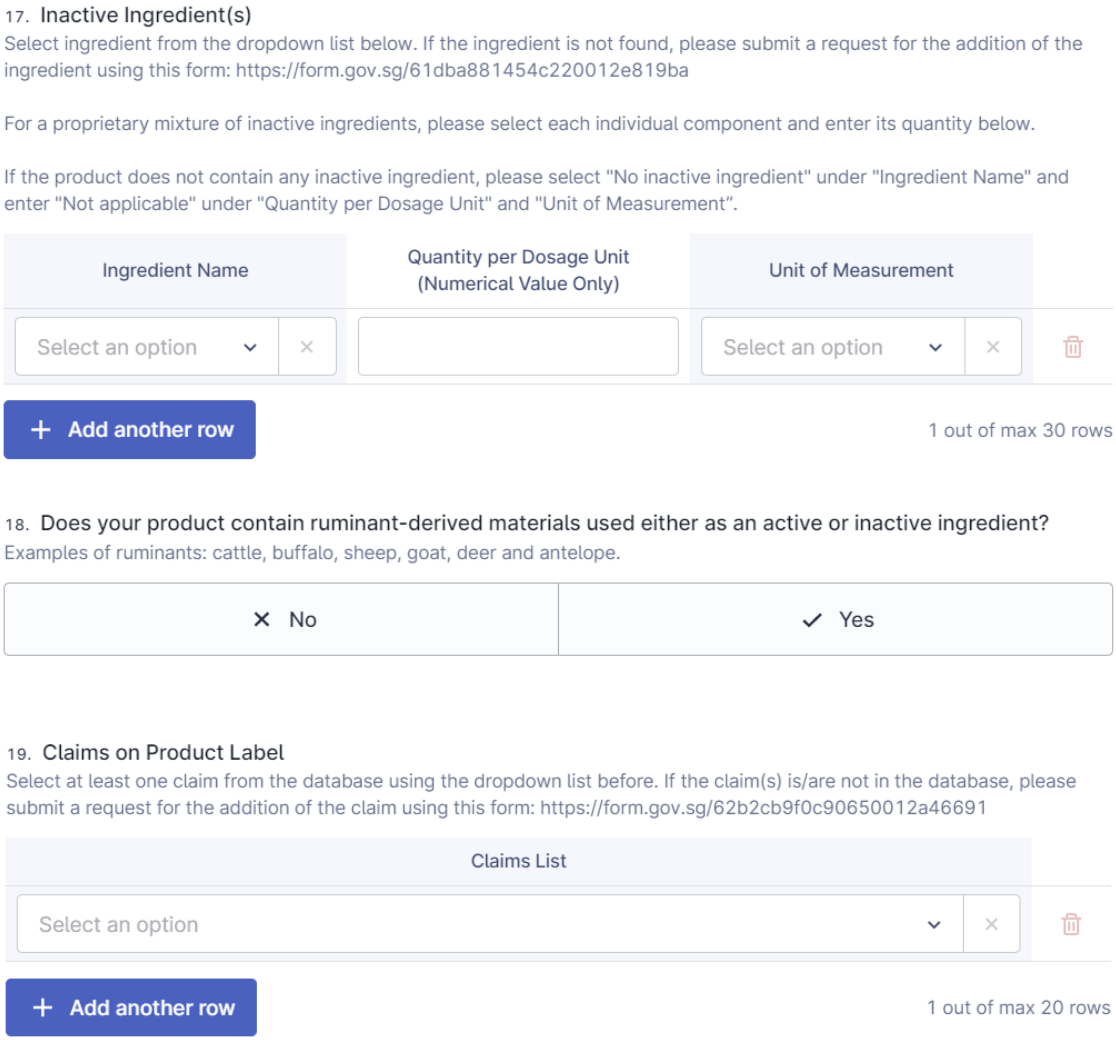
f) Maximum Daily Unit Dose

Maximum daily unit dose refers to the maximum amount of the product that can be used per day. The unit of measurement should be included if the dosage form is non-dividing, such as granules, powders and liquids. e.g. 15g (scoop) for powders.

2.4 Section D: Ingredient Information

In this section, enter specific details of the product formulation, such as the list of all the active ingredient(s) and inactive ingredient(s) (including water) that are present in the final dosage form. A screenshot of the FormSG section D is shown below:





a) Active Ingredient(s), Inactive Ingredient(s) and Quantity per Dosage Unit

Only products containing ingredients from the dropdown list can be notified. If the product contains ingredient(s) not found in the list, please refer to the Guidelines for Establishing the Safety of Ingredients of Health Supplements and Traditional Medicines and submit a request for the addition of the ingredient using this form.

The quantity per dosage unit refers to the amount of the ingredients in a single dose or unit of the product. For example:

- For a 200ml syrup with a single dose of 5ml, the quantity of the ingredient to be declared will be per 5ml, i.e. each 5ml of the product contains X mg of the ingredient Y

- For products in a capsule, the quantity of the ingredient to be declared will be the amount of the ingredient in the capsule.

- For a capsule containing 250mg herbal extract that is extracted from 5g of raw herb, the quantity to be declared is 5g

For products that are applied topically such as liquid, spray, cream and ointment, the quantity of each active ingredient may be expressed in terms of weight or volume or as percentage by weight or volume of the total quantity. E.g., Methyl salicylate 9g per 30g or 30% (w/w), Menthol 10mL per 100mL or 10% (v/v), Camphor 1g per 25g or 4% (w/w).

Dealers are to ensure that the recommended daily dosages of the ingredients used in the product are within safe levels that are appropriate for the target consumers. Only a numerical value should be entered in the field "quantity per dosage unit".

For a proprietary mixture of inactive ingredients, please select each individual component and enter its quantity in the submission.

b) Ruminant-derived Materials

This section applies to all materials of ruminant origin that are used in the preparation of both active ingredients that contribute to a product's intended function (e.g. sheep placenta) and inactive ingredients that do not contribute to the intended function of the product (e.g. gelatin). Examples of ruminants include cattle, buffalo, sheep, goat, deer and antelope.

If the product contains ruminant-derived materials, please submit a TSE undertaking form. More information on TSE can be found in the Guidelines for Minimising the Risk of Contamination of Transmissible Spongiform Encephalopathy in Chinese Proprietary Medicines, Health Supplements and Traditional Medicines.

c) Claims on Product Label

Claims in this section refer to any message or representation in relation to the product's indications, health benefits or action. Only products labelled with claims from the dropdown list can be notified. If the product contains claim(s) not found in the list, please refer to the Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines and submit a request for the addition of the claim using this form.

Please ensure that all the claims found on the product label have been selected from the dropdown list and dealers are to hold evidence to substantiate the product claims.

Please refer to the List of Health Claims for Health Supplements and Traditional Medicines for easy reference of the allowable claims.

2.5 Section E: Manufacturer Particulars

Manufacturer refers to the finished product manufacturer. Please indicate if the manufacturer is a local or overseas manufacturer, and select the manufacturer from the dropdown list. For manufacturers not found in the list, please select "Others", and enter the name of the manufacturer.

The dropdown list provided serves only as reference and is not to be construed as an endorsement of the manufacturers or their products. Dealers are to ensure that the manufacturer's licence is valid.

A screenshot of the section with selection of a local manufacturer whose name is not found is shown below:

For products manufactured overseas, please provide us with the importer name. This refers to the name of the local importer of the finished product. Please enter the same company name as indicated in Section A of the application form, if the company submitting the notification is also carrying out the importation.

Dealers are required to ensure that their products are manufactured in accordance with good manufacturing standards. More information on the guidelines for manufacturing standards can be found here.

2.6 Section F: Assembler Particulars

Assembler refers to the company repacking the product e.g. changing the pack size of a 1000 capsules per bottle into 200 capsules per bottle, or relabelling the product to another brand name.

Please provide us with the assembler's name, if any. Otherwise, please enter "NA" in the field.

2.7 Section G: Declaration and Undertaking

For company or manufacturer that is currently under investigation by any authority, including overseas authority, for non-compliance, please provide details of the non-compliance(s) in the form.

Please review all the declaration and undertaking (see Appendix 3) and indicate acceptance by ensuring that all the boxes under this section are checked before submitting the form.

3 List of information required in the notification form

Please ensure that the below information is collated before proceeding with the submission, as the form cannot be saved as draft.

Section A: Company Particulars
1. Company Name
2. Local Address
3. Postal Code
4. Contact Number
Section B: Company Representative's Particulars
1. Salutation
2. Name
3. Designation
4. Contact Number
5. Email
Section C: General Product Details
1. Product Type
2. Product Subtype
3. Product Name
4. Dosage Form
5. Pack Size
6. Maximum Daily Unit Dose
Section D: Ingredient Information
1. Active Ingredient(s) – Ingredient Name, Quantity per Dosage Unit, Unit of Measurement
2. Inactive Ingredient(s) – Ingredient Name, Quantity per Dosage Unit, Unit of Measurement
3. Information on whether product contains ruminant-derived materials
4. Claims on Product Label
Section E: Manufacturer Particulars
1. Location of Manufacturer – Local or Overseas
2. Manufacturer Name
3. Importer Name (for overseas manufacturer)
Section F: Assembler(s) Particulars (if any)
1. Assembler Name
Section G: Declaration and Undertaking
1. Information on whether the company/manufacturer is currently under investigation by any authority for non-compliance

Appendix 2 - 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.
- 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	

Document number	Documents	Points to note	Submitted (Y/N)
		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 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	

Document number	Documents	Points to note	Submitted (Y/N)
		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: a) Date of report b) Brand name (if applicable) and product name c) Batch number d) Name of substance(s) tested e) Reference(s) to the relevant specifications and testing procedures f) Test result(s), including limit(s) of detection* g) 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 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.	

Document number	Documents	Points to note	Submitted (Y/N)
		• 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: h) Date of report i) Brand name (if applicable) and product name j) Batch number k) Name of substance(s) tested l) Reference(s) to the relevant specifications and testing procedures m) Test result(s), including limit(s) of detection* n) 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	
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		

Document number	Documents	Points to note	Submitted (Y/N)
		• 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 and TM for more information.	
13	TSE undertaking form	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	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	The product linkage form should be completed and signed by the company representative.	

Appendix 3 - List of Declaration and Undertaking

1. I declare that the information provided in the form is current and correct.

2. I understand that the information I am submitting about my product will form the basis for the HSA's verification of this submission and its notification outcome.

3. I undertake to inform HSA if the product is subsequently not allowed for sale, or if there are any changes in the classification or legal status of the product in the country of origin.

4. I understand that the notification outcome only applies to my product based on the information submitted and/or may be subsequently submitted by me and acknowledged by HSA (as the case may be). I understand that it is my responsibility to ensure that each batch of my product continues to meet all the legal requirements and published guidelines, and conforms to the standards and specifications of the product that I have declared to HSA.

5. I undertake to provide HSA with documentation to support the standards and specifications of the product, where requested. I undertake to inform HSA should there be any changes to the product information.

6. I understand that I cannot place reliance on HSA’s acknowledgement of the notification of my product in any legal proceedings concerning my product where my product has failed to conform to the standards and specifications that I have declared to HSA.

7. I undertake that batches of this product will not be sold or supplied locally unless I have checked that the results of toxic heavy metals, microbial contamination and any other substances as required by HSA have met the applicable requirements.

8. I declare that this product is not a counterfeit.

9. I undertake to stop the sales, conduct product recall, provide supply records and comply with other instructions by HSA should it be found adulterated with substances listed under Poisons Act and/or active synthetic analogues of such substances.

10. I undertake to report all serious adverse effects* of the above product to HSA within 7 days upon receipt of such information. I will also report product safety issues and conduct recalls of unsafe or defective product if detected or when directed by HSA.

11. I undertake to ensure that there are no false or misleading claims in product label and advertisements.

12. Where applicable, I undertake to apply for the relevant permits before carrying out any advertisement or sales promotion of the above product. I understand that notification of the above product does not imply that the product name and/or its claims will be allowed for advertising purposes.

13. I undertake to not use the CHP product notification outcome as a marketing tool to advertise or promote the above product.

**"Serious adverse effects" mean any side effects or adverse reaction that:*

- *results in death;*
- *is life-threatening;*
- *requires in-patient hospitalisation or prolongation of existing hospitalisation;*
- *results in persistent or significant disability or incapacity; or*
- *consists of a congenital anomaly or birth defect*

For more information on reporting of adverse events, please refer to this link.

Appendix 4 – Post-notification Amendment Submission

This appendix describes the processes and the information necessary for submitting an amendment notification via FormSG.

1 Types of amendment

1.1 There are 2 types of amendment submissions:

1. Minor amendments (Do-and-Tell)
   - Changes that do not affect the safety and quality information of the notified product
   - **Do not** require HSA's approval of the changes before implementation

2. Major amendments
   - Changes that may affect the safety and quality of the notified product
   - Require HSA's approval of the changes before implementation

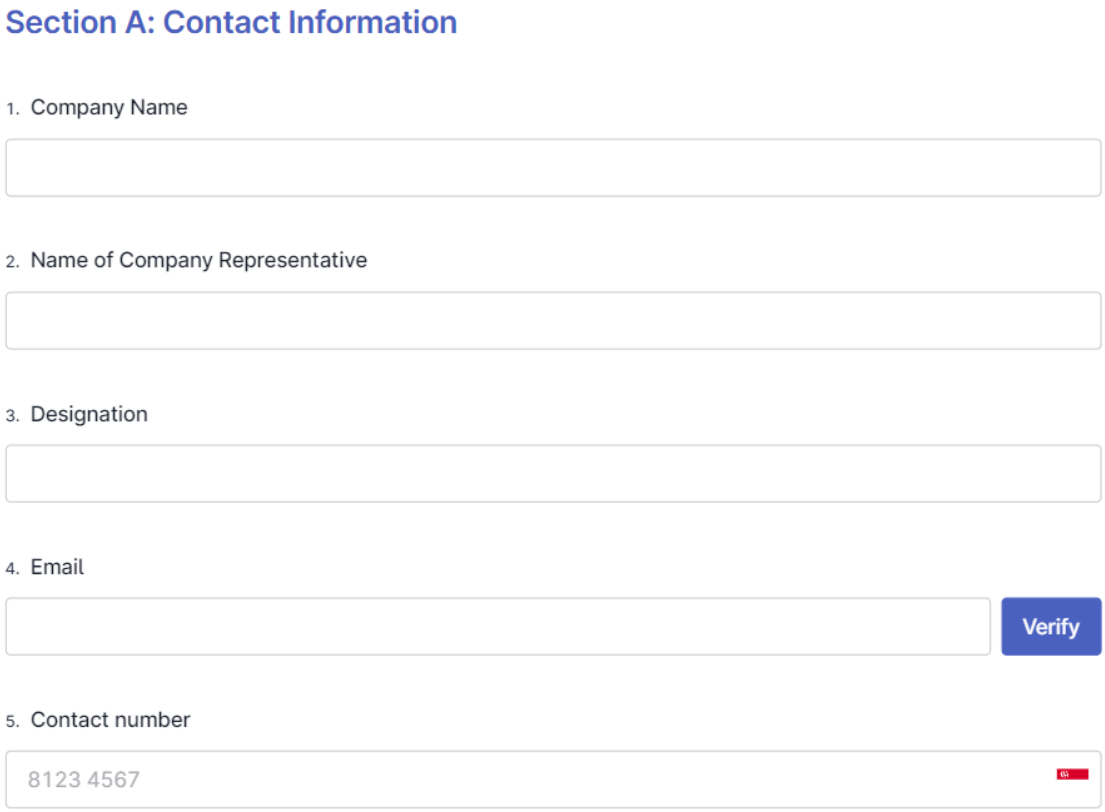
1.2 Please refer to Tables 1 and 2 below for the list of required supporting information for amendment submission. Please note that other additional documents may be requested by the HSA in the amendment process.

1.3 The following changes to the product information would require a new notification submission:

- Change in company responsible for the notified product
- Product name, including brand name (except for changes in spacing and/or casing)
- Dosage form of the product
- Active ingredient and/or its quantity

2 Sections of the FormSG amendment notification form

2.1 Section A: Contact information



The company name must be identical to the company that made the notification submission.

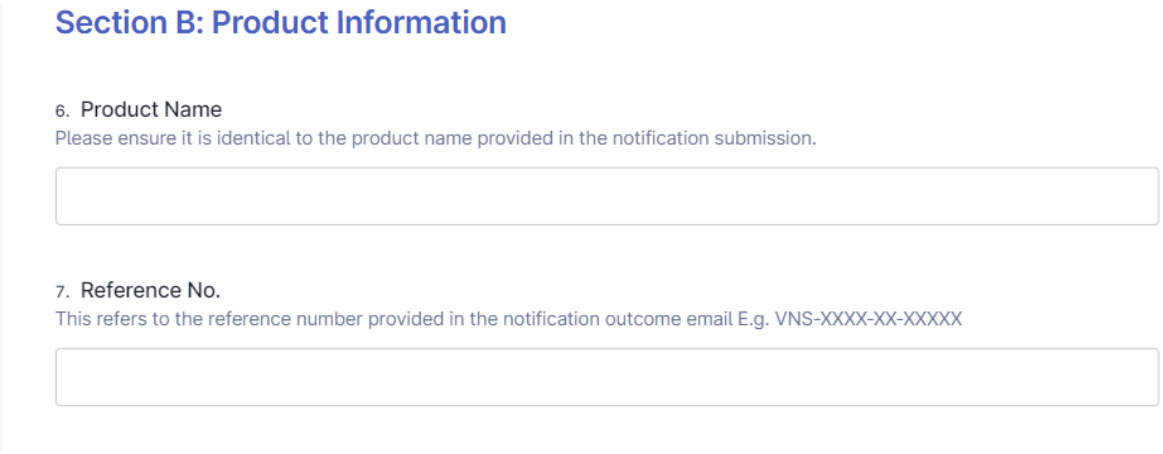
A company may authorise officers, permanent employees, all of whom are referred to as the “company representative”, to submit the amendment notification.

In this section, input the particulars of the company representative – name and designation, email and local telephone number.

Please enter and verify the company representative’s email address using a one-time password (OTP). This is to ensure that the email address is valid and correct.

If there is a direct local telephone number, input it into this section to facilitate timely communications between HSA and the company.

2.2 Section B: Product information

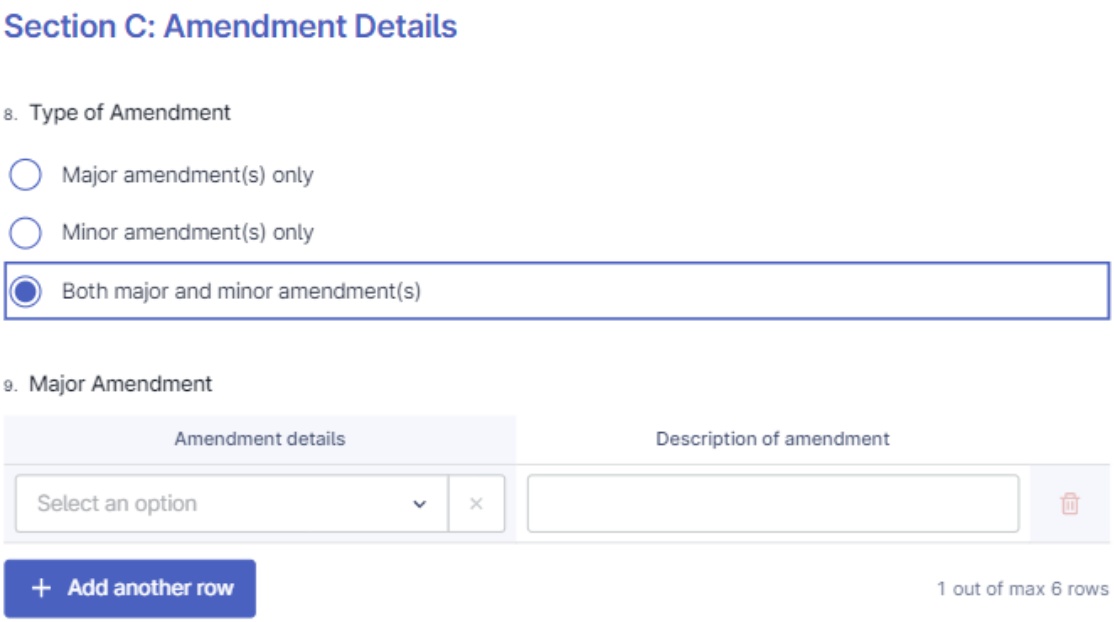


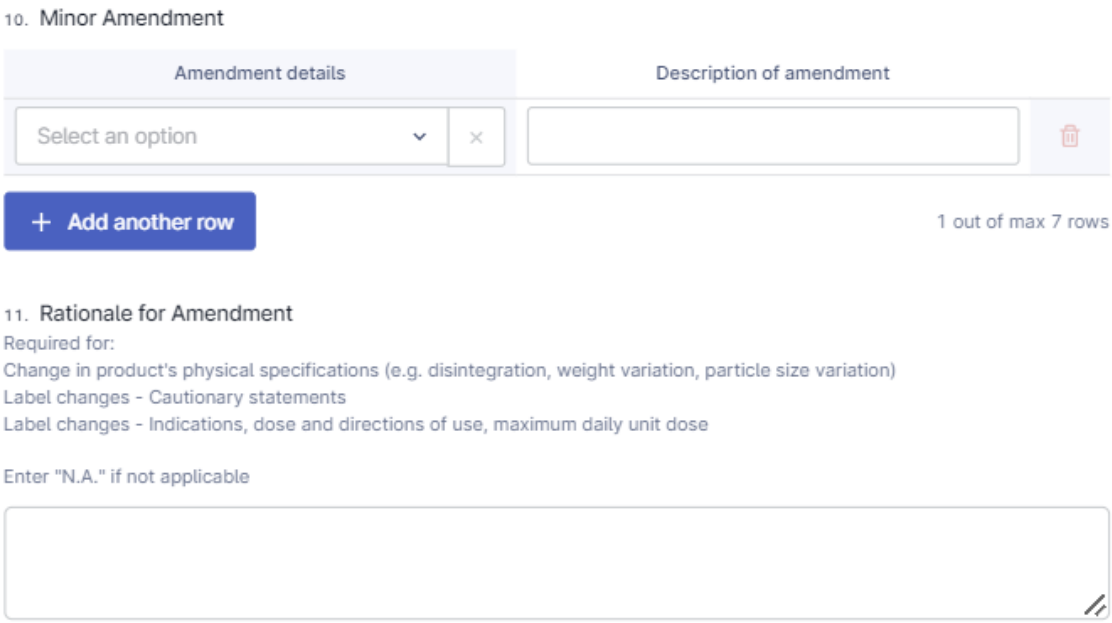
In this section, input the product name and reference number for the notification submission.

The product name must be identical to the product name provided in the notification submission. If there are any changes to the product name, a new notification submission is required.

The reference number refers to the reference number provided in the notification outcome email and is in the following format: VNS-XXXX-XX-XXXXX

2.3 Section C: Amendment Details





In this section, select the type of amendment for the product. The types of amendment can be found in Tables 1 and 2.

Company should use one form for all the intended amendments for the same product. Select the amendment from the drop-down list and provide description for each amendment. If there are more than one amendment, select “add another row” and add on the other amendment(s). For the following amendments, include the revised information in the column for “description of amendment”:

- Updated company details
- Updated details of the company representative
- Updated details of importer/assembler/distributor/product owner
- Updated pack size information

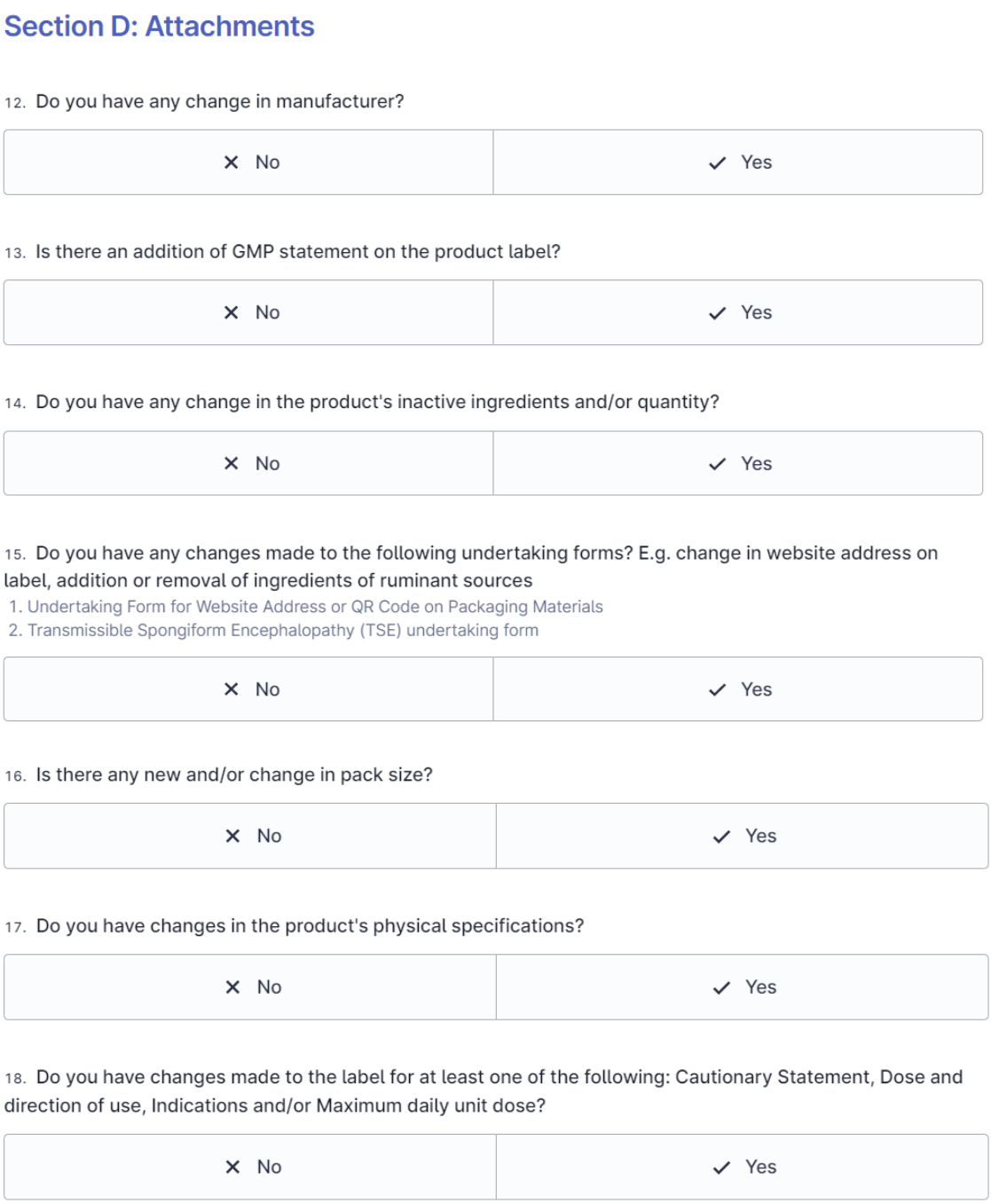
The rationale for amendment is required for the following amendments:

- Change in product's physical specifications (e.g. disintegration, weight variation, particle size variation)
- Change in cautionary statements, indications, dose, directions of use, maximum daily unit dose

For other amendments, please enter “N.A.” in the “Rationale for amendment” field as these amendments are supported by the required documents to be submitted, as stated in Table 2.

2.4 Section D: Attachments

For this section, answer the series of questions on the nature of amendments in order to attach the required documents to support the amendments made.



The acceptable attachment file format includes: JPEG, JPG, PDF, PNG, ZIP, DOC, HTML, TXT, PPT, RTF, XLS, XML, TIFF.

All documents must be submitted in softcopies. Scanned copies of the original documents in colour should be submitted and hardcopies of original documents are not required. However, HSA reserves the right to request for the submission of the original or certified true copy of the submitted document.

All documents submitted in support of an amendment submission to HSA must be in English. For documents in other languages, a certified translation or a verified translation may be acceptable.

2.5 Section E: Declaration and Undertaking

The list of declaration and undertaking for amendment submission are as follows:

1. I declare that the information provided in the form is current and correct.

2. I understand that the information I am submitting about my product will form the basis for the HSA's verification of this submission and its notification outcome.

3. I understand that the notification outcome only applies to my product based on the information submitted and/or may be subsequently submitted by me and acknowledged by HSA (as the case may be).

4. I understand that it is my responsibility to ensure that each batch of my product continues to meet all the legal requirements and published guidelines, and conforms to the standards and specifications of the product that I have declared to HSA, including the declaration and undertaking provided for the original product notification submission.

5. I undertake to provide HSA with documentation to support the standards and specifications of the product, where requested. I undertake to inform HSA should there be any changes to the product information.

6. I understand that I cannot place reliance on HSA’s acknowledgement of the notification of my product in any legal proceedings concerning my product where my product has failed to conform to the standards and specifications that I have declared to HSA.

Table 1: Supporting information for minor amendment submission

Amendment details	Amended final artwork or product label	Website undertaking	GMP Certificate
Company name (with no change in UEN number), address, contact details	✓ (if stated on label)	-	-
Name and/or contact details of company representative	-	-	-
Discontinuation of marketed pack size(s)	-	-	-
Assembler/ Distributor/ Product owner (if different from notifying company)	✓ (if stated on label)	-	-
Importer	✓	-	-
Label – Website address or QR code	✓	✓	-
Label – Addition of GMP statement	✓	-	✓
Label – Editorial or design-related (e.g. colours, layout), marketing logos (ISO, Halal, Superbrands, Vegetarian)	✓	-	-

Table 2: Supporting information for major amendment submission

Amendment details	Amended final artwork or product label	TSE undertaking	Rationale for amendment	Certificate of Analysis (including product specifications and results)	Manufacturer Licence/ Certificate	Supporting documents for rationale of amendment	Test report for heavy metal and microbial limits
Manufacturer	✓	-	-	-	✓	-	-
Change in product's cautionary statements, indications, dose, directions of use, maximum daily unit dose	✓	-	✓	-	-	✓	-
New and/or change in pack size(s)	✓ (for the new pack size)	-	-	-	-	-	✓
Change in product's inactive ingredients and/or quantity (which includes colour of product, preservatives, capsule shell)	✓ (if inactive ingredient is stated on label)	✓ (If ruminant-based gelatin is used)	-	✓ (if applicable)	-	-	✓
Change in product's physical specifications (e.g. disintegration, weight variation, particle size variation)	-	-	✓	✓	-	-	✓

Revision History

Version	Date of publication	Summary of changes*
1	July 2022	New document
2	February 2023	Included post-notification amendment process and guidance
3	July 2023	• Included medicated oils, balms and medicated plasters • Included post-notification cancellation process and guidance
4	November 2024	• Included documents related to DEG and EG • Included description of manufacturing process and finished product specifications as required documents
5	January 2025	• Editorial changes to sections on submission verification and checklist on documentary requirements

*Editorial changes are not reflected

HEALTH SCIENCES AUTHORITY

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