QUESTIONS AND ANSWERS ON VOLUNTARY NOTIFICATION SYSTEM OF HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

VOLUNTARY NOTIFICATION SYSTEM SUBMISSION

1. What is the purpose of Voluntary Notification System for health supplements and traditional medicines?

The Voluntary Notification System for health supplements and traditional medicines aims to establish a local database of reliable, good quality and safe products that consumers can refer to when they are making their purchases. It allows for better traceability and follow up actions by HSA if there are any safety or quality issues with notified products voluntary for products sold locally.

2. What type of products can be submitted for Voluntary Notification System?

Health supplements, traditional medicines, medicated oils, balms and medicated plasters can be submitted under the Voluntary Notification System. Please refer to the Guidelines on the Voluntary Notification Process and Requirements for Health Supplements and Traditional Medicines for information on how to submit a voluntary notification.

3. What are the products that fall within the pain relief category?

In the context of Voluntary Notification System, pain relief products refer to products containing ingredients commonly used in the Malay and Indian traditional paradigms for the relief of pain or inflammation. As such, pain relief claims are limited to traditional medicine products only. Pain relief claims are not to be used in health supplements.

4. Who can participate in the Voluntary Notification System?

Singapore registered companies that manufacture or distribute health supplements, traditional medicines, medicated oils, balms and medicated plasters for local sale and supply, including via local e-commerce platforms, may participate in the Voluntary Notification System. All submissions of the notification form must be made online with mandatory log-in via CorpPass of the locally registered company. Overseas companies who wish to market their products in Singapore would have to appoint a local importer or product owner, who will be responsible for the products locally. This appointed company would be the party to submit the notification.

5. My company provides consultation services to both local and overseas companies. Can I submit notification on behalf of my client?

As a consulting firm, you may request for the local company to authorise you to submit the notification on their behalf.

6. For existing products already in the market, if we were to submit notification and HSA requests for changes to label information, do we need to recall all the batches already in the market?

Once a product has been successfully notified, companies are required to ensure that the labels of the existing product in the market are the same as the final version of the labels submitted during notification. Whether the existing product has to be recalled depends on the type of changes to the label information required. Products with labelled claims that contravene legislated requirements would need to be amended as soon as possible.

If companies are able to meet the stipulated safety and quality requirements but require time to phase out old labels of the existing products in the market, the notification will be put on hold with stop-clock activated. Companies will be given 6 months to implement the revised labels. The product's notified status will only be published on the HSA's website when the label changes to the existing products in the market have been made.

7. For existing products already in the market, what happens if the notification outcome is 'rejected'? Can we still sell the product?

Whether the existing product can still be sold would depend on the issues resulting in the rejection of the notification. If the product does not comply with the legislative requirements, such as the product contains substances controlled under the Poisons Act, the company should take immediate actions to discontinue the sale of the product. For other reasons of rejection of notification, companies are encouraged to level up to relevant standards to ensure that their products are of good and consistent product quality.

8. Why is my product rejected under the Voluntary Notification System?

Generally, a product may not be accepted for notification under the Voluntary Notification System if it does not meet the stipulated safety, quality, and labelling requirements. For more details on the requirements, please refer to the Guidelines on the Voluntary Notification Process and Requirements for Health Supplements and Traditional Medicines.

9. What happens if we are unable to provide certain documents due to confidential concerns from the manufacturer?

You may request for your supplier to submit the requested information directly to HSA. All submitted documents will be treated with strict confidence.

10. Is it a requirement to provide the Transmissible Spongiform Encephalopathy undertaking form for bovine sourced gelatin capsule?

Cattle (bovine), sheep (ovine), goat, deer (cervine) and antelope are examples of animals that are considered ruminants. The use of bovine sourced gelatin capsule in a product would require the submission of the Transmissible Spongiform Encephalopathy undertaking form.

11. If another company has notified the product, would I still need to notify it?

If you are the retailer of the product, you would not need to notify the product. If you are the importer of the product, you are encouraged to notify the product that you are bringing into Singapore, even if the products are the same or similar to others that may already be notified by another company. This would allow HSA and consumers to contact the relevant importers should there be a need to do so.

12. For new products that are to be launched, does my company have to notify prior to the supply in the market or after the products have been supplied in the market? Do we have to wait for the products to be published on the HSA website before supplying?

For new products, companies that are keen to voluntarily notify these products may do so once the required documents are ready. Companies may wish to take into consideration their product availability, in relation to the publication of notified products in the List of Notified Health Supplements and Traditional Medicines on the HSA website, as consumers will expect to find the notified products in the market.

13. Once my product is notified, would there be any certification provided?

No certificate will be issued for notified products. HSA will notify the company on the outcome of the notification submission. Notified products will be published on the List of Notified Health Supplements and Traditional Medicines on HSA's website.

14. After notification is received, does the notification number need to be displayed on the product?

The notification number does not need to be displayed on the product label.

15. May I include the product notification status on an advertisement of the notified product?

For product that is notified with HSA, the following statement may be included on an advertisement:

"This complementary health product is notified with the HSA based on information submitted to the Authority. Consumer discretion is advised."

However, the advertisement should not suggest that the use of the product is promoted or endorsed by HSA.

16. Under which circumstances would my notified product be removed from the listing?

Product that is found to not meet the stipulated safety, quality and labelling requirements may be removed from listing.

17. How will HSA use the information submitted during Voluntary Notification System for post market surveillance?

Post market surveillance programme is to monitor the safety of health products and to initiate timely product recalls when necessary. The programme includes risk-based surveillance to sample products in the market, and adverse reaction monitoring. Information submitted during Voluntary Notification System would assist in the review of any safety signals or product defects so that appropriate action may be taken in a timely manner.

INGREDIENTS SAFETY

18. What are the ingredients allowed in products to be submitted for Voluntary Notification System?

HSA has identified more than 1,700 ingredients that may be used in health supplements, traditional medicines, medicated oils, balms and medicated plasters. The ingredients that are included in this positive list have a long history of safe use e.g., as documented in established references and are also commonly used in complementary health products. HSA has also taken into consideration allowable ingredients in overseas jurisdictions such as Health Canada and Therapeutic Goods Administration of Australia for similar products. To check if the ingredients in your product are in the voluntary product notification positive list of ingredients, you may use the search tool here. If the ingredient cannot be found in the list, a new ingredient request may be submitted using this form.

19. What is an inactive ingredient?

An inactive ingredient refers to an ingredient that is not intended to exert the claimed health effect at the intended dosage. Inactive ingredients help to:

a) Preserve the quality of the product
b) Improve its organoleptic properties
c) Provide aids in the manufacture, processing, preparation, treatment, packing, transport, or storage of the product

Examples of inactive substances include gelatin capsule shells, fillers, diluents, surfactants, solvents, emulsifiers, preservatives, flavours, absorption enhancers, and coloring agents.

For information on inactive substances (i.e. additives and excipients) and their appropriate levels in a product, you may refer to the ASEAN Guiding Principles for the Use of Additives and Excipients in Health Supplements, ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines, Codex General Standard for Food Additives, and Handbook of Pharmaceutical Excipients.

20. What are the requirements for evidence to substantiate the safety of an ingredient?

Ingredient safety may be supported by literature evidence such as long history of safe use in conventional food or traditional medicines or safety assessments by regulatory authorities, scientific bodies, or institution. If these are not available, scientific evidence may be submitted. For more detailed information, please refer to the Guidelines for Establishing the Safety of Ingredients of health supplements and traditional medicines.

21. Is it possible to submit new ingredients not found in the list of ingredients? How long does HSA take to approve new ingredients after submission of the requests to HSA?

Companies may submit requests for addition of new ingredients and their supporting documents using this form. The time required for the review of a new ingredient depends on the complexity and volume of such requests. Companies are encouraged to prepare the supporting documents for such requests by referring to the Guidelines for Establishing the Safety of Ingredients of health supplements and traditional medicines.

HEALTH CLAIMS

22. Is there a list of positive health claims allowed under the Voluntary Notification System?

A comprehensive list of health claims allowed for use has been published on HSA's website and has been included in the voluntary notification submission form. HSA has

also taken into consideration allowable claims in overseas jurisdictions such as Health Canada and Therapeutic Goods Administration of Australia for similar products. For more information, refer to the Guidelines for Claims and Claims Substantiation for Health Supplements and Traditional Medicines on HSA's website.

23. Is it possible to submit new health claims not found in the list of health claims? How long does HSA take to approve new health claims after submission of the requests to HSA?

Companies may submit requests for addition of new claims and their supporting documents using this form. The time required for the review of a new ingredient depends on the complexity and volume of such requests. Companies are encouraged to prepare the supporting documents for such requests by referring to the Guidelines for Claims and Claims Substantiation for Health Supplements and Traditional Medicines.

24. What are the requirements for efficacy substantiation for claims?

All health claims must be substantiated by evidence that is relevant to the claims. Literature and regulatory evidence may be used. If the evidence based on published references is not available, scientific evidence from human studies may be used. Scientific evidence could be derived from observational or interventional human studies that are well-designed in accordance with recognised scientific principles. For more information, refer to the Guidelines for Claims and Claims Substantiation for Health Supplements and Traditional Medicines on HSA's website.

LABELLING STANDARDS

25. How should I label the active ingredients of my product on the label?

The naming of active ingredient would depend on the type of ingredient used.

a) For ingredients derived from plants or animal sources, the name should be declared in scientific name of the plant or animal followed by part of the plant or animal constituting the active component, and type of preparation where applicable. The common or local name of the plant or animal may be included.
   E.g.,
   - Plant source – “Eurycoma longifolia, root, extract 100:1 equivalent to 20,000mg of fresh root (Tongkat Ali)” indicated Eurycoma longifolia as the scientific name of the plant, root as the part used, and extract 100:1 as the type of preparation. Tongkat Ali is the common name of the plant and may be included.
   - Animal source – “Bos taurus, colostrum, dried (Bovine colostrum)” indicates Bos taurus as the scientific name for cattle, colostrum as the part used, and dried as the type of preparation. Bovine colostrum is the common name and may be included.

b) For vitamins and minerals, common or chemical name should be included.
E.g.,
- Ascorbic acid or vitamin C, ascorbic acid is the chemical name of the ingredient and vitamin C is the common name
- Retinyl ascorbate or vitamin A, retinyl ascorbate is the chemical name of the ingredient and vitamin A is the common name

c) For mineral supplements in the form of a salt, the strength of the element should be declared. The chemical name of the mineral salt may be included.
E.g.,
- Ferrous sulphate (providing 10mg Iron), ferrous sulphate is the chemical name of the mineral salt and iron is the element
- Iron 10mg, iron is the element

26. If my product label has limited space, can I include a weblink or QR code on the product label to provide the required information?

For products that are very small and have limited space for the product label, the immediate label may contain minimally the following information, product name and brand name, batch number and expiry date. The full product information such as the name and quantity of active ingredients, intended purpose, dosage, and direction of use should be displayed on an accompanying outer container such as an outer box or carton box. Please refer to the Guidelines for Labelling Standards of Health Supplements and Traditional Medicines on HSA's website for more details.

The use of a QR code to provide the necessary information online may be included but should not be a replacement of the minimal labelling information required for the label. Please refer to the Guidelines on Voluntary Electronic Labelling for Complementary Health Products on HSA's website for more details.

27. What are the acceptable prefixes for expiry date and batch number on the product label?

You may consider the following commonly used prefixes on products for examples, “EXP”, “EXPIRY”, “Batch No.”, “BN”, “Lot No.” or “Lot”. You may state the expiry date and batch number in any other forms provided it is easy to understand and not misleading.

MANUFACTURING STANDARDS

28. How can I get HSA to audit my manufacturing plant for GMP certification?

Good Manufacturing Practice (GMP) certification is a voluntary scheme offered to local manufacturers of medicinal products and are interested to be certified for conformity with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP for pharmaceutical products. Please refer to HSA's website at

https://www.hsa.gov.sg/therapeutic-products/dealers-licence/certification/gmp-certificate for more details.

TESTING REQUIREMENTS

29. Why is there a need to conduct adulterant testing for products?

The submission of the laboratory test report for adulterants screening is only applicable to products intended for weight loss, pain relief and male vitality enhancement as HSA has detected instances of adulteration of health products with potent chemical pharmaceutical substances. Their presence can pose health risks to unsuspecting consumers. If your product does not fall within these product types, you are not required to submit the laboratory test report for adulterants screening. Please refer to the Guidelines for Testing Requirements of Health Supplements and Traditional Medicines on HSA's website for more details.

30. Must I perform all the testing parameters listed under each dosage form?

The recommended physical test parameters for dosage forms are necessary to ensure they consistently meet the required standards throughout the product life cycle. You are encouraged to include such testing as part of the product manufacture and batch release processes. For more information on the minimum requirements for test parameters for each dosage forms, you may refer to the Guidelines on Physical Test Parameters for Dosage Forms of Health Supplements and Traditional Medicines on HSA's website.

31. How frequent should I test my products?

You should conduct the recommended tests for every product batch release as these results are batch specific. These results should be reflected in your batch Certificate of Analysis. If these tests are not performed as part of your product batch release, you should conduct these tests separately at an accredited laboratory prior to the sale of the product in the market.

32. Must testing be conducted locally? Are test reports from overseas laboratories or manufacturer's in-house laboratory acceptable?

The performance of testing by accredited laboratories in Singapore or overseas is acceptable. Accredited laboratory refers to laboratories that have been accredited by the respective national accreditation body in the country of origin to conduct testing services in conformance to required standards. Test reports from manufacturer's in-house laboratory that is audited under Good Manufacturing Practice are also acceptable, if the tests are performed following pharmacopoeial methods or in-house validated test methods. For more information on accredited analytical testing

laboratories in Singapore, please refer to Singapore Accreditation Council's website at https://www.sac-accreditation.gov.sg/

33. Must the test results for quality specification, toxic heavy metals, microbial limits, and adulterants screening be submitted to HSA for every imported or manufactured product batch?

Test results demonstrating that the finished product meets quality specifications, toxic heavy metals, microbial limits, and adulterant screening for applicable product types on a batch of the product are required to be submitted during the notification process. Dealers are not required to submit the test results for every batch to HSA after the product is notified. Dealers are required to ensure that every batch of the products fulfil the necessary requirements before they are being sold. Please refer to the Guidelines for Testing Requirements of Health Supplements and Traditional Medicines and Guidelines on Physical Test Parameters for Dosage Forms of Health Supplements and Traditional Medicines on HSA's website for more details.

POST NOTIFICATION AMENDMENTS

34. Do companies need to inform HSA on changes in the notified products? Do companies need to wait for HSA's approval to the changes before implementation?

Companies are required to inform HSA of any changes in the product information of the notified Health Supplements or Traditional Medicines by submitting a post-notification amendment via FormSG, at least one month prior to the supply of the product with the intended change in the market.

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

Substantive changes to the product will require a new notification submission, for example:

- Product name, apart from changes to spacing and/or casing
- Company responsible for the product
- Active ingredient(s) and/or its quantity

Please refer to the Guidelines on the Voluntary Notification Process and Requirements for Health Supplements and Traditional Medicines for information on the required supporting information for amendment submission and other details.

35. If the notified product is discontinued from Singapore market, what should I do?

Companies are required to inform HSA of the cancellation of their notified product from the market. HSA only accepts online submission of the cancellation via FormSG. The product will be removed from the List of Notified Health Supplements and Traditional Medicines on the HSA's website within 5 working days from the receipt of the duly completed form.