QUESTIONS AND ANSWERS ON SAFETY AND QUALITY FOR HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

INGREDIENTS

Question 1: If my product doesn't contain prohibited or restricted ingredients, does that mean all ingredients can be used? Is there a positive ingredient list I can refer to?

Prohibited ingredients are substances that must never be used in health supplements and traditional medicines, while restricted ingredients may be used only under specific conditions like maximum dose limits or cautionary statements.

Even if your ingredients do not appear on these lists, you must still conduct thorough safety assessments for every ingredient used, including verifying appropriate dosage levels for your target population.

HSA has identified more than 1,700 ingredients that may be used in health supplements or traditional medicines. This pre-approved ingredient list is available for your reference. However, the inclusion of an ingredient on this list does not guarantee safety for your specific product. You must still check that the recommended dosage for your product is safe and whether there are restrictions for this ingredient in the Guidelines on Prohibited and Restricted Ingredients in Health Supplements and Traditional Medicines.

You remain responsible for ensuring all ingredients are safe and appropriate for their intended use.

Question 2: What ingredients are included in the pre-approved list for use in health supplements and traditional medicines?

The ingredients that are included in the pre-approved list have a long history of safe use e.g., as documented in established references and are also commonly used in health supplements and traditional medicines.

HSA has also taken into consideration allowable ingredients in overseas jurisdictions such as Health Canada and Therapeutic Goods Administration of Australia for similar products.

Question 3: The guidelines state that chromium for oral use by the general adult population should not exceed 0.5mg, and zinc should not exceed 15mg in health supplements. Are chromium (as chromium nicotinate glycinate chelate) and zinc permitted in health supplements in Singapore?

Both chromium and zinc are restricted ingredients. They are permitted in health supplements but must comply with maximum daily dose limits - 0.5mg for chromium

and 15mg for zinc for the general adult population. The specific form of chromium (such as chromium nicotinate glycinate chelate) does not change this restriction.

Question 4: Can I sell products containing these ingredients at doses higher than the specified limits? Or would they need to be registered?

Exceeding restricted limits for health supplements does not mean the product requires registration. Whether it requires registration would depend on the product's overall presentation, intended use and formulation.

Higher levels may be permitted for specific adult population groups that require increased supplementation, provided this is properly justified with the following

- Credible authoritative references or expert opinion demonstrating that supplementation above established limits is needed for your target population, and
- Medical professional assessment and recommendation regarding specific patients' additional supplementation needs

Products intended for patients with specific conditions requiring higher levels should include labelling statements indicating that the product must be used under healthcare professional recommendations and poses health hazards when consumed by persons without the intended conditions.

For more detailed information on these requirements, please refer to the health supplements guidelines on HSA website.

Question 5: **Can health supplements and traditional medicines sold in Singapore contain human-derived ingredients that have been produced through tissue culture methods (such as lab-grown human collagen)?**

Ingredients derived from human parts are prohibited in health supplements and traditional medicines. This prohibition applies to human-derived ingredients regardless of whether they are directly extracted or produced through tissue culture methods.

This restriction is in place for safety considerations.

Question 6: Where can the botanical names of ingredients be obtained?

The botanical names may be obtained from several authoritative sources. These include:

- The *Flora of North America* (available at http://www.fna.org) provides comprehensive botanical nomenclature for North American species
- The *International Plant Names Index* (IPNI) at http://www.ipni.org offers a database of botanical names and associated bibliographic details

- *The Plant List* (http://www.theplantlist.org), a working list of all known plant species, is another reliable resource

Additionally, the botanical names may also be found in reputable monographs and pharmacopoeias.

Question 7: What is inactive ingredient?

Inactive ingredient refers to 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 colouring 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.

Question 8: 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 institutions. 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.

LABELLING

Question 9: How should the country of manufacture be presented on product label?

The label should clearly indicate the country of manufacture with no ambiguity from the phrasing used. This may be presented as:

- "Made/Manufactured in <country>"
- Manufacturer's address, with the country stated clearly

Question 10: Should the vitamin quantities on product label reflect the initial amount or the amount remaining near the expiry date?

Manufacturers should formulate their products with appropriate vitamin levels to ensure they meet the product specifications throughout the shelf life and is appropriate for the product's intended use and target population. The labelled vitamin content should remain within the acceptable range of the product specifications until expiry.

Question 11: Can I include logos such as vegan, GMP or other certification marks on the label?

Logos that are likely to create false or misleading impressions about the product's formulation, composition, quality or safety should not be included on the product label.

For example, if you wish to include a GMP (Good Manufacturing Practice) logo, you should ensure that the manufacturer is certified to acceptable GMP standards in accordance with the Guidelines for Manufacturing Standards for Health Supplements and Traditional Medicines.

Question 12: 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.

1. 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.

2. 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

3. 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

Question 13: 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.

Question 14: **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.

CLAIMS

Question 15: Is there a list of positive health claims for health supplements and traditional medicines?

A comprehensive list of health claims allowed for use in health supplements and traditional medicines has been published on HSA's website. 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.

Question 16: What are the requirements for efficacy substantiation for claim?

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.

MANUFACTURING STANDARDS

Question 17: 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

Question 18: What CHP requires adulterant testing?

Products intended for weight loss, pain relief and male vitality enhancement would require adulterant testing as HSA has detected instances of adulteration of health products with potent chemical pharmaceutical substances. Their presence can pose health risks to unsuspecting consumers. Please refer to the Guidelines for Testing Requirements of Health Supplements and Traditional Medicines on HSA's website for more details.

Question 19: 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.

Question 20: How frequently 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.

Question 21: 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/

Question 22: 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.

PRODUCT DEFECTS AND RECALLS

Question 23: What are the product defects to be reported to HSA?

A product defect is an issue related to the manufacture or packaging of product that compromises its safety and quality, potentially resulting in public health concerns.

Product defect that affects the safety and quality of the product and may cause potential harm to the patient or public health, must be reported to HSA.

Product defects that need to be reported to HSA are those that may cause death, may be life-threatening, may result in hospitalisation, may cause persistent or significant disability or incapacity in a person.

Question 24: What are considered non-reportable product defects?

Non-reportable product defects are minor issues that do not pose safety risks to a user. These include:

- Minor typographical errors on the product label that do not affect critical information (e.g. product name, strength, dosage instructions)
- Dented shipping cartons or damage to secondary packaging
- Isolated incidents of chipped tablets
- Minor differences in the artwork or design of the packaging

Question 25: Can I continue selling other product batches during a defect-related recall?

This depends on the nature of the defect. You should investigate whether the defect affects a specific batch and whether other batches are affected. You could refer to the Guidance for Industry Procedures for Reporting of Adverse Effects, Product Defects and Product Recalls for Cosmetic Products (section 3.7) for information.

If your investigation points to an issue that affects beyond a specific batch, you should suspend sales of all affected batches and should inform HSA of the product recall. You could refer to the Guidance for Industry Procedures for Reporting of Adverse Effects, Product Defects and Product Recalls for Cosmetic Products (section 4) for information.