

## QUESTIONS AND ANSWERS ON HEALTH SUPPLEMENT (HS)

### CONTROLS ON HEALTH SUPPLEMENTS

#### 1. What are the requirements for the manufacture, importation and sales of HS?

HS are not subject to approvals and licensing by HSA for their importation, manufacture and sales. HSA prohibits the addition of medicinal ingredients such as steroids in HS. HSA also sets strict limits on toxic heavy metals in these products. Dealers (importers, manufactures, wholesale dealers and sellers) have the obligation to ensure that their products are not harmful or unsafe, and that they confirm with the published guidelines at <https://www.hsa.gov.sg/health-supplements> by HSA.

#### 2. Would HSA issue Free Sales Certificate or similar export certificates for HS sold locally?

In general, HSA does not issue Free Sale Certificates for HS. The Singapore Customs issues Certificate of Free Sale for goods sold locally. Please enquire directly with the Singapore Customs at [www.customs.gov.sg](http://www.customs.gov.sg).

For quasi-medicinal vitamins and mineral products, you can contact us at <https://crm.hsa.gov.sg/event/feedback> for information on Certificate for Exporter of Quasi Medicinal Products.

#### 3. Does the HSA regulate dealers of HS marketed by Multi-level marketing (MLM) companies?

All health products that fall within the scope of HS are under the purview of HSA. They are required to meet the relevant regulatory requirements and standards on safety and quality as stipulated by HSA.

MLM and pyramid selling schemes in Singapore are regulated by the MLM and Pyramid Selling (Prohibition) Act ("MLM Act"). The Ministry of Trade and Industry administers this MLM Act. Legitimate businesses such as master franchises or arrangements that satisfy certain conditions are exempted under the MLM and Pyramid Selling (Excluded Schemes and Arrangements) Order (Exclusion Order). For more information on MLM schemes and exemptions, please visit the website: <https://www.mti.gov.sg/Legislation/Legislation/Multi-level-Marketing-and-Pyramid-Selling>

#### **4. How does HSA regulate HS that are sold on online platforms?**

Local dealers selling HS via online stores are also required to comply with the requirements and standards stipulated by HSA.

### **SAFETY AND QUALITY**

#### **1. Is it mandatory to meet the revised heavy metal limits by 1 Sep 2020?**

All HS supplied in the market after 1 Sep 2020 must meet the revised heavy metal limits. Products that do not meet the revised limits should be recalled from the market.

#### **2. How often should dealers test for heavy metals in their HS?**

To ensure that each production batch of HS is not contaminated with high levels of heavy metals, dealers should conduct heavy metals testing for every production batch of the product. Dealers should be prepared to submit the test results to HSA when requested.

#### **3. Are HS manufacturers that follow the ICH Q3D Guidance on Elemental Impurities considered to have fulfilled the requirements by HSA on heavy metal limits (Arsenic, Cadmium, Lead and Mercury)?**

HS manufacturers are to comply with the specific heavy metal limits as stated in HSA's regulatory guidelines, and ensure the safety and quality of their products. The ICH Q3D guidelines presents a process to assess and control elemental impurities in drug products. These principles of risk assessment can be applied to elemental impurities in health supplements beyond those specified by HSA.

#### **4. Why is there a maximum limit for vitamins and minerals in HS?**

Vitamin and mineral supplements is a major category of HS purchased by consumers locally. These products are intended for general health maintenance purposes e.g. support good health and growth, and are sold in stores without medical supervision.

As the daily consumption of high levels of vitamins or minerals can increase the risk of unwanted adverse effects on health, HSA has provided recommendations on the maximum daily levels of vitamins and minerals for the normal healthy adult population.

HSA's recommended maximum daily limits in adult HS are aligned to the ASEAN's Guidance on Maximum Levels of Vitamins and Minerals Allowed in Health

Supplements. If you intend to manufacture, import or sell HS with vitamins and minerals, please refer to the guidance at <https://www.hsa.gov.sg/health-supplements>.

## **CLAIMS AND LABELLING**

### **1. What are the labelling requirements for HS marketed in Singapore?**

Please refer to the following web-link for more information on labelling requirements for HS: <https://www.hsa.gov.sg/health-supplements/overview>

### **2. Is there a published listing of permitted claims for HS?**

HS can be labelled with claims on supporting or maintaining health and well-being. HSA has published a listing of claims suitable for use in HS on HSA's website. You may access the list at <https://www.hsa.gov.sg/health-supplements/claims>.

### **3. Do we need to substantiate health claims that relates to specific physiological function?**

In order to ensure that health claims made on products are unbiased and truthful, all health claims should be supported by adequate and good quality evidence gathered from scientific reviews, meta-analysis articles or documented health benefits from reference text. It is the responsibility of dealers to hold evidence to support their product claims, and provide the information to HSA when required.

### **4. Are consumer testimonial statements acceptable as health claims?**

Consumer testimonials are individual experiences for the use of the health supplement and cannot be generalised to all consumers. Hence, testimonial claims may not be suitable as evidence to substantiate the functions of a HS.