Annex A

Key Regulatory Controls for CHP under the HPA

An overview of the key regulatory controls along the supply chain is provided in Figure 1 below, and further details are elaborated in this Annex.

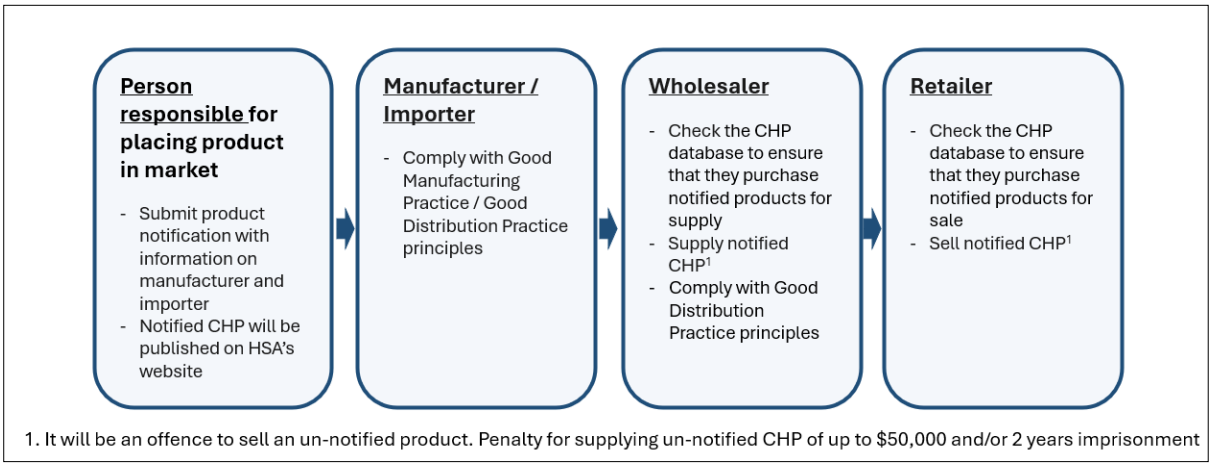

Figure 1. Overview of proposed regulatory controls of CHP along the supply chain

A) Product Notification Requirements

No product premarket evaluation is required for CHP marketed in Singapore, instead a notification system will be put in place to enable traceability of all CHP marketed in Singapore. To note, CHP that contain new[1] active ingredients not in HSA's pre-approved list of active ingredients will first require those ingredients to undergo a safety review by HSA before they can be notified.

The person who is instrumental in causing the CHP to be available for sale in Singapore (i.e. "person responsible")[2] must notify HSA of each product prior to its first supply in Singapore. This person may be the brand owner, manufacturer[3] or importer[4]. Information required for product notification submission is listed below:

- Name, address and contact details of the person responsible
- Product information
    - Product name

[1]A new active ingredient will undergo a safety review by HSA, based on documented history of safe use or scientific data from animal and/or human studies.

[2]Adapted from the definition of "person responsible for placing a cosmetic product in the market" under the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations, referring to "the person in Singapore who is instrumental in causing the cosmetic product to be available in Singapore".

[3]Manufacturer refers to the person who manufactures a health product, where manufacture means the making, fabrication, production or processing of a health product, and includes any process carried out in the course of doing so, as well as the packaging and labelling of the health product before it is supplied.

[4]Importer refers to the person who imports a health product, where import means to bring a health product into Singapore whether by land, sea or air.

- Dosage form
- Product type (e.g. vitamin and mineral supplement)
- Name and quantity of active ingredients
- Name and address of manufacturer
    - Name and address of assembler[5], if any
- Name and address of local importer, if any

The following information will be published on HSA's website for public reference, along with a caveat statement that the information is based on the industry's self-declaration, has not been verified by HSA and does not constitute HSA's approval:

- Notification reference number
- Name of person responsible for placing the product in the market
- Product name
- Dosage form
- Product type

The person responsible must undertake compliance with the stipulated regulatory requirements. The person must also carry out re-notification at a specified frequency, to update on changes to dealer or product information.

B) Product Safety and Quality Requirements

The requirements on product safety and quality that would be prescribed in legislation include:

- Prohibited substances that are not allowed to be present in CHP, including herbs and medicinal substances regulated under the Misuse of Drugs Act, Poisons Act, Health Products (Therapeutic Products) Regulations, and Health Products (Active Ingredients) Regulations;
- Restricted substances that can be allowed in CHP if they meet specific conditions of use e.g. maximum daily dose, mandatory cautionary labelling; and
- Limits of contaminants such as limits on microbial contamination, toxic heavy metals and diethylene glycol or ethylene glycol.

C) Product Labelling Requirements

HSA would require the following information to be stated on a CHP label:

- Product name and dosage form
- Intended purpose
- Name and quantity of active ingredients
- Presence of certain sensitising ingredients
- Dosage and directions of use

[5]Assembler refers to the person who assembles a health product, where assemble means enclosing a health product in a container which is labelled before it is sold or supplied, or, where the health product is already enclosed in the container in which it is to be sold or supplied, labelling the container before it is sold or supplied.

- Batch number
- Expiry date
- Name and address of local person responsible for placing the product in the market
- Cautionary statements for products with restricted substances

CHP, as over-the-counter products used without medical supervision, will be restricted to be marketed for low level, self-care related claims. Allowable claims include those relating to supporting and enhancing general health, alleviating symptoms of self-manageable conditions where a delay in medical treatment would not be detrimental to the consumer, and reducing or preventing the growth of harmful bacteria or viruses. The list of acceptable health claims for CHP has been published on HSA's website for reference.

D) Record Keeping and Safety Reporting Requirements

All local manufacturers, importers, wholesalers and retailers remain responsible for compliance with relevant requirements applicable to their business activity. This enables traceability and appropriate risk-mitigation actions to be taken when necessary. The requirements are summarised in Table 1 below.

Table 1. Summary of record keeping and safety reporting requirements

	Type of Requirement	Responsible Party or Parties	Retention Period	Reporting Requirements / Information to Record
1	Keeping of Manufacturing Records	Manufacturer	1 year after product expiry	Records identifiable by batch number on each container
2	Keeping of Records of Receipt and Supply	Person Responsible, Manufacturer, Importer, Wholesaler	2 years from date of supply	• Product name and dosage form • Date of receipt/supply • Name and address of supplier or customer • Quantity of product • Batch number or other identification number
3	Keeping of Records of Adverse Effects and Product Defects	Person Responsible, Manufacturer, Importer	2 years after product expiry	• Product name and dosage form • Date person first became aware of the event • Batch number or other identification number • Nature of the adverse effect or product defect
4	Safety Reporting of Serious Adverse Effects and Serious Product Defects	Person Responsible, Manufacturer, Importer, Supplier	-	• Serious adverse effect: report within 15 days of becoming aware • Serious product defect: report within 48 hours

	Type of Requirement	Responsible Party or Parties	Retention Period	Reporting Requirements / Information to Record
5	Notification of Product Recall	Person Responsible, Manufacturer, Importer, Supplier	-	Notify HSA no later than 24 hours before intended recall

Table 2 below shows a summary of the duties and obligations for various CHP dealers under the HPA.

Table 2: Summary of duties and obligations for CHP dealers

Regulatory Controls for CHP	Person Responsible[6]	Manufacturer	Importer	Wholesaler	Retailer
Product notification					
Submit product notification	✓	-	-	-	-
Manufacture, import and supply requirements					
Comply with good manufacturing practice principles	-	✓	-	-	-
Comply with good distribution practice principles	-	-	✓	✓	-
Comply with safety and quality requirements	✓	✓	✓	✓	✓
Comply with labelling requirements	✓	-	-	✓	✓
Comply with retail sale requirements (e.g. sale via vending machine)	-	-	-	-	✓
Record keeping					
Comply with manufacturing record keeping	-	✓	-	-	-
Comply with receipt and supply record keeping	✓	✓	✓	✓	-
Comply with defects record keeping	✓	✓	✓	-	-
Comply with adverse effects record keeping	✓	✓	✓	-	-
Safety reporting requirements					
Report serious adverse effect to HSA within stipulated timelines	✓	✓	✓	✓	✓

[6] Person responsible could be the brand owner, manufacturer, or importer, depending on specific circumstances. Relevant duties and obligations will also apply to the person responsible depending on their business activities.

Regulatory Controls for CHP	Person Responsible[6]	Manufacturer	Importer	Wholesaler	Retailer
Report serious product defect to HSA within stipulated timelines	✓	✓	✓	✓	✓
Notify HSA of product recall within stipulated timelines	✓	✓	✓	✓	✓

E) Advertisement Controls

Under the HPA, the requirements and restrictions relating to CHP advertisements will be specified in the legislation. The HPA also empowers HSA to take stronger enforcement actions for advertisement non-compliances compared to the MA, for example, HSA can order a person who publishes a contravening advertisement to carry out corrective measures. With this, the current pre-publication permit requirement under the MA is proposed to be retired and there will therefore be no pre-publication permit requirement for CHP advertisements.

The proposed requirement and restrictions for CHP advertisements are:

<u>Proposed requirement</u>

a. Sponsored endorsements that would be subject to mandatory disclosure of paid sponsorship

<u>Proposed restrictions</u>

b. False or misleading advertisements, unsubstantiated claims
c. Advertisements for un-notified CHP
d. Claims relating to diagnosis, prevention, monitoring or treatment of disease
e. Advertisements that encourage self-diagnosis, excessive use, or discourage from medical consultation or treatment
f. Advertisements that compare with other named products or brands
g. Advertisements that make assertions of guaranteed or miraculous results or no side effects
h. Advertisements that arouse unrealistic expectations of effectiveness
i. Advertisements that exploit consumer ignorance or fear
j. Advertisements that target individuals under 14 years of age
k. Advertisements that carry endorsement by government or public authorities
l. Advertisements that carry endorsement by healthcare professionals (including registered traditional Chinese medicine practitioners and allied health professionals)
m. Advertisements that offer prizes[7] to induce a purchase of CHP during sales promotion
n. Advertisements that offer CHP with therapeutic products or professional use only medical devices

[7]Prizes refer to items awarded through a competition, contest, or game of chance, where the purchase of a CHP entitles consumers to a chance of winning. Such arrangements are not allowed. However, the offering of bundled gifts and free items to every consumer upon purchase of a CHP is permitted.

o. Advertisements that offer money-back guarantees or promises of refund

F) Implementation Timeline

Since 2022, HSA has published guidelines[8] for CHP to facilitate industry compliance with the relevant safety, quality and labelling requirements. These guidelines are aligned with the ASEAN guidelines adopted at the ASEAN Traditional Medicines and Health Supplements Product Working Group, where the industry has also been represented. The guidelines cover areas such as labelling standards, testing, claims and claims substantiation, ingredient safety and manufacturing standards. HSA has also been conducting annual industry training workshops to familiarise the industry with the relevant standards.

To facilitate transition of CHP regulations from the MA to the HPA, the proposed framework will be implemented in phases, beginning in the third quarter of 2028, where the proposed requirements for record keeping, safety reporting and advertisement controls will be implemented.

A 2-year grace period will be provided for the implementation of product notification and other new requirements, to allow businesses sufficient time to align their existing products and processes with the new requirements. This 2-year period is based on feedback solicited from key industry associations. The new requirements relating to safety and quality for which the 2-year grace period applies include limits on microbial contamination, labelling requirements and appropriate manufacturing and distribution standards.

The full implementation for all requirements is targeted for the third quarter of 2030.

[8]This leads to the Health Supplement Guidelines, from which the various guidelines can be accessed from pages 4 to 7. The same guidelines are also found on pages 4 to 6 of the Traditional Medicines Guidelines.