QUESTIONS AND ANSWERS ON CHINESE PROPRIETARY MEDICINE (CPM)

CONTROLS ON CHINESE PROPRIETARY MEDICINE

1. What documents are required for the listing of a CPM? What is the estimated time to receive an approval after an application has been submitted?

The turnaround time for the application of a CPM listing is 60 working days, excluding the time taken by the company to respond to our request for additional clarifications or information. Please refer to the following link for more information on the turnaround time, listing process and documents required: https://www.hsa.gov.sg/chinese-proprietary-medicines/listing/apply

2. Does HSA conduct compliance checks on substantiation document after listing?

HSA conducts checks on CPM after listing to ensure compliance to regulatory requirements.

3. Is there a need to test for Aristolochic acid (AA) in CPMs?

Due to safety concerns, Chinese Medicinal Material (CMM) and CPMs sold and supplied in Singapore are not allowed to contain AA and their salts.

The Ministry of Health (MOH), Singapore had previously carried out a review on the overseas adverse reports of aristolochia associated with its usage in non-traditional Chinese medicine (TCM) ways, and imposed several control measures in Oct 2000. These included disallowing aristolochia herbs in non-CPM sold to the general public, additional labelling of CPM products containing aristolochia herbs to warn consumers against long term and/or inappropriate use, and record keeping by importers and wholesalers of aristolochia herbs. The MOH has been continuously monitoring the local and overseas situations closely.

In view of developments in 2003 in China and Taiwan where the control of aristolochia has been tightened due to emerging cases of adverse reports associated with TCM usage, MOH has conducted another review on aristolochia. To safeguard public health, AA and their salts (the toxic constituents of aristolochia herbs) will be controlled under the Poisons Act with effect from 1 Jan 2004. With this new measure, products (including CPM) and herbs sold and supplied in Singapore are not allowed to contain AA and their salts with effect from 1 Jan 2004.

4. Are stability studies a mandatory requirement for CPMs?

All products should meet their established physical, microbiological and/or chemical specifications under their recommended storage conditions within the determined shelf-life. Dealers (manufacturers, importers, distributors and sellers) of CPMs are responsible for ensuring that stability studies are conducted for the products that they are dealing with. Dealers should ensure that they hold evidence to justify the shelf-life of their products and provide to HSA when required. Dealers are required to hold evidence of stability studies to substantiate the shelf life of their products, and to submit to HSA when requested.

5. How does HSA regulate CPM that are sold on online platforms?

Local dealers selling CPM 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 CPM 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 CPMs?

To ensure that each production batch of CPM 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 CPM 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)?

CPM 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 CPMs beyond those specified by HSA.

CLAIMS AND LABELLING

1. What are the labelling requirements for CPM marketed in Singapore?

Please refer to the following web-link for more information on labelling requirements for CPM: https://www.hsa.gov.sg/chinese-proprietary-medicines/overview#toggle=togglepanel-labelling-requirements

2. Are consumer testimonial statements acceptable as health claims?

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

3. Can the advertisement, packaging or labels of a CPM contain claims on GMP compliance?

Any reference or claims made in advertisement or on the container or package of a CPM, which does not accurately describe the product or misleads consumers on the quality of the CPM is not allowed. GMP compliance is the manufacturing quality system standard of the factory and is not an endorsement of the quality, safety and efficacy of the product(s) manufactured. HSA does not endorse claims on GMP compliance for the purpose of advertisements or on product packaging.