

QUESTIONS AND ANSWERS ON TRADITIONAL MEDICINES, HOMOEOPATHIC MEDICINES AND MEDICATED OILS AND BALMS

REGULATION OF CHP (INCLUDING TRADITIONAL MEDICINES, HOMOEOPATHIC MEDICINES AND MEDICATED OILS AND BALMS)

1. How does HSA regulate CHP that are sold on online platforms?

Local dealers selling CHP 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 CHP 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 CHPs?

To ensure that each production batch of CHP 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 CHP 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)?

CHP 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 CHPs beyond those specified by HSA.

CLAIMS AND LABELLING

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

Please refer to the following web-links for more information on labelling requirements for different CHP product categories:

Traditional medicines: <https://www.hsa.gov.sg/traditional-medicines/regulatory-overview-of-traditional-medicines#toggle=togglepanel-labelling-requirements>

Homoeopathic medicines: <https://www.hsa.gov.sg/homeopathic-medicines#toggle=togglepanel-labelling-requirements>

Medicated oils and balms: <https://www.hsa.gov.sg/medicated-oils-and-balms#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 CHP.