APPENDIX 6 *GUIDELINE ON SUBMISSION FOR NON-PRESCRIPTION THERAPEUTIC PRODUCTS*

This document is intended to provide guidance on the submission of NDA or MAV-1 applications under the abridged evaluation route for non-prescription therapeutic products.

1 ELIGIBILITY FOR WAIVER OF NON-CLINICAL AND CLINICAL DOCUMENTS

As stated in sections 15.5 and 24.2.4 of this guidance, applicants may submit a **written request** for a waiver of non-clinical and clinical data submission. The request may be made if the product fulfils the following criteria:

(a) The product is intended for short-term treatment of self-limiting medical conditions that can be readily identified, and can be safely self-medicated without diagnosis or medical supervision by a doctor i.e. not a POM.

(b) The product should have been evaluated and approved as a non-prescription medicine, as defined below, by at least one of the following reference drug regulatory agencies:

- FDA – non-prescription drugs approved via a drug application. These exclude OTC monograph drugs that may be marketed without an approved drug application.
- Health Canada – medicines classified under Schedule II, III or Unscheduled.
- MHRA – medicines classified as P or GSL.
- Swissmedic – medicines classified under dispensing categories D or E.
- TGA – medicines listed in Schedule 2 and 3 of the Poisons Standard.

HSA will determine the product's forensic classification based on an assessment of the product's risk versus benefit profile as well as local public health implications; and

(c) The use of each active substance contained in the product should be well-documented in the latest editions of the following standard reference texts:

- *Martindale: The Complete Drug Reference*.
- *Handbook of Non-prescription Drugs*.
- *American Hospital Formulary Service (AHFS) Drug Information.*

Other well-established reference texts may be accepted if deemed appropriate by HSA.

If adequate documentation is provided, the submission of clinical efficacy and safety data of the product may not be required. Any use outside of the documented indication(s), dosage(s) and route(s) of administration will require evidence of efficacy and safety unless otherwise justified. It should be noted that anecdotal evidence of efficacy alone (for example, "*xxx has also been used in…"*) will not be accepted as evidence of safety and efficacy.

2 DOCUMENTARY REQUIREMENTS

The documentary requirements are described in section 15 in Chapter C for NDAs and section 24.2 in Chapter G for MAV-1s, with the following additional explanatory notes:

2.1 Administrative Documents

Product Labelling for non-prescription medicines should be provided in the form of a Patient Information Leaflet (PIL). The PIL must be clear, simple and readable so that consumers can understand the information about the product, its benefits, risks and appropriate use. For details of PIL labelling requirements, please refer to Appendix 7 *Points to consider for Singapore labelling*.

Documentary evidence that the product is classified as a non-prescription drug in the reference agency should be provided.

2.2 Quality Documents

The quality requirements for an NDA non-prescription medicine are the same as that of a POM product. Quality documents are generally not required for MAV-1 applications submitted via this route.

2.3 Non-clinical and Clinical Documents

Module 2 (ICH CTD) / Part IV (ACTD) of the application should include a Clinical Overview along with information from standard reference texts as listed above in section 1(c), or other supporting documents if applicable.

Modules 4 and 5 (ICH CTD) / study reports under Parts III and IV (ACTD) are generally not required for applications eligible for the waiver.

HSA may request for the complete clinical data set if deemed appropriate.

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