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 active substance(s) must not be currently classified as a POM in Singapore;
(b) The therapeutic 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:

- Australia TGA – non-prescription medicines refer to drugs substances listed in Schedule 2 and 3 of SUSDP[1].
- Health Canada – non-prescription medicines refer to medicinal products classified under Schedule II, III or U.
- US FDA – non-prescription medicines. Products registered under the FDA OTC Monograph (21 Code of Federal Regulations Chapter 1, Parts 300-499), which are marketed without prior FDA clearance, are excluded.
- UK MHRA – non-prescription medicines refer to medicinal products classified as P or GSL.

HSA reserves the right to 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

[1] Standard for the Uniform Scheduling of Drugs and Poisons

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

- *Martindale: The Complete Drug Reference*. Sweetman SC (Ed.). Pharmaceutical Press, UK.
- *Handbook of Non-prescription Drugs*. American Pharmaceutical Association, USA.
- *Remington's Pharmaceutical Sciences*. Gennaro AR (Ed.). American Pharmaceutical Association, USA and Pharmaceutical Press, UK.
- *AHFS Drug Information*. McEvoy GK (Ed.). American Society of Health System Pharmacists, USA.
- *Handbook of Pharmaceutical Excipients*. Kibbe AH (Ed.). American Pharmaceutical Association, USA and Pharmaceutical Press, UK.

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 or limited clinical reports of efficacy alone (for example, in Martindale, "*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

The administrative documents required are the same as that for the abridged evaluation route.

Product Labelling (section 1.4) 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*.

The *Proof of Approval* (section 1.8) by the drug regulatory agency should be an official approval letter or equivalent document that also states the forensic classification of the product. However, HSA may still request a CPP, if deemed appropriate.

2.2 Quality Documents

The quality requirements for an NDA non-prescription medicine are the same as that of a POM product. MAV-1 applications do not require the submission of quality documents.

2.3 Non-clinical and Clinical Documents

If the product fulfils the criteria as defined in section 1 of this appendix, then the clinical dataset in support of the application may be reduced.

The clinical part of the dossier should include a Clinical Overview and supporting information from standard reference texts as listed above in section 1(c). The supporting documents should be inserted in section 2.5 of Module 2 (ICH CTD) or section B of Part IV (ACTD). Non-clinical documents are generally not required.

HSA reserves the right to request for the complete clinical data set if it is deemed appropriate.

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