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Operations	Office of Complementary Medicines
Procedure	General overview of application screening process - technical
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1. Aim/Purpose/Scope

This Standard operating procedure (SOP) is to raise awareness and provide guidance on the requirements for screening data dossiers of new applications that have been received by the Office of Complementary Medicines (OCM).

2. Responsibility

The maintenance of the SOP is the responsibility of the Principal Scientist of the OCM's Pre-Market Assessment Section (PREMAS).

The SOP applies to OCM's Pre-Market Assessment Section (PREMAS) technical staff undertaking preliminary assessment of data before the acceptance for full evaluation.

3. Introduction/Background

This SOP provides an overview of the screening process undertaken to assess application data dossiers received by the OCM's PREMAS. It is not intended to provide exhaustive details of every aspect of the process and refers to other SOPs and assessment templates where necessary.

Where a reference is made in this SOP to another OCM's PREMAS SOP, that SOP is the latest version found on the TGA's Intranet site.

4. Policy/Procedure

All new applications received by the OCM's PREMAS undergo an administrative check in accordance with the OCM SOP *Processing Applications - APS 4 Admin Procedure*.

Following administrative processing, the application file and data dossier are given to the OCM's Principal Scientist for screening before the application can be formally accepted for evaluation. The screening process involves a brief review of submitted data package to determine the eligibility of an application to be accepted for evaluation by OCM's PREMAS.

Pre-evaluation screening assessment of an application is made as early as possible after receipt of the application. It is important that the outcome of the pre-evaluation assessment process is communicated to the sponsor as rapidly as possible. Experience dictates that early communication of pre-evaluation assessment decision(s) reduces sponsor's expectations that application(s) have automatically commenced evaluation.

There is no legislated or agreed time frame for processing of new applications by OCM. However, the pre-evaluation screening assessment process should be undertaken within 20

working days of the OCM receiving an application. Communication with the sponsor on the outcome of the pre-evaluation screening assessment process should be finalised quickly following completion of the data screen.

In general, the pre-evaluation assessment process aims to differentiate applications which are impractical, unworkable or, for whatever reason, unacceptable, from those which are suitable for evaluation, in some cases, after provision of additional information. Through implementation of this process, OCM aims to avoid the disproportionate commitment of evaluation resources to applications which are unlikely to reach finalisation without an unreasonable expenditure of resources, which adversely impacts on the budget of the office.

4.1 Application types

Applications received by the OCM's PREMAS covered by this SOP are classified as follows:

4.1.1 New product registration

This type of application is made under the section 23 of the *Therapeutic Goods Act* 1989, ('the Act'). Data dossier must contain chemistry, manufacturing and quality control (CMQC) data (for both the active ingredient(s) and the finished product), preclinical safety and efficacy data as well as clinical safety and efficacy data. The requirements for screening of this type of application are outlined in the SOP '*Product registration application screening process – technical*'.

Sections 6 and 7 of Part 1 of Australian Regulatory Guidelines for Complementary Medicines (ARGCM) provide details of data requirements for this type of an application.

4.1.2 Changes to registered complementary medicines

This type of application is made under the section 9D of the Act ('Variation application'), or in accordance with the *Therapeutic Goods (Groups) Order No. 1 of 2001* ('Grouping application').

There are two general types of change application depending if the requested change is classified as notifiable or approvable. Notifications require verification of the information supplied by the sponsor. For approvable changes, which include variation and grouping applications, an evaluation of submitted data is required.

Section 11 of Part 1 of Australian Regulatory Guidelines for Complementary Medicines (ARGCM) provides details on which changes fall into each of the above categories, and provides data requirements for each type of approvable variation application or grouping application. The requirements for screening of this type of application are outlined in the SOP '*Change application screening process – technical*'.

4.1.3 New substance for use in listed products

This type of application is not made under the Act.

Data dossier must contain CMQC data for the substance. In addition, the safety of a substance should be supported either by the preclinical safety data (and/or clinical safety data) or data demonstrating history of traditional therapeutic use, as stipulated in ARGCM. The application should be formatted and presented as stipulated in the ARGCM. The requirements for screening of this application type are outlined in the SOP '*New substance application screening process – technical*'.

Appendix 3 of Part III of the ARGCM provides details of the safety data requirements for this type of an application.

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5. References

Australian Regulatory Guidelines for Complementary Medicines (ARGCM)

Therapeutic Goods Act 1989

6. Attachments

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