R12/10082

Operations	Office of Complementary Medicines
Procedure	Approval of new excipient ingredients
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1. Aim/Purpose/Scope

The purpose of this SOP is to assist OCM staff in

procedures to be followed to allow the use of new excipients in Listed complementary medicines. This SOP is divided into two parts - new excipients for general use, and new excipients for topical use only.

2. Responsibility

[Identify the Work Group whose activity is covered by this SOP and the position within the team with particular responsibility for its creation and ongoing maintenance.]

3. Introduction/Background

New excipients for use in listed goods are generally evaluated via the same process as new active substances and the same fee structure applies. The only exception to this is for new excipients in topical preparations. However excipient ingredients permitted in listable medicines are not specified in schedule 4 of the Regulations and therefore no regulatory amendments are required to allow their use. Administrative procedures only are followed once CMEC (or other) approval has been granted.

4. Policy/Procedure

4.1 New excipients for general use

1. As with active ingredients, before a safety evaluation is progressed to CMEC, a check should be made that an Australian Approved Name (AAN) exists for the substance. If not, an application for one should be prepared as soon as possible.

2. Once a recommendation has been made to the TGA to allow the use of a new excipient (eg via CMEC decision records), a Minute should be prepared to the ARTG identifying that the substance is approved for use and requesting that its ELF flag be amended to show that it can be used as an excipient. Any restrictions on its use (eg concentration limits) should be advised to the ARTG.

3. All officers in OCM, particularly those in the Listings Unit, should be advised of this at the same time.

4. The sponsor who requested permission to use the substance should be advised by telephone as soon as possible after the ARTG has been informed of the approval.

5. In general, approval to use the new excipient should be publicised through the TGA News and the Listings Unit newsletter, but there may be circumstances where this is not appropriate.

4.2 New topical excipients

Where a topical product contains an excipient ingredient which is not in any product currently included in the ARTG, the ingredient may be able to through a slightly different route of evaluation if the conditions outlined in the Australian Guidelines for the Registration of Drugs volume 2, page 11, can be met. Note that, despite what it says in AGRD 2, this evaluation is now carried out in OCM if the excipient is to be used in a complementary medicine.

New topical excipients are assigned a special category of AAN - a provisional AAN indicated by the code PRV. The PRV status is not removed until a successful evaluation is complete.

5. References

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6. Attachments

[List any other documents that are critical to this SOP. For example: records and result sheets, logs, forms, letter templates, flow charts.]