Operations	Office of Complementary Medicines
Procedure	Preparation of Listing Notices for new substances
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Revision #	

1. Aim/Purpose/Scope

The aim of this Standard Operating Procedure (SOP) is to offer guidance on how to prepare a section 9A (5) "Listing Notice" for a new complementary medicine substance.

2. Responsibility

Responsibility for the revision and maintenance of this document rests with the Director of the Pre-Market Assessment Section (PREMAS).

3. Introduction/Background

Section 9A (5) of the *Therapeutic Goods Act 1989* (the Act) provides the Minister for Health and Ageing with the power to publish a notice in the Commonwealth of Australia Gazette, identifying that certain goods are to be placed in the part of the Australian Register of Therapeutic Goods (ARTG) for Listed goods and to specify any conditions to which the goods may be included in that part of the ARTG.

The Minister has, through the Parliamentary Secretary, delegated this authority to the National Manager of the TGA.

Schedule 4 of the Therapeutic Goods Regulations 1990 (the Regulations) outlines those goods which are required to be included in the ARTG as Listed goods. Once the Regulations are amended to require any of those goods to be included in the part of the Register for listed or registered goods, then the Listing Notice ceases to have effect.

This process is a speedy procedure to permit the use of new substances in Listed goods, but cannot be used where the Regulations:

- already permit the use of a substance but the existing requirements for use (e.g., labelling, daily dose, dosage form) are different from the intended requirements; or
- where the Regulations specifically prohibit the use of a particular substance.
  Pursuant to the commencement of the *Legislative Instruments Act 2003* on 1 January 2005, effect is given to these notices through registration on the Federal Register of Legislative Instruments (FRLI), rather than gazettal.

Further information about drafting legislative instruments and the FRLI is available in *A Guide to Legislative Instruments* which is available on the TGA Intranet at: http://intranet.tga/legal/leginst.pdf

4. Policy/Procedure

4.1 Timelines for a Listing Notice

Note that the preparation of Listing Notices to allow use of new substances in Listed goods is a high priority matter that is undertaken with minimum delays. If you have responsibility for this process and are going to be away during the process, you should seek the assistance of another officer who can progress matters in your absence.

Work on preparation of a Listing Notice should commence as soon as the relevant Advisory Committee on Complementary Medicines (ACCM) recommendation (or other recommendation) is endorsed, or approval to proceed is given by the Head of OCM. The shortest time, to date, for preparation and publication of a Listing Notice is ten (10) working days. Generally, it is considerably longer than this.

4.2 Preparation of Regulatory Impact Assessment

See: http://intranet.tga/tgacorporate/regulatory-reform-assessing.htm

4.3 Preparation of a Listing Notice

Check that there is not already a permission to use the substance as an active ingredient or an excipient in Listed goods. If a substance is already permitted under schedule 4, albeit with different restrictions, then it is not suitable for publication in a Listing Notice. In the event when the substance is upgraded to the status of an active ingredient from excipient use only, the Listing Notice must be prepared.

A recommendation to include a new substance in Schedule 4 must be available before the Listing Notice is drafted. This recommendation may be one from the ACCM, recorded in their Minutes and recommendation record. Alternatively, the recommendation may be generated by the OCM without the input from any TGA advisory committee, because the safety of a new substance is adequately established by the evaluation report.

A Listing Notice should be initiated each time the ACCM (or the OCM) recommends a new substance is suitable for use in Listed goods. However, a recommendation must be subsequently accepted by the OCM Head. Thus, a Minute to the OCM Head, seeking agreement to commence the listing process for a new substance must be drafted as soon as possible after ACCM recommendation and his/her decision on that recommendation should be obtained (i.e., signed Minute) before the commencement of the drafting process of a new Listing Notice.

Occasionally a recommendation may be received from the Head of the Office of Medicines Authorisation (OMA). This recommendation must be documented and any Listing Notice drafted in accordance with this recommendation, unless there is good reason to diverge from the recommendations.

The PREMAS Officer who did the scientific evaluation of the substance has the responsibility for drafting the Listing Notice and associated documentation (see below) and providing them to the Director of PREMAS for comment.

The draft Listing Notice, in addition to according with the original recommendation, must be meaningful (i.e., it must be able to be translated into an easily understood requirement for sponsors of listed goods) and must clearly define the substance in question (and restrictions where relevant).

Australian Approved Names (AANs) or Australian (approved) Herbal Names (AHS) must be used wherever possible. Therefore, officers drafting the Listing Notice should confirm with

the Naming Committee Secretariat (currently Wendy Smith) that the name used in the Listing Notice is the AAN or AHN.

A draft Compositional Guideline, if required, must be prepared.

Draft a Listing Notice including all the new substances that are to be allowed in Listed goods and any restrictions surrounding their use in Listed goods. The draft Listing Notice and other related documents should be saved electronically in the TRIM container:
2010/002024: "THERAPEUTIC ADMINISTRATION - LEGISLATION - Regulations - Section 9(a) Listing Notices 2010 – OCM".
For example, save Listing Notice number 5 as: LN 5 – Listing Notice etc.

In 2005 and again in 2008, the OCM worked with the TGA's Legal Unit to establish standard words for Listing Notices and associated documents (e.g., Minute to Minister, Explanatory Statement). Previous Listing Notices containing appropriate wording are located in the above file.

When drafting the Listing Notice, the drafter must be careful that numbers, units and statements such as "not more than", "other than" are correct. It is generally preferable to use full words (e.g., milligrams) rather than abbreviations (e.g., mg).

After completing the first draft of the Listing Notice, the document should be peer reviewed within the PREMAS for comments.

The following documents must be prepared:

- Minute to the OCM Head, requesting agreement (through signature) to commence the process of drafting of the Listing Notice;
- Minute to the National Manager seeking approval (through signature) of the Listing Notice and clearance of a Minute to the Parliamentary Secretary (see next point);
- Minute to the Parliamentary Secretary advising that a Listing Notice for the new complementary medicine substance has been signed by the National Manager and will be published in the FRLI; and
- An Explanatory Statement related to the Listing Notice, for tabling in both Houses of Parliament.

4.4 Clearance of a Listing Notice

Previously, the draft Listing Notice would be sent to the Therapeutics Policy and Planning Committee (TPPC) for final approval prior to submission to the National Manager for signature. The TPPC was replaced by the Regulatory Practice Committee (RPC) which receives Listing Notices for information only.

Attach a Legal Instrument Checklist (copy located in **2010/002024**) to the Minute to the National Manager, with copies of the draft Listing Notice, Minute to the Parliamentary Secretary and Explanatory Statement as attachments.

Submit draft documents to the Director of the PREMAS then to the Principal Medical Officer for clearance. The documents including electronic versions should then be sent to the OLS for clearance of the legal content. Once cleared by the TGA Legal Unit, amendments may be necessary. After discussion of any changes with Director of PREMAS documents are submitted to the OCM Head for final clearance, then to the National Manager for signing of the Listing Notice and Minute to the Parliamentary Secretary.

Electronic copies of the documents should be provided to the Manager's Executive Assistant, in case they need to be amended.

4.5 Registration of a Listing Notice on the FRLI

Once signed by the National Manager, the documents will be sent to the OLS which will arrange publication of the Listing Notice in the FRLI and submission of the Explanatory Statement to both Houses of Parliament.

Electronic copies of the final Listing Notice (amended to include the date of signature), Explanatory Statement and Regulation Compliance Form (see Section 4.2) should be emailed to the OLS. In addition, an electronic copy of the Minute to the Parliamentary Secretary should be emailed to the TGA Parliamentary Section.

Copies of the signed documents should be returned to the OCM for filing on the latest corporate file (kept in Cabinet 6), which will have a title along the following lines: *2010/002024: "THERAPEUTIC ADMINISTRATION - LEGISLATION - Regulations - Section 9(a) Listing Notices 2010 – OCM"*.

The Legal Unit will advise the OCM when the Listing Notice has been published in the FRLI and/or the FRLI can be checked online <http://www.frli.gov.au>. Copies of these should also be placed on the relevant Listing Notice file.

4.6 Distribution of a Listing Notice

The sponsor who initiated the request for the new substance (if there was an application received) should be telephoned by the evaluator as soon as the Listing Notice is published.

As soon as possible after publication, the Electronic Listing Facility (ELF) team should be provided with a copy of the Listing Notice and requested to update the ELF Code Tables to include the new substance and any applicable restrictions.

Once the Listing Notice is published on FRLI, a link to FRLI is automatically posted on the TGA website under "Therapeutic Goods (Listing) Notices" located at http://www.tga.gov.au/legis/listing.htm.

A copy of the draft Compositional Guideline for the new substance, if applicable, should also be place on the TGA website on the "Draft Compositional Guideline" page <http://www.tga.gov.au/docs/html/compguid/compdr.htm> A timeframe of six months is generally allowed for receipt of comments from industry. To publish on the TGA website, email the TGA website at tga.website@tga.gov.au. The email should include the "Draft Compositional Guideline", the date that the consultation period closes (6 months from the start date) and the name of the person who has given the approval (must be the Branch Head).

Once the Listing Notice has been included on the TGA website, an email should be sent to all OCM Officers advising them of the new Listing Notice and inclusion of the new substance in the ELF and referring them to the document on the website. Copies of the notices should be placed on the OCM website corporate file (Cabinet 6): "*CM Assessment – Website – Information included on the TGA Website – OCM*"

Any new updates on the TGA website will be automatically included in the TGA Weekly which is circulated to TGA staff. This is done by the TGA Communication Section. The information will also circulate to external stakeholders via the TGA Update, a fortnightly email summary of changes made to the Therapeutic Goods Administration website.

5. References

- *Therapeutic Goods Act 1989*: http://www.tga.gov.au/legis/index.htm
- *A Guide to Legislative Instruments*: http://intranet.tga/legal/leginst.pdf
- *Best Practice Regulation Handbook*: http://www.finance.gov.au/obpr/docs/handbook.pdf

6. Attachments

Attachment 1 – Checklist for Section 9A(5) Listing Notices

Attachment 1

Checklist – Section 9A(5) Listing Notices

Action	Done	Date	Action officer
Does a recommendation exist and has it been accepted?	☐		
Check that the AAN is correct	☐		
Check that a draft Compositional Guideline, if required, has been prepared	☐		
Draft Listing Notice (get help from Legal Unit if necessary)	☐		
Prepare a "For Information" paper for the Regulatory Practice Committee (RPC) with a copy of the draft Listing Notice attached	☐		
Draft the following documents (using the appropriate templates): - Minute to the National Manager - Minute to the Parliamentary Secretary - Explanatory Statement for Parliament - Legislative Instrument Checklist	☐		
All clearances outlined on Legislative Instrument Checklist obtained?	☐		
Documents cleared through OCM Head, with signature on Minute to the National Manager?	☐		
Papers delivered (hard and electronic copies) to National Manager?	☐		
Listing Notice and Minute to the Parliamentary Secretary signed by the National Manager?	☐		
Electronic copies of signed Listing Notice, Explanatory Statement and Regulation Compliance Form sent to OLS?	☐		
Electronic copy of Minute to the Parliamentary Secretary sent to the Parliamentary Section?	☐		
Listing Notice published in FRLI?	☐		
Sponsor notified of publication in FRLI?	☐		
ELF Team requested to include substance in ELF?	☐		
Copy of Listing Notice and draft Compositional Guideline, if relevant, placed on TGA website?	☐		
OCM notified of approval of substance?	☐		