Update to Industry - Indications for Listed Medicines

Dear Member,

CMA and its regulatory members have, over the last few years been progressing work in relation to the Permitted Indications Project. Recent work has included revising a list of current indications that the TGA considered as including wording that could arguably be termed a "restricted representation"[1]. In addition, the TGA identified a number of standard indications, which arguably refer to treatment of a disease, condition, aliment, or defects which are likely to meet the definition of a 'serious form'.

On the 10 October, CMA provided TGA with a detailed response to a range of proposed "re-worded" indications and "priority removal" of indications which were proposed to be archived. The response to TGA can be read here. The Board of Complementary Medicines Australia also made representations at the highest level at TGA to cease work on the indications project whilst the Government's Expert Panel on deregulation conducted a comprehensive review of the regulatory regime for Complementary Medicines

Summary of recent changes:

- The TGA will archive indications referred at Attachment 1 on the **24 November 2014**. That is the indications will be unable to be selected through ELF by sponsors of new medicines.
- Indications that refer to a disease specified in Attachment 1 will be archived, apart from osteoporosis and neural tube defects, which are to be progressed for advertising permission under section 42DK of the Act. CMA has submitted a general application for advertising approval for references to neural tube defects.
- Indications which include unqualified references to arthritis or osteoarthritis will be archived however alternative indications referring to 'mild arthritis' and 'mild osteoarthritis' will be made available.
- TGA acknowledges the comments received from Industry and that these more general indications (at attachment 3) will not replace the old indications for many individual medicines and that the evidence packages associated with an archived indication may not support the "replacement indication".
- CMA will engage in further discussion with the TGA as to the future steps of the Permitted Indications Project in light of the Governments review of medicines and medical devices and the deregulation agenda more broadly.

Once archived, these indications will no longer be available for selection in the ELF for new products. TGA insist that existing products will not be affected in any way by these changes in the ELF. However, sponsors are reminded that although existing products will not be affected by the changes, sponsors should be aware that the archived indications may not be compliant with the regulatory requirements, particularly if they are included or used as a basis for therapeutic claims on a medicine label or in other advertising.

[1] The use of restricted representations in advertising (including on medicine labels) requires prior approval of permission under section 42DF of section 42DK of the Act

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A detailed overview of the archival process is included at Attachment 2.

TGA have reviewed the indications at Attachment 3 to ensure they are likely to comply with the regulatory requirements if they are selected for a medicine and included or used for the basis of a therapeutic claim on the medicine label. Ultimately it remains the responsibility of the sponsor to comply with the regulatory requirements, despite where the indication is made available in the ELF.

Attachment 1

Disease/condition/aliment/defect [2]
Anencephaly
Benign prostatic hypertrophy
Carpal tunnel syndrome
Chronic fatigue syndrome
Glue ear
Neural tube defects
Osteoporosis
Pterygium
Rheumatoid arthritis
Spina bifida
Tinnitus

Excerpt from letter to CMA 1 April 2014: current coded indications and arthritis claims
"Arthritis is defined in Stedman's Medical Dictionary as *inflammation of a joint; state characterised by inflammation of the joints*. Part 2, Table 1 of Appendix 6 of the Advertising Code includes "diseases of joint, bone, collagen and rheumatic disease" for which advertising of serious forms is restricted.

At its meeting on the 16 May 2013, the Complaints Resolution Panel (CRP) considered the issue of whether a reference to arthritis was a restricted representation. Of note, in paragraph 23 of its determination for complaint 2013-03-005, the CRP states:

> where an unqualified reference to arthritis is made, it is not only possible but in fact very likely that a consumer will interpret the reference to extending to rheumatoid arthritis. This is less likely to occur if a reference is confined to osteoarthritis or is qualified by words such as "mild" or "minor".

The TGA agrees with the CRP that an unqualified reference to arthritis is likely to be taken by a responsible consumer to be referring to joint diseases that are generally not accepted to be appropriate to be diagnosed and or treated without consulting a suitable healthcare practitioner, and generally accepted to be beyond the ability of the average consumer to evaluate accurately and treat safely without regular supervision by a qualified healthcare practitioner. Such a reference in advertising without prior approval is therefore likely to constitute a references that breaches section 5 (2) of the Advertising Code in the absence of an approval under section 42DF of the Act or permission under section 42DK(1) of the Act.

Further, the TGA state that they are aligned with the CRP in that if **arthritis** is qualified by terms such as "mild" or "minor" it is less likely to be taken by a reasonable consumer to be a reference to a serious form of a condition. In the absence of any other relevant considerations with respect to the content of the advertisement, a reference to "mild arthritis" is unlikely to amount to a restricted representation.

[2] This list is not exhaustive. Terms synonymous with those listed would also meet the definition of serious.

In relation to **osteoarthritis**, the TGA position is aligned with the CRP in that a reference to osteoarthritis is unlikely to be taken by a responsible consumer to refer to rheumatoid arthritis and is more likely to be taken by the consumer to refer to arthritis that has already been diagnosed as such by a suitable healthcare professional. However, given that there can be severe cases of osteoarthritis that require close management by a healthcare practitioner, references to osteoarthritis should also be qualified by the use of "mild" to ensure they do not amount to a restricted representation.

Attachment 2 & 3

Attachment 2

Overview of the upload and archival process for indications in ELF

On **24 November 2014**

- The 24 new indications at Attachment 3 will be uploaded into the electronic application portal and will be available for a sponsor to select when they list their medicine.
- The indications referred to in Attachment 1 will be 'archived'.

Archived indications will no longer be able to be selected within the online applications forms in ELF. However, these indications will remain active in the system and the validation rules so that any existing medicine listing which includes these old indications will still validate. In this regard, the changes will not affect existing medicines which include old indications in their ARTG entry and no applicant will be forced to group or otherwise change their existing listings.

For the removal of doubt, some scenarios are provided below:

- If you list a new product, you will not have access to the archived indications.
- If you make a correction to the listing of an existing product and the listing contains an archived indication, the application will still validate with the old indications.
- If you make a change, including to the indications for an existing product, the application will still validate with the archived indications.
- If you remove archived indications from your listing, you will not be able to re-add these old indications.

Notwithstanding the above advice, sponsors who continue to use archived indications for their medicine and medicine label without prior approval under section 42DF is likely to constitute a reference in breach of section 5(2) of the Advertising Code.

The new indications are provided as a tool to assist sponsors select indications that are appropriate for listed medicines. The use of the new indications is not mandatory and a sponsor can still choose to use the free text field as they consider appropriate. It is ultimately the responsibility of the sponsor to ensure that their medicine complies with the regulatory requirements, including that the overall presentation of their medicine (including any indications) is acceptable.

Attachment 3

New indications

Code	Indication
SCI-BDEAHE-MS	Maintain/support ear health
SCI-BDEAHF-MS	Maintain/support healthy ear function
SCI-BDEAHR-MS	Maintain/support healthy hearing
SCI-BDEAIT-RE	May relieve itchy ears
SCI-BDENFAW-DR	May help decrease/reduce/relieve fatigue/weariness/tiredness
SCI-BDENLV-EP	May help enhance/improve/promote/increase energy levels
SCI-BDENLV-MS	Maintain/support healthy energy levels
SCI-BDEYFU-MS	Maintain/support healthy eye function
SCI-BDEYHE-MS	Maintain/support eye health
SCI-BDEYSI-MS	Maintain/support healthy/normal eyesight/vision
SCI-BONJARA-TR	May temporarily relieve swollen and aching joints associated with mild arthritis
SCI-BONJARI-TR	May temporarily relieve joint inflammation/ swelling associated with mild arthritis
SCI-BONJARM-EI	May help enhance/improve/promote/increase joint mobility in mild arthritis
SCI-BONJARP-TR	May temporarily relieve joint pain/ache associated with mild arthritis
SCI-BONJARRH-RE	May relieve mild rheumatic aches and pains
SCI-BONJARRHP-RE	May relieve mild rheumatic joint pain
SCI-BONJOAAP-RE	May relieve pain associated with mild osteoarthritis
SCI-BONJOAS-RE	May relieve symptoms of mild osteoarthritis
SCI-MAPRFU-MS	Maintain/support healthy/normal prostate function
SCI-MAPRHE-EP	May help enhance/promote prostate health
SCI-MAPROS-AM	May assist in the maintenance of a healthy prostate
SCI-NUMIDE-AP	May assist in the prevention of mineral [XX] deficiency when dietary intake is inadequate
SCI-NUNUDE-AP	May assist in the prevention of [nutrient XX] deficiency when dietary intake is inadequate
SCI-NUVIDE-AP	May assist in the prevention of vitamin [XX] deficiency when dietary intake is inadequate