

lyfe for OICG mailbox 31/5/2012

Priority list for finalising draft compositional guidelines

Background

A review of Compositional Guidelines that remain in 'Draft' format has been an on-going project within the Therapeutic Goods Administration (TGA). Both draft and finalised compositional guidelines had been available on the TGA website until a website upgrade was conducted in May 2011. At that time, all draft compositional guidelines were removed from the website, although they are available from the TGA upon request.

Priority lists for finalisation of draft compositional guidelines had been presented at the TGA-industry liaison (OICG) meetings on 2 occasions (November 2007 and August 2009). On the basis of these lists, the TGA has been reviewing and revising all draft compositional guidelines. Once finalised, draft compositional guidelines become 'current' and have been re-published on the TGA website.

The following draft compositional guidelines had been finalised before May 2011:

| | |
|-----------------------------|---|
| Athrospira maxima | Arthrospira platensis |
| Black boned chicken powder | Bovine colostrums powder |
| Conifer phytosterol complex | Demineralised fish proteoglycan extract |
| Hydroxycitrate complex | Sugar cane wax alcohols |

The following draft compositional guidelines had been withdrawn because pharmacopoeia monographs have become available:

Glucosamine sulfate (USP, as various salts of glucosamine)
Lutein (USP)
Lycopene (USP)
Rutin trihydrate (BP, as rutoside trihydrate)
Tilactase (USP, as Lactase)

Current situation

A revised priority list was recently discussed with OICG (February 2012) and members suggested that the priority should reflect the number of products on the Australian Register of Therapeutic Goods (ARTG) associated with an ingredient, as well as the number of requests made for a particular compositional guideline since removal of these documents from the website.

The following rationale was offered for considering the priority to progress draft Compositional Guidelines. The priority list is attached (Attachment 1).

While recognising that ingredients that have a large number of associated products on the ARTG should have their draft compositional guidelines finalised as soon as possible, considerations were

also given to the amount of work required to complete a particular draft document. Draft compositional guidelines that can be finalised relatively swiftly were placed ahead of those where information was lacking and/or extra research required. A draft compositional guideline that had large interest since the removal of the draft documents from the TGA webpage, was also given a higher priority even though it may not have as many associated products. Recently developed draft compositional guidelines that were placed on the website since 2011 were also prioritised for finalisation if no significant issues were raised during the consultation period.

Since May 2011, the following draft compositional guidelines have been finalised and published:

- Alpha- casozepine enriched hydrolysed milk protein
- DHA-rich oil derived from microalgae *Schizochytrium* sp.
- Fish oil – natural
- Larix arabinogalactan
- Steviol glycosides
- Zeaxanthin

Attachment 1

| Compositional Guidelines Priority | | |
|--|-------------------|----------------------------------|
| Ingredient | Proposed Priority | Priority at OICG 27 ^a |
| Amylase | 1 | 3 |
| Cellulase | 1 | 3 |
| Citrus bioflavonoids extract | 1 | - ^b |
| Euphausia superba oil | 1 | - |
| Hesperidin | 1 | - |
| Lipase | 1 | 3 |
| Molybdenum trioxide | 1 | 4 |
| Proteases | 1 | 3 |
| Quercetin | 1 | - |
| | | |
| Ademetionine ((S)-S-adenosylmethionine ('S-AMe')) | 2 | 2 |
| Bovine lactoferrin | 2 | 2 |
| Bovine whey Ig-rich fraction | 2 | - |
| Deer velvet antler powder ^c | 2 | - |
| Deer velvet antler slice ^c | 2 | - |
| Leptospermum scoparium oil ^c | 2 | - |
| Levocarnitine and its salts and derivatives | 2 | 2 |
| Magnesium citrate - dibasic tetrahydrate ^c | | |
| Refined emu oil | 2 | 4 |
| Rhodiola rosea powdered root extract | 2 | - |
| Rhodiola rosea root dry/powder | 2 | - |
| Royal jelly and derivatives | 3 | 2 |
| | | |
| Asparagus racemosus dried root | 3 | 4 |
| Calcium lactate gluconate | 3 | 3 |
| Santalum spicatum (Australian Sandalwood) | 3 | 4 |
| Shark cartilage | 3 | 2 |
| Tocotrienols complex - palm | 3 | 3 |
| Trametes versicolor hyphae aqueous extract - powder | 3 | 4 |
| Trametes versicolor proteoglycan concentrate | 3 | 4 |
| Vegetable oil phytosterol esters | 3 | - |
| Wheat dextrin | 3 | - |
| | | |
| Calcium- β -hydroxy- β -methylbutyrate (monohydrate) | 4 | 4 |
| Canarium indicum oil | 4 | 4 |
| Caralluma adscendens var. Fimbriata | 4 | - |
| Chorella vulgaris powder | 4 | - |
| Conifer green needle complex | 4 | 4 |
| Morinda citrifolia dried fruit powder | 4 | 4 |
| Morinda citrifolia juice | 4 | 4 |

| | | |
|---|---|---|
| Omega-3 fish oil phytosterol esters | 4 | - |
| Pseudowintera colorata leaf | 4 | 4 |
| Streptococcus thermophilus | 4 | 4 |
| Terminalia bellirica | 4 | - |
| Thiamine phosphoric acid ester chloride | 4 | 4 |
| Trefriw wells minerla water | 4 | 4 |
| Undaria pinnatifida powder | 4 | 4 |

^aat OICG 27, there were two priority 1 draft compositional guidelines - 'Fish oil from the liver of fish' and 'Fish oil from the whole body of fish'. 'Fish oil from the liver of fish' draft compositional guideline was withdrawn because there is no associated ingredient approved for use in listed medicines; the 'Fish oil from the whole body of fish' draft compositional guideline has been replaced by the 'Fish oil -natural' compositional guideline which has been finalised.

^bdash (-) indicates that the draft compositional guideline was not on the list at OICG 27

^cindicates a draft compositional guideline that had been developed since 2011