**Technical Alert**

## Regulatory Updates

Dear member,

CMA would like to provide the following updates that represent the work of its regulatory member committees and working groups. Please feel welcome to contact Emma Burchell via Emma.Burchell@cmaustralia.org.au for information or feedback.

## TGA approach to Compositional Guidelines

CMA is pleased to advise members that we have received confirmation from the TGA that the Complementary Medicines Branch will cease the 'formal' six-week consultation process on compositional guidelines that relate to new ingredients permitted for use in listed medicines.

As members would be aware, CMA has advocated for a change to this business practice for a number of years, most recently in our reform agenda and response to the expert panel conducting the review of medicines and medical devices regulation

### *Background*

The CMA's position is that compositional guidelines being generated from a paid application should, once approved, be published on the TGA website as a final compositional guideline. This would assist in streamlining the business process and be an incentive for industry to apply for the listing of new substances.

There are a number of reasons that the compositional guideline consultation period is of no added value and is an unnecessary business process for both the regulator and the industry:

- The process and the publication of compositional guidelines on the TGA website would not prevent another sponsor from submitting a paid application for a similar substance, with its own specific compositional guideline, for separate assessment.
- As described in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM), a sponsor may request that the TGA consider amending a compositional guideline at any time based on justifications relating to the safety profile of the ingredient. In addition, as the guidelines are not underpinned by legislation, a sponsor is able to justify a variation from a specification in the document.
- Formal consultation on a compositional guideline contributes to the confusion around the status of the document. Requesting submissions, and transitioning the document from 'draft' to 'final' adds to these misconceptions.

CMA position to the TGA on draft Compositional Guidelines 2012
Exert on Compositional Guidelines to the Expert Panel 2015



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## NZ Ministry of Health workshop update

CMA members recently participated in workshops on the NZ Natural Health & Supplementary Products Bill.

As a follow on from the workshops, the Ministry made available a draft list of ingredients for inclusion to the Permitted Ingredients List (PIL) under the Natural Health Products Bill.

The Ministry continues to receive requests for additional ingredients to be considered for inclusion. Analysis has now been completed on a range of new requests and the attached is an updated draft PILs list as of 13 July, 2015.

Please note, some of the ingredients submitted require more analysis due to their complexity and are still in the process of being considered. Industry are invited to send any requests for ingredients to be added, or any other feedback on the list, to naturalhealthproducts@moh.govt.nz

Where it is appropriate to do so additional ingredients will be added to the list. It is requested that, if possible, requests include the taxonomic and common names, an international non-proprietary name (if one exists) and a pharmacopoeia name citing the pharmacopoeia or a chemical registry number citing the registry.

There will be a public consultation on the NZ regulations related to the scheme, likely to be held later this year, in which CMA members will have opportunity to participate.

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## CMA Regulatory Policy Committee

Members of CMA's Regulatory Policy Committee met in June to discuss a range of technical and policy issues.

### Business Process Review to Complementary Medicines

Members were provided with updates to the TGA's Business Process Review to Complementary Medicines. The CM BPR Working Group was established to provide a communication mechanism between the Industry and TGA on issues relating to the reforms to the market authorisation processes for registered complementary medicines and new substance applications.
The next TGA-Industry meeting will take place towards the end of August 2015.
Members are invited to provide feedback to the below consultation documents to Emma.Burchell@cmaustralia.org.au.

Consultation documents

- High level work plan
- Quality & efficacy considerations Listed vs Registered medicines
- Proposed target times for Registered Complementary Medicines & New medicine applications (Power point)
- Complementary medicines categories - draft application categories and timeframes



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**New substances proposed for expedited evaluation:**
**Response from member consultation**

CMA has long advocated for a streamlining of new substance applications for use in listed medicines in Australia. We are active in working with the TGA in the review to the business processes for complementary medicines, with the aim of gaining efficiencies for new substance applications and registered complementary medicines applications.

We have been working to put forward a list of potential new substances that *may* be subject to an expedited evaluation or risk assessment, including potential substances approved by Health Canada and or where substances have been subject to previous TGA review.

The purpose was to provide industry with a list of evaluations and risk assessments completed by or pending completion by the TGA and a list of substances that could be considered to be suitable for an expedited evaluation or risk assessment. In anticipation of future work, CMA sought industry feedback on the draft list, specifically advice in relation to the prioritisation of these substances, which has now been completed (see table 1).

CMA Briefing paper and proposed ingredients list

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## IADSA Regulatory updates

Members will find a range of regulatory updates from the IADSA Newsflash, including an interesting read on 'A new wind is blowing across the world'.
Click here to read the IADSA Newsflash.

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## Current calls for comment

### TGA ½ Yearly Performance Reports

On the 23 June, the TGA Industry Consultative Committee (TICC) discussed the development of the new Regulator Performance Framework key performance indicators (RPF KPIs). Through the process of developing the new Performance Framework, the TGA has considered its entire reporting framework, including the Half Yearly Performance Report (HYPR).

As such, CMA members are invited to view the document "TGA Half Yearly Performance Report: Principles for review" and provide any relevant feedback to Emma.Burchell@cmaustralia.org.au
Comments are welcome by COB Thursday, 20th August, 2015.



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In general, CMA is of the position that the HYPR remain a half yearly report. We do, however, seek feedback from members as to whether there are any sections or specific tables within the report that are not relevant for industry and could be removed?

*Please note that the publication of the HYPR for the period January-June 2015 will be postponed while this review is being conducted.*

**PICS GMP Guide**

The EU has revised Chapter 1, 2, 6 and 7 of the EU GMP Guide on "Quality Systems", "Quality Control" and "Outsourced Activities", respectively.

As the PIC/S and EU GMP Guides must remain aligned, and requirements should be equivalent, comments from industry on the revisions should only aim at clarifying those requirements which may be unclear or confusing.

The PIC/S Secretariat has prepared a revision of the same chapters of the PIC/S GMP Guide (see PS/INF 69/2014, PS/INF 70/2014 & PS/INF 71/2014). This revision is based on the EU text and shows the amendments in track changes. Where these changes are not relevant for PIC/S (e.g. reference to EU specific legislation), the PIC/S Secretariat has proposed alternate wording (highlighted in yellow).

The PIC/S Secretariat requested that non-EEA members provide comments by the end of August 2015. Given the September meeting proposed for the TGA-Industry Working Group on GMP (TIWGG), of which CMA is a member, the TGA has managed to seek an extension for feedback by one month to the end of September 2015.

CMA therefore invites members to consider the proposed changes and identify where any revisions may be inappropriate for the complementary medicines sector, so that we may flag these with our CM technical working group in consideration of developing specific Australian guidance documentation as required.

Attachments provided for information and comments include:

- **PIC/S Sub-committee on harmonisation of GMP** – Recommendations to Comments Received from Australia and other Participating Authorities for Revised PIC/S Chapters 1, 2, 6, and 7.
- **Revised chapter 1** – Pharmaceutical quality systems, quality control, product quality review and quality risk management (track changed)
- **Revised chapter 2** – Personnel, key personnel, training, hygiene and consultants (tack changed)
- **Revised chapter 6** – Quality control, good quality control laboratory practice, On-going stability programme and technical transfer of testing methods (tack changed)
- **Revised chapter 7** – Outsourced activities.

Click here to download the full set of documents.
Please send your comments to submissions@cmaustralia.org.au by **Friday 31, July 2015**.
If you have any questions or require further information please contact Emma Burchell on (ph.) 02 6260 4022 or email: emma.burchell@cmaustralia.org.au



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