Technical Alert

Now Available:

- **Incorporated *Therapeutic Goods Act 1989***
- **Therapeutic Goods Advertising Code – Public Consultation**
- **New Ingredients - Updated Application Form**
- **Guidance for pre-assessed medicine applications including AUST LA (Assessed Listed) and AUST R (Registered) Complementary Medicines**
- **ACCC Country of Origin Guidance for Complementary Healthcare Products**
- **Registration forms and program for the TGA Inaugural GMP Forum**

Incorporated Therapeutic Goods Act

The compilation of the *Therapeutic Goods Act 1989* ('the Act'), which now incorporates the amendments from the *Therapeutic Goods Amendment Bill No. 1 of 2017* legally effective from 6 March 2018, has now been uploaded onto the Federal Register of Legislation (FRL).

The new Act incorporates significant amendments to the regulatory framework for complementary medicines, including introduction of the permitted indications, relevant changes to sponsor certifications under the Act, the introduction of the new pathway for complementary medicines, and a new advertising framework.

The incorporated Act on the FRL can be located here and for download in PDF or Word.

Therapeutic Goods Advertising Code – Public Consultation

The public consultation of the Therapeutic Goods Advertising Code (TGAC) has now been released on the TGA website. The available consultation documents for comment are:

- The draft of the TGAC 2018.
- The draft of associated TGAC 2018 guidance.
- A comparison table of TGAC 2015 and the proposed 2018 TGAC.

Submissions are due by **Friday, 27 April 2018** and may be made here. CMA will be providing an industry submission and encourages all industry stakeholders to provide individual submissions to have their say in this overall process that is available to all industry and non-industry stakeholders.

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In particular, feedback on the following is being sought:

- Suggested improvements to the draft(s)
- Impacts and/or costs to your business
- Perceived benefits and risks
- Suggestions for further guidance or education.

Comments may be provided to the CMA Secretariat for the industry submission at technical@cmaustralia.org.au

New Ingredients - Updated Application Form

The TGA have published an updated form for new ingredients (substances, to accord with the new business processes introduced by the Therapeutic Goods Act and Regulations, including new application categories and fees.

The new form is available here.

Version 1 of the guidance for completing the application for a new substance for use in listed complementary medicines is available here with complementary medicine fees and charges listed here.

Guidance for pre-assessed medicine applications including AUST LA (Assessed Listed) and AUST R (Registered) Complementary Medicines

The following information has been released or updated for pre-assessed complementary medicine applications:

AUST LA – Assessed listed (new pathway) medicines:

- Version 1 of the Assessed Listed Medicine Evidence Guidelines.
- Version 1 of the CTD Module 1: Administrative information for assessed listed medicines
- Mandatory requirements for an assessed listed medicine application to pass preliminary assessment
- Version 1 of the Guidance for completing the application form for an assessed listed medicine

AUST R – Registered complementary medicines

- Mandatory requirements for an effective registered complementary medicine application.

All pre-assessed applications including AUST LA and R complementary medicines:

- Updated general dossier requirements.

ACCC Guidance – Country of Origin labelling

The Australian Competition and Consumer Commission (ACCC) have published the '***Country of origin labelling for complementary healthcare products - a guide for business***' on their website here.

Country of Origin representations on the labels of Complementary Medicines such as "Made in Australia" are not mandatory but may be made voluntarily by businesses. The above guidance does not constitute law or legal advice but is intended to assist with the interpretation of the Australian Consumer Law for complementary medicine businesses.

Representations about goods in Australia must be truthful and accurate. The Australian Consumer Law also sets out several 'safe harbour' defenses which provide an extra degree of legal protection for businesses that choose to make country of origin claims about their goods. If your claim satisfies a safe harbour, you will have the benefit of a statutory defense against an allegation that the country of origin claim is false, misleading or deceptive.

CMA is pleased to have worked with the ACCC on the development of this guide to broaden the scope of claims available than were originally proposed for the complementary medicine industry.

Registration forms and program for the TGA Inaugural GMP Forum

The proposed program and registration forms for the TGA inaugural GMP Forum are now available on the TGA website here. CMA is pleased to support the development of this Forum through the TGA-Industry Working Group on Good Manufacturing Practice (TIWGG).

Registrations close **Friday, 8 June 2018** with delegates encouraged to register as soon as possible as late registrations after 8 June will incur a large surcharge. Registrations may be downloaded and complete the registration form and submit it to GMPForum2018@health.gov.au

When: Tuesday, 26 June 2018
Time: 8.30am – 5.00pm AEST
Where: SMC Conference & Function Centre, 66 Goulburn Street, Sydney NSW 2000

The Forum will be of significant interest to industry personnel involved in the quality assurance, regulation, risk assessment and good manufacturing practice of medicines and API manufacture, including personnel working for medicine-based small and medium enterprises (SMEs) and regulatory consultants.

ENDS

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