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Complementary Healthcare Council (CHC) – Events

CHC and other Events in 2013

<table>
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<tr>
<th>Event</th>
<th>Date/Location</th>
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<tbody>
<tr>
<td>CHC Parliamentary Reception</td>
<td>Monday 18th March, Canberra</td>
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<tr>
<td>CHC Regulatory Obligations Seminar</td>
<td>Monday 18th March, Canberra</td>
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<tr>
<td>Nutracon USA</td>
<td>6-7 March 2013, Anaheim, CA USA</td>
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<td>Natural products Expo West Trade Show</td>
<td>8-10 March 2013, Anaheim CA USA</td>
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<td>IADSA - ASEAN harmonisation on health supplements</td>
<td>24 April 2013,</td>
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<td>IADSA - AGM</td>
<td>25 April 2013, Jakarta Indonesia</td>
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<td>Vita Foods Europe</td>
<td>14-16 May 2013,</td>
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<td>CHC Advertising and Compliance Seminar</td>
<td>June 2013, dates TBC</td>
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<td>NBJ Sumit</td>
<td>23-26 July 2013, Dana Point, California</td>
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<td>CHC National Conference and Industry Awards</td>
<td>3-5 September 2013, venue TBC</td>
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<td>Go Vita Conference</td>
<td>15-19 September 2013, Alice Springs</td>
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<tr>
<td>SupplySide West International Trade Show</td>
<td>14-16 November 2013</td>
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Complementary Healthcare Council (CHC) – Working for Members

CHC Pre-Budget submission to the Australian Government

The CHC has submitted its 2013/14 pre-Budget Submission outlining several key initiatives with the aim of increasing the economic contribution of industry, and improving population health outcomes whilst potentially reducing the pressure on the Australian Government’s Health Budget.

Features of the new framework plan put forward in the submission include:

- Modified product registration pathway to incentivise research and innovation.
- Mechanisms to facilitate market exclusivity for a period of time to encourage innovation and support ongoing clinical trials.
- Mutual recognition with comparable overseas regulators.
- An equitable proportion of NHMRC funding allocated for complementary medicines research, and

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Government recognition and specific support for complementary medicines export development and import replacement.

Key recommendations from the CHC 2013/14 pre-Budget submission include:

- $1 million over two years to assist the TGA to implement regulatory reforms
- $500,000 over two years to develop a complementary medicines industry-wide plan
- $400,000 over two years to overcome barriers to complementary medicines innovation, and
- $700,000 over three years to bring evidence-based Indigenous medicines to market
- $800,000 over two years to undertake a stock-take of Indigenous medicines

To view key recommendations and the media release, click here. The CHC 2013-14 pre-Budget Submission can be viewed in full, here.

Consultation: ANZTPA Regulatory Scheme - discussion paper

The TGA and Medsafe, are seeking comment and input from stakeholders on the discussion paper, proposing the high level features of a possible framework for regulation of therapeutic products within the ANZTPA as part of a joint scheme to regulate therapeutic products in Australia and New Zealand.

The Australian and New Zealand Governments announced their agreement to proceed with a joint scheme for regulation of therapeutic products in June 2011, along with the proposal that it be administered and overseen by the Australia New Zealand Therapeutic Products Agency (ANZTPA)

The discussion paper put forward for comment outlines:

- Medicines covered and Standards applied
- Manufacturing principles and licensing
- Products approvals, classifications, statutory timeframes, conditions and data protection
- Obtaining information
- Exemptions
- Post-market monitoring and compliance
- Spontaneous adverse event reporting and risk management
- Surveillance and testing
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- Recalls & public notification
- Therapeutic products’ seizure and promotion
- Provision of expert advice
- Fees and charges, and
- Review of decisions

As industry members, this is an opportunity to have your say and contribute to the framework in which Complementary Medicines are regulated. The CHC encourage you to consider the proposals in the ANZTPA discussion paper in view of shaping a better outcome for industry.

To view the discussion paper click here, and see under ‘Consultation Documents’.

Please provide your feedback to submissions@chc.org.au by 14 February for submission to ANZTPA by 21 February.

Current consultations and reviews

- **ARGCM Part B**: Comments welcome to CHC by Monday 11 February 2013 for submitting to the TGA by 18 February 2013.

- **Permitted (coded) indications for listed medicines**: Comments welcome to CHC by: 7 March 2013 for submission to TGA 15 March 2013.

- **ANZTPA**: Description of a possible joint regulatory scheme for therapeutic products under ANZTPA. Comments welcome to CHC by 14 February 2013 for submission to ANZTPA by 21 February 2013.

- **Draft compositional guideline**: Calcified Lithothamnion tophiforme
  Comments to CHC by 19 February for submission to TGA: 26 February 2013.

- **Draft Compositional guideline** for Trefriew Wells mineral water. Comments welcome to CHC by 1 March for submission to TGA 8 March 2013.

Coded Indications Working Group meeting

Members of the CHC Coded Indications working group will meet on Wednesday, 6 February 2013. The group will focus on reviewing the industry accumulated list of coded indications in comparison to the TGA consultation list. Key areas of input will centre on...
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around the comprehensives of codes captured, alternative mechanisms for the addition of new coded indications, and appropriate implementation and transitional arrangements.

Members are encouraged to input into this consultation by sending comments to submissions@chc.org.au before 7 March 2013.

Over the Counter Business Process Review (OTC BPR)
The over the counter business process review working group will meet with the TGA on the 13 February 2013. A demonstration of the proposed new sponsor application portal will be conducted and a draft implementation plan tabled along with guidance documents developed to date.

Complementary Healthcare Council (CHC) – Board & Technical Committees

Regulatory Policy Committee (RPC)
The RPC Committee met via teleconference on the 30 January to provide members with an update on key regulatory reform issues and progression. Items discussed included the evidence required to support indications for listed medicines, coded indications for listed medicines, introduction of a draft position paper addressing weight loss and biomarker issues as well as current consultation underway. Other issues addressed included the progression of the publication of Listing compliance reviews, risk profiling for complementary medicines, and upcoming TGA meetings on the labelling and packaging of registered complementary medicines.

Therapeutic Goods Administration (TGA)

TGA review of requirements for labelling and packaging of medicines supplied in Australia
As part of the TGA’ s review of requirements for the labelling and packaging of medicines in Australia, the following document has been published: Labelling and Packaging practices: A summary of some of the evidence’. The document contains some of the published evidence that the TGA has gathered regarding key issues and concerns about labelling and packaging of medicines and relates mainly to prescription and non prescription medicines. Then, in conjunction with consultation on other planned reforms to complementary medicines regulation, a subsequent paper and consultation workshops will address labelling options for Listed complementary medicines.
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The review will place primary importance on:

- The presentation of the information on the medicine containers or on the boxes within which they are supplied.
- Visual aspects that contribute to the usability of the information provided, and
- Facilitating the safe use of the medicine by health care professionals and consumers.

Pharmacovigilance: Changes to the Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines

Sponsors of all medicines on the Australian Register of Therapeutic Goods (ARTG) are now required to comply with the new pharmacovigilance document that came into effect on 10 November 2012.

Please note: This includes sponsors reporting to the TGA the name and contact details of the person (‘the nominated contact person’) responsible for fulfilling the sponsor’s reporting requirements described in the pharmacovigilance document. The sponsor must notify the TGA of this person within 15 calendar days of entering a product on the ARTG, and within 15 calendar days of any change in details of the nominated contact person.

The TGA has recently updated the way in which nominating the contact person can be done and ensures a complete sponsor record on eBS.

From now on notifying the TGA of the nominated contact person for pharmacovigilance, or updating those details, can be done by completing the Client Details form (sections 1, 3 & 4) available on the eBS website under the eBS Access Forms link (see Section 2.1).

Address for submitting the completed Client Details form is:

Mail: TGA eBS Help Desk
      Therapeutic Goods Administration
      PO Box 100
      Woden ACT 2606

Fax: TGA eBS Help Desk
     02 6232 8581
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Changes to the Pharmacovigilance requirements and recommendations can be viewed here.

**Australian Adverse Event Report Statistics**
In December 2012, the TGA released the 2011 statistics for Adverse Event Reports of medicines in Australia. A synopsis of the report shows the TGA received approximately 14,400 adverse event reports in 2011; a breakdown of which shows that:

- 52% came from Pharmaceutical Companies
- 12% from Hospitals
- 7% from GPs
- 18% from State and Territory Health Departments
- **3% from consumers**
- 8% from other sources such as community Pharmacists and specialists.

These figures are of particular note in the consideration of regulatory reviews relating to listed complementary medicines.

Furthermore, the TGA estimates it received around 1,200 reports per month in 2011; and considers the elevated report levels may be associated with a number of factors including:

- A greater number of drugs on the ARTG
- The possibility that GPs are reporting adverse events via sponsors, that would account for the slight drop measured in the reporting rates of GPs in 2011.

To view the report, click here.

**Complementary Medicines Reform timetable (updated)**
The TGA has updated the Complementary Medicines reform timetable to include current progress and expected timeframes.

**TGA Structure Updated**
The TGA has updated its structure of the core groups along with the addition of ANZTPA. Please find the updated TGA structure here.
Nutrition, health and related claims Standard 1.2.7 becomes law

The new Standard replaces the transitional Standard 1.1A.2 that was broader in its regulatory terms of prohibitions to health, nutrient and medical advice claims on labelling and advertisements. Standard 1.2.7 which came in to place on January 18, 2013 and includes a three year transitional period, provides new definitions and criteria:

- What constitutes a Health Claim e.g. Express or implied relationships to food and health.
- Standards and requirements for making Health Claims e.g. “Low fat”.
- General vs High level claims.
- Substantiating food Health Claims via the new Nutrient Profiling Scoring Criterion (NPSC).
- Requirements for endorsement and independent endorser bodies relating to food and health claims.

Details of Standard 1.2.7 can be found [here](#).

Health claims on food labels and in advertisements

Standard 1.2.7 for nutrition, health and related claims also sets the guidelines relating to how food-health relationships must be substantiated before being able to make a claim on labels or in advertising. General level health claims can be based on one of over 200 pre-approved substantiated relationships. Businesses also have the option of self-substantiating general level health claims. This information can be found [here](#).

Foods that carry health claims will need to meet specific compositional provisions along with the requisites set using the Nutrient Profiling Scoring Criterion (NPSC) before a health claim can be made. Please note FSANZ are currently updating the NPSC members are advised it should be available shortly.

Businesses in Australia and New Zealand will have 3 years from January 18, 2013 to meet these Nutrition, Health and Related Claims set out in the new Standard 1.2.7. For further reading regarding Standard 1.2.7 –, click [here](#).

To view the Standard legislation, click [here](#).
International

**WHO welcomes international treaty on mercury**

The harmful impacts of mercury on human health, the environment and eco systems are now being recognised on a global scale in light of extensive analysis of evidence and high level intergovernmental negotiations, which have taken place with the involvement of over 140 countries.

The World Health Organization (WHO) has welcomed the approval of a new international convention looking to reduce levels of exposure to mercury on a global scale. Apart from setting measures to control mercury emissions in the environment, there will be steps taken in view of phasing out of mercury thermometers and blood pressure measuring devices used in health care by 2020, as well as the “phasing-down” of the use of dental amalgam.

For the full WHO article, click [here](#).

**Why evidence & substantiated claims are so important**

Looking at what is happening in the EU at the moment in relation to the Nutrition Health Claims Regulations (NHCR), it is more apparent than ever that in order to safeguard the incorporation and use of certain nutrients in health products, there needs to be clear and substantial evidence to support any claims. Probiotics, CoQ10, Lycopene and Lutein, amongst others, all have their fates in the air after their “implied” health claims were rejected by the EU NHCR, which could mean their removal from supplements; and further underscores the value and necessity of substantiating health claims. To read further, click [here](#).

**Functional Food vs Supplementation Trends: Research shows people calling more on food as source of nutrition**

Research from the Institute of Food Technology in Chicago shows that US consumers are not only becoming more nutrition-conscious, but that they are also looking to food sources to provide nutrients, and this is being attributed to the inverse trend in the decline of supplementation use. Reasons for this include beliefs around the nutrient value and benefits and synergy of whole foods vs supplements; with concerns regarding bioavailability of supplements rating highly, along with questions around the long-term effects on digestive health. To view the article, click [here](#).
Implications of strict claims regulations seen in EU

Interestingly, it has been observed that with the enforcement of the EU NHCR, there has been a growth in numbers for ‘medical device’ applications for food supplement products not authorized by the EU NHCR, for example, such as fibre and cranberry. To read more, click here.