# Communiqué: Chinese Medicine Reference Group

The second meeting of the Chinese Medicine Reference Group (the reference group) was held in Sydney on 23 August 2017.

Details of membership and the terms of reference are available under the About us section at www.chinesemedicineboard.gov.au and were noted by reference group members.

Apologies were received from:

- Sophy Athan (written report submitted and distributed), Community representative, AHPRA Community Reference Group (CRG);
- Pip Brennan, Community representative, The Health Consumers' Council (WA); and
- Lyndal Soper (and Allison Jones attended on her behalf), Community observer, Therapeutic Goods Administration (TGA).

In attendance were:

- Debra Gillick, Executive Officer, Chinese Medicine
- Ms Anita Rivera and Ms Rachael Davies from AHPRA Communications

## Chair of the Chinese Medicine Board of Australia (the Board), Professor Charlie Xue

The Chair welcomed everyone to the second meeting, acknowledged the Traditional Custodians of the land on which this meeting took place and paid respect to Elders past and present, then conducted a review of the agenda for prioritisation of the discussion time.

No members had any potential conflict of interests to declare related to the agenda.

Members recalled the terms of reference noting in particular that the group is primarily for information sharing and advice, and is not a decision-making committee.

Board progress arising from the previous meeting included:

- further work and discussion on improving reporting of adverse events by Chinese medicine practitioners (on agenda again for this meeting)
- further work on advertising and a recent publication of a CMBA Position Statement about therapeutic claims in advertising to the public (tabled at this meeting)
- the Quick reference guide for Chinese herbal dispensing was published
- the Board proceeded to make contact and consult with practitioners with a PPP[1] categorised as outer regional, remote or very remote
- a presentation about the AHPRA national public awareness campaign organised for today's meeting, and
- further engagement with the TGA (on agenda again for this meeting).

## Information from community representatives

### AHPRA CRG member, Ms Sophy Athan

The group:

- noted a written report provided by Ms Athan

[1] Principal place of practice (PPP).

- noted with thanks that at the CRG meeting on Tuesday 8 August 2017 Ms Athan sought input from the CRG for today's meeting and also reported on the work of the reference group so far. The CRG:
    - indicated that it supports work that is underway to improve communication with the community and consumers while ensuring that quality and safety standards for patients/consumers are maintained
    - considers it critical that practitioners adhere to the scope of work as advertised and comply with the advertising guidelines developed by AHPRA for all Boards, and
    - indicated that if there was ever a need to consult with the CRG it is available to do that formally as part of its agenda.
- noted the various examples of the Board following up on advice and input from this group, and
- noted that the areas which need the most ongoing work will be adverse event reporting and continued efforts to promote effective communication with both the professional and general communities.

## Information from the TGA

**Ms Allison Jones, Director, Listing Compliance Section, Complementary and OTC[2] Medicines Branch, TGA**

Ms Jones gave an update on:

- adverse event reporting in the TGA including:
    - planned development of an enhanced online reporting system including improved access, enhanced signal management and improved data analytics
    - under-reporting of ADRs[3] related to complementary medicines
- staffing updates and changes at the TGA and Australian Department of Health
- the ongoing progress related to the MMDR[4] especially:
    - the permitted indications reform which is due for implementation in January 2018, that TGA has published a draft list of permitted indications and draft lists of evidence qualifiers on its website for consultation, until **31 October 2017**. During this period, stakeholders can review and provide comments on the lists and propose additional indications or evidence qualifiers, at no cost, before the lists being finalised. When the list becomes a legislative instrument, an application fee will apply to add new indications and qualifiers. She particularly encouraged the Chinese medicine sector to provide input during the consultation process
    - transitional arrangements related to the above
    - planned post-market auditing
    - ongoing work in the area of advertising to eliminate the existing pre-approval process, and
    - the new pathway for some listed medicines where the sponsor wishes to use substantial indications which will be assessed by the TGA and the product will have an AUSTL(A) number.
- impending legislative amendments.

## Board items and activities

**AHPRA national public awareness campaign (guests Ms Anita Rivera and Ms Rachael Davies from AHPRA Communications)**

The group:

- noted a comprehensive presentation on a recent AHPRA community engagement campaign
- noted that all National Scheme[5] website traffic is increasing, with the most popular pages being the *Register of practitioners* and the tribunal/court reports, and
- offered the following suggestions:
    - When promoting compliance it is more effective to provide details about *how* to comply and/or *what* to change. Some AHPRA letters are too generic and can confuse rather than help.
    - A focus on educative messages from tribunal/court outcomes would be helpful, perhaps in the form of case studies.

[2] Over the counter (OTC).
[3] Adverse drug reactions (ADR).
[4] Medicine and Medical Devices Review (MMDR).
5 National Registration and Accreditation Scheme (the National Scheme).

- In order for members of the public to choose registered practitioners they need to be able to find them; a post-code search option on the register would be helpful.
- Take into account the varying levels of English proficiency in the Chinese medicine sector.

**Upcoming/current consultation on reviews of registration standards and code of conduct (Chair Policy Planning and Communication Committee and Community Member of the Board, Dr David Graham)**

The group:

- noted an update on upcoming consultations including:
  - *Registration Standard: Professional indemnity insurance arrangements.*
  - *Registration Standard: Continuing professional development.*
  - *Guidelines: Continuing professional development.*
  - *Registration Standard: Recency of practice*.
  - Common *Code of Conduct*.
  - *Guidelines for advertising regulated health services*.
- noted that the Infection prevention and control guidelines for acupuncture practice are due for review and that:
  - the current guidelines remain accurate and relevant
  - there are considerations that weighed in favour of delaying, and
  - the Chinese medicine sector had been advised of these considerations through the Board's newsletter.
- The most important consideration is that the National Health and Medical Research Council (NHMRC), in collaboration with the Australian Commission on Safety and Quality in Healthcare, is updating the *2010 Australian Guidelines for the Prevention and Control of Infection in Health Care* which are referenced in the Board's guidelines. The Board agreed that it should wait for release of the new NHMRC guidelines. Any substantive changes to NHMRC guidance would result in the Board reviewing its guidelines in any case, regardless of a review falling due.

**Update on *Guidelines for Safe Chinese herbal medicine practice* and *Chinese herbal nomenclature compendium* (Dr David Graham)**

The group noted an update that:

- the guidelines become fully effective on 12 November 2017, and
- the herbal nomenclature compendium (and user guide) has been updated following the release of a revised (2015) edition of *The pharmacopoeia of the People's Republic of China* (PPRC) (Chinese language version) and will be republished soon.

**Update on access to restricted herbs (Dr David Graham)**

The group noted an update that:

- two primary processes will be necessary:
  1) a case to Health Ministers for the Board to endorse practitioners, and
  2) a case to the TGA to modify the SUSMP.[6]
- the process will be lengthy and complex and needs:
  - profession-wide consensus on the strategy (a meeting is scheduled).
  - consultation with a wide range of stakeholders
  - AHPRA processes for developing a case for presentation to Health Ministers
  - the detailed case to be accepted and approved by the Ministerial Council
  - the SUSMP to be amended and then adopted by each State or Territory
  - approved training for candidates for endorsement
  - amendment to the accreditation standard
  - Board procedures to endorse suitable practitioners
  - supply controls in place by herbal suppliers, and
  - mechanisms for monitoring.
- some helpful element already in place are:

[6] Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

  - *Guidelines for safe Chinese herbal medicine practice*
  - endorsement procedures under the National Law
  - AHMAC and (being drafted) AHPRA guidelines, and
  - establishment of the Scheduled Medicines Experts Committee.
- major questions for consideration are:
  - what is the public health and safety issues?
  - what are the benefits versus the risks?
  - how would any risks be managed?
  - how would this enhance practice?

**Advertising (Dr David Graham)**

The group:

- noted:
  - a presentation on advertising obligations and recent work being completed to deal with complaints and improve compliance
  - that there are National Law obligations related to advertising regulated health services and also TGA obligations related to advertising therapeutic goods, and
  - that general guidance for practitioners has been published on the AHPRA website and the Board will be developing more-specific guidance for Chinese medicine.
- suggested that practitioners might benefit from professional development on evaluating evidence and that this be raised with the professional associations, and
- suggested that the Board consider building this somehow into CPD requirements.

## Practitioner and professional association items

**Update on reporting adverse events in Chinese Medicine:**

The group:

- noted that Allison Jones partially addressed this in her report from a TGA perspective but added:
  - that TGA is interested in helping in disseminating information to Chinese medicine practitioners
  - there is a community misperception that complementary medicines are all completely safe
  - that Chinese medicine is a specific component of the marketplace and the practitioners are an important conduit for information and education, and
  - all suspected reactions should be reported and this is very useful information particularly when reports are aggregated; it is a non-judgmental process which can result in important remedies.
- noted that reporting of adverse events related to devices is also a priority
- noted the Board's position that:
  - reporting adverse events is a core responsibility for all healthcare practitioners
  - encouraging adverse event reporting by registered Chinese medicine practitioners is a public safety issue and fits in the role of the Board, and
  - Chinese medicine practitioners have an obligation to report in accordance with the *Code of Conduct* and the *Guidelines for safe Chinese herbal medicine practice*.
- noted a presentation and update from Kevin Ryan who is in discussion with professional associations and educational institutions
- noted that there is no national data on the incidence of pneumothorax caused by the insertion of acupuncture and other needles
- discussed a good example of a reporting process being implemented by one of the educational institutions
- advised that reporting adverse events needs to be "normalised" so that practitioners will not be resistant or hesitant to report, and
- suggested that the Board consider building this somehow into CPD requirements.

## Education institutions update

**Update on recent changes to AQF / TEQSA[7] and how this effects accreditation and approval for registration purposes**

[7] Australian Qualifications Framework and Tertiary Education Quality and Standards Agency (TEQSA).

The group noted a presentation by Prof. Tony Zhang and Ms Nic Andronaco including:

- for the professional accreditation process:
    - the support provided is encouraging and helpful, and
    - opportunities for improvement include: more explicit description of the documentary requirements, less duplication with the monitoring and annual reporting requirements.
- there is repetition in the various accreditation requirements (i.e. professional and TEQSA requirements) and there could be improved coordination or information sharing
- particular challenges in education now include skills for work readiness (teamwork, communication, vocational competence and marketing skills), and
- what interest there might be in the profession to do more mentoring for new graduates.

The group:

- confirmed with the institutional representatives that the current methodology of disseminating information for student from the Board (via the Executive Officer) is effective
- discussed the importance of embedding contemporary health consumer expectations in the current cohorts of students
- noted that we are awaiting the impending report from the Accreditation systems review, and
- noted plans for a review of the Accreditation Standards for Chinese medicine over the next year.

## Industry update

The group noted:

- a comprehensive presentation from Dr Ma which covered:
    - an overview of the Chinese medicine  market in China
    - an overview of quality control activities with strong activity related to raw herbs in China and Hong Kong and related to granules in China and Taiwan
    - that in the context of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) most herbs are now farmed but the permit process is a barrier because it does not distinguish between farmed and wild sourced herbs, and
    - the lack of standards for herbs in Australia.
- that the Chinese Medicine Registration Board of Victoria developed a proposed *Suppliers' code of practice for the sale and supply of Schedule 1 (S1) herbs*, which may be a useful reference for future work (the EO will provide this to Mr Ma), and
- that the Board will investigation further with the TGA the regulatory quality control of raw herbs used in health care in Australia.

## Member feedback, reporting this meeting and planning next meeting

The group:

a. Agreed that this meeting had been useful and informative, the meeting content was strategic and covered important high level policy issues and it is a valuable opportunity to network with the diverse participants.
b. Strongly confirmed the importance and value of community representation at this group.
c. Strongly confirmed the value of TGA participation at this forum.
d. Was pleased at the follow-up of matters discussed at the previous meeting.
e. Noted that the diversity of membership is a significant strength of this group.
f. Noted that the group is primarily for information sharing and advice and is not a decision-making body.
g. Requested a report-back from the Board on follow-up activities emerging from these meetings.
h. Agreed that a communiqué be circulated for comment again and then published on the Board website.
i. Noted that members are encouraged to bring any issues to the table to expand the Board's knowledge and awareness but noted that the Board is very focussed on its core legislative functions.

**Professor Charlie C Xue**
Chair, Chinese Medicine Board of Australia

August 2017