**Shanghai talk: October 2016**

Thank you for the invitation to participate in this very useful meeting

Slide 1. I would like to describe the progress being made in the use of TCM in Australia and the performance structure that is being implemented to ensure its correct use. Australia is a young country as far as the non-indigenous population goes dating from the late 1700s and Chinese came to Australia in 1800s and particularly during the gold rush period of the 1850’s and TCM has been a part of our health system since then.

Slide 2. Any medical system such as TCM is composed of a number of fundamental components: the informatics (nomenclature, coding and classification) to enable the capture and exchange of information, the evidence base to support the validity of the medical system, the training and education of the practitioners, defining acceptable clinical practice, the quality of the treatments in terms of their quality, safety and efficacy such as medicines and medical devices and lastly the actual use of treatments by both patients and practitioners.

Slide 3. To ensure good outcomes from such a medical system, there should be a supporting performance framework which involves the registration of practitioners and the regulation of treatments and these rely on Research and Development (R&D) to provide the evidence base for the medical system and the subsequent capture of that knowledge gained from R&D in the form of standards, guidelines etc. to define acceptable training, practice and quality.

Slide 4. So I would now like to cover each of these four contributing factors to a performance framework for TCM practised in Australia.

Slide 5. The starting point is R&D which provides the knowledge and evidence base and I would like to thank Profs Charlie Xue and Tony Zhang of the RMIT University for some of this information.

Slide 6. As TCM is modernised with new manufacturing techniques, new devices, new formulations, new types of presentations such as tablets and capsules or even granules, the need for scientific rather than traditional evidence will become more expected and necessary.

Slide 7. There are a number of universities in Australia active in R&D in TCM and various research groups, some with international links, have been established within the universities. For example the RMIT University hosts the WHO collaborating centre for Traditional Medicine.

Slide 8. The main sources of funding for R&D are from government or university grants and some overseas funding is also an important contributor. R&D is a very important area for strong international collaboration and information sharing.

Slide 9. However the funding for R&D overall is quite modest. For example the main source of government funding is via the National Health and Medical Research Council which amounted to about A$69m over a 9 year period and this was for research grants covering the whole complementary medicine sector, not just TCM.

Slide 10. However there are increasing numbers of international liaisons particularly with China, for example the China Australia International Research Centre for CM at the RMIT University.

Slide 11. and the Zhendong Australia China Centre for Molecular TCM at the University of Adelaide.

Slide 12. and a very active group in Australia is the National Institute of Complementary Medicine at the Western Sydney University which has agreements with various overseas groups particularly in China.

Slide 13 and 14 summarise some of the research areas in herbal medicine and acupuncture. Clinical research projects are registered by the Therapeutic Goods Administration and following where possible the CONSORT reporting standards.

Slide 15. The main points for R&D in Australia are: while the funding pool is relatively small in Australia, there are increasing liaisons with other research groups and increasing numbers of researchers are being trained. Overall there is a need for more well designed studies to support the future of Chinese Medicine practice.

Slide 16. Next we more onto the documentation of acceptable performance.

Slide 17. This involves collating the knowledge gained from R&D to define acceptable quality, safety and efficacy (or effectiveness) of both treatment products and practitioner services.

Slide 18. This documentation includes Codes such as for Good Manufacturing Practice, clinical guidelines, standards including for products, educational standards for practitioners, and pharmacopoeias.

Slide 19. Australia has been an active participant in ISO/TC 249 which is developing international standards for TCM. ISO/TC 249 is involved in standards which can cover not only for TCM but also are relevant for related medical systems such as Kampo and Korean Medicine.

Slide 20. An international standard provides a globally agreed benchmark which underpins global consistency in practice and products and also benefits international trade and commerce by removing barriers which may be caused by differing local or regional requirements.

Slide 21. The main technical areas of work for ISO/TC 249 at this stage are international standards in the following elements of a medical system; informatics, product quality and safety and the rational use through service standards such as for product labelling. I believe another valuable area in the future for the committee would be standards for practitioner education and training.

Slide 22. ISO/TC 249 has been busy and since it started in 2009, its work as resulted in 22 standards which have been published or are near to being published and many more in the pipeline.

Slide 23. Australia is also publishing clinical guidelines based on scientific evidence, and

Slide 24. has issued a number of guidelines for the profession as part of the registration process for practitioners such as a Code of Practice, guidelines on infection control for acupuncture and guidelines for the practice of herbal medicine.

Slide 25. The main points are that good standards, guidelines etc. require reliable information derived from good quality R&D, the documents need to be based on consensus by a wide range of interested and involved stakeholders and the resources must be kept up to date.

Slide 26. Based on these building blocks, we now come to the regulation of Chinese Medicine products in Australia.

Slide 27. CM has been included in the regulatory system for therapeutic products in Australia since about 1990 and is risk based regulation where the level of regulation is commensurate with any potential risk for the patient.

Slide 28. The Australian regulatory system requires most commercial therapeutic goods to be entered on the Australian Register of Therapeutic Goods before they can be legally supplied into the market. Commercial Chinese medicine products are regarded as low risk and are entered at a lower level on the register as **listed** medicines.

 Medicines individually prepared for individual patients are exempt from the register as the treatment is based on the professional expertise of the practitioner and the patient should have been given enough information on the benefits and risks of the treatment by their practitioner to make their own informed decision. Practitioners or suppliers of listed medicines are prevented from using a number of potentially more harmful herbs which are used traditionally in China.

There are several risk factors which will escalate a listed medicine to a higher level of regulation: certain ingredients, a sterile product such as an injection or its purpose is to treat more serious medical conditions.

Slide 29. shows in the risk based regulatory framework how standards and other regulatory mechanisms are applied. Listed medicines are entered through a self-assessment process by the product’s sponsor and the product must comply with GMP manufacturing standards and other relevant standards for quality and safety. They are subject to post marketing monitoring including for adverse events.

Slide 30 shows the types of evidence of efficacy required in the risk based framework. For listed medicines both scientific and traditional evidence (where relevant) are accepted. Traditional evidence is regarded as generally having lower reliability that well designed scientific studies.

Slide 31: Traditional use is defined as use for at least 75 years and claimed benefits for a listed medicine are limited to a statement of health benefit rather than a significant therapeutic effect and, where applicable, the label advises that the evidence of effectiveness is based on traditional use.

Slide 32. The main points for the regulation of treatments are Chinese medicines are: that they are regarded as low risk if they meet the requirements for classification as a listed medicine, if the supplier wants to make more substantial therapeutic claims then scientific evidence is required. While medicines prepared individually for a patient are exempt, there are restrictions on the range of allowable herbs. Modernisation of CM will increase the expectation and need for scientific evidence.

Slide 33. Now to move onto the registration of practitioners.

Slide 34. The key underlying principles are the protection of the public by ensuring that practitioners are competent and ethical. The legislation is based on only allowing registered practitioners to use certain titles such as Chinese medicine practitioner, Chinese herbal medicine practitioner or acupuncturist – it does not rely on trying to define the range of techniques or practices used.

Slide 35. Practitioners apply for registration and are assessed by their qualification and compliance with certain standards. These standards are similar or the same to those for thirteen other health professions in Australia including western medicine practitioners, nurses, dentists and pharmacists. There are advertising requirements and post registration monitoring.

Slide 36: Tertiary courses in Chinese Medicine at the degree level are accredited against an accreditation standard.

Slide 37. There are over 4,700 registered CM practitioners in Australia and they can be registered in the disciplines of Chinese herbal medicine, Chinese herbal dispensing or acupuncture or a combination of these.

Slide 38. 28% of registered CM practitioners gained their qualification overseas but this figure is likely to decrease now that the period for the more lenient transitional arrangements has expired. Nearly all practitioners are in private practice and there are no TCM hospitals in Australia. There is no government subsidy for the cost to patients for CM treatment but some private health insurers do give rebates for CM services.

Slide 39. The main points for the registration of practitioners are that CM practitioners are registered like other health profession, English proficiency is required, there are some restrictions on the use of herbs that would be regarded in China as having a traditional use and to date there is little integration of CM into the broader health system.

Slide 40. Finally the main challenges for CM in Australia are: 1. Some, particularly western trained doctors challenge evidence based on traditional use and criticize the limited amount of reliable scientific evidence, 2. The boundaries around the protected professional titles, which registration of practitioners relies on, can be circumvented – for example a person who wants to avoid registration because they may not be qualified can continue to treat people by calling themselves a herbalist rather than a CM herbalist and dry needling is promoted by other non-registered people (the advantage for a registered practitioner is that the public has confidence in the skills of a registered health practitioner), and 3. there is little integration of CM into the broader Australian health system as yet however with the performance framework now in place, greater integration should be expected to occur over time.

Slide 41. My overall summary is that TCM in Australia is well positioned for the future with a good performance framework in place although is it still ‘work in progress’.

 Thank you