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# Regulation & standardisation of TCM in Australia

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# Introduction to the regulation and standards development on TCM in Australia: Opportunities & Challenges.

## Overview



- Chinese medicine regulation in Australia
- Standard setting in Australia
- TC249 participation through Standards Australia HE031
- Opportunities & challenges



# Chinese medicine *practitioner* regulation

*National* registration introduced July 1, 2012

**First and only Western nation**

Implications for service funding, **integration**, cross referrals, quality of care

> 4,000 registered TCM practitioners (62% CHM, 97% acupuncture)

# Towards a Safer Choice: The Practice of Chinese Medicine in Australia (Bensoussan and Myers, 1996)

- Practice of TCM
- Benefits
- Risks
- Workforce review
- Patient analysis
- Professional associations (24)
- Education programs
- Regulation of TCM practice internationally
- Australian regulatory context
- Assessing the need for regulation



# Protection of Title (2012)

Illegal to use a title unless Registered

Protected titles are:

- Chinese Medicine practitioner
- Acupuncturist
- Chinese herbal medicine practitioner
- Chinese herbal dispenser
- any similar title

Access to >2,000 ingredients (including herbs)

# Chinese Herbal Medicine Regulation in Australia

## 澳大利亚草药医疗法规

### Herbal medicine use 中草药的使用

#### Raw herbs, individual herb extracts 生药, 单一草药提取物

- Dispensed by practitioners for individual patients.  
由中药执业者为每一位病人配药。
- Controlled by Quarantine (infestation) and Customs (restricted substances, endangered species); not the TGA.  
由检疫与海关部门管理, 而非药监局。
- Practitioners are liable.  
执业者负有责任。

#### Manufactured medicines sold by practitioners and in shops 在商店与执业者所卖的成药

All are regulated by the TGA.  
Level of regulation depends on the therapeutic claim and herbs used.  
为药监局统一管理。对其管理的层次标准取决于其所声称的疗效以及其所使用的草药。

Listed medicines  
列册药物

Registered medicines  
注册药物

# Australian assessment of Chinese herbal medicines

Two tiered approach based on risks:

- *Listed* medicines: limited therapeutic claims, non-serious disease, can only contain any of 2000 ingredients determined to be low risk.
- *Registered* medicines: higher claims, higher risk category, individually evaluated for quality, safety and efficacy.

Listed medicines

Pre-evaluated - safety and quality

Low risk

Registered medicines

Pre-evaluated - efficacy

High Risk



Food Therapies

Schools of Nutrition, Dietetics



P 300 C P 375 C P 100 C Black



Pharmaceutical Drugs



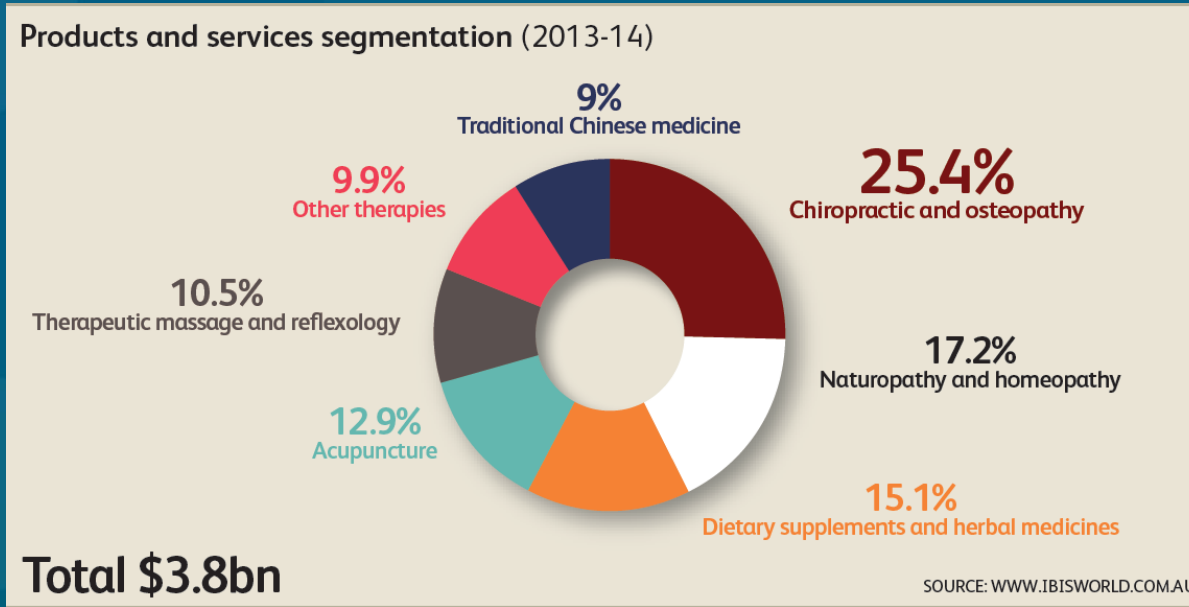
Tablets 125 micrograms



Schools of Pharmacy, Medicine

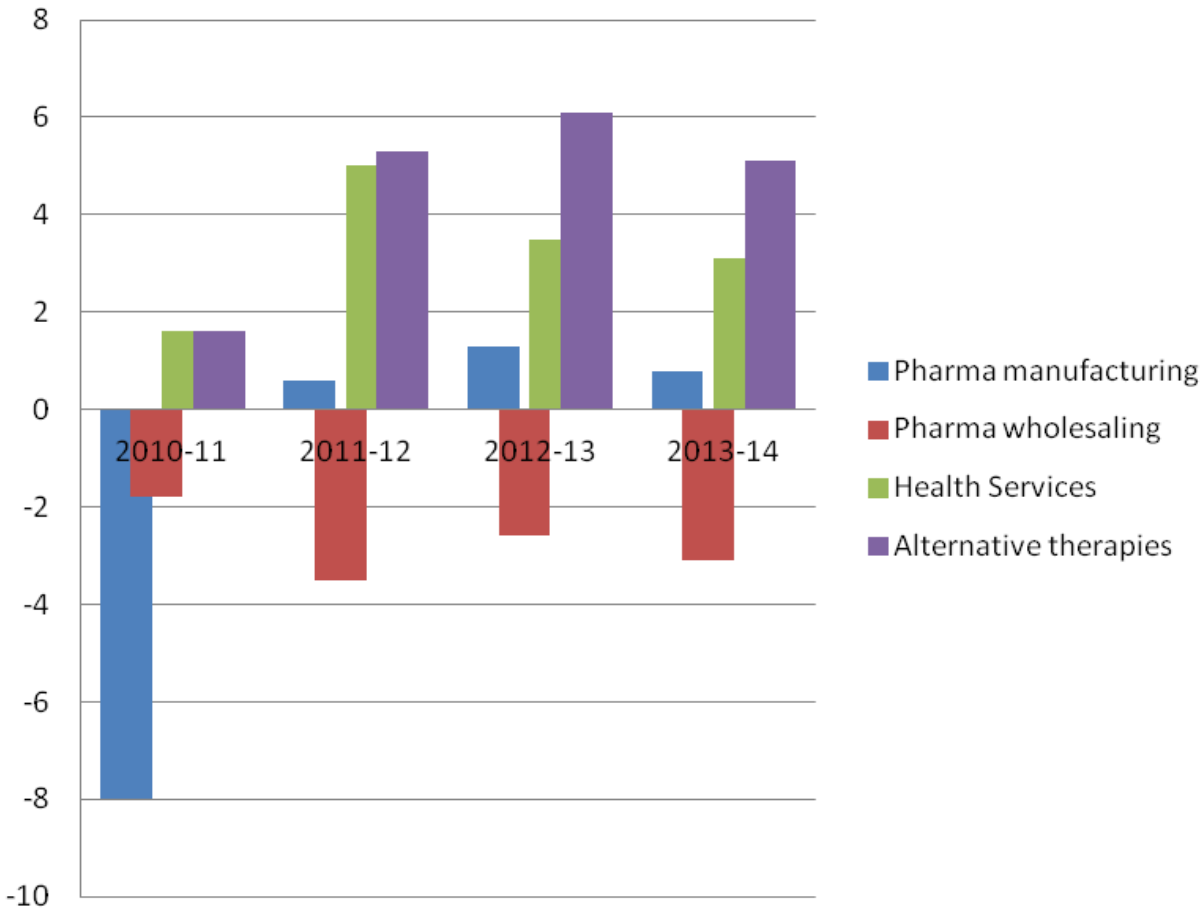


# Complementary medicine use in the community



- \$3.8B in 2013-14 with 4.1% growth in last 5 years
- 2 in 3 Australians use CM as part of their integrative healthcare; 40% for a national health priority area
- ~20million consults pa in herbal medicine, naturopathy, acupuncture, chiropractic & osteopathy
- 5-8,000 active CM clinicians (excluding massage)

# Growth of related industries



[www.IBISWorld.com.au](http://www.IBISWorld.com.au)  
(May 2014 Report)

Revenue  
**\$3.8bn**

Profit  
**\$269.6m**

Annual Growth 09-14  
**4.1%**

Wages  
**\$1.4bn**

Annual Growth 14-19  
**3.4%**

Businesses  
**28,741**

# Forecasts for TCM use

- 75% of westerners use complementary medicine each year - Chinese medicine is the fastest growing
- Growth will continue steadily with :
  - an ageing population and increasing prevalence of chronic disease
  - need to manage healthcare costs away from hospital care
  - need to minimise risk in managing chronic disease - diet, exercise, non-pharmaceutical, non-surgical options

# Participation in ISO TC249



# Standards Australia HE031



# Opportunities

- Internationally agreed minimum standards?
- Improved safety?
- Authenticity?
- A common language & practice?



# Challenges

- ‘TCM’ vs East Asian medicine/TEAM
- Resistance to over-standardisation & over-regulation
- Impact of globalisation





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*Thank You*

Any comments or questions to  
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