AUSTRALIAN REGULATORY DEVELOPMENTS IN COMPLEMENTARY MEDICINE

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CRITICAL METHODS, TRANSLATIONAL RESEARCH

OVERVIEW

- FREE TEXT PROBLEMS
- PROCESS THAT LED TO THERAPEUTIC GOODS (PERMISSABLE INDICATIONS) DETERMINATION NO.1 OF 2018
- CONTROVERSIES AND CONCERNS
- OUTCOME TO DATE
- CONCLUSIONS

FREE TEXT

- Allowed companies to make their own claims using free text as long as they held evidence on these claims

GLOBAL LEGAL DEVELOPMENTS IN TCIM

- WHO has developed recommendations that member states incorporate traditional medical knowledge into healthcare delivery and into regulatory systems
  - *WHO Traditional Medicine Strategy 2014-2023*
- WIPO has developed an extensive body of work promoting recognition of the validity of traditional knowledge globally, including health traditions
  - WIPO/WHO/WTO joint publication *Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade* on Intellectual Property and Traditional Cultural Expressions in Health
- UNESCO *Convention on the Protection and Promotion of the Diversity of Cultural Expression* extends to traditional medicine
- Traditional medicine knowledge being recognised as important irrespective of origin
  - e.g. Nicaragua *Ancestral Traditional Indigenous Medicine Law (Law 759 - 2011)* and *Natural Medicine, Complementary Therapies & Natural Products Law (Law 774 - 2011)*
- The right to traditional *and* complementary medicine increasingly enshrined in national constitutions (e.g. Art. 44 in Ecuador, Art. 118a in Switzerland)
- Case Law (*Shakoor v Situ* [2000] 4 All ER 181; *Kingsford & Kingsford* [2012] FamCA 889)

REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION (MMDR)

July 2015: the Expert Panel released their recommendations arising from the review – including 19 recommendations to improve the regulation of complementary medicines

September 2016: Government response released – accepted the majority of the review's recommendations in full or in-principle – identified the need for consultation with stakeholders in progressing the reforms

January ~~2017~~2018(2019?): After drawn-out legislative process Senate Committee reviews and approves with transitional phase

More flexibility for sponsors, but more surveillance and stricter penalties for breaches

STREAM 1: ENHANCING THE LISTING FRAMEWORK

Recommendation	Government Response
Recommendation 34: Capacity to refuse to list	Supports the intent of the recommendation
Recommendation 37: Online searchable catalogue of permissible ingredients	Accepts the recommendation
Recommendation 38: Establishing a list of permitted indications	Accepts the recommendation

TGA PERMITTED CLAIMS LIST

Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 [Provisions]

- Sponsors listing a medicine on the ARTG will only be able to use indications from a permitted indications list
- The *free text* field will no longer be available
- TGA will also have the ability to create a non-permitted indications list e.g. smoking cessation
- Final (proposed) list of 1019 such indications
  - 140 indications which must be supported by scientific evidence
  - 879 indications that can be supported by a tradition of use, such as TCM, Ayurveda, etc. (e.g. 'Balance Yin and Yang', 'Upraise/lift sunken middle Qi', 'Pacifies Kapha', 'Increases Pitta' and 'Replenish Essence')
  - 95% of submitted claims were rejected (e.g. "adrenal fatigue" – neither scientific nor traditional, despite widespread adoption by TCIM; biomarker claims – e.g. glucose)

THERAPEUTIC GOODS (PERMISSABLE INDICATIONS) DETERMINATION NO.1 OF 2018

- To contain list and provide flexibility for sponsors the indications don't have to be exactly 'word for word' on label or advertising material
- *But* the intent and meaning of the indication must not change this will give flexibility to sponsors and contain the size of the list
  - ARTG indication: 'Maintain/support bowel regularity'
  - Label indication - same meaning: 'X helps maintain regular bowel movements'
  - Label indication – different meaning: 'X relieves constipation'
- *Must only refer to:*
  - health enhancement
  - health maintenance
  - prevention or alleviation of dietary deficiency;
  - a health benefit for a non-serious forms of a disease, ailment, defect or injury
- Permitted indications can only refer to conditions that are: – self-diagnosable – self-manageable
- A delay in medical treatment would not be detrimental to the consumer

USING INDICATIONS

1. Select tradition of use (Optional)

Indications that do not specify a tradition of use are by default scientific

2. Select core permitted indication (Mandatory)

At least one core indication is selected in ELF using drop down lists or key word search

3. Select specifying qualifiers (Optional)

Sponsors can choose to apply one or more pre-approved qualifiers to each core permitted indication by selecting from a drop down list

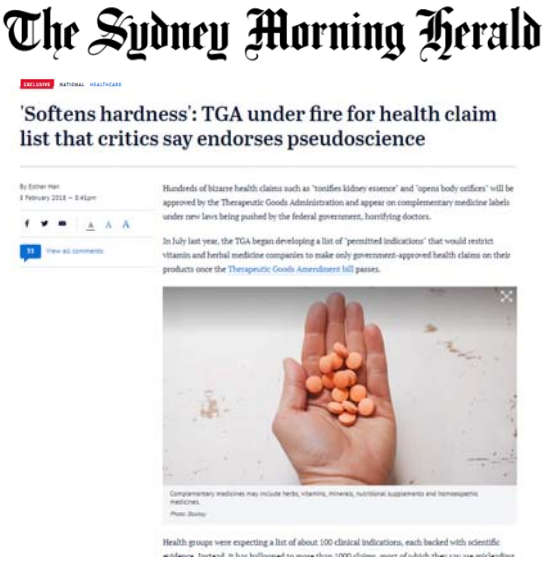
Healthy target population | Effectiveness | Time of use

Tradition of use	Core permitted indication	Specifying qualifiers
N/A	Relieves muscle aches and pains	**Healthy target population:** 'in healthy individuals' **Effectiveness:** 'Temporarily' **Time of use:** 'after exercise'

Final permitted indication on product label

E.g. Temporarily relieve muscle aches and pains after exercise in healthy individuals

CONTROVERSY AROUND TRADITION CLAIMS


The Sydney Morning Herald

'Softens hardness': TGA under fire for health claim list that critics say endorses pseudoscience

- Should they be legitimised?
- Traditional medicine claims for East Asian medicines are now included in ICD-11
  - Other TCIM being codified for later inclusion
  - By definition, does this makes them 'legally recognised' diagnoses?
- Most TCIM diagnoses are 'functional', not 'physiological'
  - IBS (Rome III Criteria)
  - DSM for mental health disorders
  - If TCM removed should these also be allowed?
- Yes, they sound funny
  - Pseudoscience or linguistic/cultural difference?

PROPOSED DISCLAIMERS

- All indications citing traditional evidence must include the following statement: *"This traditional indication is not in accordance with modern medical knowledge and there is no scientific evidence that this product is effective"* - **"THE NEGATIVE DISCLAIMER"**
- FDA DSHEA DISCLAIMER: "*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease*"
- Homeopathic disclaimers:
  - HEALTH CANADA: "*this product is based on traditional homeopathic references and not modern scientific evidence*"; US FDA

OUTCOME: FAILED AMENDMENTS

Senator DI NATALE (Victoria—Leader of the Australian Greens) (10:46): by leave—I move amendment (2) on sheet 8353.

(2) Schedule 2, item 15, page 19 (after line 24), after subsection 26BF(5), insert:

(6) All indications citing traditional evidence must include the following statement: This traditional indication ***is not in accordance with modern medical knowledge*** *and there* ***is no scientific evidence that this product is effective****.*

- Labor (Zappia): "*traditional medicines listed on the ARTG will have to include a statement to the effect that the efficacy claims have not been independently assessed*"

OUTCOME: STATED REASONS

- **Research suggests disclaimers are ineffective**
  - Russo France and Bone (2005) "Policy makers' paradigms and evidence from consumer interpretations of dietary supplement labels." *J Consumer Affairs* 39(1) 27-51
  - Mason et al (2007) "The impact of warnings, disclaimers, and product experience on consumers' perceptions of dietary supplements" *J Consumer Affairs* 41(1) 74-99.
  - Kesselheim et al (2015) "Mandatory disclaimers on dietary supplements do not reliably communicate the intended issues." *Health Affairs* 34(3) 438-446.
- **Australia is a pluralistic society**
  - "Offensive and disrespectful"
- **Inconsistent with international agreements**
  - WHO Traditional Medicine Strategy and other international agreements
- **Inconsistent with other Australian regulatory and legal structures**
  - e.g. AHPRA; case law
- **Compliance programs to be strengthened**
- **Scope creep**
  - "Other disclaimers will be required if this one is approved"
- **Significant opposition to the proposals to reduce/remove list or disclaimer**

CONCLUSION

- Are traditional claims and traditional evidence appropriate at all?
- If they are allowed, how should they be regulated?
- How should distinction between scientific and traditional evidence be communicated to consumers?
- How do we differentiate valid versus invalid traditional claims?
- What level is okay? How much is enough?

THANK YOU

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