REGULATION OF TRADITIONAL AND COMPLEMENTARY MEDICINE (T&CM) IN MALAYSIA: ISSUES & CHALLENGES FROM A LEGAL PERSPECTIVE

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OUTLINE

- Overview
- Governance of the Practitioners and Practice of T&CM
- Governance of the Traditional Medicine Products
- Issues and Challenges
- Future plan
MALAYSIA POPULATION
32.4 MILLION PEOPLE
Est in 2nd quarter of 2018
Department of Statistic Malaysia
DEFINITION OF T&CM

A form of health-related practice

To prevent, treat/manage ailment/illnesses/preserve the mental and physical well-being of an individual

Excludes medical or dental practices used by a medical or dental practitioner respectively

Traditional Malay Medicine
Traditional Chinese Medicine
Traditional Indian Medicine
Islamic Medical Practice
Homeopathy
Complementary Therapies

Traditional and Complementary Medicine Act 2016 [Act 775]
T&CM SECTORS IN MALAYSIA

Areas
- Practice
- Practitioner

Regulations
- Traditional and Complementary Medicine Act 2016
- National Skills Development Act 2006
- Malaysian Qualifications Agency Act 2007
- Department of Skills Development
- Malaysian Qualification Agency

Regulatory Authority
- T&CM Council
- T&CM Division (as Secretariat to the Council)
- Ministry of Health
- Ministry of Human Resources
- Ministry of Higher Education

Education and training
- Skills Sector
- Higher Education Sector
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GOVERNANCE OF T&CM

- T&CM Act 2016
- Regulations supporting T&CM Act 2016
- Policies, Guidelines, Directives, Standard Operating Procedures

Statutory-Regulation

Self-Regulation
REQUIREMENTS OF THE ACT 775

An Act to provide for the establishment of the Traditional and Complementary Medicine (T&CM) Council to regulate the T&CM services in Malaysia and to provide for the matters connected there with.

In short, the Act is to:
- Ensure the high quality, effectiveness and safety of the T&CM practices.
- Determine eligibility requirements for each type of T&CM practices.
- Render compulsory registration of T&CM practitioners.
- Enforce the legislation.
IMPLEMENTATION OF THE T&CM ACT (ACT 775)

- **Enforcement of T&CM Act 2016 [S1(2)]**
  - **Establishment of T&CM Council [S4]**
  - **T&CM Regulations [S60]**
  - **Disciplinary Proceedings [S60(2)(k)]**

**Recognized practice areas [S20]**
- **Forms & manner in applications for registration [S60(2)] [S22, 23, 24, 26]**

**Registration criteria**
- Eligibility requirements for each practice area [S5(b)]
- Recognise qualifications conferred by higher education institutions [S5(c)]
- Recognise academic qualifications or skills certificate [S5(d)]
- Apprenticeship & training requirements [S5(e)]

**Registered T&CM practitioner**

ENFORCEMENT BY SECTIONS (1st Phase)

ENFORCEMENT BY SECTIONS (2ND PHASE)
Membership of the Council

S6. (1) The Council shall consist of the following members who shall be appointed by the Minister on the recommendation of the Director General:

- **S6(1)(a):** $\leq 3$ representatives from MOH
- **S6(1)(b):** $2$ representatives from local universities with expertise in T&CM fields
- **S6(1)(c):** $\leq 3$ registered practitioners in the public service
- **S6(1)(d):** $\leq 8$ individuals from private practice representing the designated T&CM practitioner bodies in Malaysia
- **S6(1)(e):** $5$ individuals who possess sufficient experience & expertise in the relevant industry

T&CM Council was established on 16th January 2017

Chairman of the Council = Director General of Health Malaysia
TRADITIONAL AND COMPLEMENTARY MEDICINE (RECOGNIZED PRACTICE AREAS) ORDER 2017

- It was made by the Health Minister.
- This order comes into operation on 1st August 2017.

- The Recognized Practice Areas include:
  - Traditional Malay Medicine
  - Traditional Chinese Medicine
  - Traditional Indian Medicine
  - Homeopathy
  - Chiropractic
  - Osteopathy
  - Islamic Medical Practice
REGISTRATION OF T&CM PRACTITIONERS

Any person intending to practise T&CM in any recognized practice area (with recognized qualifications as specified by the Council) -> provisional registration

Not less than 1 year residency with any hospital or institution in Malaysia approved by the Council

Practicing Certificate (every 12 months) -> Registered Practitioner
REGISTRATION OF T&CM PRACTITIONERS

- No person shall practise in any practice area which is not a recognized practice area.

- A registered practitioner shall not practise a recognized practice area unless he holds a valid and subsisting practising certificate.

- All practicing certificate shall be displayed in such manner as may be prescribed at the registered practitioner’s place of practice.
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DEFINITION OF TRADITIONAL PRODUCT

- Any product used in the practice of **indigenous medicine**, in which the drug consist solely of one or more **naturally occurring** substances of a **plant**, **animal** or **mineral**, of parts thereof, in the non-extracted or crude extract form, and a homeopathic medicine.

- It shall not include any sterile preparation, vaccines, any substance derived from human parts, any isolated and characterized chemical substances.
REGULATORY CONTROL OF TM PRODUCTS IN MALAYSIA

Control of Drugs and Cosmetics Regulations 1984

No person shall manufacture, sell, supply, import, possess or administer any product

Unless
The product is a registered product

And
The person holds the appropriate license required & issued under the CDCR
DRUG CONTROL AUTHORITY (DCA)

- Was established under the Control of Drugs and Cosmetics Regulations 1984

- DCA is to ensure the safety, quality and efficacy of pharmaceuticals, health, traditional products and cosmetic that are marketed in Malaysia.

- Its objective is being achieved through:
  - Registration of pharmaceutical, traditional products and cosmetics
  - Licensing of premises for importer, manufacturer and wholesaler
  - Monitoring the quality of registered products in the market
  - Adverse Drug Reaction Monitoring
The Control of Drugs and Cosmetics Regulations 1984 empowers the DCA to implement the registration scheme in phases i.e.

**REGISTRATION PHASES**

<table>
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<tr>
<th>Phase 1</th>
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<th>Phase 3</th>
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<td>Licensing May 1987</td>
<td>Licensing 1992</td>
<td>Licensing Manufacturer Importers Jan 1999</td>
<td>Licensing Jan 2004</td>
<td>Licensing 1 Jan 2012*</td>
<td>No licensing Requirements as registration of API is linked to products</td>
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Extemporaneous preparation - prepared and given directly to the patient by any traditional practitioner during the course of treatment

Traditional preparation that is produced only through drying, without any treatment/process involved. For example, raw herbs

Traditional preparation used as food, spices or flavouring of food which do not have any medicinal claim

Traditional preparation that is used for cosmetic purposes such as to whiten or improve the appearance of skin, hair, teeth, etc has to be registered as cosmetic product
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• Difficulty in ensuring effective implementation of the T&CM Act 2016 and the introduction of statutory regulation of T&CM practitioners.

• T&CM Premises are not adequately regulated.

• Inappropriateness and inadequacy of current product regulatory system for traditional medicine products.
ISSUES & CHALLENGES: PRACTICE I

- Difficulty in ensuring effective implementation of the T&CM Act 2016 and the introduction of statutory regulation of T&CM practitioners due to:
  - The complexity and diversity of T&CM practice in Malaysia;
  - The lack of trained personnel;
  - The lack of facilities to conduct residency training; and
  - The absence of suitable mechanisms for registering T&CM practitioners without formal training.
ISSUES & CHALLENGES: PRACTICE II

- T&CM Premises are not adequately regulated
  - Lack of appropriate law to regulate T&CM premises in both public and privates sectors
ISSUES & CHALLENGES: PRODUCTS

- Issues related to the appropriateness and adequacy of current product regulatory system

  - Some important medicinal materials that are frequently used in the practice of T&CM are listed under the Poison List or banned/restricted ingredients list in the DRGD.

  - There is no proper mechanism in place that monitor or regulate the quality of T&CM medicinal materials on import, export & distribution, and the personnel involved in these activities and dispense T&CM medicinal materials.
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FUTURE PLANS FOR T&C M

- Preparation for full enforcement of T&CM Act 2016
  - T&CM Regulations: Initial Registration of T&CM Practitioners
  - Enforcement team: Headquarters / Regional (nationwide)

- Develop an appropriate regulatory framework & guideline to regulate & monitor T&CM premises

- Strengthening the regulatory system for T&CM products materials
Thank You
Terima Kasih
Regulation of the health workforce in Australia

Sondra Davoren, Manager - Cancer Treatment and Supportive Care
McCabe Centre for Law and Cancer
Overview

- Rationale for regulating the health workforce and relationship with universal health coverage
- Options for regulating the health workforce
- Framework for health practitioner regulation in Australia
Why regulate healthcare workers?

- Public protection and patient harm
- Non-discrimination
- Prevent health worker shortages
- Address pressures of health worker migration
- Essential for access to treatment and universal health coverage
Priorities for the cancer workforce

- Building a quality cancer workforce
  
  *Inadequate education of healthcare providers is one of the most pervasive and urgent obstacles to address in delivering cancer care* (Global Health Workforce Alliance)

- Provide workers with appropriate tools and knowledge to meet the needs of individuals and communities across the cancer continuum
  - Early detection, safe and proper administration of chemotherapy, radiotherapy, and surgery, and delivering palliative care and pain and distress management
Global commitments & the health workforce

- UN Declaration on NCDs
- World Cancer Declaration
- Universal Health Coverage
- Sustainable Development Goals
AAAQ and the health workforce

International Covenant on Economic, Social and Cultural Rights Article 12:
Right of everyone to the enjoyment of the highest attainable standard of health

**Available**
Are there enough workers to meet the needs of the population?

**Accessible**
Are patients able to physically and financially access healthcare workers?

**Acceptable**
Are healthcare workers respectful of ethics and cultural, gender, and life cycle requirements?

**Quality**
Are healthcare workers competent, skilled, equipped and trained?
Workers have to be:

- Available
- Equitably distributed and accessible by the population
- Possess the required competency
- Motivated and empowered to deliver quality care that is appropriate and acceptable to the sociocultural expectations of the population
Global commitments: why regulate?

- Domestic and international drivers for regulation
- Public protection, patient centred health care, safety and quality assurance
- Integral to achieving NCD Global Agenda, World Cancer Declaration, SDGs, UHC, right to health, and WHO commitments in the WHA Resolution and Global Strategy on Human Resources for Health
How: regulation basics

• What is regulation?
  – Binding set of rules
  – Deliberate government influence
  – All forms of social or economic influence

• Usually always an activity to restrict or enable certain activities

• Will vary depending on social, political and cultural context
Good regulation:

- Legitimacy
- Proportionality
- Consistency
- Transparency and accountability
How: regulation basics

- Statutory regulation
- Co-regulation
- Self-regulation
Regulation basics

Common features of healthcare worker regulation:

• Requirements for entry into a profession
• Requirements to become registered or licensed
• Standards to maintain registration
• Codes of conduct and professional standards
• Ways to deal with people who breach the standards

Source: http://iris.wpro.who.int/bitstream/handle/10665.1/12622/9789290617235_eng.pdf
Entry, registration and licensing

- Operates to limit entry to the health care profession
- Ensure currency of qualifications, fitness to practice
- Protect the community by assuring the quality and safety of health service provision
Regulation of health practitioners in Australia

Australian Health Practitioner Regulation Agency

- National Boards
- Accreditation authorities

State, territory and regional Boards

National Law
Registered health practitioners

- Aboriginal and Torres Strait Islander health practice
- Chinese medicine
- Chiropractic
- Dental practice
- Medicine
- Medical radiation practice
- Nursing and midwifery
- Occupational therapy
- Optometry
- Osteopathy
- Pharmacy
- Physiotherapy
- Podiatry
- Psychology
Registered vs Unregistered Practitioners

Registered practitioners
National boards responsible for:
– Registration of qualified & competent professionals;
– Developing & applying standards, codes & guidelines for the profession;
– Monitoring of suitability to practise;
– Discipline in relation to unprofessional conduct, professional misconduct, unsatisfactory professional performance & impairment.
Unregistered health practitioners

8 General health service providers not to make claims to cure certain serious illnesses

(1) A general health service provider must not claim or represent that the provider is qualified, able or willing to cure cancer or other terminal illnesses.

(2) A general health service provider who claims to be able to treat or alleviate the symptoms of cancer or other terminal illnesses must be able to substantiate such claims.
Health complaints frameworks

Important part of the healthcare worker regulation matrix

+ Highlight weaknesses in a health practice / system

+ Encourage improvement

+ Can reassure patients / clients of health care service quality
Health complaints framework - Victoria

Who can complain?

Typically, a patient (or person in receipt of healthcare)

Sometimes carers or family members

Sometimes health practitioners
What can a complaint be about?

• Usually defined in legislation – ‘about a health service’

• Breach of occupational standards, scope of practice, professional conduct and practice, charges…

• Claims about curing cancer, or prolonging the life of someone with cancer
How are complaints handled?

- Alternative dispute resolution—before or instead of court action
- Investigate and negotiate resolution between patient and provider
- Options to appeal to a court or judicial body—greater punitive powers
Other options

• Consumer protection laws

• Human rights / patient rights

• Civil litigation / medical malpractice, negligence
Thank you for your attention.
The role of law in advancing Universal Health Coverage and strengthening cancer prevention and control

Jonathan Liberman, Director
McCabe Centre for Law and Cancer
Universal health coverage (UHC)

- Defined by WHO: *where all people obtain the health services they need (prevention, promotion, treatment, rehabilitation, and palliative) of sufficient quality to be effective, without undue financial hardship.*
The need for universal health coverage

• At least half of the world’s population still do not have full coverage of essential health services

• About 100 million people are still being pushed into “extreme poverty” (living on 1.90 USD or less a day) because they have to pay for health care

• Over 800 million people (almost 12% of the world’s population) spent at least 10% of their household budgets to pay for health care
Sustainable Development Goal (SDG) 3

GOOD HEALTH AND WELL-BEING
The 2030 Agenda for Sustainable Development & the SDGs

 TARGET 3.4

• By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
The 2030 Agenda for Sustainable Development & the SDGs

- Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
The 2030 Agenda for Sustainable Development & the SDGs

TARGET 3B

- Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries,
- Provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health
- Provide access to medicines for all
Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States.
It’s a matter of human rights
Article 12:
The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
UN Convention on the Rights of the Child

Article 24:

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure
What’s the role for law?
What’s the role for law?

Looking at both:

• Specific legal interventions for different aspects of prevention, screening, diagnosis, treatment, supportive care, survivorship

• Legal underpinnings / good governance for health systems
Thank you for your attention.