Traditional and Complementary Medicine (T&CM) Act
What Should You Know?

5th August 2015
Traditional and Complementary Medicine Division
Ministry of Health Malaysia
Outline

1) Updates from WHO perspective

2) Overview of T&CM regulatory framework in Malaysia
   - T&CM Act 2013
• WHO perspective
The Regional Strategy for Traditional Medicine in the Western Pacific (2011-2020)

Strategic Objectives

1. To include traditional medicine in the national health system
2. To promote safe and effective use of traditional medicine
3. To increase access to safe and effective traditional medicine
4. To promote protection and sustainable use of traditional medicine resources
5. To strengthen cooperation in generating and sharing traditional knowledge and skills
WHO Traditional Medicine Strategy 2014-2023

Strategic Objectives

1. To build the knowledge base for active management of T&CM through appropriate national policies

2. To strengthen quality assurance, safety, proper use and effectiveness of T&CM by regulating T&CM products, practices and practitioners

3. To promote universal coverage by integrating T&CM services into health care service delivery and self-health care
Figure 6: Difficulties faced by Member States regarding regulatory issues related to the practices of T&CM

- Lack of research data: 105
- Lack of mechanisms to control and regulate T&CM advertising and claims: 83
- Lack of appropriate mechanisms control and regulate herbal products: 78
- Lack of appropriate mechanisms to monitor and regulate T&CM providers: 75
- Lack of financial support for research on T&CM: 68
- Lack of expertise within national health authorities and control agencies: 67
- Lack of mechanisms to monitor safety of T&CM practice: 65
- Lack of cooperation channels between national health authorities to share information about T&CM: 63
- Lack of mechanisms to monitor safety of T&CM products, including herbal medicines: 60
- Lack of education and training for T&CM providers: 58
- Other: 15

Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.
Figure 5: Regulations on T&CM practitioners

- With regulations on T&CM practitioners: 56 (43.5%)
- With no regulations on T&CM practitioners: 17 (13%)
- Not answered: 56 (43.5%)

Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

Figure 3: T&CM education at university level

- With T&CM at university level: 39 (30%)
- No T&CM education at university level: 72 (56%)
- Not answered: 18 (14%)

Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.
• How about Malaysia?

Regulatory framework of T&CM in Malaysia

T&CM Act 2013
**Important milestones in the development of T&CM in Malaysia**

- **1987**
  - A proposal for research in alternative medicine was prepared

- **1996**
  - T&CM Unit was formed under the Family Health Development Division

- **1998**
  - T&CM Standing Committee was established

- **1999**
  - Formation of five umbrella bodies for T&CM

- **2000**
  - Herbal Medical Research Center was launched

- **2001**
  - National Policy on T&CM was launched

- **2002**
  - Global Information Hub and National Committee in R&D for Herbal Medicine was established

- **2004**
  - T&CM Division was established
Important milestones in the development of T&CM in Malaysia

- 2007: Kepala Batas Hospital
- 2008: Putrajaya Hospital
- 2009: Sultan Ismail Hospital
- 2007: Duchess of Kent Hospital
- 2010: Sultanah Bahiyah Hospital
- 2010: Port Dickson Hospital
- 2010: Sarawak General Hospital
- 2010: T&CM Branch Offices in north, south, east zones and Sarawak were established
- 2011: Sultanah Hajjah Kalsom Hospital
- 2011: Raja Perempuan Zainab II Hospital
- 2011: T&CM Branch Office in Sabah was established
- 2012: Cheras Rehabilitation Hospital
- 2012: T&CM Bill 2012 was passed in Parliament
- 2012: National Cancer Institute
- 2013: MAWIP
- 2013: Likas Hospital
- 2013: T&CM Act 2013 was gazetted
- 2014: Jasin Hospital
- 2014: Strategy of T&CM in Primary Health Care was launched
- 2015: Masai Health Clinic
- 2015: T&CM Branch Office in Perak was established
Regulatory Divisions within the Ministry of Health related to the T&CM sector in Malaysia

**Product**
- Sales of Drugs Act 1952
- Poison Act 1952
- Dangerous Drugs Act 1952 (...etc)
- Drug Control Authority
- National Pharmaceutical Control Bureau (NPCB)

**Practitioner**
- T&CM Act 2013
- T&CM Council
- T&CM Division (T&CMD)

**Training**
- T&CM Act 2013
- T&CM Council
- T&CM Division (T&CMD)

**Research**
- National Committee on Research and Development of Herbal Medicine
- Institute for Medical Research (IMR)
Regulate the practice of T&CM practitioners

Ensure all T&CM practitioners undergo formalised system of education and training

Establish a registry of all T&CM practitioners

Facilitate the development of standards and criteria in T&CM

Regulation and monitoring of accredited learning centers, setting the quality and standards of T&CM programmes

Facilitate and as a collaborator for research and scientific evaluation of T&CM
# Institutions providing T&CM courses in Malaysia

<table>
<thead>
<tr>
<th>No.</th>
<th>Institutions</th>
<th>Courses Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Southern College Skudai</td>
<td>a. Bachelor Degree of Traditional Chinese Medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3+2</td>
</tr>
<tr>
<td>2.</td>
<td>Tunku Abdul Rahman University Sungai Long Campus</td>
<td>a. Bachelor of Traditional Chinese Medicine (Hons)</td>
</tr>
<tr>
<td>3.</td>
<td>INTI International University College</td>
<td>a. Bachelor of Traditional Chinese Medicine (Hons)</td>
</tr>
<tr>
<td>4.</td>
<td>Cyberjaya University College of Medical Sciences (CUCMS)</td>
<td>a. Bachelor of Homeopathy (Hons)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Diploma in Islamic Medical Practices</td>
</tr>
<tr>
<td>5.</td>
<td>Management and Science University (MSU)</td>
<td>a. Bachelor in Traditional Chinese Medicine (Hons)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Diploma in Traditional Chinese Medicine</td>
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<tr>
<td>6.</td>
<td>International Medical University (IMU)</td>
<td>a. Bachelor of Science (Hons) Chinese Medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Bachelor of Science (Hons) Chiropractic</td>
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<tr>
<td>7.</td>
<td>Malacca College of Science and Management</td>
<td>a. Diploma in Natural Medicine</td>
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<tr>
<td>8.</td>
<td>Lincoln University College (Main Campus)</td>
<td>a. Diploma in Traditional Chinese Medicine</td>
</tr>
</tbody>
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Updated July 2015
T&CM Act 2013 [Act 756]

**WHAT?**
- What is T&CM Act 2013?
- What does it covers?

**WHO?**
- Who need to register?

**HOW?**
- Regulatory mechanism?

**WHEN?**
- Date of enforcement?
T&CM Act 2013 [Act 756]

Part I: Preliminary
Part II: The T&CM Council
Part III: General Administration
Part IV: Registration of T&CM Practitioners
Part V: Obligations & Duties of Registered Practitioners
Part VI: Disciplinary Proceedings
Part VII: Patient’s Rights
Part VIII: T&CM Practitioner Body
Part IX: Enforcement
Part X: General
Part XI: Transitional Provision

11 Parts
63 Sections

An Act to provide for the establishment of the T&CM Council to regulate the T&CM services in Malaysia & to provide for matters connected therewith.

Date of Gazettement: 8th February 2013
Date of Enforcement: To be determined by Minister of Health (BY PHASES)
S3. “practice of T&CM” means a form of health-related practice designed to prevent, treat or manage ailments or illness or preserve the mental & physical well-being of an individual & includes such practices as traditional Malay medicine, traditional Chinese medicine, traditional Indian medicine, homeopathy, & complementary therapies, but excludes medical & dental practices used by a medical & dental practitioner respectively.
S20(2). The Minister may, after considering the recommendation of the Council, by order published in the Gazette, prescribe the practice areas as recognised practice areas.
Regulatory Mechanism

• A person intending to practice T&CM in any recognised practice area shall apply to the T&CM Council to register and shall comply with any qualifications as specified by the T&CM Council for that recognised practice area.

• S23(3). A practitioner may be registered in one or more recognised practice areas if he satisfies the eligibility requirements for those practices areas and has paid the prescribed fee.

• S25. A person who is not a registered practitioner shall not, directly or indirectly practice T&CM services.

<table>
<thead>
<tr>
<th>Offence</th>
<th>Penalty</th>
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<tbody>
<tr>
<td>1st offence</td>
<td>Fine not exceeding RM 30,000 / imprisonment not exceeding 2 years / both</td>
</tr>
<tr>
<td>Subsequent offence</td>
<td>Fine not exceeding RM 50,000 / imprisonment not exceeding 3 years / both</td>
</tr>
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</table>
Transformation from **Self-Regulation** to **Statutory-Regulation**

- Currently, T&CM in Malaysia is under self-regulatory mode.
- T&CM Practitioner Bodies are appointed by the Ministry of Health (MOH) to self-regulate the practitioners through the compliance of codes of ethics and practice.
- To date, MOH has appointed 8 T&CM Practitioner Bodies representing different types of T&CM modalities available in Malaysia.
- T&CM practitioners are encouraged to register with the appointed Practitioner Bodies.
## T&CM Practitioner Bodies

| Federation of Chinese Physicians and Medicine-Dealers Associations of Malaysia (FCPMDAM) | Federation of Complementary & Natural Medical Associations, Malaysia (FCNMAM) |
| Federation of Chinese Physicians & Acupuncturists Association of Malaysia (FCPAAM) | Pertubuhan Perubatan Tradisional India Malaysia (PEPTIM) |
| Malaysian Chinese Medical Association (MCMA) | Persatuan Kebajikan dan Pengubatan Islam Darussyifa’ |
| Majlis Perubatan Homeopathy Malaysia (MPHM) | Gabungan Pertubuhan Pengamal Perubatan Tradisional Melayu Malaysia (GAPERA) |

T&CM Practitioner Bodies: National bodies that are registered with the Registrar of Societies.
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(2). Chairman of the Council = Director General of Health Malaysia

S10. Quorum = 11

S17(1). The Council may, with the approval of the Minister, in writing, subject to such conditions, limitations or restrictions, delegate any of its functions as may be appropriate to –
(a) any designated practitioner body; or
(b) any person as the Council deems fit.
S5. The Council shall have the following functions:

a) to advise the Minister on matters of national policy relating to T&CM practice;

b) to establish the eligibility requirements for each practice area;

c) to recognise qualifications conferred by any institutions of higher learning established under any written law in Malaysia or any institutions of higher learning recognized and authorized by any countries outside Malaysia for the purpose of registration under this Act;

d) to specify the appropriate academic qualifications or recognized skills certificate issued pursuant to the National Skills Development Act 2006 [Act 652] which are or is necessary before a person may apply to be a registered practitioner;

e) to specify the necessary apprenticeship and training requirements including rules for undergoing apprenticeship, the scope of responsibilities and permitted conduct or activities of apprenticeship, duration of apprenticeship and post-qualification apprenticeship;

f) to register individuals who will provide T&CM services to the public;
Functions of T&CM Council

g) to **issue practising certificates** to registered practitioners who have satisfied the prescribed conditions and paid the prescribed fees;

h) to develop **codes of professional conduct**, rules relating to the professional conduct of registered practitioners, including penalties for breach of such codes or rules;

i) to develop, undertake, prescribe and mandate any matter relating to or connected with the **practice** of T&CM or the **professionalism** of such practice;

j) to specify, provide for and administer a **complaints** procedure and process;

k) to develop rules upon which registered practitioners are to **refer** their patients to medical practitioners or dental practitioners, as the case may be;

l) to obtain such relevant **information** from practitioners, and to provide the same to the Minister;

m) to carry out such functions as may be specified by this Act; and

n) to carry out all such other activities as may be directed by the Minister and such direction shall be consistent with the purposes of this Act.
Regulatory Hierarchy

Minister of Health

T&CM Council [S4-17]

T&CM Division
Secretary [S16] = Registrar [S18]

Designated Practitioner Bodies [S42-47]

Registration / Practising Certificate

Enforcement

T&CM Practitioners
Local Practitioners

- Traditional Indian Medicine: 58
- Homeopathy: 334
- Islamic Medical Practices: 486
- Complementary therapy: 2159
- Traditional Malay Medicine: 2401
- Traditional Chinese Medicine: 8408

Total 13,846 practitioners

*Voluntary registration with MOH (e-Pengamal) (Nov. 2008 – May 2015)

Note: Voluntary registration with MOH has been withheld since June 2015.
Foreign Practitioners

Criteria to be fulfilled:

1. Must possess basic qualifications relevant to the area of practice

2. Have adequate working experience
   - ≥ 5 years for degree holders
   - ≥ 3 years for diploma and below

3. Able to perform transfer of technology

4. Age > 27 years old for degree holders; Age > 23 years for diploma and below

4. Company must be registered with the Companies Commission of Malaysia and licensed by the relevant local authority

5. Advertisement to recruit locals must be conducted first prior to hiring foreign practitioners

Total 203 practitioners

Based on the number of supporting letters issued by MOH (Jan. 2013 – May 2015)
**Practitioner**

- Local
  - Provisional Registration [S22]
  - 1 year residency
  - Registered Practitioner [S23]
  - Practicing Certificate [S26]
  - renew every 12 months

- Foreigner
  - Temporary Registration [S24]
  - A registered practitioner outside Malaysia
  - Temporary Practicing Certificate
Who?
Council VS registered practitioner [S36(1)]

What?
Jurisdiction VS Punishment

How?
Disciplinary jurisdiction [S36(2)]
Disciplinary punishment [S37]

Mechanism
[S36(3), S60(2)(k)]
T&CM Regulations
Online Public Engagement (till 31/7/15)
(http://tcm.moh.gov.my/v4/bmelayu/modules/mastop_publish/?tac=Seranta_Awam_Atas_Talian)
S48(1). The Minister may, in writing, authorise any medical officer of health, health inspector of the MOH & any local authority, any public officer & suitably qualified person to exercise the power of enforcement under this Act.

**Enforcement power of Authorised Officer**

<table>
<thead>
<tr>
<th>Section</th>
<th>Power</th>
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<td>50.</td>
<td>Power of investigation</td>
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<td>51.</td>
<td>Stop order</td>
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<td>53.</td>
<td>Search &amp; seizure with warrant</td>
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<td>54.</td>
<td>Power to enter premises</td>
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<tr>
<td>55.</td>
<td>Power to take sample</td>
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<tr>
<td>56.</td>
<td>Access to computerised data</td>
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</table>
S63(1). Any **practitioner body who before coming into operation of this Act** undertakes or performs its functions as a governing body of a practice area shall **cease to so undertake** or perform such functions **until it has been designated** as a designated practitioner body under S42.

S63(2). Any register of practitioners kept & maintained by a practitioner body immediately before coming into operation of this Act shall be deemed to be registers kept & maintained under S19 & shall be deemed to form part of such register of practitioners.

S63(3). Any **practitioner who is registered with a practitioner body who before coming into operation of this Act** undertakes or performs its functions as a governing body of a practice area shall apply to be registered under this Act & shall be **exempted from S22 (Provisional Registration).**
Objectives to be achieved

• Ensure **public safety**
• **Professionalism** of T&CM practitioners
• **Empower patients** to be aware of their rights and responsibilities so that they can be alert towards fraudulent / bogus practitioners
Preparation for Enforcement of T&CM Act 2013

• T&CM Regulations

• Establishment of T&CM Council

• Development of residency programmes to satisfy the requirements of provisional registration (training modules for each practice area)

• Proposal for T&CM service scheme (expansion and recruitment)
  – T&CM Council: Secretariat
  – Enforcement team: Headquarters / Regional (nationwide)
  – T&CM units
T&CM Regulations 2015 (Draft)

In exercise of the powers conferred by section 60 of the T&CM Act 2013, the Minister makes the following regulations.

<table>
<thead>
<tr>
<th>PART</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>Preliminary</td>
</tr>
<tr>
<td>II</td>
<td>Registration of practitioners</td>
</tr>
<tr>
<td>III</td>
<td>Traditional and Complementary Medicine Registers</td>
</tr>
<tr>
<td>IV</td>
<td>Disciplinary Proceedings</td>
</tr>
<tr>
<td>V</td>
<td>Miscellaneous</td>
</tr>
</tbody>
</table>

Online Public Engagement (till 31st July 2015)
(http://tcm.moh.gov.my/v4/bmelayu/modules/mastop_publish/?tac=Seranta_Awan_Atas_Talian)
Thank You

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