National Regulatory Conference 2015
"Transformation Towards A New Regulatory Paradigm"

4th-6th August 2015
One World Hotel, MALAYSIA

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

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

Outline

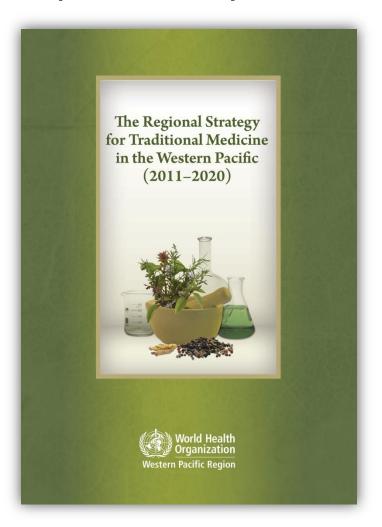
- 1) Updates from WHO perspective
- 2) Overview of T&CM <u>regulatory framework</u> in Malaysia
 - T&CM <u>Act</u> 2013

WHO perspective

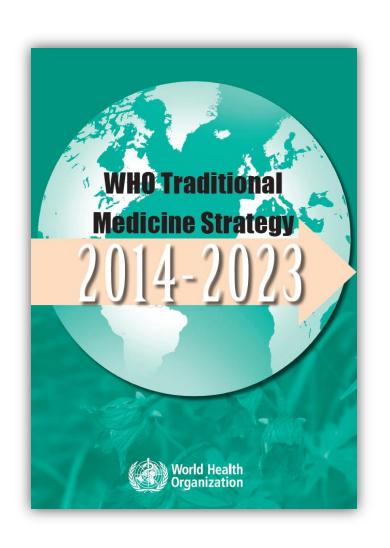
The Regional Strategy for Traditional Medicine in the Western Pacific (2011-2020)

Strategic Objectives

- To include traditional medicine in the national health system
- 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
- To strengthen cooperation in generating and sharing traditional knowledge and skills



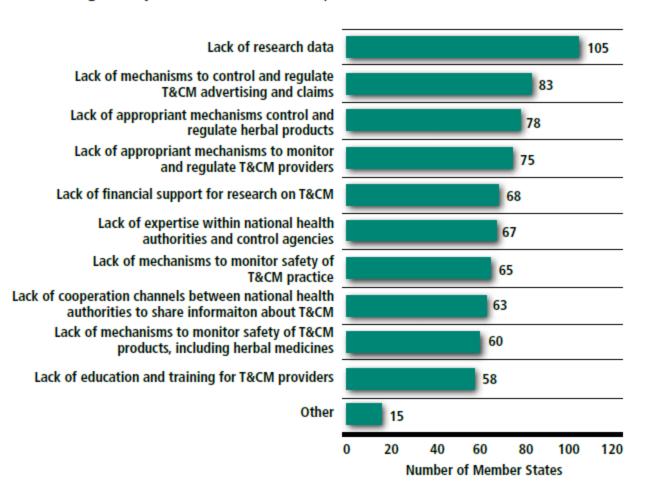
WHO Traditional Medicine Strategy 2014-2023



Strategic Objectives

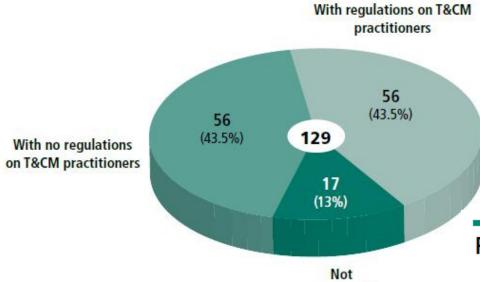
- 1. To build the knowledge base for active management of T&CM through appropriate national policies
- 2. To strengthen quality assurance, safety, proper use and effectiveness of T&CM by regulating T&CM products, practices and practitioners
- 3. To promote universal coverage by integrating T&CM services 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



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

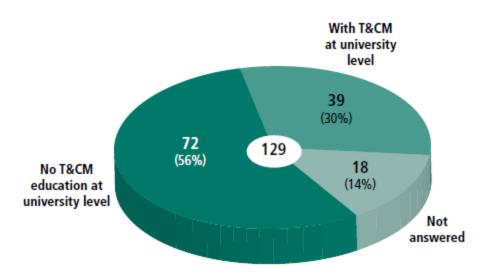
Figure 5: Regulations on T&CM pratitioners



answered

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

Figure 3: T&CM education at university level



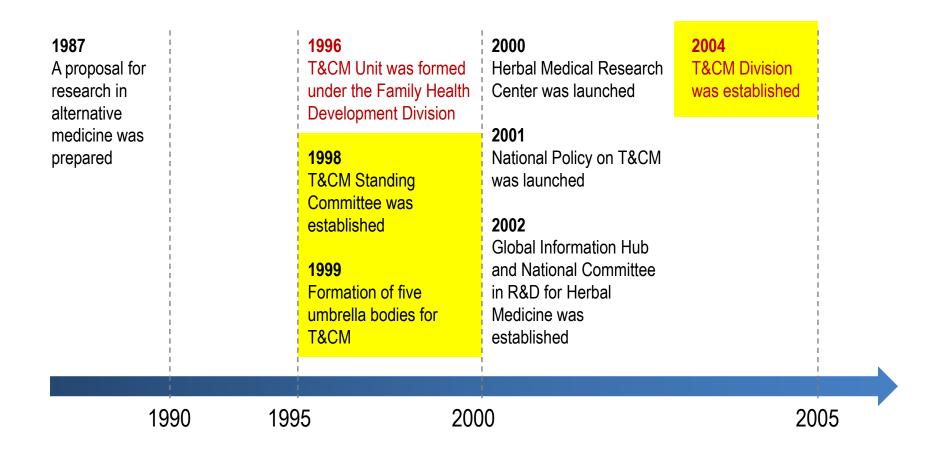
Source: Interim data from 2nd WHO TRM global survey as of 11 June 2012.

How about Malaysia?

Regulatory framework of T&CM in Malaysia

T&CM Act 2013

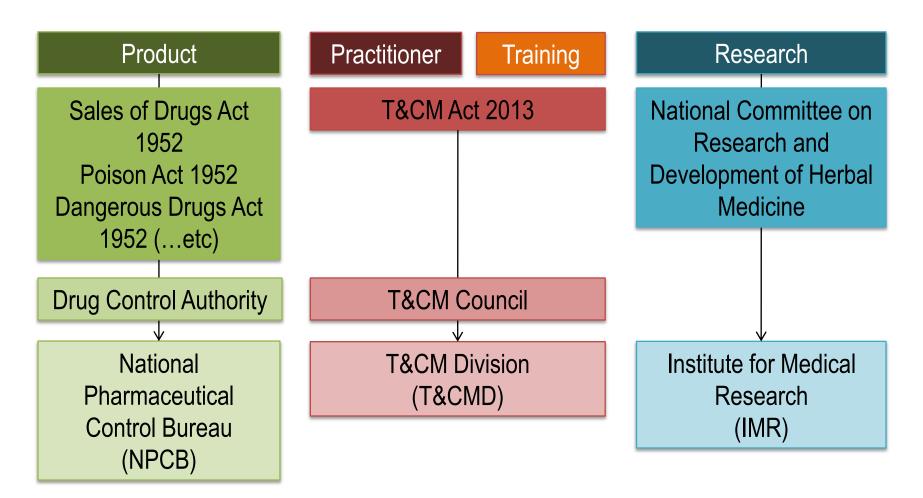
Important milestones in the development of T&CM in Malaysia



Important milestones in the development of T&CM in Malaysia

2007 Kepala Batas Hospital 2008 Putrajaya Hospital Sultan Ismail Hospital 2009 Sultanah Nur Zahirah Hospital Duchess of Kent Hospital	Sultanah Bahiyah Hospital Port Dickson Hospital Sarawak General Hospital T&CM Branch Offices in north, south, east zones and Sarawak were established	Zultanah Hajjah Kalsom Hospital Raja Perempuan Zainab II Hospital T&CM Branch Office in Sabah was established	Cheras Rehabilitation Hospital T&CM Bill 2012 was passed in Parliament	2013 MAWIP Likas Hospital National Cancer Institute T&CM Act 2013 was gazetted Strategy of T&CM in Primary Health Care was launched Masai Health Clinic	2014 Jasin Hospital	2015 T&CM Branch Office in Perak was established
2005	2010 2	011 2	012	2013	2014	2015

Regulatory Divisions within the Ministry of Health related to the T&CM sector in Malaysia



Regulate the practice of T&CM practitioners

Facilitate and as a collaborator for research and scientific evaluation of T&CM

T&CM Division

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

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

Establish a registry of all T&CM practitioners

Facilitate the development of standards and criteria in T&CM

Institutions providing T&CM courses in Malaysia

No.	Institutions		Courses Offered
1.	Southern College Skudai	a.	Bachelor Degree of Traditional Chinese Medicine 3+2
2.	Tunku Abdul Rahman University Sungai Long Campus	a.	Bachelor of Traditional Chinese Medicine (Hons)
3.	INTI International University College	a.	Bachelor of Traditional Chinese Medicine (Hons)
4.	Cyberjaya University College of	a.	Bachelor of Homeopathy (Hons)
	Medical Sciences (CUCMS)	b.	Diploma in Islamic Medical Practices
5.	Management and Science University	a.	Bachelor in Traditional Chinese Medicine (Hons)
	(MSU)	b.	Diploma in Traditional Chinese Medicine
6.	International Medical University (IMU)	a.	Bachelor of Science (Hons) Chinese Medicine
		b.	Bachelor of Science (Hons) Chiropractic
7.	Malacca College of Science and	a.	Diploma in Natural Medicine
	Management		
8.	Lincoln University College	a.	Diploma in Traditional Chinese Medicine
	(Main Campus)		

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]

Focus On Practice & Practitioner Only

Part I: Preliminary

11 Parts 63 Sections

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: <u>Disciplinary Proceedings</u>

Part VII: Patient's Rights

Part VIII: T&CM Practitioner Body

Part IX: Enforcement

Part X: General

Part XI: <u>Transitional</u> Provision

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

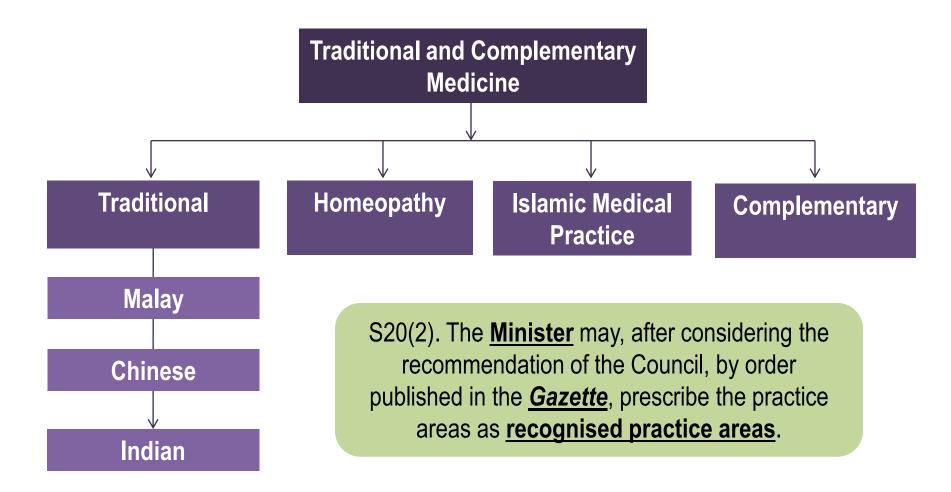
Date of Enforcement:
To be determined by
Minister of Health

(BY PHASES)

Practice of T&CM

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.

Common T&CM Practices in Malaysia



Regulatory Mechanism

- A person intending to <u>practice T&CM in any recognised practice area shall apply to</u>
 the T&CM Council to register and shall comply with any qualifications as specified by the T&CM Council for that recognised practice area.
 Statutory regulation (Multi-profession)
- S23(3). A practitioner may be registered in <u>one or more recognised practice areas</u> if he satisfies the eligibility requirements for those practices areas and has paid the prescribed fee.
- S25. A person who is <u>not a registered practitioner shall not, directly or indirectly practice T&CM services</u>.

Offence	Penalty
1 st offence	Fine not exceeding RM 30,000 / imprisonment not exceeding 2 years / both
Subsequent offence	Fine not exceeding RM 50,000 / imprisonment not exceeding 3 years / both

Transformation from <u>Self</u>-Regulation to <u>Statutory</u>-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.

T&CM Council

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

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, <u>delegate any of its functions</u> as may be appropriate to –

- (a) any designated practitioner body;or
- (b) any person as the Council deems fit.

S6(1)(e). 5
individuals who
possess
sufficient
experience &
expertise in the
relevant industry

S6(1)(a). ≤ 3 representatives from MOH

T&CM Council (≤ 21 + 1) S6(1)(b). 2
representatives
from local
universities with
expertise in T&CM
fields

S6(1)(d). ≤ 8
individuals from
private practice
representing the
designated T&CM
practitioner bodies
in Malaysia

S6(1)(c). ≤ 3

registered

practitioners in the public service

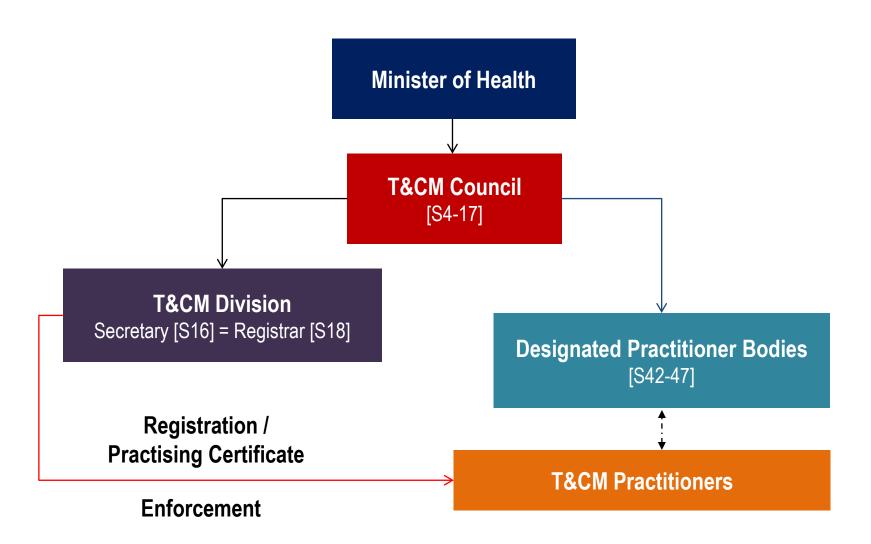
Functions of T&CM Council

- 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 <u>recognise qualifications</u> 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 <u>apprenticeship and training requirements</u> 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;

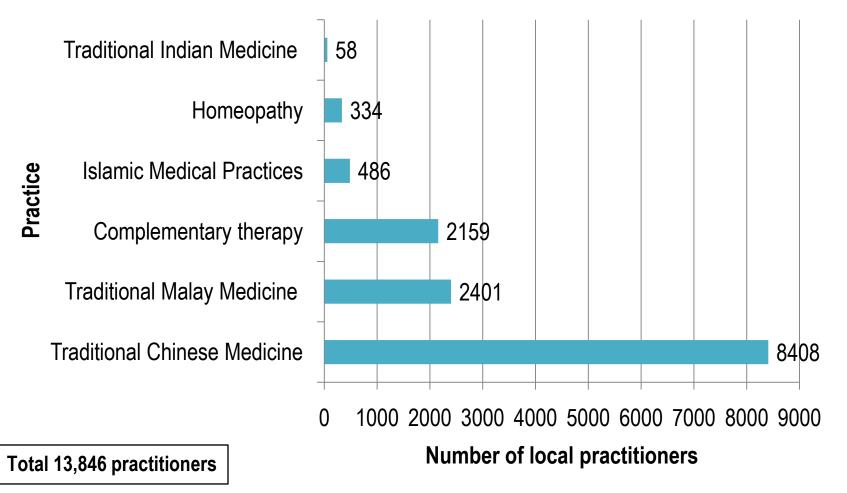
Functions of T&CM Council

- g) to <u>issue practising certificates</u> to registered practitioners who have satisfied the prescribed conditions and paid the prescribed fees;
- h) to develop <u>codes of professional conduct</u>, 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 <u>refer</u> their patients to medical practitioners or dental practitioners, as the case may be;
- to obtain such relevant <u>information</u> 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



Local Practitioners

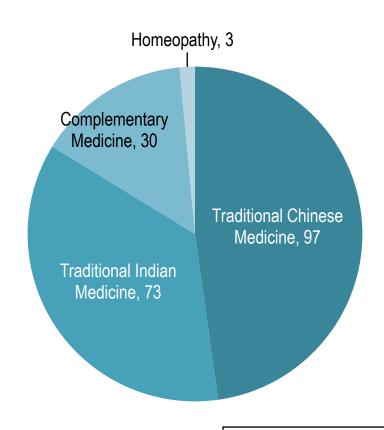


^{*} Voluntary registration with MOH (e-Pengamal) (Nov. 2008 – May 2015)

Foreign Practitioners

Criteria to be fulfilled:

- 1. Must possess basic qualifications relevant to the area of practice
- 2. Have adequate working experience
 - \geq 5 years for degree holders
 - ≥ 3 years for diploma and below
- 3. Able to perform transfer of technology
- Age ≥ 27 years old for degree holders;
 Age > 23 years for diploma and below
- Company must be registered with the Companies Commission of Malaysia and licensed by the relevant local authority
- 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

Registration flow

- Local

Provisional Registration [S22]

1 year residency

Registered Practitioner [S23]

Practicing Certificate [S26]

renew every 12 months

- Foreigner

Temporary Registration [S24]

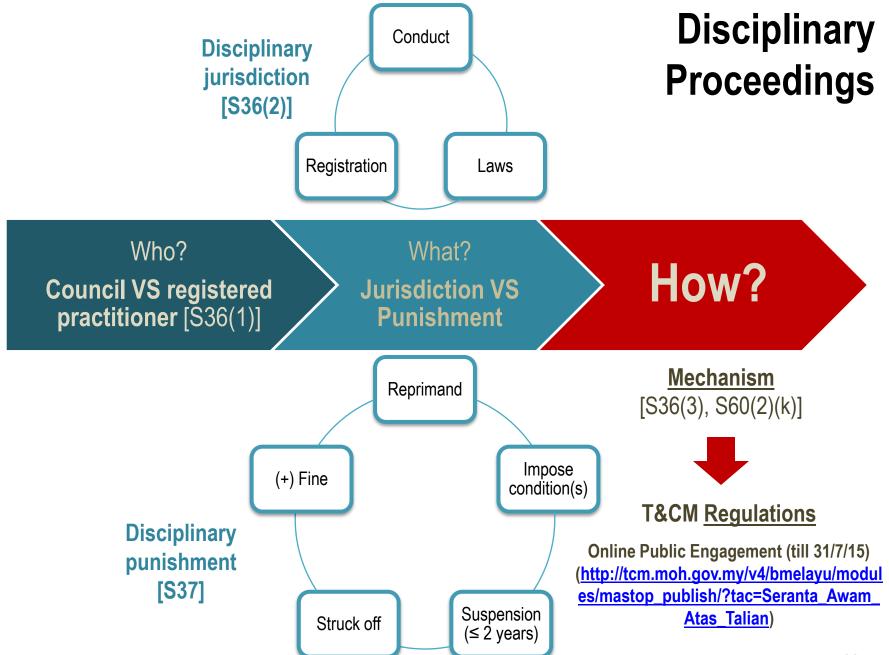


A registered practitioner outside Malaysia



Temporary Practicing Certificate

Obligations & S29. Use of **Duties of** titles & abbreviations Registered S35. Mandatory S30. Duty to refer patients practice **Practitioners** standards in to medical or dental governance & practice codes practitioner **Obligations & Duties of** S31. Duty to Registered S34. report any **Practitioners** epidemic or other Registered localised practitioners outbreaks of may incorporate diseases, etc., to the Registrar S33. S32. Use of Advertisement medical device & promotion



Enforcement

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

Section	
50.	Power of investigation
51.	Stop order
53.	Search & seizure with warrant
54.	Power to enter premises
55.	Power to take sample
56.	Access to computerised data

Transitional

S63(1). Any <u>practitioner</u>
<u>body who before</u>
<u>coming into operation</u>
<u>of this Act</u> undertakes or
performs its functions as
a governing body of a
practice area

S63(2). Any register of practitioners kept & maintained by a practitioner body immediately before coming into operation of this Act

S63(3). Any <u>practitioner</u> 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 <u>cease to so</u>
<u>undertake</u> or perform such functions <u>until it</u>
<u>has been designated</u>
as a designated practitioner body under S42.

Shall be deemed to be registers kept & maintained under S19 & shall be deemed to form part of such register of practitioners.

Shall apply to be registered under this Act & shall be exempted from S22 (Provsional Registration).

Objectives to be achieved

- Ensure <u>public safety</u>
- 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 <u>Regulations</u>
- Establishment of T&CM <u>Council</u>
- Development of <u>residency</u> 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.

PART	
- 1	Preliminary
II	Registration of practitioners
III	Traditional and Complementary Medicine Registers
IV	Disciplinary Proceedings
V	Miscellaneous

5 Parts 27 Regulations

Online Public Engagement (till 31st July 2015)

(http://tcm.moh.gov.my/v4/bmelayu/modules/mastop_publish/?tac=Seranta_Awam_Atas_Talian)

