THE IMPORTANCE OF INTERNATIONAL STANDARDS

DR DAVID GRAHAM, CHAIR, ISO/TC 249

THE ISSUE

The use of TCM is expanding rapidly across the world yet, in many countries, there is little or no quality control around the products or practitioners .

How will this situation adversely impact on the consumer, trade and the future acceptance of TCM?

How can countries be encouraged and assisted to ensure the quality of TCM in their markets?

WHAT OUTCOMES ARE NEEDED?

- protect public health and safety
- protect the integrity, quality and reputation of TCM and related TMs
- support national and international trade and commerce

THE OBJECTIVE

The aim is to provide international standards to assist countries to sensibly and appropriately manage TCM and related products and services in their markets

International standards:

- Provide a resource for countries to establish quality control of products and procedures
- Smooths out variations across markets due to differences between national standards and requirements

ISO DEFINITION OF A STANDARD

'A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure materials, products, processes and services are fit for their purpose'

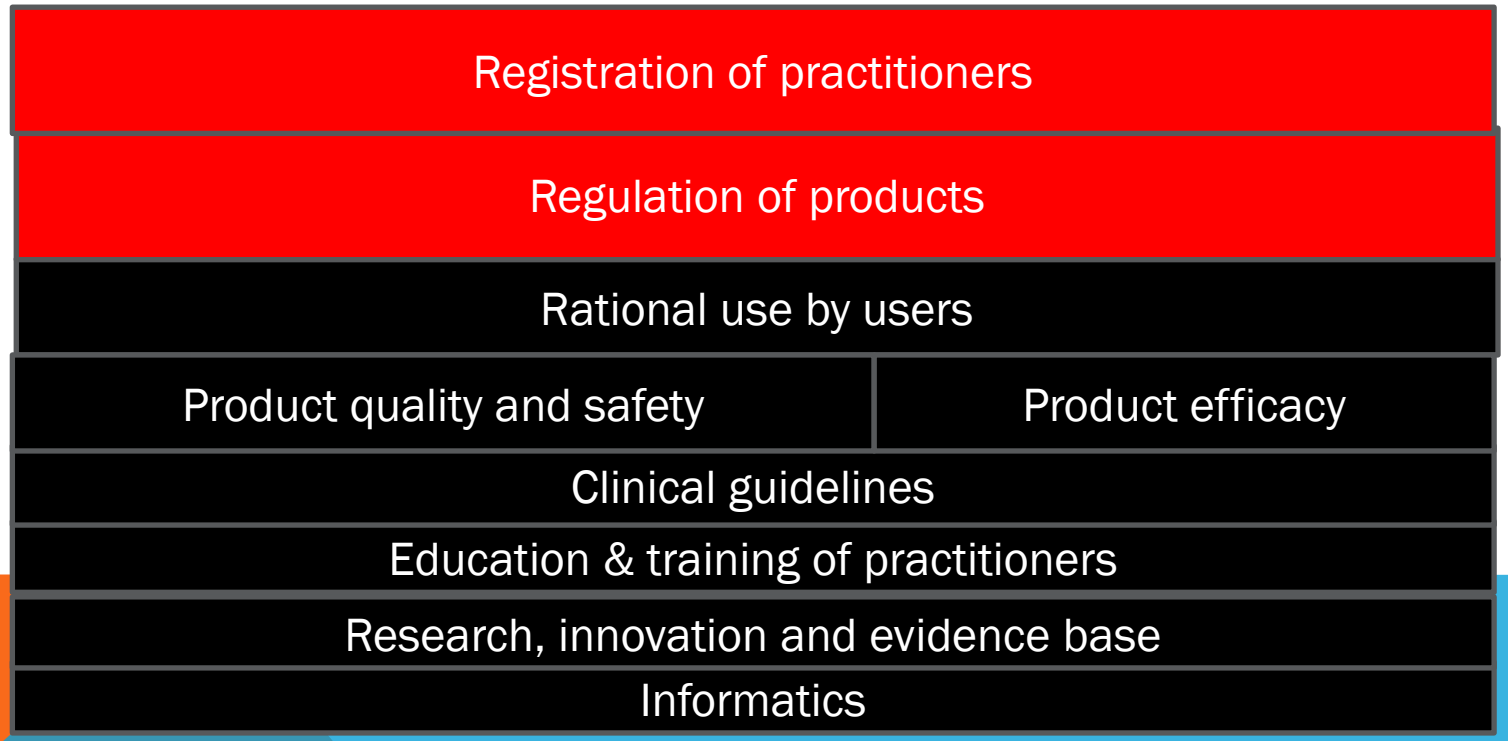
ISO is the largest standards development organisation and its standards are globally recognised and accepted.

ISO agreed to establish ISO/TC 249 initially in the area of TCM

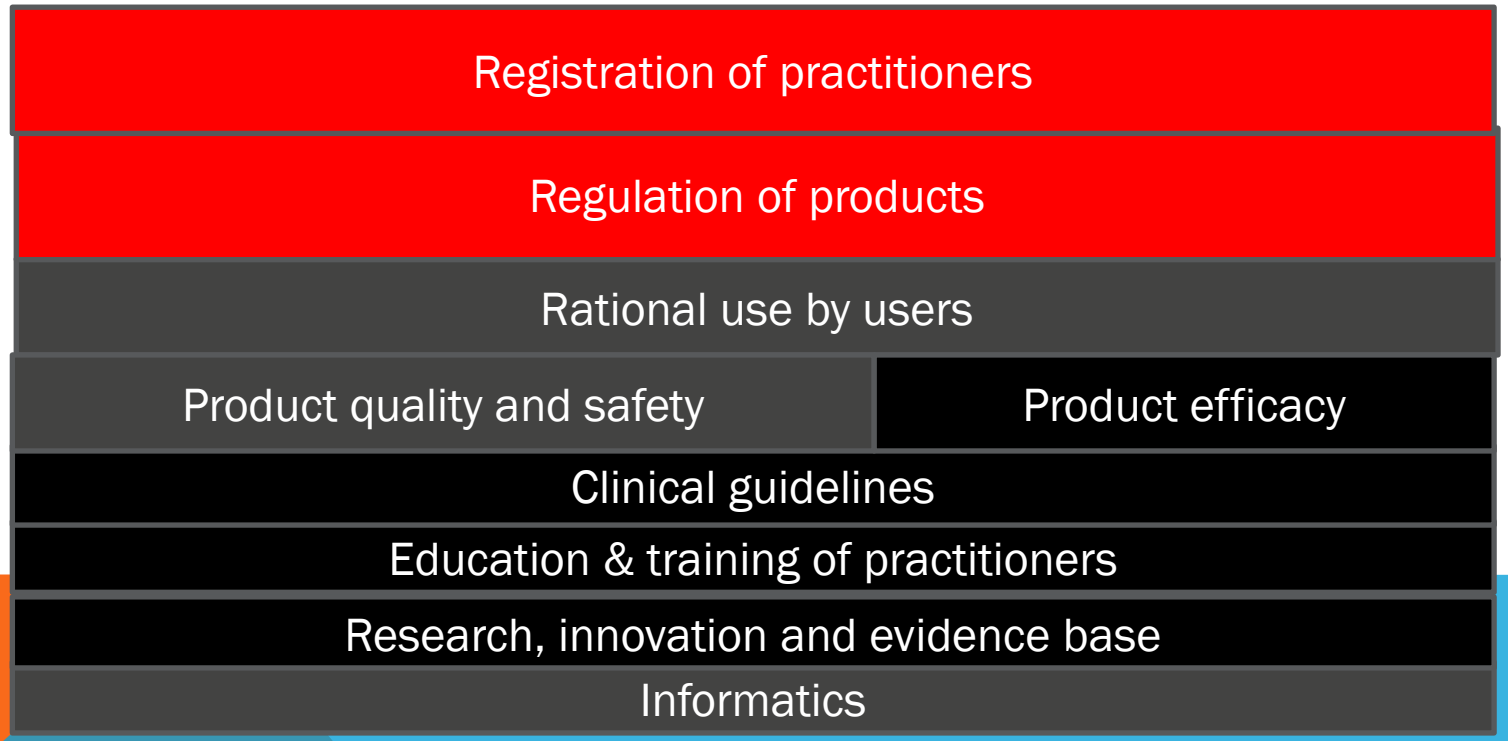
THE BENEFITS OF AN INTERNATIONAL STANDARD

- Underpins the international use and acceptable practice of a health modality
- Assists global consistency, e.g. practice, terminology, common understanding
- Protects the reputation of the modality
- Assists in setting national standards
- Assists harmonisation, trade and information exchange
- Protects the community
- Assists acceptance and use of the health modality
- Supports integration within health care more generally

Elements of a medical system



Technical areas covered by ISO/TC 249



CURRENT STRUCTURE OF ISO/TC 249

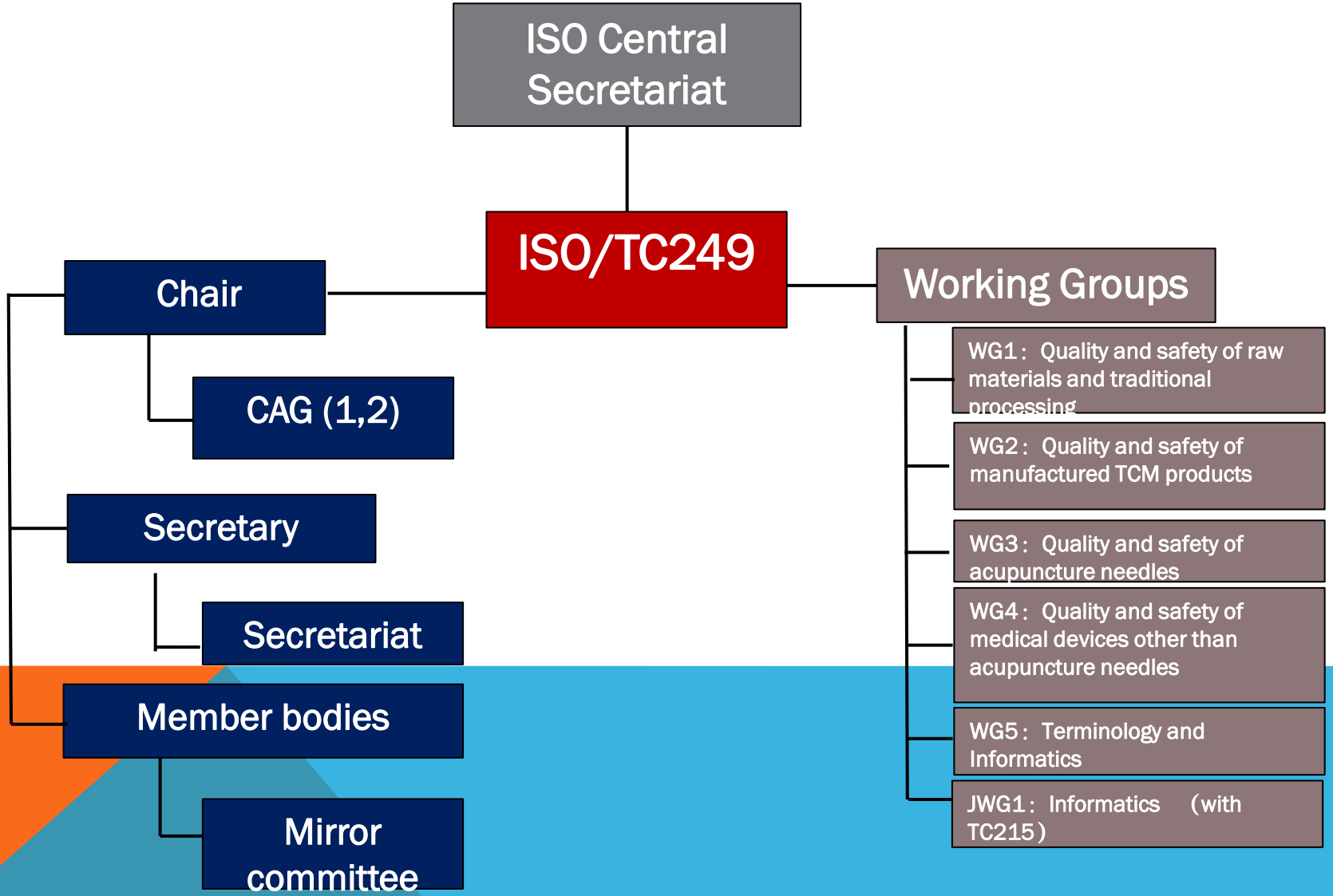
Main Technical Committee

5 Working Groups :

- WG 1: Quality and safety of raw materials and traditional processing
- WG 2: Quality and safety of manufactured products
- WG 3: Quality and safety of acupuncture needles
- WG 4: Quality and safety of other medical devices
- WG 5: Terminology and Informatics

One joint working group with ISO/TC 215 (health informatics)

STRUCTURE


ISO Central Secretariat
ISO/TC249
Chair
CAG (1,2)
Secretary
Secretariat
Member bodies
Mirror committee
Working Groups
WG1：Quality and safety of raw materials and traditional processing
WG2：Quality and safety of manufactured TCM products
WG3：Quality and safety of acupuncture needles
WG4：Quality and safety of medical devices other than acupuncture needles
WG5：Terminology and Informatics
JWG1：Informatics （with TC215）

COUNTRIES PARTICIPATING IN ISO/TC 249

Participating Countries (21)		Observing Countries (14)
Australia (SA)	Mongolia (MASM)	Barbados (BNSI)
Austria (ASI)	Netherlands (NEN)	Finland (SFS)
Canada (SCC)	Singapore (SPRING SG)	France (AFNOR)
China (SAC)	South Africa (SABS)	Hong Kong (ITCHKSAR) (Correspondent member)
Czech Republic (UNMZ)	Spain (AENOR)	Ireland (NSAI)
Germany (DIN)	Switzerland (SNV)	Israel (SII)
Ghana (GSB)	Thailand (TISI)	Lithuania (LST)
India (BIS)	Tunisia (INNORPI)	New Zealand (SNZ)
Italy (UNI)	USA (ANSI)	Poland (PKN)
Japan (JISC)	Viet Nam (STAMEQ)	Romania (ASRO)
Korea, Republic of (KATS)		Seychelles (SBS) (Correspondent member)
		Sweden (SIS)
		United Kingdom (BSI)
		Zimbabwe (SAZ)

LIAISON ORGANISATIONS FOR ISO/TC 249

ISO/TC249

- **TC215** — Health informatics
- **WHO** — World Health Organization
- **WFCMS** — World Federation of Chinese Medicine Societies
- **WFAS** — The World Federation of Acupuncture-Moxibustion Societies

ISO CRITERIA FOR GLOBAL RELEVANCE OF STANDARDS (DIRECTIVES, PART 1, ANNEX SM)

- Meets regulatory and market needs
- Does not distort the market
- Does not impair fair competition
- Does not stifle innovation and technological development
- Performance based, not design prescriptive

OVERALL PROGRESS OF ISO/TC249 PROJECTS

Published	DIS	Ready for DIS	CD	WD	AWI
2	3	2	2	3	9

WG1	WG2	WG3	WG4	WG5	JWG1
2	3	1	7	3	4

There are 19 projects are within TC249 work programme and 15 NWIPs are under way of NP balloting.

PUBLISHED INTERNATIONAL STANDARDS

ISO 17217-1:2014
Traditional Chinese medicine – Ginseng seeds and seedlings – Part 1: Panax ginseng C.A. Meyer

ISO 17218:2014
Sterile acupuncture needles for single use

CHALLENGES IN MOVING FORWARD

- Much of TCM is based on observation and experience over extended periods of time rather than what is now called scientific evidence.

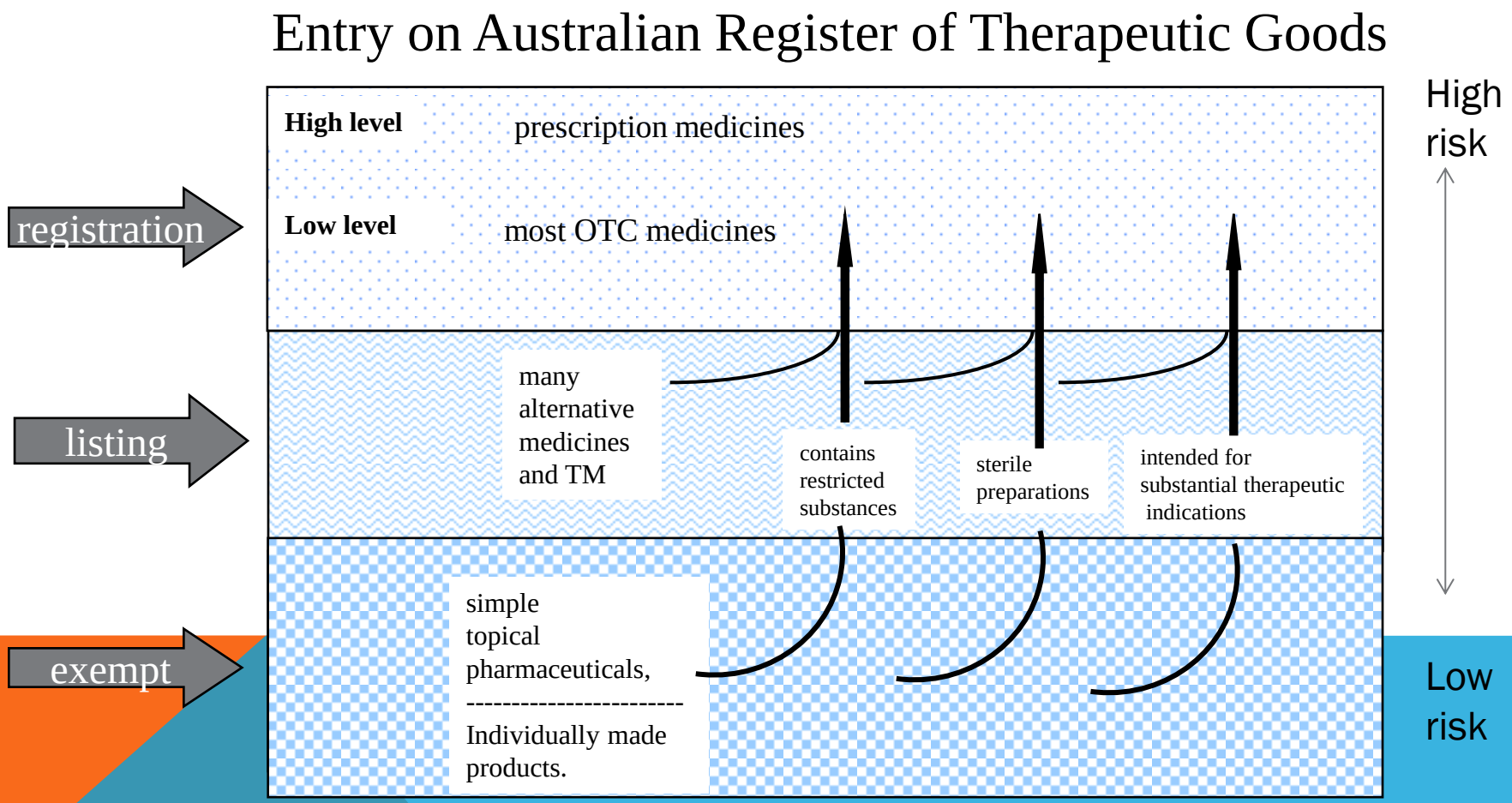
  How can or will governments use these observational histories to ensure the welfare of their citizens?

- TCM is continually being modernised through new presentations, through new formulations and through new methods of manufacture.

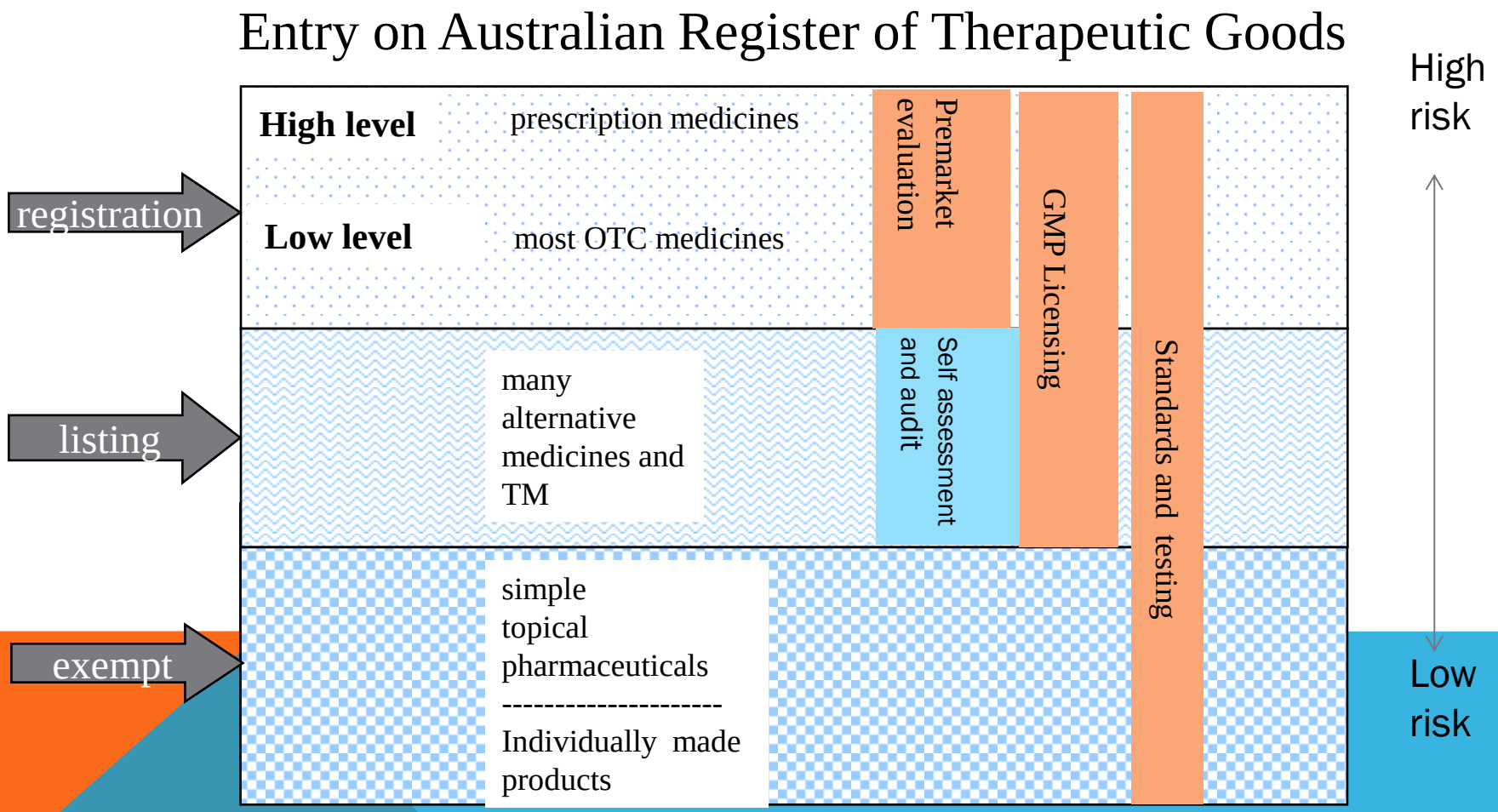
  How can or does the traditional history apply to modernised products ?

Using Australia as an example

Risk-managed regulation of medicines

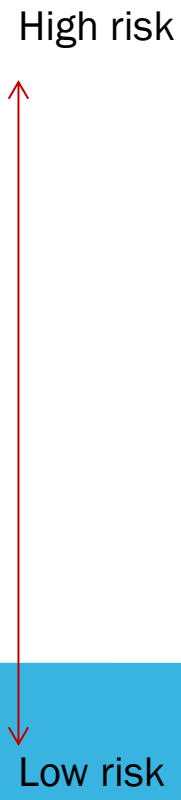


Risk-managed regulation of medicines



Levels of evidence for efficacy

	Type	Method	Evidence
Prescription Medicine	Registered medicine	Independent evaluation of evidence	Scientific : RCT/ Metaanalysis
OTC Medicine	Registered medicine	Use of approved active substance	Scientific
TM/CAM	Listed medicine	Self certification that suitable evidence held. Audit	Traditional and/or scientific
Individual patient medication	Exempt from Register	Informed consent by patient	Practitioner expertise (registration)



INTERNATIONAL STANDARDS (OR GUIDELINES) PROVIDE A FUNDAMENTAL AND HARMONISED RESOURCE TO ASSIST COUNTRIES TO ENSURE THE QUALITY CONTROL OF PRODUCTS AND SERVICES

Thank You