

Traditional knowledge and genetic resource (TK & GR), Traditional medicine and biodiversity and benefit sharing: what Thailand should do

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TPP - Chapter 18 - Intellectual Property

- Article 18.16: Cooperation in the Area of **Traditional Knowledge**
 - 1. The Parties recognise the relevance of intellectual property systems and traditional knowledge associated with genetic resources to each other....
 - 2. The Parties shall endeavour to cooperate...to enhance the understanding of issues connected with **traditional knowledge associated with genetic resources, and genetic resources**
 - 3. The Parties shall endeavour **to pursue quality patent examination**, which may include:

TPP- Patent examination

- (a) that in determining **prior art**, relevant publicly available documented information related to **traditional knowledge** associated with genetic resources may be taken into account;
- (b) an opportunity for third parties to cite, in writing... prior art disclosures that may have a bearing on patentability, including prior art disclosures related to **traditional knowledge** associated with **genetic resources**
- (c) ..., the **use of databases or digital libraries** containing **traditional knowledge** associated with genetic resources; and
- (d) cooperation in the **training of patent examiners** in the examination of patent applications related to **traditional knowledge** associated with genetic resources.

WHO and traditional medicine-1

- May, 2009: World Health Assembly adopted the Beijing Declaration on Traditional Medicine
 - “Traditional medicine should be further developed based on research and innovation in line with the **"Global strategy and plan of action on public health, innovation and intellectual property"** ... WHA61.21...
 - Governments, international organizations and other stakeholders should collaborate in implementing the global strategy and plan of action”.

WHO and traditional medicine-2

- **24 May 2014: WHA67.18 - Traditional medicine**
Recalling resolutions ...WHA61.21,...on traditional medicine...to update the WHO traditional medicine strategy 2002–2005

- The New WHO Global TRM strategy 2014-2023 was endorsed

Global Strategy and plan of action on public health, innovation and intellectual property – GSPA-PHI- WHA61.21

Element 1. Prioritizing research and development needs

(1.3) encouraging research and R&D in **traditional medicine** (TM) in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples

(a) set research priorities in **TM**

(b) support developing countries to build their capacity in R&D in **TM**

(e) support early-stage drug R&D in **TM** systems in developing countries

Element 3. Building and improving innovative capacity

● need to frame and develop and support effective policies that promote the development of capacities in developing countries related to health innovation.

● Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, **intellectual property and TM**

Element 3 devoted to TM

3.4) supporting policies that will promote innovation based on **TM** within an evidence-based framework in accordance with national priorities and taking into account ... international instruments

- (a) establish and strengthen national and regional policies to develop, support, promote **TM**
- (b) encourage and promote policies on innovation in the field of **TM**
- (c) promote standard setting to ensure the quality, safety and efficacy of **TM**, including by funding the research necessary to establish such standards
- (d) encourage research on mechanisms for action and pharmacokinetics of **TM**
- (e) promote South-South collaboration in **TM**
- (f) formulate and disseminate guidelines on good manufacturing practices for **TM** and laying down evidence-based standards for quality and safety evaluation.

RESOLUTION

OF THE

WHO REGIONAL COMMITTEE FOR SOUTH-EAST ASIA

SEA/RC59/R9

INTERNATIONAL TRADE AND HEALTH

- To ensure the involvement of health ministries in the process of negotiating trade agreements in order to identify opportunities and mitigate the possible risks of these agreements with regard to public health
- To develop capacity in relevant ministries in the assessment of the implications of international trade agreements on health of the population in order to effectively participate in the trade negotiation
- to improve the capacity of the National Regulatory Authorities
- to continue to assist Member States in their efforts to build capacity, and identify and assess the public health implications of international trade agreements;
- to provide technical support and expertise to Member States to draft policies, laws and regulations or establish practices and to promote the exchange of information among **Member States to address public health challenges and leverage opportunities to improve health in the context of international trade agreements**
- to mobilize resources to support the works related to Trade and Health
- to assist Member States in developing necessary legal and economic frameworks within the country to avail of the flexibilities allowed in TRIPS Agreements,
- to assist Member States in strengthening their National Regulatory Authorities.

Sri Lanka

- Assessment tool developed for GSPA -Sri Lanka
 - 28-29 April 2014: "Promoting innovation and access to health products in Sri Lanka by National Assessment Tool" assessment tool developed for GSPA
 - 26 September 2014: "Second National Consultation on Promoting innovation and access to health implementation GSPA"
 - Report formally accepted by MOH on 13 March 2015

Outcomes of India and Sri Lanka study on TM

● Challenges

- Large informal sector -Quality assurance and control in manufacture
- Communication between the policy makers of Western medicine and Ayurvedic medicine is not adequate- developing the pharmacopaeia
- Lack of trained resource person in herbal product regulation bodies.
- Focus on pharmacovigilance inadequate
- legal classification of herbal drugs
- Trade specific challenges: food products use for medicinal purposes
 - Monoculture- interrupt or displace **traditional** forms
 - Sustainability of **traditional** processes for the preservation of biological and plant resources
- Patent issue in medicinal products -Traditional Knowledge Digital Library launched by the Government of India, is an example.
- IPR management

Proposed Strategic Objectives, Expected Outcomes and Indicators for Traditional, Complementary and Alternative Medicine (T/CAM) in SEAR

Strategic Objective	Expected outcome	Proposed Indicator
SO4. To promote protection and sustainable use of traditional medicine resources	Mechanisms for the protection and sustainable use of traditional medicine resources are established	<p>Access to databases for patent knowledge to enable development of sustainable management systems related to T/CAM</p> <p>Information for conservation and cultivation program for endangered species of traditional medicinal plants and non plant products</p>

Traditional medicine (TM) is unique

- TM source of some modern antimalarial drugs (artemisinin and quinine derivatives)
- TM presents public health challenges.
 - WHO: "inappropriate use of traditional medicines or practices can have negative or dangerous effects" ... "further research is needed to ascertain the efficacy and safety" of many TM practices
- becoming a lucrative, multinational business:
 - in 2012, 32 billion dollars spent in US on dietary supplements, projected to increase to 60 billion dollars in 2021: Nutritional Supplements Flexing Muscles As Growth Industry: <http://www.forbes.com/sites/davidlariviere/2013/04/18/nutritional-supplements-flexing-their-muscles-as-growth-industry/#2158eeb24255>

Intellectual Property Rights, Protection of Plant Varieties

- TRIPS Art 27 (3): protection of plant varieties through an effective sui generis system
- The International Union for the Protection of New Varieties of Plants (UPOV)
 - The Plant Variety Protection Act B.E.2542 (1999) (Thailand) ('PVP Act of Thailand')

Convention on Biodiversity (CBD)

- CBD: June 5, 1992
 - Access to genetic resources subject to prior informed consent Art 15 (5)
 - Sharing results of research Art 15 (7)
 - Policing obligations mandatory disclosure of sources of plant genetic resources in patent applications ; not as condition of patentability but fines

New Models of Benefit Sharing

- Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits- WHA64.5, 24 May 2011
- TM: sui-generis protection : plant genetic resources maintained by long-term occupant communities : indigenous peoples
 - Research leads by TK : bio prospecting leading to drug development
 - Sustainability and compensation by large multi-national pharmaceuticals, agribusiness, and biotech firms
 - IPR Management models
- Promoting diversity for future innovation – product differentiation in agreements

New forces –technology and internet: Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014

Option 1

Option 2



Acknowledgements

- WHO, Public health innovation and intellectual property rights: report of the commission on intellectual property rights, innovation and public health, (WHO 2006), at 161
- WHO, “Fact Sheet no. 134: Traditional Medicine,” (May 2003), available at <http://www.who.int/mediacentre/factsheets/2003/fs134/en/>.
- Documenting Traditional Medical Knowledge, Prepared by, Ryan Abbott, M.D., J.D., M.T.O.M. March 2014, World Intellectual Property Organization.

Thank you