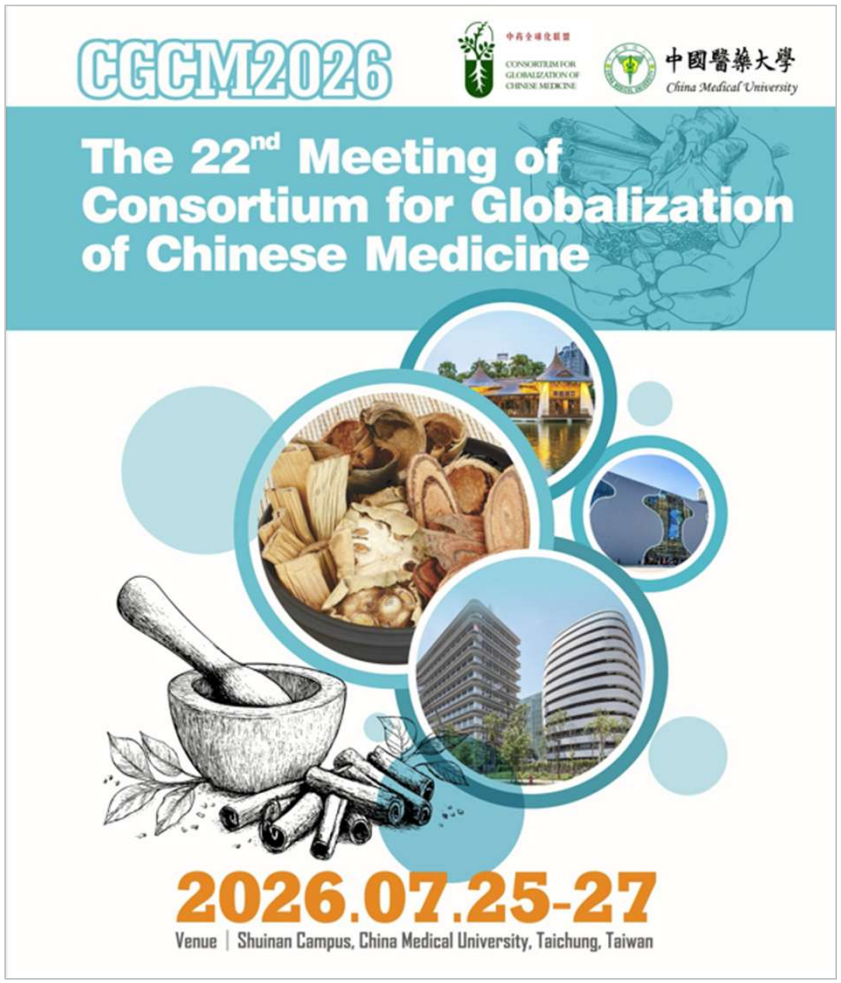



# Regulations and Interregional Collaborations in Academia, Government, and Industry Session

**25 July 2026 14:30-17:30 (180 min)**

# Agenda: Regulations and Interregional Collaborations in Academia, Government, and Industry Session

***Chairpersons Welcome (2 min)***

- Mr. Peikwen CHENG – Chairperson - Co-Founder and CEO, Yiviva; Co-President, Stanford Alumni in Healthcare

**Regional Regulations and Collaborations (165 min)**

Moderators (5 min)

- Dr. Qihe XU – Co-Chairperson - Director, The King's Centre for Integrative Chinese Medicine; Faculty, King's College London
- Dr. Jinhui DOU – Co-Chairperson; former Botanical Review Team Leader, Center for Drug Evaluation and Research (CDER), FDA

Speakers (160 min)

- Taiwan – Dr. Yi-Chang SU, Director, National Institute of Chinese Medicine (20 min)
- Hong Kong – Mr. Yu Ling Abraham CHAN – Founder, Chairman, CEO & Executive Director, PuraPharm; TCM All-sector Hong Kong Centre and the Shouchuang Chinese Medicine Initiative (20 min)
- Mainland China – Mr. Peikwen CHENG – Overview of "Dual-driven by regulatory science and policy reconstruction: Traditional Chinese medicine (TCM) new drugs accelerate development - A critical review of highlights in registration and regulation of TCM and natural medicine new drugs in China (2021—2025)" (15 min)
- United States – Dr. Jinhui DOU – Co-Chairperson; former Botanical Review Team Leader, Center for Drug Evaluation and Research (CDER), FDA (20 min)
- Europe – Dr. Rudolf BAUER, Emeritus Professor, University of Graz - (20 Min)
- International – Dr. Qihe XU - Advancing Traditional, Complementary and Integrative Medicine: International Standards Are Now Available (15 min)
- Yiviva – Mr. Peikwen CHENG – Advancing Botanical Medicines Globally: Case study – YIV-906 (15 min)
- United Kingdom – Mr. George HE – Executive Director, UK Centre of Chinese Medicine (CCMUK), Resilience, Reconfiguration and Adaptive Innovation: Multi-dimensional Governance of Sustainable Chinese Medicine Supply Chains in the UK under VUCA Conditions (15 min)
- Australia – Dr. Yu-Ting SUN - Professional identity and sense of belonging in the Traditional Chinese Medicine workforce: implications for integration and sustainability (10 min)
- Vietnam – Dr. Huynh Thi Luu Kim HUONG - Regulation and Scientific Collaboration in Vietnamese Traditional Medicine: Insights from University – Hospital Partnerships (10 min)

**Overall Q&A (10 min)**

**Closing remarks (3 min)**

01

TAIWAN

*Prof. Yichang Su*
*Director of National Research Institute of Chinese Medicine (NRICM)*
*Director-General of Department of Chinese Medicine and Pharmacy*
*Ministry of Health and Welfare, Taiwan*

# A New Era for TCM New Drug Development in Taiwan

- Administrative goal shifted from management to development (regulations as **enabler** vs gatekeeper)
- Dual track: **real-world evidence alongside randomized trials**
- Amendment of the **New TCM Clinical Trials Guideline**, a draft Guideline on **Acceptance of RWE**, and a three-phase framework for reclassifying products as **OTC by use and safety** rather than by preparation type.
- Innovation Park and NRICM **restructuring** by 2027

**8 months**

NRICM 101 moved from clinical guideline to licensed drug and European export in eight months; roughly four million people worldwide have now used

02

HONG KONG

*Mr. Abraham Chan*
*Founder, Chairman & CEO, PuraPharm;*
*Shouchuang Chinese Medicine Initiative*

## Hong Kong: The Global Trust Hub for High-Quality Chinese Medicinal Herbs Introducing the Shouchuang Trading Platform

- The quality bottleneck sits upstream, at the **raw material**
- Hong Kong as a **neutral trust hub** for global trade
- **Certified suppliers, batch testing, escrow-protected payment**

- transparent and reliable bridge between high-quality growers in the East and discerning users in the West,
- Solving the critical challenge of sourcing herbs that are verifiably compliant with **specific international standards**.

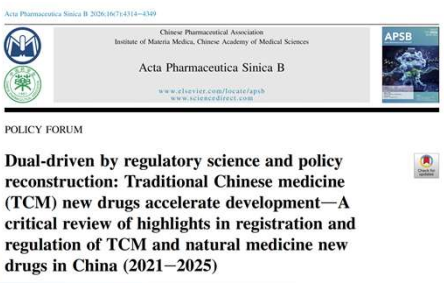
**44 herbs**

in the Phase 1 catalogue, launched 9 April 2026

守創
SHOUCHUANG
守創中藥貿易平台

03

MAINLAND CHINA




*On behalf of Zhao J., Chen S, Tang J et al. (2026), Acta Pharmaceutica Sinica B*
*Summarized and presented by Peikwen Cheng*

# Dual-Driven Regulatory Science & Policy Reconstruction

- **Regulatory science and policy reconstruction**, purpose-built for TCM
- Three combinations Registration Review - progressive evidence chain: **TCM theory, human experience, clinical trials**
- Four categories: **Innovative TCM, Modified TCM, Classical Formulas, Same Name and Formula**
- Article 75 raises bar for marketed TCM

**7×**

more new TCM drugs approved, 2021–2025 versus 2016–2020 (74 vs 11)

Zhao J. et al. (2026), Acta Pharmaceutica Sinica B, 16(7):4314–4349. doi:10.1016/j.apsb.2026.05.027 (open access).

04

UNITED STATES

*Dr. Jinhui Dou — former Botanical Review Team Leader, CDER, US FDA*

## From Farms and Labs to Patients - Case Studies on Advancing Botanicals and TCM Natural Products to New Drugs and Biologics

- **Product-focused**: the entire mixture is the drug, identification of active constituents is not essential, and relevant bioassays can support quality
- **Prior human use eases early phases**, not confirmatory trials (often two Phase III). US patient data is required, but the US share can be modest:
- **CMC and GMP** are the most underestimated hurdles

**4**

plant-mixture botanicals approved since the 2004 guidance. Veregen (2006), Fulyzaq/Mytesi (2012), NexoBrid BLA (2022) and Filsuvez (2023)

05

EUROPE


*Prof. Rudolf Bauer*
*Emeritus Professor, University of Graz; former Chair, TCM Working Party, EDQM*

## The European Herbal Market and Regulatory Landscape

- Three routes: 1) **full marketing authorization** (complete preclinical and clinical dossier), 2) **well-established use** (10 years on market plus at least one clinical study), and 3) **traditional use** registration (30 years' use, 15 in the EU, no trial required — but restricted to mild, OTC-appropriate indications. All three demand a complete quality dossier.
- Market drifting from registered medicines to **food supplements**
- 103 TCM monographs at Ph. Eur. — none yet at EMA. Only about **seven TCM products are registered** in Europe, nearly all single-plant preparations.

**€15B**

European herbal product market in a single quarter (Q4’25). led by Germany, Italy, France, Poland and Spain

06

INTERNATIONAL

*Dr. Qihe Xu*
*Director, The King's Centre for Integrative Chinese Medicine, King's College London*

## Advancing Traditional, Complementary and Integrative Medicine: International Standards Are Now Available

- Integration must be built on **integrity** and "**evidence-based**". Objective (vs subjective) measures
- Scoping review across 11 countries and 25 years
- Mostly consensus-based — **evidence is the next gap**

**1,624**

international standards and good-practice guidelines identified. 33 international organizations issuing them

07 YIVIVA *Mr. Peikwen Cheng, Co-Founder and CEO, Yiviva*

## Advancing Botanical Medicines Globally: Case Study YIV-906

- **Takes a village**. Collaboration from clinical trials to CMC to R&D
- An 1,800-year-old formula modernized as a cGMP oral capsule, with **Mech QC batch-to-batch consistency** and stability.
- **Systems biology mechanism of action**: Immunomodulator in TME and cytoprotector in GI: improves efficacy and tolerability
- 260 patients treated (liver, pancreatic, colorectal, rectal cancers). Phase 2b **proof of concept** data in hepatitis B+ hepatocellular carcinoma study in US, Mainland China, Hong Kong and Taiwan.

**2.4×**

progression-free survival improvement in Phase 2b liver cancer

08

UNITED KINGDOM

*Mr. George He — Executive Director, UK Centre of Chinese Medicine; UCL School of Pharmacy*
Co-Authors: Prof. Michael Heinrich, Dr Anthony Booker, Prof. Monique Simmonds
School of Pharmacy, University College London.

# Resilience, Reconfiguration and Adaptive Innovation

*Multi-dimensional Governance of Sustainable Chinese Medicine Supply Chains in the UK under VUCA Conditions*

- UK Chinese medicine supply chain is **SME-dominated**, trust-based and voluntarily registered with post-Brexit ambiguity
- **Perception Gap**. 67% self-rate as resilient, yet 56% experienced supply disruption in 3 years
- **gravest threat is reputational**: a single high-profile safety or authenticity failure could trigger restrictive regulation and erode access sector-wide
- Building a **Supply Chain Resilience** Index for practitioners

**38%**

consistently receive batch-specific certificates of analysis

09

AUSTRALIA

*Dr Yu-Ting Sun, Associate Professor Liz Thyer*
*School of Health Sciences, Faculty of Health, Western Sydney University*

# Understanding the Professional Ecosystem of Chinese Medicine in Australia

- Australian **workforce is small and static**: 4,839 registered practitioners, 0.6% of the regulated health workforce, 89% in private practice
- **Identity and belonging** drive career sustainability. practitioners navigate a cultural conversation as well as delivering therapy.
- Practitioner voice must inform education and policy

**0.6%**

of Australia's regulated health workforce

10

VIETNAM

*Huong Thi Luu Kim Huynh, Lan Phuong Le Thi*
*Faculty of Traditional Medicine, University of Medicine and Pharmacy at Ho Chi Minh City, Ho Chi Minh City, Vietnam*

# Regulations And Scientific Collaboration In Vietnamese Traditional Medicine: Insights From University – Hospital Partnerships

- **Traditional medicine embedded** across hospitals and community care, under Ministry of Health supervision.
- Herbal medicines and traditional formulations are authorized under the Law on **Pharmacy** 2016. **Statutory licensure, Pharmacopoeia VI, GACP-WHO quality control**
- University–hospital partnerships building the evidence base

**2023**

new Law on Medical Examination and Treatment governing TM licensing

11

Q&A

## Panel Discussion and Q&A

- GACP/GAP implementation in China (Chan). **layers of middlemen** make enforcement genuinely difficult. Shouchuang uses senior **political access** to reach growers
- Agrochemical standards diverge (Dou): **USP tests for more pesticides** than the Chinese Pharmacopoeia.
- **Animal and mineral constituents** (Dou, Bauer, He): acceptable within a US botanical mixture alongside plant herbs — though a single animal-derived product becomes a biologic. Europe, **heavy-metal limits**, absent monographs and low public acceptance make licensing commercially unwise

COMMON THEMES

# Bottom-up Patient Demand, Policy Progress, More Work Ahead

## BEDSIDE to BENCH to BEDSIDE

01 From Raw Material to Batch Consistency

02 From Experience-based to Evidence-Based

03 Subjective vs Objective Endpoints, New Technologies

## MULTI-FUNCTIONAL / MULTI-DISCIPLINARY ALIGNMENT

01 Macro Alignment – From Policy to Incentives

02 Product Positioning (Drugs vs Supplements)

03 It Takes a Village (Patients/Doctors/Payors..)