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The King's Centre for Integrative Chinese Medicine

伦敦国王学院整合中医药学中心

KING'S College LONDON

Harmony without being uniform: International Guidelines & Standards in Traditional Medicine Research

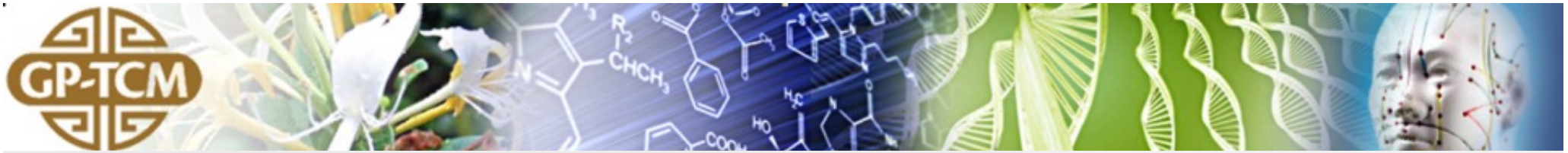
和而不同——传统医药研究的国际标准与规范

Dr Qihe Xu's keynote PPT, The 2023 China APEC Cooperation Fund International Symposium, Beijing, China, 5th July 2023.

徐启河博士在中国-APEC合作基金国际研讨会上的主题演讲PPT （2023年7月5日 · 中国北京）

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2023 China APEC Cooperation Fund International Symposium
Regulatory Science & International Sharing of TM S&T Innovation
Beijing, China, 5th July 2023

Harmony without being uniform: International Guidelines & Standards in Traditional Medicine Research

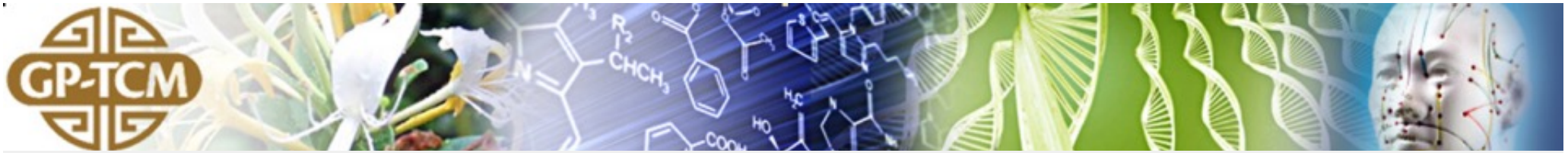
和而不同——传统医药研究的国际标准与规范

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Director, King's Centre for Integrative Chinese Medicine
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Board Member, the GP-TCM Research Association
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Good Practice——The GP-TCM Definition

“规范”的定义

- **Broadly,** it is compliance with commonly accepted guidelines for medical research
- **Technically**, it is GxP (good practice guidelines) specific to traditional medicine
- **Strategically**, it is collaboration and sharing
- **Pragmatically**, it is striving for consensus while respecting differences

- 广义地讲：遵守国际公认的规则
- 技术层面：中医药相关的标准与指南
- 策略地讲：合作共享
- 实用的原则：求同尊异

Uzuner H, et al. J Ethnopharmacol. 2012;140:458-68 (94 citations)

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Harmony without being uniform: GxP in TM

求同尊异、和而不同的传统医药技术标准与指南

Standards & GxP guidelines

标准与指南

More internationally harmonised

国际同化度较高的标准与规范

Regional guidelines with international importance

具有国际影响力的区域性标准与规范

Who publishes more internationally harmonised standards?

制订高同化度标准与指南的国际组织

- International Standardization Organization (ISO)
  国际标准化组织
- World Federation of Chinese Medicine Societies (WFCMS)
  世中联
- World Health Organization (WHO)
  世卫组织
- International consortium, societies and journals
  国际协作组织、学会与学术期刊

ISO/TC 249
ISO中医药技术委员会

- 2009-2023, ISO has collaborated with WFCMS in publication of **95 standards on quality, safety and processing procedures of TCM raw materials & products;**
- >30 ISO drafts are being developed.

- 2009-2023年， ISO与世中联等合作，发布了95个中医药原材料和生产成品质量、安全性和加工程序的国际标准。
- >30国际标准正在制定过程中

For details, please visit:

https://www.iso.org/committee/598435.html

WFCMS publishes their own standards
世中联独立发表的国际标准

No	WFCMS 国际标准与指南 (n=22 by Nov. 2022))	发布时间
22	SCM 54-2020 中药处方要求 (TCM prescription)	2022-08-23
21	SCM 54-2020 中药调剂要求 (Dispensing)	2022-08-24
20	SCM 54-2020 中药给付要求 (Delivery)	2022-08-24
19	SCM 55-2020 中药煎服要求 (Decoction and taking)	2022-08-24
18	SCM-C 0039-2020 温控红外灸疗垫	2022-05-05
17	SCM-C 0014-2019 糖脂代谢病（瘅浊）中西医结合诊疗技术规范	2022-05-05
16	SCM-C 0011-2018 牛胶原肽粉	2022-05-05
15	SCM0051-2019 国际中医远程会诊服务规范	2022-05-05
14	SCM-C 0008-2017 耳穴探测仪	2022-04-28
13	SCM0050-2019 国际中医远程教育服务规范	2022-04-28
12	SCM0041-2014 世界中医药学科体系类目	2022-04-28
11	SCM0027-2019 凉茶饮料 (Liangcha herbal drinks)	2022-04-28
10	SCM0026-2019 浮针疗法技术操作规范	2022-04-28
9	SCM0024-2018 标准化煎药中心基本要求 (Standardised decoction-making centre)	2022-04-28
8	SCM0023-2019 热敏灸技术操作规范	2022-04-28
7	SCM0020-2017 中医药健康旅游服务要求	2022-04-28
6	SCM0018-2017 国际中医临床实践指南 糖尿病	2022-04-28
5	SCM0012-2014 国际中医医师测试与评审规范	2022-04-28
4	SCM0010-2012 世界中医学专业核心课程	2022-04-28
3	SCM0008-2011 国际中医医师专业技术职称分级标准	2022-04-28
2	SCM0004-2010 诊所设置与服务标准	2022-04-28
1	SCM0003-2009 世界中医学本科（CMD 前）教育标准	2022-04-28

Please visit: http://www.wfcms.org/index.php/list/52.html

WFCMS drafts，e.g. Network Pharmacology Evaluation Method

世中联指南草案，比如网络药理学评价方法



Prof. LI Shao

Tsinghua University

Chair, WFCMS Specialty Committee of Network Pharmacology

Li S, et al. WFCMS Specialty Committee of Network Pharmacology.

Network Pharmacology Evaluation Method Guidance - Draft.

World J Tradit Chin Med 2021;7:146-54

https://www.wjtcm.net/text.asp?2021/7/1/146/310934

WHO traditional medicine strategy & update

世卫组织传统医学战略、更新与展望

- 2002. WHO traditional medicine strategy 2002-2005.
- 2013. WHO traditional medicine strategy: 2014-2023.
- 2022. Updates and future reporting – Traditional medicine.

WHO standards in acupuncture nomenclature and benchmark series on acupuncture, tuina, Ayurveda, Unani training & practice

世卫组织针灸术语, 以及针灸、推拿、印度传统医学指南

Updates and future reporting - Traditional medecine
Report by the WHO Director-General. 75th WORLD HEALTH ASSEMBLY. 12 April 2022
https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_42-en.pdf

WHO Standards of TM terms and translation

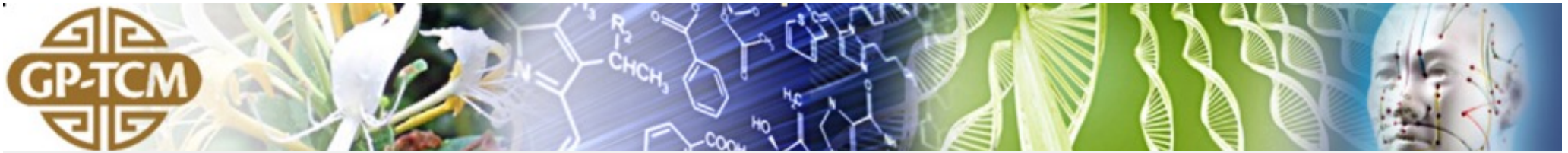
世卫组织引领传统医学术语翻译的标准化

- WHO international standard terminologies on traditional medicine in the Western Pacific Region. 2007: pp1-356
- WHO international standard terminologies on traditional Chinese medicine. 2022; pp1-453

WHO standardises TM diagnosis, bringing it in ICD-11

世卫组织标准化传统医学诊断，并将其带入国际疾病分类目录

- WHO. Chapter 26. Supplementary Chapter Traditional Medicine Conditions - Module I. ICD-11. International Classification of Diseases 11th Revision; The global standard for diagnostic health information. 1999; in effect, Jan. 2022.



WHO guidelines on TM research & evaluation and herbal GMP was the foundation of the FP7 GP-TCM collaboration

世卫组织传统医药研究评估方法指南与草药生产规范

- WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine. 2000; p1-74 (>1000 citations)
- WHO Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines. 2007, pp 1-72 (>60 citations)

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Good Practice in TCM Research in the Post-genomic Era (GP-TCM，2009-2012)
后基因组时代中医药研究的良好实践

- A €1m project funded by the European Commission, under its 7th Programme Framework
- 25 countries, 110 institutions & enterprises, >200 members
- Aimed at promoting EU-China collaboration in modernisation of TCM research



Uzuner H, et al. TCM research in the post-genomic era: good practice, priorities, challenges and opportunities. J Ethnopharmacol. 2012;140:458-68.

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Prof. Kelvin Chan
University of Sydney



Prof. Pierre Duez
University of Mons



Prof. Monique Simmonds
Royal Botanic Gardens

Chan K, et al.

Good practice in reviewing and publishing studies on herbal medicine, with special emphasis on traditional Chinese medicine and Chinese materia medica.

J Ethnopharmacol. 2012;140(3):469-75.

(203 citations)

World Flora Online - The WFO Plant List

https://wfoplantlist.org/plant-list

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Dr Andrew Flower

Prof. George Lewith

University of Southampton

Flower A, et al.

Guidelines for randomised controlled trials investigating Chinese herbal medicine.

J Ethnopharmacol. 2012;140(3):550-4.

(96 citations)

Reporting RCTs of herbal interventions: an elaborated CONSORT statement.

Gagnier JJ, et al; CONSORT Group.

Ann Intern Med. 2006;144:364-7.

(690 citations)

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Hugh MacPherson
Professor of Acupuncture Research
University of York

Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement.

MacPherson H, et al; STRICTA Revision Group.

Acupunct Med. **2010**;28:83-93.

(1565 citations)

↑

Standards for reporting interventions in controlled trials of acupuncture: the STRICTA recommendations.

MacPherson H, et al.

Complement Ther Med. **2001**;9:246-9.

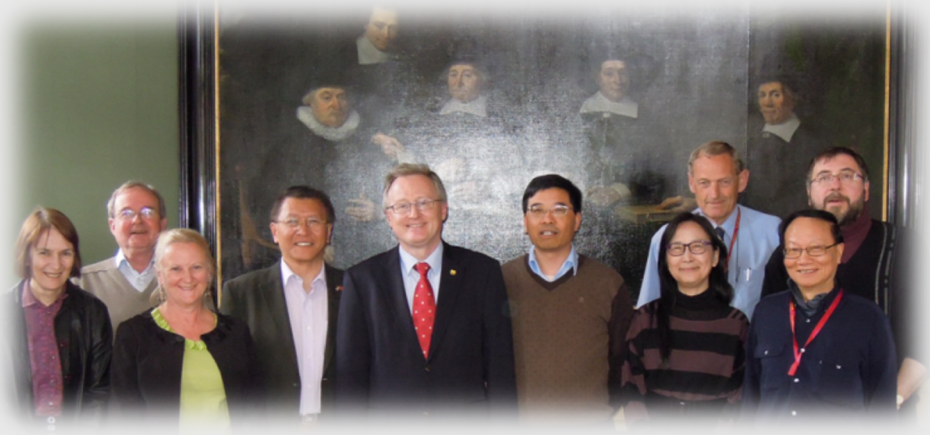
(262 citations)

Good Practice in TCM Research Association (GP-TCM RA) founded in 2012

中医药研究学会

Founding BoD members, 2012

(absent: De-an Guo and Aiping Lyu)



GP-TCM RA Presidents, 2012-2024



Rudolf Bauer
(2012-4)



De-an Guo
(2015-6)



Tai-Ping Fan
(2017-8)



Aiping Lyu
(2019-20)



Monique Simmonds
(2021-2)



Clara Lau
(2023-4)

GP-TCM Research Association
中医药规范研究学会

http://www.gp-tcm.org

- **7 interest groups will each organize their GxP webinars regularly.**
  - Acupuncture;
  - Clinical Studies;
  - Clinical Practice;
  - Pharm/Tox;
  - Publication;
  - Quality control;
  - Regulatory Science.
- **Open-access newsletters:**
- **Free membership**

GP-TCM RA GxP Workshop, Nov. 2022

规范的学术探讨: 为纪念学会成立十周年，GP-TCM RA 2022年11月29日成功举办了 《中医药规范讲座》网络会议



Organiser: Dr Mei Wang
GP-TCM RA President-elect
Regulatory IG Chair

- 农业规范：Good Agricultural Practice (GAP)
- 实验室规范：Good Laboratory Practice (GLP)
- 生产规范：Good Manufacturing Practice (GMP)
- 流通规范：Good Distribution Practice (GDP)
- 临床规范：Good Clinical Practice（GCP）



Organiser: Prof. Rob Verpoorte
Past GP-TCM RA BoD Member
Publication IG Chair

Open access to the GP-TCM RA GxP Workshop lectures:

http://www.gp-tcm.org/index.php/2022/10/01/gp-tcm-ra-good-practice-based-workshop/



Prof. Zhaoxiang Bian
Chair, Clinical Studies
Interest Group
GP-TCM RA

CONSORT Extension for Chinese Herbal Medicine Formulas 2017: Recommendations, Explanation, and Elaboration.

Cheng CW, et al; CONSORT-CHM Formulas 2017 Group.
Ann Intern Med. 2017;167(2):112-121.

(186 citations)

Flower A, et al.
Guidelines for randomised controlled trials investigating Chinese herbal medicine.
J Ethnopharmacol. 2012;140(3):550-4.

(96 citations)

ConPhyMP guidelines

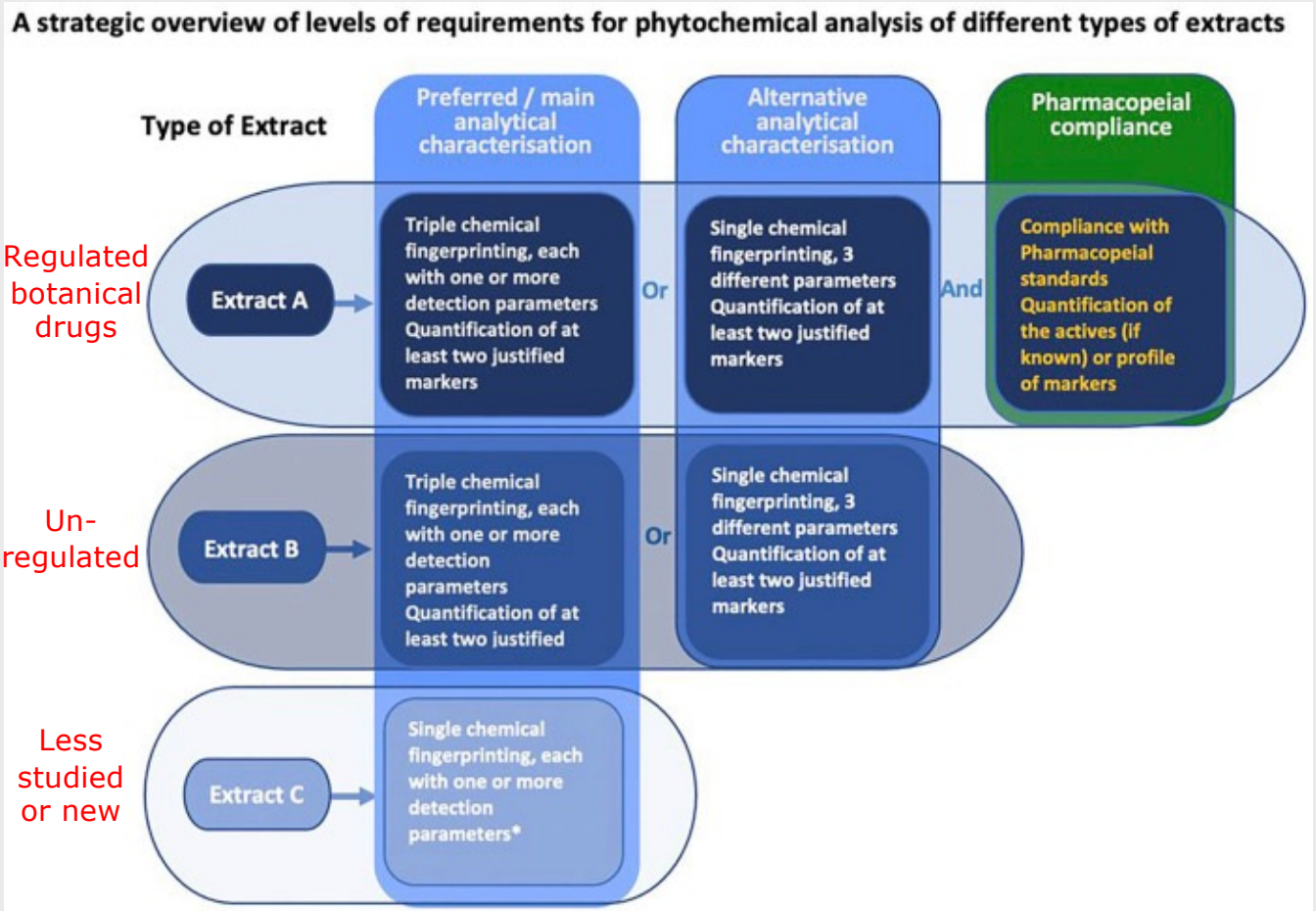
药用植物鉴定、命名、提取、化学分析的指南

- Heinrich M, et al. **Best Practice in the chemical characterisation of extracts used in pharmacological and toxicological research: The ConPhyMP Guidelines.** Front Pharmacol. 2022;13:953205.



Prof. Michael Heinrich

University College London



Important Roles for International journals

国际学术期刊的指南

- *Frontiers In Pharmacology – Ethnopharmacology*
- *Phytomedicine*
- *J Ethnopharmacology*
- *Br J Pharmacology*
- *……*

Regional guidelines with international importance

具有国际影响力的区域性标准与规范

- Pharmacopoeias, e.g., Ph. Eur. TCM Working Party
  药典，譬如：欧洲药典中药工作组
- EMA/HMPC
  欧洲药监局草药委员会
- The US FDA
  美国药品食品管理局
- NATCM-sponsored guidelines on proprietary TCM
  国家中医药管理局《中成药治疗优势病种临床应用指南》
- Journal guidelines & GxP academic fora
  杂志的指南与规范的学术探讨

The European “Dual Carriage Way”

欧洲式草药管理

- EDQM Ph. Eur. TCM Working Party
  欧洲药品质量管理局欧洲药典中药组 → Herbal drugs 药材
  - Herbal drug granules（药材颗粒剂）are regulated as food supplements in most EU member states;
  - In Germany, however, they are “presentation medicinal products” and their quality monographs are being documented in a supplement to the German Pharmacopoeia.
- Committee on Herbal Medicinal Products, European Medicines Agency（EMA/HMPC）
  欧洲药监局草药委员会 → Proprietary products 成药

Wang M et al. Key quality factors for Chinese herbal medicines entering the EU market. Chin Med. 2022; 17: 29.

Since 2004, HMPs are regulated by HMPC/EMA under two categories:

欧洲药监局草药委员会的成药归管办法

- Traditional Use Registry (TUR, **传统应用注册**):

  GMP+30y safe use

- Marketing Authorisation (MA, **市场许可**):

  GMP + efficacy & safety established by RCT

Traditional use registration (TUR)

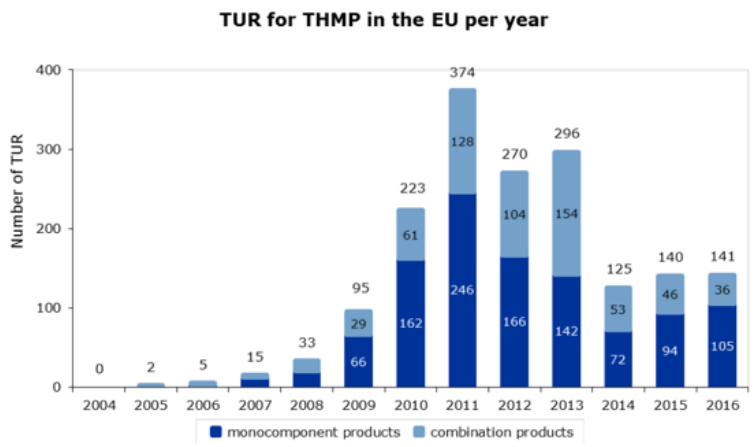


Figure 1

Number of traditional use registrations (TUR) for THMP in the EU grouped by year of registration for monocomponent and combination products (2004 until December 2016; total 1719).

Well-established use marketing authorization (WEU MA)

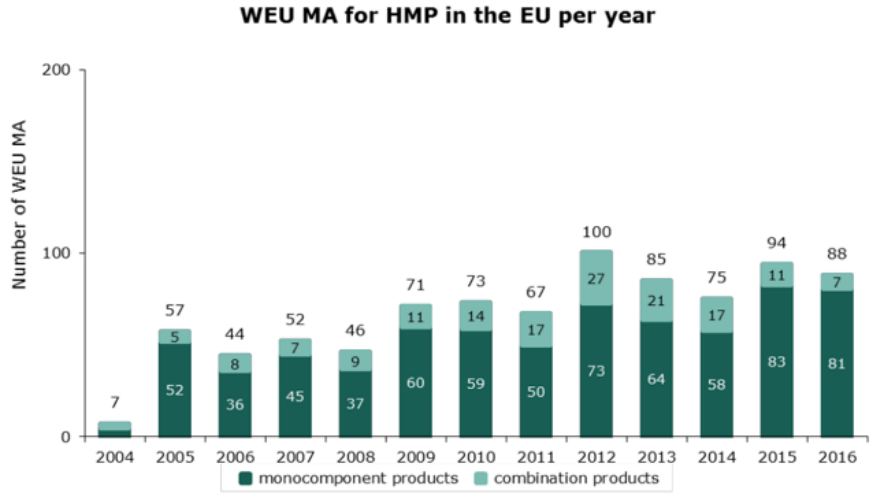


Figure 2

Number of well-established use marketing authorisations (WEU MA) for HMP in the EU grouped by year of authorisation for monocomponent and combination products (2004 until December 2016; total 859).

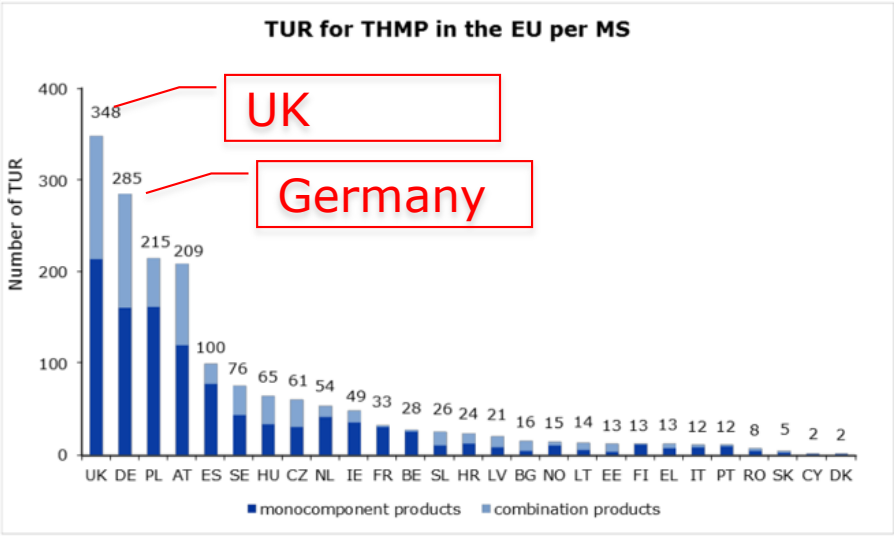


Figure 3

Number of granted TUR for monocomponent and combination THMP in EU Member States (since implementation of Dir. 2004/24/EC until 31 December 2016). Total 1719: 1089 for monocomponent products, 630 for combination products (No TUR granted for IS, LI, LU and MT).

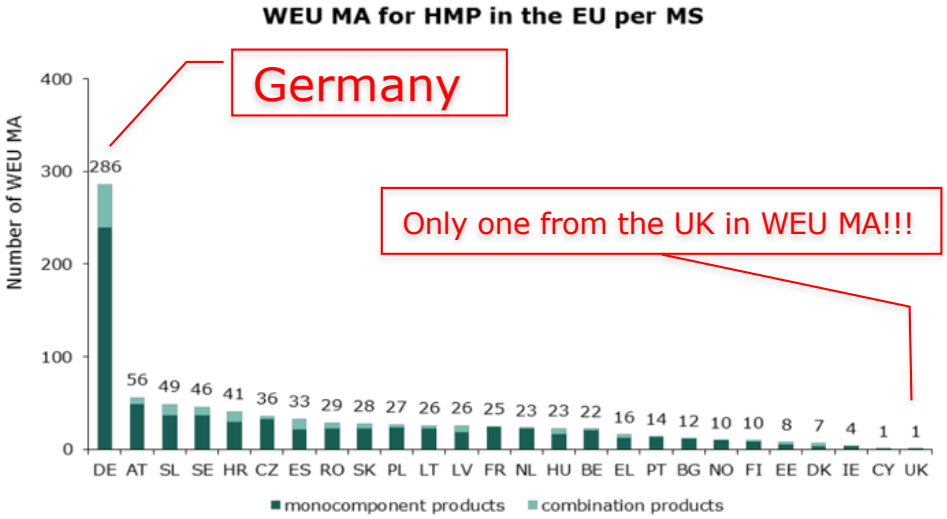


Figure 4

Number of granted WEU MA for monocomponent and combination HMP in EU Member States (since implementation of Dir. 2004/24/EC until 31 December 2016). Total 859: 704 for monocomponent products, 155 for combination products (No WEU MA granted for IS, IT, LI, LU and MT).

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106706.pdf

The US way: Totality-evidence for botanical drugs
FDA“全证据”模式：成功注册的草药凤毛菱角

- **Only three approved prescription botanical drugs (2006; 2012; 2023)**
  - Sinecatechins, Veregen®;
  - Crofelemer, Mytesi™, is sourced from the red bark sap of the Croton lechleri tree that grows in the Amazon;
  - NexoBrid, a mixture of enzymes (凤梨酵素) from the stem of the *Ananas comosus* (pineapple plant) that dissolves dead tissue caused by a burn so that the healing can start.
- **OTC botanical drugs** under the OCT botanical drug review: cascara, psyllium, senna, etc.
- **Dietary Supplement** cannot make a disease claim to diagnose, cure, mitigate, treat or prevent disease.

Wu C, et al. *J. Nat. Prod.* 2020, 83, 2, 552–562

Lee SL, et al. *Science* 2015;347 (6219 Suppl): S32-34

National TCM Administration of China guidelines on proprietary TCM use in integrative medicine

国家中医药管理局《中成药治疗优势病种临床应用指南》

By July 2022,

- 29 guidelines and 8 drafts have been published;
- 26 more are in the pipeline.

Conclusions & Discussions

- Regulators around the world often adopt distinct regulatory approaches suitable to their specific needs;
- Nonetheless, great progress has been made in the past decade in developing TM-related guidelines & standards:
  - **GP-TCM (RA), ConPhyMP and CONSORT** led the development of good practices in herbal naming, QC, extraction & clinical studies.
  - **WHO** led in devising guidelines on TM terminology & diagnosis, herbal GMP, and nomenclature, training and practice of acupuncture, tuina, Ayurveda & Unani;
  - **ISO has collaborated with WFCMS** in publishing ~100 standards of TCM products; and
  - **WFCMS also publishes standards in TCM prescription, dispensing, delivery, decoction and taking**,…

Challenges: Dissemination, endorsement, implementation & refinement

- **A cross-sectional study of the endorsement of reporting guidelines in 1039 Chinese medical journals in 2022;**
- **24.1% endorsed CONSORT for reporting RCTs, but only 0.8% endorsed CONSORT extensions;**
- **14.8-17.2% endorsed STROBE, PRISMA, STARD, CARE:**
  - *CARE:* Case report guidelines
  - *STARD: U*pdated list of essential items for reporting diagnostic accuracy studies
  - *PRISMA:* Preferred reporting items for systematic reviews and meta-analyses
  - *STROBE:* STrengthening the Reporting of observational studies in epidemiology
- **<0.7% endorsed SPIRIT, TRIPOD, AGREE and RIGHT:**
  - SPIRIT: Standard protocol items: Recommendations for interventional trials
  - TRIPOD: Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis
  - AGREE: Appraisal of guidelines, research, and evaluation; and
  - RIGHT: Reporting items for practice guidelines in healthcare

Duan Y, et al. BMC Med Res Methodol. 2023;23:20.

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谢谢！

