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Traditional Chinese Medicine: A Statement by EASAC and FEAM

The recent proposed revision by the World Health Organization (WHO) of the International Classification of Diseases coding tool (ICD-11)¹ brings some important reforms for medical practice, for example for the classification of mental health disorders (Anon 2019a). However, the revision of ICD-11 also brings a major problem in adding a chapter on traditional Chinese medicine (TCM). This publication will be very influential: *"health statistics form the basis of almost every decision made in health care today ... ICD is the bedrock for health statistics ... ICD codes can have enormous financial importance, since they are used to determine where best to invest increasingly scant resources."*²

TCM is a term that covers a wide range of practices (Box 1), often viewed with scepticism by those in the medical and scientific communities who are not TCM practitioners.

Box 1 What is TCM?

TCM has a long history, based on philosophical systems, and its diagnostic approaches are subjective and patient-based rather than relying on differential disease diagnosis. In TCM, signs and symptoms are gathered primarily through inquiry and observation and minimal physical examination (pulse and tongue) to interpret as a diagnostic syndrome.

In therapy, TCM practitioners employ various mind and body practices, including acupuncture, tai chi, herbal product ingestion, skin cupping and moxibustion (dried herbs burned near the skin). Treatments included within the wide TCM category are very different from one another. They can only be considered to form a group of therapies from the perspective of history/ethnology ("traditional") and geography (Chinese).

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¹ ICD-11 was released June 2019 for adoption by Member States and will come into effect January 2022, see <https://icd.uk.who.int>. The TCM chapter is described on <https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2fcd%2fentity%2f718687701>.

² "WHO ICD-11: Classifying disease to map the way we live and die" 18 June 2018, www.who.int/health-topics/international-classification-of-diseases.

Box 1 (continued)

One of the basic principles of TCM is that vital energy, qi, circulates through body channels, connected to organs and functions. Concepts of body and disease used in TCM have not been substantiated by conventional scientific investigation. This lack of a science base often makes TCM mechanisms and claims neither verifiable nor falsifiable by scientific experimentation. In Europe it is difficult to reconcile TCM with mainstream medicine and its frameworks for regulation.

Moreover, TCM practitioners may disagree on what treatment would be appropriate for a particular patient and there is also often disagreement in making a diagnosis. In addition to the problems this variability and uncertainty causes in selecting an appropriate healthcare intervention, one other consequence is that patient cohorts will be inconsistently defined for research purposes.

TCM is an integral part of health services in some Asian countries, but although there has been some convergence there is no agreed international standard to allow collection of comparable data between countries and no common starting point for testing efficacy of interventions or monitoring safety.

The production and delivery of TCM has become a large industry with estimates of US\$60 billion a year and an annual growth rate above 10%.

Sources include National Institutes of Health National Center for Complementary and Integrative Health; Cancer Research UK; ICD-11; Cyranoski, 2018.

Hitherto, countries using TCM in their health services have varied in methods for implementation and evaluation so it might be assumed, in theory, that efforts to investigate and standardise TCM classification should be welcomed. The greater risk, however, is that the inclusion of TCM in the new diagnostic coding of ICD-11 may lead some to see it as a legitimisation of what are actually unfounded claims (Anon 2019b). In the absence of agreement on tenets or a shared commitment to employing scientific principles for demonstrating claims, it is premature to try to include TCM, or other complementary and alternative medicine (CAM) within a unifying diagnostic classification tool. Indeed, this inclusion may be contrary to the scientific principles on which ICD has been built. The introduction of TCM into international diagnostic classifications has implications not just for diagnostic revision but, in consequence of those impacts, for therapeutic approaches also.

In this short Statement, with the objective to demonstrate the challenges raised for EU and national policy-makers and European health systems, EASAC and FEAM add our voices to those who have expressed concern about this ICD-11 reclassification to include diagnostic approaches that are not yet, and may never be, adequately validated according to established scientific and regulatory criteria. There is risk in misleading patients and doctors and in increasing pressures for reimbursement by public health systems at a time of limited resources. At the same time as we express this concern, we nonetheless recognise as highly valuable some of the points made by WHO and others in arguing for TCM and other CAM to

be scrutinised in detail according to standardised procedures:

- We agree with the underlying principle that the proponents of TCM and other CAM should be invited to seek the same rigorous assessment as is applied to innovative, evidence-based medicines (from state-of-the-art clinical trials) developed and regulated worldwide.
- We accept that WHO has tried to make clear that their chapter in ICD-11 on TCM does not refer to, nor endorse, any specific form of treatment (Anon 2019a). However, because of the perceived encouragement created by ICD-11 inclusion of TCM as a core principle and system of medicine, the qualification may be misconstrued or ignored.
- We agree that there have been examples where traditional medicine, Chinese or otherwise, has been subjected to thorough preclinical investigation and proven in rigorous clinical trials to contribute significant health benefit. The example of artemisinin therapy for malaria is notable (WHO, 2015). The success of artemisinin as an anti-malaria agent is due to meticulous research in pharmacognosy and medicinal chemistry, combined with clinical trials. Many of the artemisia TCM preparations tested originally had little reproducibility of activity. The compound that has been approved by medicinal product agencies is a chemically modified version of the naturally occurring molecule in order to improve its pharmacokinetic properties. It is well known that many natural products have significant pharmacological activities and provided the basis

for much of modern medicine. And, there may be many more such leads to therapeutic benefit³. But, none of this means that other claims can be accepted uncritically, even if the objective to ensure access for all to the benefits of medicine is worthy.

Strategies for treatment or prevention of disease must be judged by medicinal criteria such as mechanism of action, means of administration, effects on physiology and psychology, for example. All treatments, whether pharmacological, manual or psychological, need to consider dose and frequency of administration or number and length of treatment sessions. With particular regard to the use of acupuncture, there is an extensive database on publications assessing the evidence for various clinical indications in the Cochrane collaboration on complementary medicine⁴. The use of acupuncture remains controversial, for example for pain relief (Cummings et al. 2018).

Claims must be differentiated by focussing impartially on the accumulated TCM evidence to determine where new leads for diagnosis and therapy can be elucidated. Research and innovation must be at the heart of medicine. The WHO ICD-11 initiative risks stimulating an indiscriminate acceptance of products and diagnostic practices that have not been sufficiently investigated by standardised procedures and whose scientific justification is weak. A lack of comparability in the evidence base for the range of diagnostic procedures now encompassed in ICD-11 also risks public confusion and the undermining of confidence in evidence-based medicine. Our particular concerns include the following:

- European patients may be encouraged to self-administer unregulated products or seek unregulated diagnostic procedures outside of the remit and responsibility of public health services. This raises issues for efficacy, particularly if patients delay seeking evidence-based healthcare. There are also serious safety concerns. Multiple risks of harm from herbal ingredients have been documented (e.g. see Byard et al. 2017; Zhou et al. 2019) and in the absence of an approved framework for quality and formulation, adulteration and dose variation may bring additional health risks (Ching et al. 2018). Interaction with other medications is,

additionally, a serious threat. It is also noteworthy that, contrary to common assumptions, acupuncture is not necessarily harmless (Chan et al. 2017). It is not our present purpose to review the evidence on TCM or to make judgement on particular practices, rather to emphasise the need for consistency in applying common standards to all of medicine. Although there is a very large literature on TCM, we note that clinical studies often fail to meet expected methodological criteria and high-quality evidence is often lacking (for example as concluded from a systematic review of the literature on use of Chinese herbal medicines for rheumatoid arthritis, Pan et al. 2017). Follow-up surveillance and procedures for assessing liability, where necessary, may also be weak.

- European patients may be encouraged to seek diagnosis according to the proffered TCM precepts through public health services, thereby causing additional pressures on limited resources. It is likely that there will be increasing demands for these services across the EU. The European Commission, the EMA and Member State health authorities must revisit their regulatory strategies to ensure that appropriate, evidence-based patient information is readily accessible.

We have expressed concern previously (EASAC, 2017) about problems in the EU caused by the European Commission and Member States developing management frameworks for CAM without requiring the rigorous evidence for quality, efficacy and safety that would be expected for any other (pharmaceutical) medicinal product. Following the principles we proposed in that previous work, we now make the following recommendations on TCM:

- There should be consistent proof underlying the regulatory requirements for scrutiny to demonstrate efficacy, safety and quality for all products and practices for human medicine. There must be verifiable and objective evidence, commensurate with the nature of the claims being made. In the absence of such evidence, a product should be neither approvable nor registrable by national regulatory agencies for the designation medicinal product. The current EU Directive on Traditional Herbal Medical Products (Directive 2004/24/EC

³ EU-funded research can make a significant contribution to building the evidence base for TCM pharmacological activity. For example, the European Commission-funded project TCMCANCER (completed in 2013) identified novel lead compounds from medicinal plants exhibiting anticancer activity *in vitro* in several cancer cell lines. Of course, this was only a beginning and there is need for considerable further research in experimental animal models before reaching the clinical trial stage, but it exemplified how systematic biological study can provide new impetus to TCM. In conducting research on natural products, it is important also for the EU to continue to align its international systems with the Nagoya Protocol on sharing benefits from the use of genetic resources and traditional knowledge, implemented in EU Regulation No 511/2014, see <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511>. There is also continuing need for work on the characterisation and authorisation of Chinese medicinal plants to remove the potential for confusion in identification (Leon and Yu-Lin, 2017), see www.kew.org/science/our-science/projects/chinese-medicinal-plants-materia-medica.

⁴ See <https://cam.cochrane.org>. There is also a large database of all publications including Cochrane reviews on acupuncture in the evidence compiled by the UK National Institute for Health and Care Excellence, <https://evidence.nhs.uk/search?q=acupuncture>.

amending Directive 2001/83/EC) was established to provide a simplified regulatory approval process for traditional herbal medicines, and national procedures are overseen by the national competent authorities. However, designated categories within this legislation allow treatment based on traditional or well-established use in the absence of robust evidence. Medicinal herbal products registered by the European Medicines Agency for traditional use have the requirement of *“bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years in the Community”*⁵.

Thus, the regulation is essentially to ensure that the product is harmless and there is no real requirement for demonstration of effect. As recommended in our previous assessment of homeopathy (EASAC, 2017) it would now be timely to reassess the validity and value of continuing to allow these simpler regulatory approval categories to apply.

- Diagnostic procedures should also be evidence-based and include validated diagnostic instruments to provide objective, reliable, reproducible assessment and reduce inter-rater variability. Whatever the diagnostic approach utilised, practitioners should be appropriately trained and audited by professional bodies.
- Similarly, use of other TCM procedures such as acupuncture should be evidence-based to demonstrate efficacy and safety, and subject to professional standards.
- Evidence-based public health systems and medical insurance systems should not reimburse products and practices unless they are demonstrated to be efficacious and safe by rigorous pre-marketing testing: a robust evidence base is essential for all medicines.
- The composition of standardised TCM remedies should be labelled in a similar way to other health products. That is, there should be an accurate, clear, verifiable and simple description of the ingredients and their amounts present in the formulation. TCM diagnostic and therapeutic procedures should, likewise, be clearly explained in patient information literature.
- Advertising and marketing of TCM products and services must conform to established standards of accuracy and clarity⁶. Promotional claims for efficacy, safety and quality should not be made without demonstrable and reproducible evidence.

We recognise that the necessary reform of regulatory frameworks can take significant time, but it should be started. And, until that reform is achieved, we urge attention now to ensuring consistency in labelling, advertising, other information provision, and reimbursement together with the enforcement of professional standards to support consumer safety.

Currently, the medical and scientific communities in the EU and worldwide are actively engaged in tackling the collective targets set in the Sustainable Development Goals (SDGs). Generating a robust and coherent evidence base that is applicable to all of healthcare is vitally important for efforts in addressing multiple SDGs—to support current medical practice and to generate new resources for innovation. Particularly relevant for SDG3 (good health), but also for SDG4 (quality education), SDG9 (industry, innovation and infrastructure), SDG10 (reduced inequalities) and SDG17 (partnership). We urge the WHO to reflect further on how it supports robust discussion and clarifies prospective use of TCM and other CAM as part of the responsible science necessary for achieving the SDGs and for mapping the burden of disease.

We also urge the European Commission and Member States to do more to ensure that all medical products and procedures are subject to an appropriate level of evaluation for quality, safety and efficacy consistent with standardised testing procedures. Because of its history of interest in CAM⁷, the European Parliament is also asked to engage with citizens, other stakeholders and policy-makers to seek the evidence, help stimulate debate and clarify the issues.

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⁵ https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2004_24/dir_2004_24_en.pdf.

⁶ For example as recommended in the UK, “Health: Chinese herbal medicine or traditional Chinese medicine”, Advertising Standards Authority/Committee of Advertising Practice, August 2015, www.asa.org.uk/advice-online-health-chinese-herbal-medicines-or-traditional-chinese-medicine.html. The UK advertising practice bodies also recently published advice on acupuncture advertising claims, emphasising the requirement for robust evidence, February 2019, www.asa.org.uk/advice-online/health-acupuncture.html.

⁷ For example, “Complementary and alternative therapies for patients today and tomorrow” Study for European Parliament ENVI Committee IP/A/ENVI/2017-10 PE 614.180, by DG Internal Policies, Environment, Public Health and Food Safety, 2017, at time of parliamentary workshop on current status of CAM, including TCM, in Europe and the policy framework.

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