EHTPA and RCHM response to the WHO's proposed revision of ICD-11

November 2019

In 2005, World Health Organization (WHO) published a report examining the national policies for traditional medicine and the regulation of herbal medicines, based on the first global survey on Traditional and Complementary Medicine (T&CM.). In order to monitor global trends, WHO conducted a second global survey during 2010–2012 (second survey), and a further survey during 2016–2018 (update survey). This data made it possible to compare the information and data, and to identify global trends. The World Health Organisation recently released the "WHO global report on Traditional and Complementary Medicine 2019" which examined the findings from the surveys.[1]

The recent proposed revision by the WHO of the International Classification of Diseases coding tool (ICD-11)[2] is of particular interest as it adds a supplementary chapter on Traditional Medicine Conditions. This supplementary chapter refers to disorders and diagnostic patterns which originated in traditional Chinese Medicine and that are still commonly used in China, Japan, Korea, and in many other countries around the world (including the UK and EU). The document does note: "**This supplementary chapter is a subclassification for optional use.**".

There has been considerable interest caused by this proposed revision e.g.[3,4], The EASAC/FEAM statement agrees with a number of inclusions in the proposed revision, for example:

- "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 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."

However, the EASAC/FEAM statement does list some concerns, including:

- "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. additional health 2019) and in the absence of an approved framework for quality and formulation, adulteration and dose variation may bring 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."

The statement also makes a number of recommendations, for example:

- "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 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."

The EASAC/FEAM statement has drawn considerable media interest e.g.

- "Doctors call for tighter regulation of traditional Chinese medicine" The Guardian (6/11/19):[5] "Europe's leading doctors are to call for tighter regulation of traditional Chinese medicine, anxious that recent recognition by the World Health Organization will encourage the use of unproven therapies that can sometimes be harmful."
- "Some European doctors think Chinese medicine should come with a health warning" CNN (17/11/19).[6]

The EHPTA and its professional association member the RCHM (a key professional association that oversees and voluntarily regulates practitioners of Chinese Herbal Medicine in the UK), agree that there is a key need for

tighter regulation of all herbal medicine to ensure safety, quality and efficacy of treatment. In the absence of herbal medicine regulation in the UK following Her Majesty's Government's disappointing u-turn in February 2017[7], the EHTPA and its Professional Association members continue to effectively voluntarily regulate the herbal practitioner sector. This ensures that: 1) high quality, accredited training courses are available to produce skilled, effective and safe practitioners; 2) a strict professional code of practice and ethics is maintained to ensure patient safety; 3) high quality continued professional development is available for all practitioners to ensure clinical knowledge is maintained; 4) herbal practitioner suppliers must be able to demonstrate GMP-like standards for their products and; 5) the public can easily find highly qualified, safe and effective herbalists to treat a wide-range of self-limiting illnesses – saving the NHS a considerable amount of money by freeing up GP time and resources for more complex illnesses.

Suitably trained herbal medicine practitioners will know which illnesses they can safely treat, and when they need to refer patients to medical practitioners for treatment. They receive in-depth pharmacology training, that allows them to identify potential herb-drug interactions and are trained to be observant for adverse herb reactions and to report issues via the MHRA's yellow card scheme. The whole sector is constantly working to maintain standards of herbal medicines, particularly with the British Herbal Medicine Association's Herbal Practitioner Supply Scheme (https://bhma.info/index.php/hpss/) and the RCHM's Approved Supplier Scheme (http://rchm.co.uk/index.php).

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References

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