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Editorial

The therapeutic value of natural products derived from Chinese medicine—A systems based perspective

The research and development pipeline for new drugs is a challenge and increasingly there is a focus on the potential of natural products as sources for new pharmaceuticals [1]. Powerful analytical tools and technologies such as genomics, proteomics, metabolomics, bioinformatics and provide new opportunities to identify and characterise such products. The benefits of using 'omics' technologies help to ensure that robust ethno-botanical and ethno-medical studies in traditional medicines may help to provide inexpensive, accessible, safe and reliable new and improved medicines and treatments. However, modern natural product chemistry should not be detached from traditional practice, respecting the indigenous nature, use and availability of products. If the value of natural products is to be recognised, this needs to be optimised through multidisciplinary and international collaboration.

Good Practice in Traditional Chinese Medicine (GP-TCM) initiative http://project.gp-tcm.org/ was a European Coordination Action funded under the 7th framework programme. The overall aim of the project was to inform best practice and harmonise research on the quality, safety and efficacy of Traditional Chinese Medicine (TCM) in EU Member States using a functional genomics approach, facilitated through exchange of opinions, experience and expertise among scientists in Europe and China [1]. Although the project ended in October 2012 with the publication of a special issue of the Journal of Ethnopharmacology [2], the GP-TCM consortium has continued to be a sustainable organisation by developing into the GP-TCM Research Association in order to further encourage these goals and by developing the Association to expand this European-Chinese network globally [3].

Special interest groups have been set up for Quality Control, Pharmacology and Toxicology, Clinical Studies, Regulatory Affairs, and Acupuncture, which reflect the key areas initially considered in the initial project http://www.gp-tcm.org/work-packages/. These groups are active in proposing standard protocols for methodology, and prioritising areas for future research. TCM uses a unique theoretical system and has an individualised and holistic approach to describe health and disease, based on the philosophy of a balance of Yin-Yang. GP-TCM RA aims to promote best practice in research on quality, safety and efficacy of TCM, in particular inform best practice, and harmonise research of safety and efficacy of TCM, in particular in Chinese herbal medicines and acupuncture.

The 3rd Annual meeting of the GP-TCM Research Association was held in Nanjing, China in July 2014 in conjunction with the 5th annual Conference of the Speciality committee of the TCM Pharmaceutical Analysis of the WFCMS. Organised by the China Pharmaceutical University (CPA) and the Shanghai Institute of Materia Medica (SIMM), it attracted over 380 participants from 16 countries including: China, United States, United Kingdom, Canada, Germany, The Netherlands, Austria, Japan, India and South Africa.

Participants presented their recent research in traditional Chinese medicine and other traditional medicine systems. These abstracts are published in this issue of EuJIM and show case only some of the wealth of research being conducted in China and worldwide on TCM and include abstracts from the 8 plenary lectures and 45 invited speakers [4]. The conference covered an array of topics including chemistry, quality, pharmacology, toxicology, clinical studies, systems biology, regulatory affairs, new drug discovery.

The regulatory status for traditional medicines/herbal medicines in different countries was presented and discussed in depth. Dr. Werner Knöss, the Chairperson of Committee on Herbal Medicinal Products, European Medicines Agency, delivered the opening keynote introducing the current regulatory framework of herbal medicinal products in the EU. His talk, "European Regulatory Framework for Herbal Medicinal Products – Challenges for Traditional Medicines" described the registration and regulatory framework for herbal medicines, especially for traditional medicines in EMA. Different traditions in the Member States of the EU are being harmonized by European community monographs and European legislation also provides professional options for non-European traditional medicines. But it was pointed out that great challenges in access to the market were facing traditional medicinal products. A professional strategy which fulfils the current European technical

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requirements on quality, efficacy and safety of medicinal products is required. The questions and answers regarding traditional medicinal products market access in The Netherlands was presented by Dr Emiel Van Galen, the head of the Herbal Medicine Department of Medicines Evaluation Board of The Netherlands. He exemplified the successful registration of a TCM herbal product called Diao Xin Xue Kang, coated capsules (Dioscorea nipponica rhizoma, dry extract) by Dutch medicines authority in March 14th of 2012. This is the first and only TCM product registered in Europe to date after the release of Directive 2004/24/EC of The European Parliament and of the Council in 2004. The registration procedure and experience of this approved TCM product could be treated as a model for other TCM herbal products for registration in Europe and definitely is a great encouragement for other intentional manufacturers in China. The similarities and differences in the market access and regulatory requirements for Herbal Products in Europe and the USA were further discussed by Dr Thomas Brendler.

Elaboration of quality standards in different Pharmacopoeias as well as the new approaches for herbal quality control was another topic which was comprehensively discussed. Prof. Gerhard Franz, the chairman of TCM working party of European Pharmacopoeia delivered a lecture on the status report of TCM herbal drug quality monographs in Europe. He detailed the inclusion criteria of Chinese herbal drugs in the TCM Herbal Drug Working Program of the European Pharmacopoeia and also the elaboration procedures of these monographs. Clearly challenges were still remained for the elaboration process, especially for those processed (Paozhi) TCM herbal drugs. So far, 45 TCM herbal quality monographs have been adopted European Pharmacopoeia with 30 more herbs are still in the drafting process. Dr Shang-mei Shi, director of TCM department, Chinese Pharmacopoeia, introduced the recent development of TCM quality standards in Chinese Pharmacopoeia and the progress in the ongoing publication of 2015 edition of Chinese Pharmacopoeia. New approaches and methodologies for herbal analysis and quality control were also extensively discussed in the section dedicated to chemistry and quality of herbal medicines, such as ambient mass spectrometry, linear calibration using two reference substances for overall quality control, capillary electromigration, supercritical fluid chromatography, chemometric modelling of analytical data, multiple mass spectrometry-based glycomic approach, methods for identification of chemical markers, approach for quality control of complex herbal formulas.

There were also many lectures covering a wide variety of themes on traditional medicine/natural medicines, systems biology, toxicology, pharmacokinetics, modern research on TCM theory, action mechanisms. There was also a specific emphasis on the new drug discovery using traditional medicine/natural medicine as resources, in which quite a few new drugs or drug candidates of this type were developed or in the process of development.

Acupuncture is a key component of TCM and consists of stimulating specific acupuncture points by the insertion of fine needles into the skin in order to correct imbalances in the flow of qi/ energy through channels or meridians in the body. Acupuncture also featured in this conference with presentations on the current state of the evidence base.

Moxibustion, an integral part of traditional Chinese medicine (TCM), is a technique that applies heat using a herbal preparation, *Artemisia vulgaris*, for acupuncture point stimulation. Possible mechanisms of action have focussed on anti-inflammation and immunoregulation theories. Although used as an intervention for a wide range of conditions, research on moxibustion has mainly been carried out in China. In this issue, the systematic review by Sun et al. [5] on moxibustion for treating rheumatoid arthritis has been chosen as the 'Editors choice', partly to further stimulate research on this under researched topic which is part of common clinical practice. Using seven Chinese and English databases eight RCTs met the inclusion criteria. These trials were mostly of low methodological quality with high risk of bias, but meta-analysis suggested there were beneficial effects when using moxibustion, either alone or the combination with Western medicine for rheumatoid arthritis. Results should be interpreted with caution but hopefully it will encourage others to start to carry out research in this area.

There are few studies on the relationship between the use of Pilates and quality of life. Rodríguez-Fuentes et al.'s [6] before and after study indicates that there were benefits in terms of physical and mental health related quality of life (as measured by the SF-36), for climacteric women who took part in a 12 week Pilates programme. Although observational in nature, the authors recognise that further research should include a control group and long-term follow-up to assess whether any positive results can be maintained.

There is a real global concern about the trend to growing antibiotic resistance. ReDuNing (RDN), is a patented traditional Chinese medicine, widely used as both an anti-inflammatory and as an anti-infective. Experimental data on its use against influenza viruses and viral pneumonia is limited. A study reported in this issue demonstrates significant changes in histopathology, lung index, nucleoprotein (NP) gene expressions and inflammatory markers against H1N1 influenza virus after RDN administration to restraint-stressed mice [7]. This is an area where natural product development could have great importance in coming years.

Inflammatory bowel disease (IBD) is characterised by chronic inflammation. Current conventional pharmaceutical management is often associated with unacceptable adverse effects which may limit their use especially for prolonged treatment. *Triphala* is a popular traditional Ayurvedic formulation used to treat various diseases. It consists of a mixture of various powdered dried fruits and is known to possess free radical scavenging activity and is traditionally used as protective agent for the gastrointestinal tract. In a laboratory assay, aqueous *Triphala* extract was assessed for Nitric oxide (NO) scavenging and anti-lipid peroxidation activities [8]. The authors suggest that *Triphala* may become can be a very useful treatment for managing IBD, promote gut health and may have potential beneficial actions for use in colorectal cancer given that normal issue architecture was restored, a reduction in inflammation was observed and there were changes in gene expression.

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